

## **SUPPORTING STATEMENT PART A**

### **Medicare Fee-for-Service Early 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 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/Uniform Program Integrity Contractors (ZPICs/UPICs), 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/suppliers. CMS follows four parallel strategies in meeting this goal: 1) preventing fraud through effective enrollment and through education of providers/suppliers and beneficiaries, 2) early detection through, for example, medical review and data analysis, 3) close coordination with partners, including ZPICs/UPICs, 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) (<https://www.cms.gov/manuals/downloads/pim83c03.pdf>), CMS requires MACs to analyze claims to determine provider/supplier compliance with Medicare coverage, coding, and billing rules and take appropriate corrective action when providers/suppliers 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/suppliers and beneficiaries fairly.

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/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 medical record 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/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 but before the payment is made. 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/supplier on prepayment medical record review, the contractor would perform a probe review. A probe is prepayment or postpayment medical record review of a small sample of claims for a specific billing code. Generally comprised of 20 to 40 claims, a probe is used to confirm that the provider/supplier is billing the program in error. This allows for a determination as to whether a problem exists and ensures that providers/suppliers are not unnecessarily burdened and that contractor medical review resources are appropriately utilized.

Recently, the CMS has expanded a medical review strategy called Targeted Probe and Educate (TPE) nationally. This strategy combines a review of a sample of claims with education to help reduce errors in the claims submission process. When performing medical review as part of TPE, 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 may be referred to CMS for additional action. Providers/suppliers may be 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.

For this information collection, CMS and its agents request medical records. As discussed in more detail in Chapter 3.2.3 of the PIM, medical records include any additional documentation, other than what is included on the face of the claim that supports payment for the item or service billed. For Medicare to consider coverage and payment for any item or service, the information submitted by the provider/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 practitioner/lab/ambulance notes and includes:

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.

When conducting medical record review, the contractor specifies documentation they require in accordance with Medicare's rules and policies. Providers/suppliers may submit 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 count all claims for which there was 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 because the provider/supplier did not respond to the contractor's request for additional documentation.

Upon completion of the medical review, a payment determination is made based on the supporting documentation which validates the appropriateness of the furnished item or service. In cases where a provider/supplier does not respond to a request for additional documentation, the payment determination may be denial. Any determination must be documented and include the rationale for the decision. Contractors are required to follow Medicare rules, including but not limited to The Social Security Act, Code of Federal Regulations, National Coverage Determinations and Local Coverage Determinations. 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/UPIC.

## **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/UPICs 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 Centers for Medicare & Medicaid Services (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 were 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, 100-08 which can be found at

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only->

[Manuals-IOMs-Items/CMS019033.html](https://www.cms.gov/Manuals-IOMs-Items/CMS019033.html).

### 3. Improved Information Techniques

Medicare contractor requests for information are made using written, case specific additional documentation requests (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).

### 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 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. 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 (100-08), Chapter 3, Section 2.3.2 (<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 medical review determinations 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 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 7, 2018 (83 FR 5425). 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 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 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.

**Early Review of Medical Records**

Currently, MACs are conducting primarily prepayment reviews following the Targeted Probe and Educate (TPE) process. The TPE review and education process includes a review of 20-40 claims followed by one-on-one, provider-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, provider specific, one-on-one education. Providers/suppliers with high error rates after round two will continue to a third and final round of probe reviews and education. In addition to education at the conclusion of each 20-40 claim probe review, MACs also educate providers throughout the probe review process, when easily resolved errors are identified, helping the provider to avoid additional similar errors later in the process. Contractors may also perform prior authorization reviews before the claim is submitted.

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. We believe that while there is a lot of variation 30 minutes is appropriate, this is especially true due to recent advances in technology. 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. 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. Where claims are denied on that basis, subject to CMS instructions, providers and suppliers may submit an attestation statement indicating the signature is theirs. We estimate this will be applicable on approximately 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 Collection Burden Estimate & Cost

<b>Activity</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>
Prepayment Review	2,331,778 <sup>1</sup>	0.50	1,165,889	\$36.58	\$ 42,648,220
Prior Authorization	46,700	0.50	23,350	\$36.58.	\$ 854,142
Attestation	31,800	0.25	7,950	\$36.58	\$ 290,811

<sup>1</sup> This number has dropped from 3.1 million reviews in 2015 secondary to implementation of CMS policy to decrease non-clinical reviews that are focused only on documentation validation.

TOTAL	2,410,278	n/a	1,197,189	\$36.58	<b>\$ 43,793,173</b>
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## 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

<https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm>) information we estimate an average hourly rate of \$18.29<sup>2</sup> with a loaded rate of \$36.58. This equates to a cost of \$43,793,173 per year or \$131,379,519 for three years. This impact is allocated across providers and suppliers nationwide.

The CMS also estimates the provider/supplier cost of mailing medical records to be \$10.60 per submission. This estimation was derived by determining the average weight of a submitted medical record and the average United States Postal System (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 680.4 grams or 1.34 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 rate for a parcel not exceeding two pounds is \$10.60. More detailed information about USPS rates can be found at <https://pe.usps.com/cpim/ftp/manuals/dmm300/Notice123.pdf>

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 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 \$10.60 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 \$5.30 cost for each electronic submission.

The CMS estimates that 17% of medical records are submitted through USPS while 83% are submitted electronically. These estimates are based on CMS' data of medical record transmission modality. The CMS estimates that the total provider/supplier cost burden for medical record transmission is \$14,946,132 annually or \$44,838,396 for three years.

<sup>2</sup> Based on 2016 mean hourly wage for M-29-2071- Medical Records and Health Information Technicians, Bureau of Labor Statistics

**Annual Number of Provider/Supplier Submissions = 2,410,278**

Submission Method	Number of Submission	Cost of each Submission	Total Provider/Supplier Submission Cost
Electronic	83% of 2,410,278 = 2,000,531	\$5.30	\$10,602,814
USPS	17% of 2,410,278 = 409,747	\$10.60	\$4,343,318

**Total: \$14,946,132**

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 \$58,739,305 total annual cost burden to providers/suppliers.

**Total Annual Providers/Suppliers Cost Burden**

Annual Collection Cost	\$43,793,173
Annual Submission Cost	\$14,946,132
Total	<b>\$58,739,305</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 complex medical review are \$318 million over three years based on the fully loaded costs including overhead. The average amount per year is \$106 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. Due to changes in the CMS' medical review processes, CMS is decreasing the burden hours by -400,761 hours (from 1,597,950 to 1,197,189 hours).

16. Publication or Tabulation

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

17. Expiration Date

The expiration date and OMB control number will appear on the first page of the data collection instrument (top right-hand corner).