

## **SUPPORTING STATEMENT PART A**

### **Medicare Fee-for-Service Prepayment Review of Medical Records**

**CMS-10417/OMB control number: 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 provider/supplier, in order to protect the Medicare trust fund from vulnerabilities.

The Social Security Act (SSA) §1893 established Medicare's Integrity Program under which the Secretary promotes the integrity of the Medicare program by entering into contracts to carry out integrity type activities. Medicare contractors include, but are not limited to, Uniform Program Integrity Contractors (UPICs), Medicare Administrative Contractors (MACs) and the Recovery Audit Contractors (RA). The primary principle of the Medicare Integrity Program (MIP) is to detect and combat fraud, waste and abuse of the Medicare and Medicaid programs. We do this by making sure CMS is paying the right provider the right amount for services covered under our programs. We work with providers, states, and other stakeholders to support proper enrollment and accurate billing practices. Our work focuses on protecting patients while also minimizing unnecessary burden on providers.

The Program Integrity Manual (PIM) reflects the principles, values, and priorities of the MIP. As discussed in the PIM (Publication 100-08), CMS requires MACs to analyze claims to identify providers/suppliers that may be non-compliant with Medicare coverage, coding, and billing rules. The goal of MAC administrative actions is to identify and correct the behavior in need of change and prevent future inappropriate billing. Chapter 3 of the PIM stipulates the MACs' priority is to minimize potential future losses to the Medicare Trust Funds through targeted claims review. Chapter 3 can be accessed at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c03.pdf>.

The CMS, through the Medicare contractors, performs data analysis to identify aberrant or unusual billing patterns. When data analyses reveal aberrant or unusual billing patterns, MACs employ a variety of mitigation activities aimed at reducing them. One such activity is conducting medical record review or audits. This requires MACs to select specific claims identified as potentially inappropriately billed and request supporting medical and other documentation to support the request for payment. The request for supporting medical documentation includes sending an additional documentation request (ADR) letter. The ADR is sent to providers/suppliers who submitted the selected claims for Medicare payment. Using the supporting documentation they receive, contractors can ascertain if the request for payment (the claim) is for an item or service meeting Medicare coverage, coding and payment rules. The supporting medical documentation provides a more comprehensive clinical picture to support coverage and other determinations than does a review solely of the information presented on the face of the claim.

Medical record reviews require the assessment of supporting clinical documentation submitted by rendering providers and suppliers, upon request. These reviews can be performed prepayment or post payment. Post payment medical record reviews involve requesting the supporting documentation after the item or service has been furnished, and after the claim has been paid. Prepayment medical record review involves requesting the supporting documentation after the item or service was furnished, but before the claim is paid. This package is limited to the cost and time burden associated with prepay medical record review. The administrative action of post payment medical record review is mandated in the requirement found in §1893 of the SSA and thus not subject to the PRA requirements.

Medical record review requires the reviewer to make a payment determination based upon clinical or other judgments about whether an item or service is covered (e.g. has a benefit category, is not statutory excluded, and is reasonable and necessary), and properly coded and compliant with documentation and payment rules. In order for this determination to be made, the provider/supplier must submit a copy of the medical records in response to the ADR sent by the Medicare contractor to support the item/service. For example, in prepayment medical record review for a bedside commode that has already been furnished, the provider/supplier submits documentation for review after the claim is submitted for payment, but before the payment is made. This documentation includes, but is not limited to, physician/practitioner notes, supplier notes and other medical documentation that supports the medical necessity of the claim.

MACs and UPICs are two review contractors that conduct prepay medical review as well as post pay medical review. Other review contractors conduct post pay medical review only. The UPIC's prepay medical review activities focus on suspicion of fraudulent activity. The MAC's prepay medical review activities aim to correct inappropriate billing behavior of providers/suppliers in order to submit claims correctly. Historically, MACs have conducted prepay medical review on a particular item/service/drug/device that included all providers or suppliers submitting a subject claim. Currently, MACs conduct prepay medical review subject to the requirements of Medicare's Targeted Probe and Educate (TPE) program. Instead of including all providers/suppliers submitting a specific type of claim, TPE requires MACs to identify providers and suppliers exhibiting outlier billing behaviors only. Examples of outlier billing behaviors 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 designee. The result is that there are less claims subject to review, but more education aimed at outlier claim submitters. Data analysis 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).

TPE combines a review of a sample of claims with education to help reduce errors in the claims submission process. As noted, when performing TPE medical review, MACs focus on specific providers/suppliers within the service rather than all providers/suppliers billing a particular service. Providers/suppliers with continued high error rates after three rounds

of TPE are referred to CMS for additional action. Providers/suppliers are removed from the review process after any of the three rounds of probe review if they demonstrate low error rates, or sufficient improvement in error rates, as determined by CMS or the MAC. While program savings are realized through denials of payment for inappropriate provider/supplier billing, the optimal result occurs when compliance is achieved and providers/suppliers no longer incorrectly code or bill for non-covered services.

As discussed in Chapter 3.2.3 of the PIM and below, medical records include additional documentation, other than what is included on the face of the claim, that support payment for the item or service billed. For Medicare to consider coverage and payment for any item or service, the request for payment by the provider/supplier (e.g., claims) must be supported by the documentation in the patient's medical records. The contractor shall include requests for the following types of documentation in the ADR letter such as, but not limited to:

Clinical evaluations, physician/practitioner evaluations, consultations, progress notes, physician/practitioner'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/practitioner and/or provider/supplier.

Practitioner/lab/ambulance notes include all documents that are submitted by practitioners, 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.

Contractors are required to follow Medicare rules, including, but not limited to, The Social Security Act, The Code of Federal Regulations, National Coverage Determinations and Local Coverage Determinations. They use their expertise to make clinical judgments when making medical review determinations. Reviewers take into consideration the clinical condition of the beneficiary as indicated by the beneficiary's diagnosis and medical history when making these determinations. The MAC will refer the claim to the UPIC at any time during the medical review process if the MAC detects possible fraud. Our figures include the total of all claims for which there was an additional documentation request for prepay medical record review purposes.

## **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 UPICs are tasked, under §1893 of the Act, with performing medical record review audits 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 and to determine the amounts due.

## 2. Information Users

CMS is the Federal agency that operates the Medicare program. Addressing improper payments in the Medicare fee-for-service (FFS) program and promoting compliance with Medicare coverage and coding rules is a top priority for the CMS. Preventing Medicare improper payments requires the active involvement of every component of CMS and effective coordination with its partners including various Medicare contractors and providers.

The Medical Review program is designed to prevent improper payments in the Medicare FFS program. Whenever possible, MACs are encouraged to automate this process; however it may require the evaluation of medical records and related documents to determine whether Medicare claims are billed in compliance with coverage, coding, payment, and billing policies.

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/suppliers submitting claims for payment when data analysis indicates aberrant billing patterns or other information which may present a vulnerability to the Medicare program. Extensive instructions to CMS contractors on medical review processes and procedures are contained in CMS' Program Integrity Manual, Publication 100-08, which can be found at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019033.html>.

## 3. Improved Information Techniques

Medicare contractor requests for information are made using written, case/claim specific ADR letters, requesting specific information from a specific provider/supplier. Some collection of requested information could involve the use of automated, electronic, or other forms of information technology at the discretion of the submitter. The CMS offers electronic submission of medical 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](http://www.cms.gov/esMD). The Medicare contractors also provide portals that providers/suppliers may use to submit their documentation electronically.

## 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 as 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, the total claims impact on all businesses is less than one-tenth of one percent of claims submitted. We do not know the number of the small businesses that will be impacted. Based on §1815(a) and §1833(e) of the Social Security Act, Medicare has had a long standing expectation that providers/suppliers requesting Medicare payment collect and maintain medical records to support their request for payment. The retention of the requested information by practitioners is a routine business practice. In cases where the respondent is not the entity ordering the service/item/device, the respondent must work with ordering practitioner to obtain the necessary medical documentation to support their request for payment (e.g., claim). 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. 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 45 days** – Providers and suppliers are notified that they have 45 days to respond, as discussed in the PIM (Publication 100-08), Chapter 3, Section 2.3.2, available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c03.pdf>

**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/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 payment determinations based on medical record review, ensuring that billed items or services should be covered by the Medicare program. The information assists them in determining error rates, education opportunities, 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 example, 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 May 18, 2021 (86 FR 26921). A 30-day notice published in the Federal Register on October 5, 2021 (86 FR 54980).

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 collected.

11. Sensitive Questions

There are no questions of a sensitive nature.

## 12. Burden Estimate

As mentioned earlier, Medicare providers/suppliers are expected to maintain records to support their request for Medicare payment. The burden associated with prepayment review is the time and effort necessary for the provider/supplier of services to gather the supporting documentation for the Medicare claim as indicated in the ADR letter and to forward the materials to the Medicare contractor for review.

The CMS expects that this information will generally be maintained by providers/suppliers as a normal course of business and that this information will be readily available.

### **Review of Medical Records**

Currently, MACs are conducting primarily prepayment reviews following the TPE process. The TPE review and education process includes a review of 20-40 claims followed by one-on-one, claim-specific education to address any errors identified in the providers/supplier's reviewed claims. Providers/suppliers with moderate and high error rates in the first round of reviews will continue on to a second round of 20-40 reviews, followed by additional, claim specific, one-on-one education. Providers/suppliers with high error rates after round two will continue to a third, and final round of reviews and education. In addition to education at the conclusion of each 20-40 claim review, MACs also educate providers throughout the review audit process when easily resolved errors are identified. This helps the provider/supplier avoid similar errors later in future rounds, or future billing practices.

The CMS estimates that it will take the provider/supplier an average of 30 minutes to locate, photocopy and transmit this information to the contractor upon request. 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. Under 5 CFR 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.

We believe that while there is a lot of variation, 30 minutes is appropriate and a realistic estimate due to recent advances in technology. The information being collected already exists in the medical record when the practitioner ordered an item or performed a medical service for the beneficiary they were treating or when a supplier furnishes an item/service ordered by a practitioner.

We also anticipate some burden for providers/suppliers whose claims are denied based on the lack of a legible signature. Historically, if a claim was denied based on the lack of a legible signature, the MAC would send a separate ADR specifying the need for a signature attestation. In today's Medicare medical review TPE program, a signature attestation is requested in the original ADR sent to the provider/supplier. Thus, it is rare that a separate ADR and a separate expenditure of time and money is required. Accordingly, we no longer estimate cost and time burdens associated with signature attestations. Finally, in previous PRA estimates, we have included cost and time estimates associated with the prior authorization. However, all prior authorization medical review PRA estimates are covered under CMS-10711, CMS-10708, and CMS-0524, and are no longer reported in this estimate.

Summary Table: Annual Collection Burden Estimate & Cost

| <b>Prepayment Medical Record Review</b> | <b>Number of Provider/Supplier Submissions</b> | <b>Collection Time per Submission (Hours)</b> | <b>Total Provider/Supplier Burden Hours</b> | <b>Provider/Supplier Per Hour Cost</b> | <b>Total Provider/Supplier Burden Cost</b> |
|---|--|---|---|--|--|
| MAC Prepayment                          | 427,166  | 0.50  | 213,583                                     | \$41.00                                | \$8,756,903                                |
| UPIC Prepayment                         | 58,466   | 0.50  | 29,233                                      | \$41.00                                | \$1,198,553                                |
| <b>TOTAL</b>                            | <b>485,632</b>                                 | <b>n/a</b>                                    | <b>242,816</b>                              | <b>\$41.00</b>                         | <b>\$9,955,456</b>                         |

### **Respondent Cost**

The CMS estimates that average time for office clerical activities associated with this task to be 30 minutes. Based on the Bureau of Labor Statistics information, we estimate an average hourly rate of \$20.50<sup>1</sup> with a loaded rate of \$41.00. This equates to a cost of \$9,955,456 per year. This impact is allocated across providers and suppliers nationwide.

The CMS also estimates the provider/supplier cost of mailing medical records to be \$10.81 per submission. This estimation was derived by determining the average weight of

<sup>1</sup> Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook*, Medical Records and Health Information Technicians, on the Internet at <https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm> (visited September 28, 2020).



a submitted medical record and the average United States Postal Service (USPS) rate for mailing them.

The CMS queried several Medicare contractors and determined that on average providers/suppliers submit 134 pages per medical record. One piece of paper weighs approximately 4.5 grams. Thus 134 pages weighs 603 grams or 1.33 pounds. The USPS rates are determined by weight and service region. There are nine USPS service regions. Rates differ by region, so we averaged the rates. The average USPS ground rate for a parcel not exceeding two pounds is \$10.81. More detailed information about USPS rates can be found at [https://pe.usps.com/text/dmm300/Notice123.htm#\\_c037](https://pe.usps.com/text/dmm300/Notice123.htm#_c037).

Many of the records are received electronically which have lower associated costs than USPS mail. CMS now offers electronic submission of medical documents (esMD) to all providers and suppliers who wish to use a less expensive alternative for sending in medical documents. Additional information on esMD can be found at <https://www.cms.gov/esMD>. In addition, most Medicare contractors have portals which permit providers/suppliers to securely submit medical records electronically. It is difficult to determine costs associated with submitting medical records electronically. Many providers/suppliers have electronic medical records which may require a few key strokes to transmit while others might scan records and send electronically. Some may elect to FAX medical records. We believe all electronic submissions are lower cost than the \$10.81 USPS rate for a parcel not exceeding 2 pounds. For the purpose of burden estimation, we applied half the USPS rate to determine the cost of electronic submission. Thus, we assume \$5.41 cost for each electronic submission.

The CMS estimates that 48% of medical records are submitted through USPS while 52% are submitted electronically. These estimates are based on information obtained from the MACs regarding method of medical record transmission modality. The CMS estimates that the total provider/supplier cost burden for medical record transmission is \$3,886,027 annually.

**Annual Number of Provider/Supplier Submissions = 485,632**

| Submission Method | Number of Submission     | Cost of each Submission | Total Annual Provider/Supplier Submission Cost |
|-------------------|--------------------------|-------------------------|--|
| Electronic        | 52% of 485,632 = 252,529 | \$5.41                  | \$1,366,180                                    |
| USPS              | 48% of 485,632 = 233,103 | \$10.81                 | \$2,519,847                                    |
| <b>Total:</b>     |                          |                         | <b>\$3,886,027</b>                             |

To estimate total cost burden to providers/suppliers, we added the total annual collection cost to the total annual submission cost and arrive at a \$13,841,483 total annual cost burden to providers/suppliers.

**Total Annual Providers/Suppliers Cost Burden**

|                        |                     |
|------------------------|---------------------|
| Annual Collection Cost | \$9,955,456         |
| Annual Submission Cost | \$3,886,027         |
| Total                  | <b>\$13,841,483</b> |

13. Capital Costs

There are no capital costs associated with this collection. Providers/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 prepay medical review are \$162 million over three years based on the fully loaded costs including overhead. The average amount per year is \$54 million per year.

15. Changes in Burden

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. However, burden has decreased as a result of the implementation of Medicare's TPE medical review program, and the transition of prior authorization burden to a separate information collection request (OMB control numbers: 0938-1368, 0938-1293 and pending ICR - Repetitive, Scheduled Non-Emergent Ambulance Transport (RSNAT) Prior Authorization National Model (CMS-10708) . In addition, we no longer estimate cost and time burdens associated with signature attestations. CMS is decreasing the burden hours by 954,373 hours (from 1,197,189 to 242,816 hours).

16. Publication or Tabulation

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

17. Expiration Date

There are no instruments associated with this data collection.