Medicare Program: Termination of Non-Random Prepayment Review (CMS-6022-P)

Background

The Centers for Medicare and Medicaid Services (CMS) is requesting the Office of Management and Budget (OMB) approval of the collections required for complex medical review identified in conjunction with the proposed regulation entitled Medicare Program: Termination of Non-Random Prepayment Review (CMS-6022-P). CMS performs medical utilization review and/or fraud review activities. 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. They request clinical and other documents to support the need for the items or services provided from providers or suppliers who submit claims for payment from the Medicare program, when data analysis indicates aberrant billing patterns which may present a vulnerability. Based on the information they receive as part of their reviews, contractors can more accurately review submitted claims. Manually reviewing the information presented on the face of the claim, does not always ensure a fair and equitable payment decision without this additional documentation providing a more comprehensive clinical picture. This regulation sets forth criteria to lessen the burden on providers and suppliers, by establishing clear limits and conditions determining the amount of time a provider may remain on medical review.

Non–random prepayment complex medical review is the evaluation of medical records or any other documentation by a licensed medical professional prior to Medicare payment. Complex medical review determinations require the reviewer to make a clinical judgment about whether an item or service is covered, and is reasonable and necessary. In order for this determination to be made the provider or supplier would submit a copy of the medical records that indicate that the items or services billed are covered, and are reasonable and necessary for the condition of the patient. This type of review delays payment until the contractor is able to make a determination that the items or services billed are covered and are reasonable and necessary. The proposed rule (CMS-6022-P) only applies to terminating a provider or supplier from non-random prepayment complex medical review. (A detailed description of the concepts for performing the different types of non-random prepayment medical review functions are located in our manual instructions at http://www.cms.hhs.gov/manuals/108_pim/pim83toc.asp).

The contractor employs data analysis procedures to identify claims that may be billed inappropriately. These procedures 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 his designees.

Before a contractor places a provider or supplier on non-random prepayment complex medical review, the contractor would perform a probe review (that is, 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 complex medical review. Performing medical review on a sample of claims for a specific billing code before placing the provider or supplier on non-random prepayment complex medical review allows for a determination as to whether a problem exists and ensures that contractor medical review resources are targeted appropriately and that providers and suppliers are not unnecessarily burdened.

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) this may result in the provider or supplier being placed on non-random prepayment complex medical review. Contractors target medical review activities at providers, items or services that place the greatest risk of making improper payments from the Medicare trust funds.

This activity may involve complex medical review. Complex medical review involves the application of clinical judgment by a licensed medical professional in order to evaluate medical records to determine whether an item or service is covered, and is reasonable and necessary.

Medical records include any medical 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 supplier or provider (i.e., claims) must be supported by the documentation in the patient's medical records. The patient's medical records include: physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and/or diagnostic reports and other supporting documentation. The contractor specifies which pieces of documentation they want. Providers 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 the claims do not clearly indicate medical necessity.

Any determination must be documented and include the rationale for the decision. While medical review staff must follow National Coverage Determinations and Local Coverage Determinations, they are 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 Benefit Integrity Program Safeguard Contractor.

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 fiscal intermediaries, carriers, durable medical equipment regional carriers, and rural home health intermediaries (contractors) processes claims for health services.

Furthermore these contractors and some of our program safeguard contractors are tasked, under §1893 of the Act to perform 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.

§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.

CMS estimates that its Medical Review activities are directly responsible for yearly program savings of over $4 billion.

2. Information Users

The information required under this collection is requested by Medicare contractors, and is requested of providers or suppliers submitting claims for payment from the Medicare program when data analysis indicates aberrant billing patterns which may present a vulnerability to the Medicare program.

3. Improved Information Techniques

This collection of information does not involve the use of automated, electronic, or other forms of information technology. Requests for information are made using written, case specific additional documentation requests (ADR) letters, requesting specific information from a specific provider or supplier. The use of a standard form would be unfeasible.

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 presents a program vulnerability. However, since this collection will not impact a substantial number of small businesses, and the retention of the requested information is a routine business practice, the economic impact is minimal. Requesting only the information needed to make payment determinations only in cases where vulnerability exists, further reduces this impact.

6. Less Frequent Collections

Since this information is only collected when potential program vulnerability exists, less frequent collections of this information would be imprudent.

7. Special Circumstances

More often than quarterly - This information is collected on an as-needed basis. When contractors determine that a provider 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 are notified that they have 30 days to respond , as already currently required in the Program Integrity Manual (100-08), Chapter 3, Section 4.1.2.

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 regulation 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. Medicare 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. MR is not performed to create statistical pictures of Medicare utilization (except for the CERT error rate). Contractors may use statistical tools to target medical 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 high level of payment error or documented educational efforts have failed to correct billing

problems. The calculation of a provider'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 for this information collection request published on June 9, 2006.

9. Payments or Gifts to respondents

No payments or gifts will be given to respondents.

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

Section 421.405 of the regulation CMS-6022-P outlines the proposed requirements and process for the termination and extension of non-random prepayment complex medical review, a form of complex medical review.

The burden associated complex medical review is the time and effort necessary for the provider or supplier of services to locate and obtain the supporting documentation for the claim to Medicare and to forward the materials for submission to Medicare contractors for review.

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

CMS estimates that it will take the supplier or provider no longer than 20 minutes to

locate, photocopy and transmit this information to the contractor upon request. Over the past three years, Medicare contractors have performed complex medical review on an average of 2.9 million claims.

The total annual burden associated with this regulation is estimated to be 966,000 hours (2.9 million requests for medical records x 20 minutes).

Respondent Cost

CMS estimates that it should take an office clerk no more than 20 minutes to complete the activities associated with this collection. At an average salary of $11.94 per hour, this represents a cost of $11,534,040.00.

13. Capital Costs

There are no capital costs associated with this collection.

14. Costs to Federal Government

Over the past three years, costs associated with performing complex medical review has averaged $60,000,000

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. This collection does not represent a change in policy or burden. We increased our estimate to 20 minutes due to comments on the 6022-P regulation.

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.

18. Certification Statement

There are no exceptions to the certification statements.