**SUPPORTING STATEMENT PART A**
**Medicare Fee-for-Service Recovery Audit Prepayment Review Demonstration and Prior Authorization Demonstration**
**CMS-10421, OCN: 0938-NEW**

## Background

The Centers for Medicare & Medicaid Services (CMS) is requesting the Office of Management and Budget (OMB) approval of the collections required for two demonstrations of prepayment review and prior authorization. As discussed in greater detail below, the first demonstration would allow Medicare Recovery Auditors to review claims on a pre-payment basis in certain states. The second demonstration would establish a prior authorization program for Power Mobility Device claims in certain states.

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, Program Safeguard Contractors (PSCs), Zone Program Integrity Contractors (ZPICs), affiliated contractors (ACs), 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 Centers for Medicare & Medicaid Services 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 through, for example, medical review and data analysis, (3) close coordination with partners, including PSCs, ZPICs, ACs, MACs, and law enforcement agencies, and (4) fair and firm enforcement policies. Fraud is an improper payment, but not all improper payments are fraud.

In addition, the Medicare Fee for Service Recovery Audit program is mandated by the Tax Relief and Health Care Act of 2006 and utilizes Recovery Audit Contractors to identify improper payments paid by Medicare to fee-for-service providers on a post-payment basis.

The CMS through the Medicare contractors performs medical utilization review and/or fraud review activities in order to mitigate vulnerabilities. In order to adequately discharge their obligations under the Medicare Integrity Program 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, for example, 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. 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. 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, 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, California, Michigan, Texas, New York, North Carolina, Louisiana, and Illinois were all identified as high risk fraud states, many as part of the Stop Gap program. Further, Power Mobility Devices (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 California, Florida, Michigan, New York and Texas 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, California, Florida, Illinois, New York and Texas 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. PMDs are DME items with a high reimbursement rate and have been susceptible to fraud.

Evidence of such fraud, including 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 California, Florida, Illinois, Michigan, New York and Texas.
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> In October 2010, the FBI indicted 73 people in several cases for organized crime activities related to health care fraud based in New York and California.
>
> 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 California woman was sentenced after serving as patient recruiter in a nearly $1 million power wheelchair fraud scheme.

In September 2009 four Raleigh, North Carolina 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 Florida including a 2003 guilty plea of a Miami Beach man who charged $5 million in fraudulent Medicare claims.

As several indictments and news pieces have shown, some of the fraudulent suppliers are moving out of Florida and into Michigan. 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, Texas 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.

**CMS' proposed two demonstrations: 1. Recovery Audit Prepayment Reviews and 2. Prior Authorization of Power Mobility Devices (PMDs).**

1. Recovery Audit Prepayment Review which will allow Medicare Recovery Auditors (RACs) to Review Claims on a Pre-Payment Basis

A claim can be reviewed by a variety of review entities to determine proper payment. The MACs and the ACs review claims on a prepayment basis to confirm the medical necessity of the billed item or service. The ZPICs and PSCs also review provider/supplier claims on a prepayment basis when there is suspicion of fraudulent activity. In this demonstration, CMS will pilot the use of Recovery Auditors (RACs) to increase the number of prepayment reviews performed in order to limit vulnerabilities in FL, CA, MI, TX, NY, LA, IL, PA, OH, NC, and MO. All of these contractors (i.e., RACs, MACs, and ACs) will work in concert to review vulnerable areas of the Medicare Program in order to limit improper payments or fraud.

Prepayment complex medical review determinations require the reviewer to make a clinical or other judgment about whether an item or service is covered (i.e. meet the criteria of a Medicare benefit category, are not statutory excluded, and are reasonable and necessary), properly coded and compliant with documentation rules. In order for this determination to be made, the provider or supplier must submit a copy of the medical records to support the item/service. In prepayment complex medical review, the provider/supplier submits documentation for review after the claim has been submitted for payment but before payment has been made.

The contractors employ data analysis procedures to identify claims that may be billed inappropriately. These procedures are discussed in the Program Integrity Manual and may be based on claims data (national and/or local), beneficiary complaints, or data from other organizations (for example, Office of Inspector General and Government Accountability Office). When a contractor identifies a likelihood of sustained or high level of payment error, the contractor may request supporting medical record

documentation. Examples that signify a likelihood of a high level of payment error are dramatic change in the frequency of use, high cost, high risk problem-prone areas, or unexplained increases in volume when compared to historical or peer trends.

For this information collection, CMS and its agents request additional documentation, including medical records, to support the claim. As discussed in more detail in Chapter 3 of the Program Integrity Manual, additional documentation includes any medical documentation, beyond what is included on the face of the claim that supports the item or service that is billed. For Medicare to consider coverage and payment for any item or service, the information submitted by the provider or supplier (e.g., claims) must be supported by the documentation in the patient's medical records. The term "additional documentation" refers to medical documentation and other documents such as supplier/lab/ambulance notes and includes:

> Clinical evaluations, physician evaluations, consultations, progress notes, physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation is maintained by the physician and/or provider.
>
> Supplier/lab/ambulance notes include all documents that are submitted by suppliers, labs, and ambulance companies in support of the claim (e.g., Certificates of Medical Necessity, supplier records of a home assessment for a power wheelchair).
>
> Other documents include any records needed from a biller in order to conduct a review and reach a conclusion about the claim.

When conducting complex medical review the contractor specifies documentation they require in accordance with Medicare's rules and policies. In addition, providers and suppliers might supply additional documentation not explicitly listed by the contractor. This supporting information may be requested of providers and suppliers submitting the claim by CMS and its agents on a routine basis in instances where diagnoses on a claim do not clearly indicate medical necessity, or if there is a suspicion of fraud.

2. Prior Authorization of Power Mobility Devices (PMDs)

CMS will also pilot prior authorization for Power Mobility Devices. Prior authorization will allow 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. CMS will conduct this demonstration in California, Florida, Illinois, Michigan, New York, North Carolina and Texas based on beneficiary address as reported to the Social Security Administration and recorded in the Common Working File (CWF).

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. This demonstration would add 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 NCD/LCD requirements (accessible at www.cms.gov/MCD). 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 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 will begin three months into the demonstration, 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 case or claim, a determination is made about the appropriateness of the item or service. Contractors are required to follow Medicare rules, including but not limited to National Coverage Determinations and Local Coverage Determinations, 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 PIM 3.3.1.3 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. 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, MAC policy articles

attached to an LCD or listed in the Medicare Coverage Database, national coverage decisions, and local coverage determinations.

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

**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, 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 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 the Recovery Audit Prepayment Review, requests for information are made using written, case specific additional documentation requests (ADR) letters, requesting specific information from a specific provider or supplier and in some cases this documentation can be submitted through electronic means. 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 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 prepayment review or 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. CMS welcomes comments from the public on ways to make the reviews conducted under these two demonstrations less burdensome while also accomplishing our other goals.

6. Less Frequent Collections

For the Recovery Audit Prepayment demonstration, since the information is only collected when potential program vulnerability exists, less frequent collections of this information would be imprudent. CMS and its agents continue to refine their tools for identifying improper billing practices.

For the Prior Authorization demonstration, 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 Recovery Audit Prepayment Review demonstration, providers and suppliers are notified that they have 30 calendar days to respond, as discussed in the Program Integrity Manual (100-08), Chapter 3, Section 3.2.3.2. For the prior authorization demonstration requests are self paced. In the event the supplier receives an ADR on a claim that supplier will be notified that they have 30 calendar days to respond, as discussed in the Program Integrity Manual (100-08), Chapter 3, Section 3.2.3.2.

**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. Under the Recovery Audit Prepayment Review demonstration, Recovery Audit Contractors and CMS may use statistical tools to establish the need for prepayment review, for instance contractors may select a statistically valid sample of claims in order to calculate overpayments in cases where a provider/supplier has demonstrated a sustained or high level of payment error or documented educational efforts have failed to correct billing problems. 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

The 60-day Federal Register notice published on February 7, 2012 (77 FR 6124). The 30-day Federal Register notice published on May 29, 2012 (77 FR 31616). The Centers for Medicare and Medicaid Services (CMS) received 4 complete comments from stakeholders

related to CMS-10421.

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 collected.

11. Sensitive Questions

There are no questions of a sensitive nature.

12. Burden Estimate

The burden associated with prepayment review and 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

CMS can use demonstration authority, derived either through new or existing legislation,

in order to conduct demonstrations. Some demonstrations will require the collection and review of medical records in order to ensure compliance for payment. These demonstrations will allow additional resources to conduct additional review. CMS is starting two demonstrations. These demonstrations are: (1) Recovery Audit Prepayment Review which will allow Medicare Recovery Auditors to review claims before they are paid to ensure that the provider complied with all Medicare payment rules in FL, CA, MI, TX, NY, LA, IL, PA, OH, NC, and MO; and (2) Prior Authorization of Power Mobility Devices (PMDs) which will implement Prior Authorization for scooters and power wheelchairs for all people with Medicare who reside in seven states with high populations of fraud- and error-prone providers (CA, IL, MI, NY, NC, FL and TX).

Recovery Audit Prepayment Review

The demonstration will be implemented in the seven high fraud states of Florida, California, Michigan, Texas, New York, Louisiana, and Illinois and the four states within the recovery auditor jurisdiction with the highest number of short hospital stays Pennsylvania, Ohio, North Carolina, and Missouri. This will allow CMS to evaluate whether Recovery Auditors can have an impact on the amount of improper payments that can be prevented through prepayment review without requiring additional MIP funding. The demonstration would also evaluate if the increased amount of prepayment review can have a significant impact on lowering the error rate and lowering the risk of fraudulent occurrences. Claims reviewed by the Recovery Auditors would be chosen based on the Comprehensive Error Rate Testing (CERT) program, HEAT Strike Force initiatives, the results of the predictive modeling, and other data sources. Claim information would be shared between contractors using existing secure connectivity. These claims will be reviewed in the same manner that the MACs review the claims on a pre-payment basis. We believe that at the height of this demonstration the Recovery Auditors will review 150,000 claims annually.

Prior Authorization of Power Mobility Devices

The Prior Authorization of Power Mobility Devices demonstration will implement prior authorization, a tool utilized by private-sector health care payers to prevent improper payments and deter fraud. 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 estimates that at its the height will involve the review of 325,000 cases on an annual basis based on the unlimited resubmissions allowed for the prior authorization request.

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.

| Activity | Responses Per Year (i.e. number of reviewed claims) | Time per Response (hours) | Total Burden Per Year (hours) | Total Burden Hours Per Year ($) |
|---|---|---|---|---|
| Recovery Auditor Pre-payment review Demonstration | 150,000 | 0.5 | 75,000 | $ 2,524,500.00 |
| PMD Demonstration | 325,000 | 0.5 | 162,500 | $ 5,469,750.00 |
| Signature Attestation | 4,750 | 0.25 | 5,560 | $ 187,149.60 |
| TOTAL | 479,750 | n/a | 243,060 | 8,181,400 |

All estimates are based on the highest of the 3 years. Since these demonstrations must ramp up, year 1 numbers are expected to be lower than year 3. However we assumed year 3 numbers for the purposes of estimating.

Respondent Cost

CMS estimates that average time for office clerical activities associated with this task to be 30 minutes. Based on Bureau of Labor Statistics information we estimate an average hourly rate of $16.83 with a loaded rate of $33.66. This equates to a cost of $8.2 million for 3 years (or $24.6 million per year). This impact is allocated across providers and suppliers nationwide.

CMS also estimates the cost of mailing medical records to be $5 per request for prepayment review or prior authorization. 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 325,000 claims for which the mailing costs are doubled. In sum, CMS estimates the costs are $1.6million.

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 complex medical reviews on the cases/claims are $72 million over 3 years based on the fully loaded costs including overhead.

15. Changes in Burden/policy

This is a new collection. This PRA package focuses on a discussion of two 3-year demonstration projects for this information collection request. 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.

16. Publication or Tabulation

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

17. Expiration Date

We are seeking to not display the expiration date on the Recovery Audit Prepayment Review ADR letters. Inclusion of the expiration date would be impractical on the ADRs.

18. Certification Statement

There are no exceptions to the certification statements.