SUPPORTING STATEMENT PART A
Fee-for-Service Recovery Audit Prepayment Review Demonstration and
Prior Authorization Demonstration
(CMS-10421 – OMB control number - 0938-1169)

Background

The Office of Management and Budget (OMB) approved the information collection request entitled the "Medicare Fee-for-Service Recovery Audit Prepayment Review Demonstration and Prior Authorization Demonstration" with the control number 0938-1169 on July 23, 2012. On June 13, 2014 OMB approved the emergency PRA package entitled the "Medicare Fee- for-Service Recovery Audit Prepayment Review Demonstration and Prior Authorization Demonstration" with the control number 0938-1169 which allowed for the Centers for Medicare & Medicaid Services (CMS) to expand the Prior Authorization demonstration into 12 additional states.

The CMS is now requesting OMB to continue approval of the collection required for the Power Mobility Device (PMD) demonstration only as the Medicare Fee-for-Service Recovery Audit Prepayment Review Demonstration has ended. The PMD demonstration established a prior authorization program for PMD claims currently running in 19 states. The following paragraphs in this section reiterate the narrative background we provided in the previous PRA justification.

The Program Integrity Manual (PIM) reflects the principles, values, and priorities of the Medicare Integrity Program (MIP). The primary principle of Program Integrity (PI) is to pay claims correctly. In order to meet this goal, traditionally, Zone Program Integrity Contractors (ZPICs), and Medicare Administrative Contractors (MACs) (collectively the "contractors") must ensure that they pay the right amount for covered and correctly coded services rendered to eligible beneficiaries by legitimate providers. The CMS follows four parallel strategies in meeting this goal: (1) preventing fraud through effective enrollment and through education of providers and beneficiaries, (2) early detection of fraud, for example, through medical review and data analysis, (3) close coordination with partners, including ZPICs, MACs, and law enforcement agencies, and (4) fair and firm enforcement policies. Fraud is an improper payment, but not all improper payments are fraud.

The CMS, through the Medicare contractors, performs medical utilization and/or fraud review activities to identify and mitigate vulnerabilities. In order to adequately discharge their obligations under the MIP in Section1893 of the Social Security Act, the contractors perform manual review of claims where program vulnerabilities or potential fraud are present. When data analysis indicates aberrant or unusual billing patterns the contractor may request 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. Based on the supporting documentation they receive as part of their reviews, contractors can more accurately review submitted claims to ensure proper payment. This underlying medical documentation provides a more comprehensive clinical picture to

support or contradict coverage and other determinations, while a manual review of the information presented on the face of the claim does not always provide sufficient information. The CMS believes that increasing the amount of contractors able to do this more in depth review will help to prevent fraud, waste and abuse and pay claims correctly the first time.

Fraud

Based on previous CMS experience, Office of the Inspector General (OIG) reports, Government Accountability Office (GAO) reports, and indictments, there is extensive evidence that fraud represents a key challenge to CMS health care programs. In the 2012 Presidential budget, Florida (FL), California (CA), Michigan (MI), Texas (TX), New York (NY), North Carolina (NC), Louisiana (LA), and Illinois (IL) were all identified as high risk fraud states, many as part of the Stop Gap program. Further, PMDs have been the subject of multiple fraud alerts since at least June 1998.

These proposed demonstrations seek to protect the Medicare Trust Fund from fraudulent actions and the resulting improper payments by developing methods to investigate and prosecute fraud. In fact, these demonstrations would add to the efforts that CMS and its partners have taken in implementing a series of anti-fraud initiatives in high-risk fraud states.

The Health Care Fraud Prevention and Enforcement Action Team (HEAT), a partnership between the Departments of Justice and Health and Human Services, began a phased roll out of strike force teams in metropolitan areas of CA, FL, MI, NY, and TX in March 2007. Based on data driven evaluations, these strike force teams obtained indictments of more than 460 organizations and individuals that collectively billed the Medicare program for more than $1 billion in fraudulent claims. Durable Medical Equipment (DME) is a primary focus of investigation for these strike forces. In addition, CA, FL, IL, NY and TX have been identified by the ZPICs as states with numerous incidents of health care fraud, including the submission of fraudulent Medicare claims for DME items. The PMDs are DME items with a high reimbursement rate and have been susceptible to fraud.

Evidence of such fraud, in many cases involving DME, in these states includes but is not limited to the following:

- In February 2011, 111 health care providers in several cases were charged with health care fraud, totaling $225 million, in CA, FL, IL, MI, NY and TX.
- In October 2010, the Federal Bureau of Investigation (FBI) indicted 73 people in several cases for organized crime activities related to health care fraud based in NY and CA.
- In November 2010, an individual in Los Angeles was found guilty of health care fraud after it was shown that he recruited low-income beneficiaries to bill Medicare for expensive power wheelchairs that the beneficiaries did not want, use, or need. In another case, a CA woman was sentenced after serving as patient

recruiter in a nearly $1 million power wheelchair fraud scheme.

- In September 2009, 4 Raleigh, NC residents were charged with more than $12 million in Medicare Fraud for motorized scooters, powered wheelchairs, and other medical equipment claims submitted since 2007.
- Medicare fraud across the DME spectrum has been pervasive and well-documented in many cases in South FL including a 2003 guilty plea of a Miami Beach man who submitted $5 million in fraudulent Medicare claims.
- As several indictments and news pieces have shown, some of the fraudulent suppliers are moving out of FL and into MI. For instance, in 2010, 11 Detroit area individuals were arrested on suspicion of submitting $35 million in fraudulent claims to the Medicare program, including claims for wheelchairs.
- Fraud associated with PMDs was first recognized in Harris County, TX in 2002 and continues to be problematic. For example, three Houston-area residents were recently sentenced to prison for their roles in a multi-million dollar DME Medicare fraud scheme, including the fraudulent submission of PMD claims.

Prior Authorization of Power Mobility Devices (PMDs)

On September 1, 2012 CMS implemented a prior authorization process for PMDs (scooters and power wheelchairs) in seven states with high populations of fraud- and error-prone providers (CA, FL, IL, MI, NY, NC, and TX). Initial data indicates that the Prior Authorization Demonstration was more successful in reducing spending and improper payments for PMDs than originally anticipated. The CMS believes the recent decrease in overall spending is due in part to national Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers adjusting their billing practices and reflects suppliers complying with CMS policies, based on their experiences with prior authorization, in the demonstration states. Prior authorization is driving initial successes, ensuring that only beneficiaries who meet Medicare requirements receive a PMD. Suppliers have also increased compliance with CMS policies, based on their experiences with prior authorization, in the non-demonstration states. On October 1, 2014 the CMS will expand the demonstration to 12 additional states: Pennsylvania (PA), Ohio (OH), Louisiana (LA), Missouri (MO), Maryland (MD), New Jersey (NJ), Indiana (IN), Kentucky (KY), Georgia (GA), Tennessee(TN), Washington (WA), and Arizona (AZ), for a total of 19 states. The original demonstration requirements remain the same for all 19 states.

Prior authorization allows the applicable documentation to supports a claim be submitted before the item is delivered. In prior authorization, the provider/supplier submits relevant documents for review before the item is delivered or the service is rendered.

This demonstration seeks to protect the Medicare Trust Fund from fraudulent actions and the resulting improper payments by developing methods to investigate and prosecute fraud. In fact, this demonstration adds to the efforts that CMS and its partners have taken in implementing a series of anti-fraud initiatives in these seven States and across the

United States.

For the demonstration, a prior authorization request would be completed by the (ordering) physician or treating practitioner and submitted to the appropriate DME MAC for an initial decision. The supplier may also submit the request on behalf of the physician or treating practitioner. The physician, treating practitioner or supplier who submits the request on behalf of the physician or treating practitioner, is referred to as the "submitter." Under this demonstration the submitter will submit to the DME MAC a request for prior authorization and all relevant documentation to support Medicare coverage of the PMD item.

The prior authorization will be considered a review by CMS or its agents to confirm the coverage of the item for the beneficiary. This documentation must meet all applicable rules, policies, and National Coverage Determination (NCD)/Local Coverage Determination (LCD) requirements. After receipt of all relevant documentation, CMS or its agents will conduct a complex medical review and communicate a decision on whether the PMD meets all requirements for an affirmative prior authorization to the physician/ treating practitioner, supplier, and the Medicare beneficiary for the initial submission.

The following explains the various prior authorization scenarios:

- When a submitter sends a prior authorization request to the DME MAC with appropriate documentation and all relevant Medicare coverage and documentation requirements are met for the PMD, then an affirmative prior authorization decision notification is sent to the physician or treating practitioner, supplier and beneficiary. When the claim is submitted to the DME MAC by the supplier, it is linked to the prior authorization via the claims processing system and so long as all requirements in the applicable NCD/LCD are met, the claim is paid.

- When a submitter sends a prior authorization request with complete documentation but all relevant Medicare coverage requirements are not met for the PMD, then a negative prior authorization decision notification will be sent to the physician or treating practitioner, supplier and Medicare beneficiary advising them that Medicare will not pay for the item. If the claim is still submitted by the supplier to the DME MAC for payment, it will be denied. The supplier and/or the beneficiary can appeal the claim denial.

- In cases where documentation is submitted with the prior authorization request, but it is incomplete, the prior authorization request is sent back to the submitter for resubmission and the DME MAC notifies the physician or treating practitioner, supplier, and Medicare beneficiary.

- When the DME supplier delivers the item to the beneficiary and submits the claim to the DME MAC for payment without first receiving a prior authorization decision, the DME MAC will review the PMD claim. If the claim is determined

to be payable, it will be paid with a 25 percent reduction in the Medicare Payment. This payment reduction will not be applied for contract suppliers submitting claims for beneficiaries who maintain a permanent residence in a Competitive Bidding Area according to the CMS common working file (CWF); contract suppliers will continue to receive the applicable single payment amount under competitive bidding. The 25 percent payment reduction, which applies for failure to receive a prior authorization decision before submission of a claim, is non-transferrable to the beneficiary. This payment reduction, which began 3 months after the start of the demonstration for the original states and will be implemented 3 months after the demonstration is expanded for the new states, is not subject to appeal. For capped rental items the payment reduction will be applied to all claims in the series. After a claim is submitted and processed, appeal rights are available as normal.

Summary

Upon completion of the medical review of a prior authorization request, a determination is made about the appropriateness of the item or service. Contractors are required to follow Medicare rules, including but not limited to NCDs and LCDs, which are available on the CMS website. They are also expected to use their expertise to make clinical judgments when making medical review determinations. Contractors synthesize all submitted medical record information (e.g. progress notes, diagnostic findings, medications, nursing notes, etc.) to create a longitudinal clinical picture of the patient, then apply this clinical picture to the review criteria to make a reviewer determination on whether the clinical requirements in the relevant policy have been met.

As outlined in the Program Integrity Manual (PIM) (Internet Only Manual [IOM] 100-08 Chapter 3 Section 3.3.1.3)[1] for all clinical documentation: Clinical review judgment involves two steps:

1. The synthesis of all submitted medical record information (e.g. progress notes, diagnostic findings, medications, nursing notes, etc.) to create a longitudinal clinical picture of the patient and,

2. The application of this clinical picture to the review criteria to make a reviewer determination on whether the clinical requirements in the relevant policy have been met. The MAC, CERT, Recovery Auditor, and ZPIC clinical review staff shall use clinical review judgment when making complex review determinations about a claim.

Clinical review judgment does not replace poor or inadequate medical records. Clinical review judgment by definition is not a process that MACs, CERT, Recovery Auditors and ZPICs can use to override, supersede or disregard a policy requirement. Policies include laws, regulations, the CMS' rulings, manual instructions, NCDs,

[1] Please see PIM, Chapter 3, Section 3.3.1.1. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c03.pdf for current policy.

LCDs, and MAC policy articles attached to a LCD or listed in the Medicare Coverage Database.

If at any time during the medical review process the contractor detects possible fraud, the contractor would refer the issue to the ZPIC.

Justification

1. Need and Legal Basis

Under authorities contained in Title XVIII of the Social Security Act (the Act), the Centers for Medicare & Medicaid Services, through MACs process claims for health vices.

Furthermore, these contractors and some of our Recovery Audit Contractors and ZPIC 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 Section1893, 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.

Section 402(a)(1)(J) of the Social Security Amendments of 1967 allows CMS to conduct demonstrations to develop and demonstrate improved methods for the investigation and prosecution of fraud.

2. Information Users

The information required under this collection is requested by Medicare contractors to determine proper payment or if there is a suspicion of fraud. Medicare contractors may request the information from providers or suppliers submitting claims for payment from the Medicare program when data analysis indicates aberrant billing patterns or other information which may present a vulnerability to the Medicare program. For items with a history of aberrant billing patterns this information is requested in advance to determine appropriate payment or if there is a suspicion of fraud.

3. Improved Information Techniques

Some of this collection of information could involve the use of automated, electronic, or

other forms of information technology at the discretion of the submitter. For example the CMS offers electronic submission of medical documentation (esMD) to providers and suppliers who wish to explore this alternative for sending in medical documents. Additional information on esMD can be found at found at www.cms.gov/esMD.

4. Duplication and Similar Information

The nature of the information being collected and the manner in which it is collected precludes duplication. With the exception of basic identifying information such a beneficiary name, address, etc., there is no standard form or location where this information can be gathered.

5. Small Businesses

This collection will impact small businesses or other entities to the extent that those small businesses bill Medicare in a manner that triggers prior authorization. Consistent with our estimates below, we believe that the total claims impact on all businesses is less than one-tenth of one percent of claims submitted. We do not have the number of small business that will be impacted. The retention of the requested information by physicians is a routine business practice, however this collection impacts small businesses and all respondents in that they must work with physicians to obtain the necessary medical documentation to support their claims. The CMS welcomes comments from the public on ways to make the reviews conducted under these demonstrations less burdensome while also accomplishing our other goals.

6. Less Frequent Collections

Since PMDs represent an area where a history of program vulnerabilities exist, less frequent collection of information on these items would be imprudent and undermine the demonstration.

7. Special Circumstances

More often than quarterly - This information could be collected on an as-needed basis. When contractors determine that a provider or supplier is presenting a potential vulnerability to the Medicare Trust Fund, the contractor will request this information. However for PMDs in the demonstration States, this information will be requested for all new applicable PMDs. This process occurs on a continual basis, and delaying the collection of this information would undermine the demonstration.

Response within 30 days –For the prior authorization demonstration requests are self-generated by the provider or supplier.

More than original and two copies - There is no requirement to submit more than one copy of the requested documentation.

Retain records more than three years - This estimate does not impose any new or additional record retention requirements beyond those requirements currently in place.

Conjunction with a statistical survey - Information derived from the collection of this information is used by contractors to make medical review determinations that ensure that billed items or services should be covered by the Medicare program. Contractors and CMS only collect statistical data related to the adjudication decisions made by the contractors which assists them in determining error rates, opportunities for education, and managing their medical review program resources. Prior authorization of medical records is not performed to create statistical pictures of Medicare utilization. The calculation of a provider's or supplier's error rate is not a statistical analysis of the Medicare program.

Use of statistical data classification - This collection does not require a statistical data classification.

Pledge of confidentiality - This collection does not require a pledge of confidentiality.

Confidential Information - The Health Insurance Portability and Accountability Act Privacy Rule allows for the disclosure of health records for payment purposes. Medicare contractors have procedures in place to assure the protection of the health information provided.

8. Federal Register Notice/Outside Consultation.

A 60-day Notice will publish in the Federal Register on November 13, 2017 (82 FR 52304). No comments were received.

No additional outside consultation was sought.

9. Payments or Gifts to respondents

No payments or gifts will be given to respondents to encourage their response to any request for information under this control number.

10. Confidentiality

Medicare contractors will safeguard all protected health information.

11. Sensitive Questions

There are no questions of a sensitive nature.

12. Burden Estimate

The burden associated with prior authorization is the time and effort necessary for the

provider and/or supplier of services to locate and obtain the supporting documentation for the Medicare claim and to forward the materials to the Medicare contractor for review.

CMS expects that this information will generally be maintained by providers and/or suppliers as a normal course of business and that this information will be readily available. When a PMD claim is submitted by a supplier, CMS expects that the supplier will work with the health care provider to assemble the necessary documentation for submission upon request.

When we renew this information collection request under the Paperwork Reduction Act, we will specifically seek comments to inform this burden estimate. Under 5 C.F.R. 1320.3(a)(b)(1), "burden" means "the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency, including: (i) Reviewing instructions; (ii) Developing, acquiring, installing, and utilizing technology and systems for the purpose of collecting, validating, and verifying information; (iii) Developing, acquiring, installing, and utilizing technology and systems for the purpose of processing and maintaining information; (iv) Developing, acquiring, installing, and utilizing technology and systems for the purpose of disclosing and providing information; (v) Adjusting the existing ways to comply with any previously applicable instructions and requirements; (vi) Training personnel to be able to respond to a collection of information; (vii) Searching data sources; (viii) Completing and reviewing the collection of information; and (ix) Transmitting, or otherwise disclosing the information. We welcome comments from the public that provide information to inform this burden estimate.

A. Demonstrations

The CMS can use demonstration authority, derived either through new or existing legislation, in order to conduct demonstrations. Some demonstrations will require collection and review of medical records to ensure compliance for payment. This demonstration allow additional resources to conduct review of PMDs (scooters and power wheelchairs) for Medicare beneficiaries who reside in 19 states with high populations of fraud- and error-prone providers CA, IL, MI, NY, NC, FL, TX, PA, OH, LA, MO, MD, NJ, IN, KY, GA, TN, WA, and AZ. The original demonstration requirements remain the same in all 19 states.

Prior Authorization of Power Mobility Devices

The Prior Authorization of Power Mobility Devices demonstration implemented prior authorization, a tool utilized by private-sector health care payers to prevent improper payments and deter fraud. The CMS estimates that the per-claim burden associated with this type of review is equivalent to that for prepayment review (i.e., 30 minutes).

For the purpose of this burden estimate, CMS initially estimated that at its height, the original demonstration would involve the review of 325,000 requests on an annual basis

based on the unlimited resubmissions allowed for the prior authorization request. The PMD prior authorization program has been more efficient than initially expected for the original and the expanded states. The current per year burden is approximately 50,000 requests.

PMD Demonstration Burden

Activity	Responses Per Year (i.e. number of submitted requests)	Time per Response (hours)	Total Burden Per Year (hours)	Total Burden Hours Per Year ($)
PMD Demonstration (all)	50,000	.5	25,000	$914,500

B. Signature Attestation

We also anticipate some burden for providers and suppliers where the medical documentation submitted for one of these demonstrations fails to meet Medicare's legible identifier rules. Where claims would be denied on that basis, subject to CMS instructions, providers and suppliers have the option to submit an attestation statement indicating the signature is theirs. We estimate this will be applicable on less than 1% of the cases reviewed for these demonstrations. For that 1% of claims, we estimate it will take no more than 15 minutes to process, sign and submit the applicable attestation.

Current PRA Request

Activity	Responses Per Year (i.e. number of reviewed claims)	Time per Response (hours)	Total Burden Per Year (hours)	Total Burden Hours Per Year ($)
PMD Demonstration (all)	50,000	.5	25,000	$914,500
Signature Attestation	500	0.25	125	$4,573
Total	50,500		25,125	$919,073

Respondent Cost

CMS estimates that average time for office clerical activities associated with this task to be 30 minutes. Average labor costs (including 100 percent fringe benefits) used to estimate the costs are calculated using data available from the Bureau of Labor Statistics (https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm).We estimate an average hourly rate of $18.29[2] with a loaded rate of $36.58. This equates to a cost of approximately $920,000 per year. This impact is allocated across providers and suppliers nationwide.

CMS also estimates the cost of mailing medical records to be up to $5 per request for prior authorization. However many of the records are received via fax which have lower costs than mail. CMS now offers electronic submission of medical documentation (esMD) to providers and suppliers who wish to use a less expensive alternative for sending in medical documents. Additional information on esMD can be found at www.cms.gov/esMD. In instances when the supplier must first obtain the medical records from a health care provider, CMS estimates that the mailing costs are doubled, as records are transferred from provider to supplier, and then CMS or its agents.

We estimate that there are 37,500 requests per year for which the mailing costs are doubled. However, it is reasonable to believe that less than half the medical records (approximately 18,000) are mailed in. Therefore, CMS estimates the costs are $375,000.

13. Capital Costs

There are no capital costs associated with this collection. Providers and suppliers maintain these medical records and routinely submit them to various healthcare entities.

14. Costs to Federal Government

CMS estimates that costs associated with performing reviews on the submissions/claims is approximately $8.5 million a year based on fully loaded costs including overhead.

15. Changes in Burden

This ICR focuses on a continuation of a 3-year demonstration project. All collections will follow current documentation requirements. Medicare has long had the authority to request and collect medical information to support the medical necessity of services rendered. We are estimating the burden will be 30 minutes per case, which is consistent with previous estimates for the amount of time to complete pre-payment medical review. This has not changed from our prior supporting statement.

16. Publication or Tabulation

[2] Based on 2016 mean hourly wage for M-29-2071- Medical Records and Health Information Technicians, Bureau of Labor Statistics

There are no plans to publish or tabulate the information collected.

17. Expiration Date

There are no instruments associated with this information collection.