SUPPORTING STATEMENT PART A
Medicare Fee-for-Service Early Review of Medical Records
CMS-10417, OMB 0938-0969

Background

The Centers for Medicare & Medicaid Services (CMS) is requesting the Office of Management and Budget (OMB) approval of the collections required for prepayment review of items or services from providers and/or suppliers, in order to protect the Medicare trust fund from vulnerabilities.

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 Zone Program Integrity Contractors (ZPICs), Medicare Administrative Contractors (MACs), or other contractors designated by CMS, 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 through, for example, medical review and data analysis, 3) close coordination with partners, including ZPICs, MACs, and law enforcement agencies, and 4) fair and firm enforcement policies.

As discussed in the PIM (100-08), Chapter 3 (https://www.cms.gov/manuals/downloads/pim83c03.pdf), the CMS requires MACs to analyze claims to determine provider compliance with Medicare coverage, coding, and billing rules and take appropriate corrective action when providers are found to be non-compliant. The goal of MAC administrative actions is to correct the behavior in need of change and prevent future inappropriate billing. The MACs priority is to minimize potential future losses to the Medicare Trust Funds through targeted claims review while using resources efficiently and treating providers and beneficiaries fairly.

For repeated infractions, CMS has given the MACs discretion to initiate progressively more severe administrative action, commensurate with the seriousness of the identified problem. (Refer to PIM chapter 3, §3.7.1). The MACs deal with serious problems using the most substantial administrative actions available, such as 100 percent prepayment review of claims. Minor or isolated inappropriate billing are remediated through provider notification or feedback with reevaluation after notification. While program savings are realized through denials of payment for inappropriate provider billing, the optimal result occurs when compliance is achieved and providers no longer incorrectly code or bill for non-covered services.

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 §1893 of the Social Security Act, the contractors perform manual review of claims where program vulnerabilities are present. When data analysis indicates aberrant or unusual billing patterns, which may present a vulnerability

or potential fraud, the contractor requests clinical and other documents to support the need for the items or services provided by providers or suppliers who submitted claims for payment under the Medicare program. Based on the supporting documentation they receive as part of their reviews, contractors can more accurately review submitted claims. This underlying medical documentation provides a more comprehensive clinical picture to support coverage and other determinations that a manual review of the information presented on the face of the claim does not always allow.

Prepayment complex medical review determinations require the reviewer to make a clinical or other judgment about whether an item or service is covered (have a 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. For example, in prepayment complex medical review of diabetic test strips, the provider/supplier submits documentation for review after the claim has been submitted for payment. This documentation includes physician notes, supplier notes and other medical documentation that supports the medical necessity of the claim.

A claim can be reviewed by a variety of review entities to determine proper payment. MACs review claims on a prepayment basis to confirm the medical necessity of the billed item or service. The ZPICs also review provider/supplier claims on a prepayment basis when there is suspicion of fraudulent activity. All these contractors work in concert to review vulnerable areas of the Medicare Program in order to limit improper payments or fraud.

The contractors employ data analysis procedures to identify claims that may be billed inappropriately. These procedures are discussed in the PIM and may be based on claims data (national and/or local) beneficiary complaints, and alerts 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 of a high level of payment error include unusual patterns such as prescribing the same items and/or services for a high number of patients, consistently prescribing inappropriate treatments, unexplained increases in volume when compared to historical or peer trends, or any other reasons as determined by the Secretary or their designees.

In many cases, before a contractor places a provider or supplier on prepayment complex medical review, the contractor would perform a probe review (that is, prepayment or postpayment complex medical review of a small sample of claims for a specific billing code, generally 20 to 40 claims to confirm that the provider or supplier is billing the program in error). In the case of a widespread "item or service-specific" problem, a larger sample of claims (generally 100 claims of the item or service in question) would be subjected to prepayment or postpayment complex medical review. Performing medical review on a sample of claims for a specific billing code before placing the provider or supplier on prepayment complex medical review allows for a determination as to whether a problem exists and ensures that providers and suppliers are not unnecessarily burdened and that contractor medical review resources are appropriately utilized.

When a probe confirms that a provider or supplier is billing the program in error, and those billing errors present a likelihood of sustained or high level of payment error (for example, a high billing error rate or errors on claims representing high dollar value), the provider or supplier is placed on prepayment complex medical review. Contractors utilize medical review activities for providers, suppliers, items or services that present the greatest risk for payment errors to the Medicare trust funds.

For this information collection, CMS and its agents request medical records. As discussed in more detail in Chapter 3 of the PIM, medical records include any additional documentation, other than 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. As defined in the PIM, 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. Providers and suppliers may supply additional documentation not explicitly listed by the contractor. This supporting information may be requested 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.

We are including in our "prepayment complex review" count all claims that were submitted as a result of a request for additional documentation for medical review purposes. In some cases this means the contractor makes a claim determination without clinical review of medical documentation submitted by the provider. Appropriate non-complex reviews increase the efficiency and consistency of payment decisions. Reviews of this kind require some human intervention (e.g., for instance, to verify durable medical equipment [DME] delivery dates).

Upon completion of the medical review, a determination is made about the appropriateness of the item or service. Any determination must be documented and include the rationale for the decision. 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. They must take into consideration the clinical condition of the beneficiary as indicated by the beneficiary's diagnosis and medical history when making these determinations. 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 services.

Furthermore these contractors and ZPICs are tasked, under §1893 of the Act, with performing medical utilization review and/or fraud review activities. In order to adequately discharge their obligations under §1893, the contractors perform manual review of claims where program vulnerabilities are present.

§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.

§1815(a) and §1833(e) of the Act provides that no payment may be made to any provider or supplier unless there has been information provided to determine the amounts due.

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 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.

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. 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. The CMS offers electronic submission of medial documents (esMD) to many 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. 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 the 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 requests the information needed to make prepayment review determinations only in cases where vulnerabilities exist, which reduces this impact. The CMS welcomes comments from the public on ways to make prepayment review less burdensome while serving the goal of reducing improper billing.

6. Less Frequent Collections

Since this information is only collected when potential program vulnerability exists, less frequent collections of this information would be imprudent. The CMS and its agents continue to refine their tools for identifying improper billing practices.

7. Special Circumstances

More often than quarterly - This information is 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. This process occurs on a continual basis, and delaying the collection of this information will result in additional improper Medicare payments.

Response within 30 days – Providers and suppliers are notified that they have 30 days to respond, as discussed in the PIM (100-08), Chapter 3, Section 2.3.2.

More than original and two copies - There is no requirement to submit more than 1 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. Providers and suppliers are reminded that Medicare claims can be reopened for review at any time where fraud is suspected, or within 4 years of an initial determination for good

cause or within 1 year for any reason.

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, assists them in determining error rates, opportunities for education, and/or managing their medical review program resources. Prepayment review of medical records is not performed to create statistical pictures of Medicare utilization. Contractors 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 over payments 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 27, 2015.

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 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.

The 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 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.

A. Probe Review

As noted above, sometimes the contractor performs a probe review to determine whether prepayment review is necessary. 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, as discussed below). However, there are two types of probe review, so CMS estimates the burden separately. The contractor might conduct probe review for a small sample of claims for a specific billing code, generally 20 to 40 claims to confirm that the provider or supplier is billing the program in error. In the case of a widespread "item or service-specific" problem, a larger sample of claims (generally 100 claims of the item or service in question) would be subjected to complex medical review.

B. Prepayment Review

The CMS estimates that it will take the provider or supplier on average of 30 minutes to locate, photocopy and transmit this information to the contractor upon request. This accounts for increased emphasis of inpatient hospital claims, for which the medical records are typically large. There could be great variation on the amount of time required to assemble the medical records, depending on the type of claim under review. We previously received comments which believed the appropriate time required to assemble medical records was between 30 - 185 minutes. We believe this is a lot of variation and continue to believe 30 minutes is appropriate. 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.

Given current information, and due to the variation, we use an estimate of 30 minutes. We acknowledge that for claims involving suppliers, providers may need to spend some

time providing the documentation. We assume this in our estimate. The information being collected already exists in the medical record when the provider ordered an item or performed a medical service for the beneficiary they were treating.

C. Attestation

We also anticipate some burden for providers and suppliers whose claims are denied based on the lack of a legible signature. Where claims are denied on that basis, subject to CMS instructions, providers and suppliers are asked to submit an attestation statement indicating the signature is theirs. We estimate this will be applicable on less than 1% of the claims reviewed. For that 1% of claims, we estimate it will take no more than 15 minutes to process, sign and submit the applicable attestation.

Summary Table: Annual Burden Estimate & Cost
Year 1

Activity	**Responses (i.e. number of reviewed claims)**	**Time per Response (Hours)**	**Total Burden (Hours)**	**Total Burden Hours ($)**
Probe Review (provider specific)	23,400	0.50	11,700	$ 424,242
Probe Review (service specific)	156,600	0.50	78,300	$ 2,839,158
Prepayment Review	3,000,000	0.50	1,500,000	$ 54,390,000
Attestation	31,800	0.25	7,950	$ 288,267
TOTAL	3,211,800	n/a	1,597,950	$ 57,941,667

Respondent Cost,

The 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 $18.13 with a loaded rate of $36.26. This equates to a cost of $173.8 million for 3 years (or $57.9 million per year). This impact is allocated across providers and suppliers nationwide.

The CMS also estimates the cost of mailing medical records to be $5 per request for prepayment. The CMS now offers electronic submission of medical documents (esMD) to all providers and suppliers who wish to explore a cheaper 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 642,360 claims for which the mailing costs are doubled. In sum, CMS estimates the costs are $19.3 million.

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 review are $336 million over three years based on the fully loaded costs including overhead. The average amount per year is $112 million per year.

15. Changes in Burden/policy

Medicare has long had the authority to request and collect medical information to support the medical necessity of services rendered. We continue to estimate the burden will be 30 minutes per claim.

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 these ADR letters. Inclusion of the expiration date would be impractical on the ADRs.

18. Certification Statement

There are no exceptions to the certification statements.