

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Part 421****[CMS-6022-F]****RIN 0938-AN31****Medicare Program; Termination of Non-Random Prepayment Complex Medical Review****AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Final rule.

SUMMARY: This final rule implements requirements regarding the termination of non-random prepayment complex medical review as required under the Medicare Prescription Drug, Improvement and Modernization Act of 2003. This final rule sets forth the criteria CMS contractors will use for terminating a provider or supplier from non-random prepayment complex medical review.

DATES: *Effective Date:* These regulations are effective on January 1, 2009.

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SUPPLEMENTARY INFORMATION:**I. Background**

CMS's Medicare contracting authority has been in place since the inception of the Medicare program in 1965. Section 1874 of the Social Security Act (the Act) authorizes the Secretary to perform Medicare program functions directly or by contract.

On August 21, 1996, the Congress enacted the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104-191). Section 202 of HIPAA added section 1893 to the Act to establish the Medicare Integrity Program and to allow CMS to contract with eligible entities to perform program integrity activities. Specifically, we contract with the following entities: Intermediaries as specified in section 1816(a) of the Act; carriers as specified in section 1842(a) of the Act; and program safeguard contractors (PSCs) to perform medical, fraud, and utilization reviews, and cost report audits of Medicare claims. (Hereinafter, intermediaries, carriers, and PSCs that perform medical review functions are referred to as "contractors.") The Medicare Integrity Program is funded by the Medicare Hospital Insurance Trust Fund for activities related to Medicare Part A and Part B.

On December 8, 2003, the Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173). Section 934 of the MMA amended section 1874A of the Act by adding a new subsection regarding random prepayment reviews and non-random prepayment complex medical reviews, and requiring CMS to establish termination date(s) for non-random prepayment complex medical reviews performed by Medicare Administrative Contractors (MACs) (or intermediaries and carriers until MACs are in place). While section 1874A of the Act does not require CMS to establish termination dates for non-random prepayment complex medical reviews performed by PSCs, we have authority to apply these termination dates to medical review performed by PSCs under section 1893(b) of the Act. Applying this final rule to all contractors who perform non-random prepayment complex medical review not for benefit integrity purposes ensures that the same criteria for terminating non-random prepayment complex medical review apply to all providers and suppliers, whether they are under review by a MAC or a PSC.

Although section 934 of the MMA sets forth requirements for random prepayment review, our contractors currently do not perform random prepayment review. However, our contractors do perform non-random prepayment complex medical review. We are cognizant of the need for additional rulemaking should we wish our contractors to perform random review.

In the October 7, 2005 **Federal Register** (70 FR 58649), we published a proposed rule specifying the criteria contractors would use for the termination of providers and suppliers from non-random prepayment complex medical review as required under the MMA (hereinafter referred to as the proposed rule).

For purposes of this regulation, we are defining the following terms related to medical review activities:

Allowable charge means the dollar amount (including co-payment and deductibles) that the Medicare program will pay for a particular item or service.

Benefit integrity review means medical review of claim information and medical documentation focusing on addressing situations of potential fraud, waste and abuse.

Complex medical review means review of claim information and medical documentation, by a licensed medical professional, for a billed item or service identified by data analysis techniques or probe review to have a

likelihood of sustained or high level of payment error.

Contractor means intermediaries, carriers, Medicare Administrative Contractors (MACs), and program safeguard contractors (PSCs).

Error rate means the dollar amount of allowable charges for a particular item or service billed in error as determined by complex medical review, divided by the dollar amount of allowable charges for that medically reviewed item or service.

Initial error rate means the calculation of an error rate based on the results of a probe review prior to the initiation of non-random prepayment complex medical review.

Medical review means the process performed by Medicare contractors to ensure that billed items or services are covered and are reasonable and necessary as specified under section 1862(a)(1)(A) of the Act.

Nonclinician medical review staff means specially trained medical review staff that does not possess the knowledge, skills, training, or medical expertise of a licensed medical professional.

Non-random prepayment complex medical review means the prepayment medical review of claim information and medical documentation, by a licensed medical professional, for a billed item or service identified by data analysis techniques or probe review to have a likelihood of sustained or high level of payment error.

Non-random prepayment medical review means the prepayment medical review of claims, by nonclinical or clinical medical review staff, for a billed item or service identified by data analysis techniques or probe review to have a likelihood of a sustained or high level of payment error.

Postpayment medical review means medical review of claims, by nonclinical or clinical medical review staff, for a billed item or service after a claim has been paid.

Provider-specific probe review means the complex medical review of a small sample of claims, generally 20 to 40 claims, from a specific provider or supplier for a specific billing code to confirm that or determine whether the provider or supplier is billing the program in error.

Quarterly error rate means the calculation of an error rate based on the results of non-random prepayment complex medical review for a specific billing code for a specific quarter.

Random prepayment medical review means the prepayment medical review of claims, by nonclinical or clinical medical review staff, for a billed item or

service that has not been identified by data analysis techniques or probe review to have a likelihood of a sustained or high level of payment error.

Service-specific probe review means the complex medical review of a sample of claims, generally 100 claims, across the providers or suppliers that bill a particular item or service to confirm that or determine whether the item or service is billed in error.

Termination of non-random prepayment complex medical review means the cessation of non-random prepayment complex medical review.

II. General Overview of the Medical Review Process and Provisions of the Proposed Rule

A. Medical Review

We enter into contractual agreements with contractors to perform medical review functions. One of the functions of a contractor is to ensure the fiscal integrity of the Medicare program by conducting medical review of claims to determine whether items or services are covered and are reasonable and necessary. When a claim is submitted for payment, it may be subject to medical review before payment is made.

There are three types of non-random prepayment medical review: Automated, routine, and complex. Non-random prepayment medical review is one form of targeted medical review. An automated non-random prepayment medical review is when decisions are made at the system level, using available electronic information, without the intervention of contractor personnel. A routine non-random prepayment medical review is limited to rule-based determinations performed by specially trained nonclinical medical review staff. Automated and routine non-random prepayment medical reviews do not create an administrative burden on the provider or supplier since additional medical documentation does not need to be submitted for these types of medical reviews and payments for covered, reasonable and necessary items or services are not delayed. Therefore, these types of reviews pose no discernable administrative burden on the provider or supplier because there is no interaction between the contractor and the provider or supplier during the medical review process.

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 must 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. This final rule 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/IOM/list.asp> and then click on "Publication 100-08.")

Generally, with non-random prepayment complex medical review, the contractor employs data analysis procedures to identify claims that may be billed inappropriately. These procedures may be based on claims data (national and local), beneficiary complaints, and alerts from other organizations (for example, the U.S. Department of Health and Human Services Office of Inspector General and the 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 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 performs 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, ensures that contractor medical review resources are targeted appropriately, and ensures that providers and suppliers are not unnecessarily burdened.

When a probe confirms or determines whether 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 by the contractor on non-random prepayment complex medical review. Contractors target their medical review activities at those providers, suppliers, items, or services that pose the greatest risk of improper payments from the Medicare Trust Funds.

Complex medical review as defined in § 421.501 (proposed § 421.401), involves the application of clinical judgment by a licensed medical professional in order to evaluate medical records to determine whether an item or service billed is covered, correctly coded, and reasonable and necessary for the condition of the patient under Medicare rules.

Medical records, defined at § 421.501 (proposed § 421.401), 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 claims submitted by the supplier or provider must be supported by the documentation in the patient's medical records. The patient's medical records may include the following: (1) Physician's office records; (2) hospital records; (3) nursing home records; (4) home health agency records; (5) records from other healthcare professionals; and (6) diagnostic testing reports and other supporting documentation. The contractor specifies what documentation it needs to conduct medical review. Providers and suppliers may be required to supply additional documentation not explicitly listed by the contractor. This supporting information may be requested by CMS and our contractors on a routine basis in instances where information on the claims (for example, diagnosis, frequency, site of service) or in claims history does not clearly indicate medical necessity.

Any determination must be documented by the contractor 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 where the contractor detects possible fraud, the contractor would refer the issue to the contractor responsible for benefit integrity review.

Before the enactment of the MMA, we continued to perform non-random prepayment complex medical review until the provider or supplier met all Medicare billing requirements as evidenced by an acceptable error rate. The contractor made the determination of "acceptable error rate." As a result, some providers and suppliers have remained on non-random prepayment complex medical review for a considerable period of time.

B. Termination of Non-Random Prepayment Complex Medical Review

In accordance with section 934 of the MMA, we proposed to terminate, in most cases, a provider or supplier from non-random prepayment complex medical review no later than 1 year from the initiation of the review, or when the provider's or supplier's error rate decreases by 70 percent from the initial error rate (70 FR 58651, October 7, 2005). The initiation of review begins on the date of notification by the contractor to the provider or supplier. This letter notification would inform the provider or supplier of the results of the probe review and inform the provider or supplier that they are being placed on non-random prepayment complex medical review.

In the proposed rule, we proposed that a provider or supplier be terminated from non-random prepayment complex medical review if error rate findings indicate that the provider or supplier has corrected its billing errors, resulting in at least a 70 percent decrease from its initial error rate (70 FR 58651, October 7, 2005). For a discussion of our rationale for setting this percentage for purposes of this regulation, see the proposed rule (70 FR 58651, October 7, 2005).

We did not explicitly propose whether there is a minimum timeframe that a provider or supplier must be on non-random prepayment complex medical review. We proposed that the initial error rate would be calculated based on the probe review prior to the initiation of non-random complex prepayment medical review.

We proposed when a provider or supplier is terminated from non-random prepayment complex medical review and the contractor determines that the provider or supplier continues to have a high error rate despite educational interventions, the contractor must consider referring the provider or supplier to the contractor responsible for Benefit Integrity review. Contractors must also consider continuing educational interventions (without performing further medical review) or consider the need for post-payment medical review.

We also proposed that a contractor must extend a non-random prepayment complex medical review beyond the 1-year limit in certain situations where the provider or supplier may have altered its billing practices in such a way to avoid or minimize contractor review. We proposed if the reduction in the error rate is attributed to a 25 percent or greater reduction in the number of claims submitted for the specific billing code under review, non-random prepayment complex medical review for that provider or supplier must be extended.

We also proposed if the number of claims submitted for a specific code was reduced because the provider or supplier began billing claims using a new appropriate code, or there is another legitimate explanation for the reduced number of claims billed, at the contractor's discretion, the provider or supplier may not be required to undergo extended non-random prepayment complex medical review. If extended medical review is necessary, contractors would notify providers and suppliers in writing of the reason for the need to perform additional prepayment complex medical review.

We proposed that the contractor would evaluate the results of non-random complex prepayment medical review, and the length of time a provider or supplier remains on review, at least every quarter following the initiation of non-random prepayment complex medical review. Quarterly error-rate evaluations would be for the discrete quarter; a rolling error rate average over more than one quarter would not be appropriate. We also proposed that after the contractor determines that the provider or supplier must be terminated from non-random prepayment complex medical review, the contractor must update the claims processing system within 2 business days to ensure that the provider's and supplier's claims are no longer suspended for that specific billing error.

We proposed that once a provider or supplier is terminated from non-random

prepayment complex medical review contractors must periodically reevaluate the provider or supplier's data and retain the discretion to place a provider or supplier that appears to have resumed a high level of payment error on complex prepayment medical review. The proposed rule stated that before placing a provider or supplier back on non-random prepayment complex medical review, the contractor must conduct a probe review to confirm that there continues to be a high level of payment error (70 FR 58652, October 7, 2005). If such review finds a high level of payment error, the contractor may place the provider or supplier back on non-random prepayment complex medical review.

III. Analysis of and Response to Public Comments

We received 18 timely public comments on the proposed rule. The following is a summary of the comments received and our responses.

A. Comments Regarding the Proposed 70 Percent Decrease in Error Rate

Comment: We received several comments concerning whether the 70 percent decrease in error rate was an appropriate number in order for a provider or supplier to be terminated from non-random prepayment complex medical review. Some commenters generally agreed with this percentage and others believed it should be lower.

Response: The commenters requested many different error rates, many of which were lower than what we proposed, but we did not find consensus among the commenters for any one particular error rate. Since there was no consensus on an alternate percentage, we are leaving the percentage as originally proposed. We believe it strikes a fair balance between safeguarding the Medicare Trust Funds and providing a rational and predictable process for providers and suppliers to be removed from non-random prepayment complex medical review.

Comment: One commenter believed that the proposed 70 percent decrease in error rate should only apply to nonclinical aspects of error determination. Instead, the commenter proposed a 51 percent decrease as a threshold for reviewing clinical decision making outcomes, asserting this would improve the mathematic probability of termination in such cases because reviewers may form subjective clinical judgments from reviewing mostly documentation and being unable to clinically verify diagnoses. Also, the commenter believed a 51 percent reduction would provide small to

medium-sized providers a fair opportunity for successful termination.

Response: We believe that regardless of whether the denial is based on a nonclinical or clinical error, it is still a denial for improper payment. We continue to believe a 70 percent reduction in error rate is a reasonable percentage to use to determine whether non-random prepayment complex medical review must continue. The statute does not require us to distinguish between provider size in establishing termination dates. We believe all providers and suppliers will have a fair opportunity for successful termination, regardless of size.

Comment: One commenter believes that extensions of non-random prepayment complex medical review should be rare, and that contractors should be prohibited from using the extension authority because it contravenes our efforts to provide reliability and predictability to the termination process.

Response: In addition to the criteria set forth in § 421.505(b) (proposed § 421.405(b)) for extending non-random prepayment complex medical review, we will provide specific manual instructions to our contractors in IOM Manual 100–08 (Program Integrity Manual) to address this concern after the release of this final rule.

B. Comments Regarding the Proposed 1 Year Timeframe for Termination From Non-Random Prepayment Review

Comment: We received several comments concerning whether 1 year is the appropriate timeframe to terminate a provider from non-random prepayment complex medical review. The concern of the commenters was whether or not CMS should keep providers on review for longer than 365 days in order to obtain 4 complete quarters of data; whether the contractor will stop reviewing claims on day 365 and start to calculate the error rate on day 366; or terminate review completely on day 365 before the error rate had been calculated.

Response: We proposed that the 1-year timeframe would begin on the date provided in the letter notifying the provider or supplier of initiation of non-random prepayment complex medical review. We believe that 1 year is a sufficient amount of time for a provider or supplier to reduce its initial error rate or for the contractor to determine whether a referral to Benefit Integrity or extended medical review under § 421.505(b) (proposed § 421.405(b)) is necessary. Unless an exception applies under § 421.505(b) (proposed § 421.405(b)), the contractor must

remove a provider or supplier from non-random prepayment complex medical review after 1 calendar year (365 days) from the date of notification of non-random prepayment complex medical review regardless of whether an error rate for the fourth quarter has been calculated. Thus, they would be removed from review on day 366.

Comment: One commenter asked if a provider continues to incur a sustained or high level of payment error following termination, whether the appropriate procedure should be to place the provider back on non-random prepayment complex review. The commenter also noted that at that point, the burden of proof should shift to the contractor.

Response: We have revised proposed § 421.505(d) (proposed § 421.405(d)) to indicate that if after the 1-year termination date the provider continues to have a sustained or high level of payment error, the contractor may reinitiate non-random prepayment complex review after 6 months, but only after a probe confirms that there continues to be a high level of payment error. When a provider or supplier is terminated from non-random prepayment complex medical review after 1 year of review and the contractor determines that the provider or supplier continues to have a high error rate despite educational interventions, the contractor must consider referring the provider or supplier to the contractor responsible for benefit integrity review. Contractors must also consider continuing educational interventions without performing further medical review or consider the need for post-payment medical review.

Comment: One commenter questioned how the 1-year timeframe would be calculated if the contractor selects only 20 to 40 claims for the initial probe review and then terminates the edit.

Response: By “terminates the edit,” we believe the commenter means that after the initial 20 to 40 claims are selected, the contractor does not initiate non-random prepayment complex medical review. As previously stated, the 1-year timeframe is calculated from the date the provider or supplier is notified by letter that they are being subject to non-random prepayment complex manual review after the initial probe review is completed. A small sample (for example, 20 to 40 claims) enables the contractor to make an error rate determination in a short time period, so there is not an extended period of time when claims are paid without review. If a provider does not submit an adequate number of new claims for the probe review, the

contractor has the option to complete the sample selection from paid claims. If a significant number of claims are billed and paid during the review process, the contractor has an option to complete a post-pay review process to collect the overpayment.

Comment: One commenter asked if it is acceptable to have a provider on an intermittent non-random prepayment review for longer than 1 year if quarterly evaluation of the sample of claims shows that provider specific education has not resulted in significant improvement.

Response: In the circumstance described above and assuming that review could not be extended under § 421.505(b) (proposed § 421.405(b)), once a provider is removed from targeted non-random prepayment review, the contractor would need to conduct a new probe before it would be able to place that provider back on review and start the clock over again.

C. Comments Regarding the Proposed Provider Appeal Process

Comment: Two commenters indicated that providers and suppliers should have some ability to appeal a probe review determination which places the provider or supplier on medical review.

Response: Neither the statute nor the regulations provide the provider or supplier a right to appeal a probe review determination, which we assume the commenter means a finding by the contractor that there is a likelihood of sustained or high level of payment error. Nor does it require an expedited appeal if a provider remains on review for a given period of time. However, we note that a provider or supplier always has the ability to appeal the results of a contractor's determination on an individual claim.

Comment: Several commenters suggested that the contractors should recompute the error rate to include reversals in each appeal level.

Response: If during the 1-year timeframe a provider or supplier is successful on appeal in overturning the initial medical review determination, we have instructed contractors through manual instructions located at <http://www.cms.hhs.gov/manuals/IOM/list.asp> and then click on “Publication 100–08”) to consider such appeals results when making decisions to continue medical review activities. However, after such consideration there may still be valid reasons for the contractor to elect not to remove providers or suppliers from review. Therefore, we are giving the contractor discretion to remove the provider or supplier from review based on appeals information. Please note that

the timeframe allowed for appeal through all levels of appeal is not always accomplished within the 1-year timeframe made final in this rule. Therefore, it is not practical to require contractors to modify the error rate based on appeals results, as the appeals information may change through the levels of appeal.

D. Comments Regarding the Proposed Computation of Error Rate

Comment: One commenter suggested that the computation of the quarterly error rate should account for the supplier's accreditation and past compliance.

Response: We believe accreditation and past compliance are extremely important but in order to safeguard the Medicare Trust Fund we need to ensure that the error rate computation is based on current claims submitted.

Comment: Several commenters indicated that we do not explain the process contractors use to determine what error rate is determined to be a "high level," what mathematical probability or range constitute a "likelihood," or what time period and intensity of billing errors meet the definition of "sustained."

Response: We do not further define the terms "high level, likelihood, or sustained" in the definition of "complex medical review" under § 421.501 (proposed § 421.401) because we believe contractors need the administrative flexibility to determine whether an error rate is "high level, likely, or sustained." A variety of factors influence our determinations of such payment error such as the scope of the problem, potential risk to the Trust Fund, the risk relative to other risks identified by contractor data analysis, and past history of the provider or supplier.

Comment: One commenter stated that unless and until statistically meaningful verification of billing error is performed by a licensed medical professional through a complex review probe, a provider should not be placed on non-random prepayment complex medical review status.

Response: We believe the probe sample is an appropriate tool to determine the nature and extent of the problem. A "provider-specific probe review" may only be performed by a clinician based on problems identified by contractor data analysis. We believe that requiring a physician to review every claim in a probe would be cost prohibitive to the contractor. In addition, we note that each contractor is required to employ a physician to provide their clinical expertise. Statistically valid verification would

require a much larger sample than 20 to 40 claims, thus increasing the burden and cost to the provider or supplier.

Comment: One commenter indicated that the 1-year mark for termination is not necessarily a true calendar year for all cases under such review. The commenter stated that we proposed to allow contractors to make code-specific error rate determinations on a quarterly basis. Contractors are not required to calculate error rates at the 1-year anniversary mark after the provider is sent notice of non-random prepayment complex medical review. That means that a provider whose anniversary falls at the beginning of a quarter can remain on review almost 3 months longer than a calendar year. Another commenter asked if a quarter was any 3-month period that the contractor chooses or if it must be a financial quarter.

Response: Unless an exception applies under § 421.505(b) (proposed § 421.405(b)), the contractor must remove a provider or supplier from non-random prepayment complex medical review after 1 calendar year (365 days) from the date of notification of non-random prepayment complex medical review regardless of whether an error rate for the fourth quarter has been calculated. We will defer to the contractor as to how to calculate when the quarter begins. Depending on the timing of the initiation of non-random prepayment complex medical review, contractors may or may not have an opportunity to calculate a fourth quarter error rate for a particular provider or supplier.

Comment: Two commenters requested a tiered system that depends upon the degree of improvement in a provider's error rate, or an option that would remove a provider from review when they meet a threshold of 10 percent or less of the overall error rate.

Response: We initially considered whether a 90 to 95 percent decrease in a provider's or supplier's error rate was appropriate, but determined that, for purposes of this regulation, a 90 to 95 percent reduction in error rate would be impracticable. We continue to believe that an error rate reduction of 70 percent from the initial error rate calculated during probe review would protect the financial integrity of the Medicare program, and allow the provider or supplier a realistic opportunity to be terminated from non-random prepayment complex medical review. Our contractors will continue to retain the discretion to terminate providers and suppliers at an earlier date.

Comment: One commenter was concerned about the lack of specific quantitative measures for triggering

placement of providers on non-random prepayment complex medical review. The commenter recommended that we establish 30 percent as the national probe denial rate for triggering non-random prepayment complex medical review.

Response: In order for the contractors to have sufficient flexibility to guard the integrity of the Medicare Trust Fund, we leave the criteria for triggering review to the contractor's discretion. This allows the contractors to provide the specific level of review that best enables them to work with the provider or supplier to lower their error rate.

Comment: One commenter indicated that although we recommend limiting agency probe edits to 20 to 40 claims, and limiting service specific probe edits to 100 claims, we do not provide direction as to a minimum number of claims to be reviewed when determining whether a provider or supplier is likely to have a sustained or high level of payment error rate. The commenter recommended that we create criteria for a minimum number of records to be reviewed before determining that a provider or supplier has a likelihood of sustained or high level of payment error. The commenter stated that this should be no fewer than 10 claims on a particular probe for a quarter. Another commenter asked if provider-specific probe reviews should only include claims for the particular item or service that may be billed in error.

Response: The minimum number of claims to be reviewed in a probe will vary across provider and supplier type, volume, and service. Quarterly termination evaluation does not entail a probe. The contractor evaluates claims reviewed under the non-random prepayment complex medical review in a quarter and determines the error rate for selected claims during the quarter. The probe is used to establish the initial error rate only. The contractor does attempt to focus provider-specific probe review on those claims with items or services that may be billed in error. In the case of service specific review, the 70 percent reduction will be determined against the service-wide error rate. In some cases, service-specific review becomes a catalyst for provider-specific review of a subset of providers. In this instance, that subset would be measured against their own individual error rates. This is consistent with our Internet-Only Manual 100-08, Chapter 3, section 3.11.1.2.

Comment: One commenter requested notice and comment rulemaking on the definition of "complex medical review."

Response: The definition and description of “complex medical review” were provided in the proposed rule (70 FR 58653, October 7, 2005), and as such, were subjected to notice and comment rulemaking.

Comment: Two commenters urged us to revise the proposed provisions that require contractors terminate a provider’s or supplier’s non-random prepayment complex medical review and remove any language establishing a minimum timeframe that providers or suppliers are subject to review.

Response: We agree with the commenters and have clarified in § 421.505(b) (proposed § 421.405(b)) that contractors may extend non-random prepayment complex medical review in certain cases and have clarified in § 421.505(a) (proposed § 421.405(a)) that there is no minimum timeframe that a provider or supplier must be on review. Unless an exception applies under § 421.505(b) (proposed § 421.405(b)) a provider or supplier must be removed from review if it meets either the 1 year or 70 percent criteria set forth in § 421.505(a) (proposed § 421.405(a)), and may be removed at any time at the discretion of the contractor.

Comment: One commenter stated that updated error rate reports from the contractor to the provider need to be timely and specific, demonstrate individual claims decisions (paid or unpaid), and show a detailed accounting of how the quarterly error rate was calculated or updated.

Response: We agree that the error rate reports should be given to providers with a narrative explanation. We will provide specific manual instructions in IOM Manual 100–08 (Program Integrity Manual) to our contractors in this regard after the release of this final rule.

Comment: One commenter questioned how the error rate percentage is determined. Specifically the commenter asked if it is based on dollar amount, days of coverage, or if it depends on the type of service billed.

Response: The error rate percentage is based on dollars.

E. Comments Regarding the Proposed Documentation Requirements

Comment: We received several comments stating that the 10-minute estimated time for obtaining medical records discussed in the proposed rule (70 FR 58652, October 7, 2005) is not the correct estimate of needed time.

Response: In response to these comments, we have updated our estimate in the Collection of Information Requirements section of this final rule to 20 minutes to account for variations across providers or suppliers.

Comment: Several commenters expressed concern that medical records and chart notes should not be relied upon to determine Medicare eligibility. The commenters believe that the medical records a supplier must collect and submit are inherently ambiguous, subjective, and not suited for uniform review. The commenters also believe that physicians do not typically document specific Medicare coverage criteria in their medical records, and the records are not created with an intention that they will be reviewed by third parties who are not familiar with the patients and their medical condition. The commenters are concerned that requiring physicians to document the medical records in this fashion will place a substantial burden on the physicians, cause nonclinicians to interfere with the prescribing physicians, and will create a new and relatively unfamiliar documentation scheme.

Response: This final rule does not change existing documentation requirements. We believe that current documentation requirements for providers and suppliers are designed to provide a comprehensive picture of a patient’s history and condition. CMS and our contractors have implemented extensive educational outreach to both suppliers and the medical community pertaining to documentation requirements.

We require under § 421.505(a)(2) (proposed § 421.405(a)(2)) that providers and suppliers submit supporting medical documentation for claims under review in order for our contractors to be able to compute an error rate based on current claims. If the contractor is unable to calculate an error rate due to the failure or refusal by a provider or supplier to submit requested medical documentation, we have clarified in § 421.505(b)(1) (proposed § 421.405(b)(1)) that the contractor may extend non-random prepayment complex medical review for such a provider or supplier. Without sufficient medical records to calculate the quarterly error rate the contractor is unable to apply the regulation’s criteria to a provider or supplier in determining whether to remove it from review. We believe it is a prerequisite for these rules to apply that providers and suppliers submit the required medical documentation for claims while they are on non-random prepayment complex medical review.

Comment: One commenter estimated that the burden for a supplier to locate and obtain the supporting documentation for a claim and forward the materials to the Medicare contractor

for review will take 4.71 hours per claim.

Response: We do not believe that this time is typical across provider types. In any event, we did not propose to change documentation requirements.

F. General Comments

Comment: One commenter indicated that medical review findings are critical to performing focused education. The commenter stated that without the identified errors, local provider education and training would be less effective. The commenter believes that education would be general, based on global findings, and not specific to the provider’s issue.

Response: We agree that there are different interventions, including education, available to our contractors. This regulation does not limit those interventions.

Comment: One commenter indicated that it would be difficult to determine if shifts to other codes not subject to review are inappropriate if claims for those services are not reviewed with records.

Response: Nothing in this regulation precludes the contractor from performing record review to determine if an inappropriate shift in billing codes occurred. However, we are not requiring such additional review since in some cases shifts may be readily explained from data analysis alone.

Comment: One commenter inquired if the referral to benefit integrity could be delayed while additional provider education and validation are performed.

Response: Referral to benefit integrity may be delayed if additional provider education is needed and/or further validation is needed to evaluate a provider or supplier’s error rate. A contractor may need to extend review of a provider or supplier beyond the 1-year timeframe or even if the initial error rate has been reduced by 70 percent or more if the contractor needs to further validate whether the provider or supplier has properly reduced its error rate. In some cases, a provider or supplier may use improper billing practices to reduce its error rate to minimize or avoid review. We proposed at § 421.405(b)(1) to extend review beyond 1 year if a provider or supplier engaged in two specific types of improper billing practices: The provider or supplier stopped billing the code under review or shifted billing to another inappropriate code to avoid proper calculation of the error rate.

In the final rule, we have added two more bases for the contractor to extend review at § 421.505(b)(1) (proposed § 421.405(b)(1)) and have clarified that

review may be extended even if the provider or supplier has been on review for 1 year or has reduced its initial error rate by 70 percent or more. In addition to the proposed bases to extend review, the contractor may also extend review where the provider or supplier fails to respond to requests for medical records or the contractor determines the provider or supplier is engaging in improper claims or billing-related activities.

Because we cannot anticipate all types of improper claims or billing-related practices that providers and suppliers may engage in, we believe it is important that contractors have discretion to extend non-random prepayment complex medical review in any instance where the contractor determines the provider or supplier is engaging in improper claims or billing activities to avoid review. For example, a contractor may extend review if the provider or supplier starts billing under a different provider identification number with apparent intent to avoid proper calculation of the error rate. We believe the proposed bases for a contractor extending review may have fallen short of addressing all situations where the contractor may need to extend non-random prepayment complex medical review to evaluate whether the initial error rate has been appropriately reduced, and therefore, we are revising § 421.505(b)(1) (proposed § 421.405(b)(1)) to encompass these additional types of situations.

If there is potential fraud, we believe it is vital for the reviewing contractor to quickly make the referral to Benefit Integrity. The contractor responsible for performing the benefit integrity review can validate if potential fraud has occurred or is ongoing. If the contractor does not find any evidence of fraud, then the benefit integrity contractor can still provide education to the provider. If the contractor detects possible fraud at any time during the medical review process, the contractor would refer the issue to the contractor responsible for benefit integrity review.

Comment: Two commenters recommended that the proposed timeframe to update the claims processing system should be changed from 2 to 5 business days once a provider or supplier is taken off of prepayment complex medical review. The commenters also stated that the system security regulations will prevent most contractors from discontinuing an edit in 2 business days.

Response: Although we are not aware of what system security regulations the commenter is speaking of, we are revising § 421.505(c)(2) (proposed

§ 421.405(c)(2)) to state that the contractors' claims processing system must be updated within 5 business days after the contractor determines that the provider or supplier should be terminated from non-random prepayment complex medical review.

Comment: A number of commenters indicated that we have not issued instructions that indicate that documentation requirements for power mobility devices (PMDs) vary by patient diagnosis.

Response: We agree that we have not issued instructions that indicate that document requirements for power mobility devices vary by patient diagnosis. In addition, we believe that the example included in the proposed rule (70 FR 58651) was an inappropriate example, and therefore, we are not including that example as part of this final rule.

Comment: One commenter stated that, when a provider or supplier is terminated from non-random prepayment complex medical review and a new probe review must be performed to determine if there is a high level of payment error, the probe review cost per claim is significantly higher than provider-specific prepayment review.

Response: We realize that it may be more costly to complete a new probe review; however, we believe requiring a new probe provides assurance to the public that non-random prepayment complex review is data driven and its impact on providers and suppliers is not to be taken lightly. Contractors need to allocate resources as efficiently as possible to protect the Medicare Trust Fund.

Comment: One commenter asked that we distinguish between the medical role of the physician and the collaborative role of the supplier. The commenter believes it is not the role of the supplier to review, analyze, and interpret medical records to fill the treating physician's prescription, and that it is not in the best interest of the beneficiary for the supplier to overturn the judgment of the patient's treating physician.

Response: This final rule does not add any new documentation requirements. We note that it is the supplier's responsibility to provide a legible copy of the written prescription and any other required information. We believe that a party engaged in healthcare-related business should ensure that their staff has adequate expertise to carry out its responsibilities, and should obtain the training necessary to achieve and maintain that level of expertise.

The supplier should obtain as much documentation from the patient's medical record as it needs to determine if the Medicare coverage criteria for payment have been met. If the information in the patient's medical record does not adequately support the medical necessity for the item, then the supplier is liable for the dollar amount of the assigned claims involved unless a properly executed advance beneficiary notice (ABN) of possible denial has been obtained.

Comment: One commenter recommended that we develop an expanded version of the current Certificate of Medical Necessity (CMN), or a template that employs several open-ended questions that could easily be used by physicians, suppliers, and beneficiaries to determine if medical necessity exists and to document that need.

Response: This comment is outside the scope of this regulation. We do not address CMNs in this regulation.

Comment: One commenter asked if we expect all non-random prepayment complex medical review edits to be selecting 100 percent of a provider's claims for at least 1 year.

Response: No, contractors continue to have the flexibility to do less than 100 percent prepayment review.

Comment: One commenter asked if the 1-year timeframe is for each provider or supplier in a progressive corrective action case, or for the progressive corrective action case itself.

Response: The 1-year timeframe is for each provider placed on non-random prepayment complex medical review.

Comment: One commenter asked if the probe review finds that a provider is submitting claims to Medicare for a service that is not a Medicare benefit, would a 100 percent non-random prepayment review be appropriate until the situation is corrected.

Response: If the probe review finds that a provider is submitting claims to Medicare for a service that is not a Medicare benefit, a 100 percent non-random prepayment review is an option open to the contractor to correct the situation. This regulation applies to these types of claims, as well as other inappropriate claims. If the provider or supplier is billing non-covered services under covered codes, the contractor may wish to refer to the contractor responsible for benefit integrity review for fraud or abuse investigation. The contractor responsible for benefit integrity review has the option of continuing prepayment review during their investigative process.

Although we did not receive comments on what entities are

considered CMS contractors, we want to clarify that a new type of contractor (as mandated by the MMA), the Medicare Administrative Contractors (MACs), are also contractors for purposes of this regulation. In the proposed rule, we stated that we enter into contractual agreements with contractors (for example, intermediaries, carriers, and program safeguard contractors (PSCs)) to perform medical review functions to ensure that items or services are covered and are reasonable and necessary in accordance with Medicare coverage policies and program instructions. For clarity, we are adding MACs to the types of contractors subject to these regulations and clarifying that this rule only applies to medical review not for benefit integrity purposes.

Section 421.500 (proposed § 421.400) is revised to read as follows: “CMS enters into contractual agreements with intermediaries, carriers, program safeguard contractors (PSCs), and Medicare Administrative Contractors (MACs) to perform medical review functions to ensure that items or services are covered and are reasonable and necessary in accordance with Medicare coverage policies and program instructions.

IV. Provisions of the Final Rule

After the publication of the October 7, 2005 proposed rule, we published a final rule adding regulations to Part 421, subpart E. Therefore, the regulations in this final rule are finalized in Part 421, subpart F and the sections are renumbered as indicated throughout this final rule. We are also adopting the provisions as set forth in the proposed rule with the following changes.

In § 421.500 (proposed § 421.400), although we did not receive comments on what entities are considered CMS contractors, we are clarifying that the Medicare Administrative Contractors (MACs), are also contractors subject to this regulation. In the proposed rule, we stated that we enter into contractual agreements with contractors (for example, intermediaries, carriers, and program safeguard contractors (PSCs)) to perform medical review functions to ensure that items or services are covered and are reasonable and necessary in accordance with Medicare coverage policies and program instructions. When the proposed rule was published in 2005, the MACs were not yet established and only intermediaries, carriers, and PSCs were conducting medical review. Now that MACs are in operation, we are clarifying that MACs, as required by the statute, are also subject to this regulation. We are also clarifying in § 421.500 (proposed

§ 421.400) that this rule only applies to medical review not for benefit integrity purposes. Section 421.500 (proposed § 421.400) is revised to read as follows: “CMS enters into contractual agreements with intermediaries, carriers, program safeguard contractors (PSCs), and Medicare Administrative Contractors (MACs) to perform medical review functions not for benefit integrity purposes to ensure that items or services are covered and are reasonable and necessary in accordance with Medicare coverage policies and program instructions.

In § 421.501 (proposed § 421.401), we are adding the definition of “contractor” as used in this subpart.

We are clarifying in § 421.505(a) (proposed § 421.405(a)) that there is no minimum timeframe that a provider or supplier must be on review. We are also correcting a technical error from the proposed rule where we stated “a contractor may terminate a provider or supplier” to read “a contractor must terminate a provider or supplier” (70 FR 58653). Unless an exception applies under § 421.505(b) (proposed § 421.405(b)), providers and suppliers must be removed if they meet either the 70 percent reduction in error rate criterion or have been on review for 1 year from the initiation of such review. Providers and suppliers may also be removed at any time at the discretion of the contractor.

We are revising § 421.505(b)(1) (proposed § 421.405(b)(1)) to state that contractors have the discretion to extend non-random prepayment complex medical review if a provider or supplier fails to respond to requests for medical records, stops billing the code under review, shifts billing to another inappropriate code to avoid proper calculation of the error rate, or engages in any other improper claims or billing-related activity to avoid non-random prepayment complex medical review.

We are revising § 421.505(c)(2) (proposed § 421.405(c)(2)) to state that the contractors’ claims processing system must be updated within 5 business days after the contractor determines that the provider or supplier should be terminated from non-random prepayment complex medical review.

In § 421.405(d) of the proposed rule, we stated that contractors must periodically reevaluate the provider or supplier’s data and, if necessary, must place a provider or supplier that appears to have resumed a high level of payment error on complex medical review. Due to contractor resources, we are revising the language at § 421.505(d)(1) (proposed § 421.405(d)(1)) to state that contractors may periodically reevaluate

the provider or supplier’s data and, if necessary, may place a provider or supplier that appears to have resumed a high level of payment error on complex medical review.

In § 421.505(d)(1) (proposed § 421.405(d)(1)), we are correcting a technical error from the proposed rule at § 421.405(d) to state that a provider or supplier found to have resumed a high level of payment error is placed back on “non-random prepayment complex medical review.” In § 421.505(d)(2) (proposed § 421.405(d)(2)), we have also clarified that a provider or supplier is not placed back on such review earlier than 6 months after termination of a previous non-random prepayment complex medical review.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In summary, § 421.505 (proposed § 421.405) outlines the requirements and process for the termination and extension of non-random prepayment complex medical review, a form of complex medical review. Contractors conduct complex medical review to determine whether items or services billed are covered, correctly coded, and are reasonable and necessary for the condition of the patient. Under complex medical review the provider or supplier must submit a copy of the medical records that support the items or services billed.

The burden associated with this section 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. We expect that this

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

Based on public comments, we revised the burden estimate associated with this requirement. We increased the

allotted time from 10 to 20 minutes per provider or supplier to locate, photocopy, and transmit this information to the contractor upon request.

The total annual burden for all of the Medicare providers and suppliers associated with this requirement is

estimated to be 966,667 hours (2.9 million requests for medical records × 20 minutes per provider or supplier). The burden associated with this information collection requirement is currently approved under OMB control number 0938–0969 with a January 31, 2010 expiration date.

TABLE 1—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

OMB control No.	Respondents	Responses	Burden per response (minutes)	Total annual burden (hours)
0938–0969	1,160,000	2,900,000	20	966,667
Total				966,667

VI. Regulatory Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993, as further amended), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 (as amended by Executive Order 13258) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6.5 million to \$31.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined that this rule would not have a significant economic impact on a substantial number of small entities. We believe that this rule would decrease the costs for providers and suppliers

because it establishes guidelines for terminating a provider or supplier from non-random prepayment complex medical review. We believe this rule would decrease the time and amount of resources spent on inappropriate reviews and would ensure that Medicare payments would not be withheld for extended time periods. Because a contractor would no longer be maintaining providers or suppliers on non-random prepayment complex medical review for extended periods, administrative expenses (for example, copying, mailing, and the retention of medical documentation) would be reduced.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. The threshold level is currently approximately \$130 million. This rule would have no consequential effect on the governments mentioned or on the private sector.

Executive Order 13132 establishes certain requirements that an agency

must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation would not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 421

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as follows:

PART 421—MEDICARE CONTRACTING

■ 1. The authority citation for part 421 continues to read as follows:

Authority: Sec. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Subpart F is added consisting of § 421.500 through § 421.505 to read as follows:

Subpart F—Medical Review

Sec.

421.500 Medicare review functions.

421.501 Definitions.

421.505 Termination and extension of non-random prepayment complex medical review.

Subpart F—Medical Review

§ 421.500 Medicare review function.

CMS enters into contractual agreements with intermediaries, carriers, Medicare Administrative Contractors (MACs), and program safeguard contractors (PSCs) to perform

medical review functions not for benefit integrity purposes to ensure that items or services are covered and are reasonable and necessary in accordance with Medicare coverage policies and program instructions.

§ 421.501 Definitions.

As used in this subpart—

Allowable charge means the dollar amount (including co-payment and deductibles) that the Medicare program will pay for a particular item or service.

Benefit integrity review means medical review of claim information and medical documentation focusing on addressing situations of potential fraud, waste and abuse.

Complex medical review means all medical review of claim information and medical documentation by a licensed medical professional, for a billed item or service identified by data analysis techniques or probe review to have a likelihood of sustained or high level of payment error.

Contractor, as used in this subpart, means intermediaries, carriers, Medicare Administrative Contractors (MACs), and program safeguard contractors (PSCs).

Error rate means the dollar amount of allowable charges for a particular item or service billed in error as determined by complex medical review, divided by the dollar amount of allowable charges for that medically reviewed item or service.

Initial error rate means the calculation of an error rate based on the results of a probe review prior to the initiation of complex medical review.

Medical review means the process performed by a contractor to ensure that billed items or services are covered and are reasonable and necessary as specified under section 1862(a)(1)(A) of the Act.

Nonclinician medical review staff means specially trained medical review staff not possessing the knowledge, skills, training, or medical expertise of a licensed health care professional.

Non-random prepayment complex medical review means the prepayment medical review of claim information and medical documentation, by a licensed medical professional, for a billed item or service identified by data analysis techniques or probe review to have a likelihood of sustained or high level of payment error.

Non-random prepayment medical review means the prepayment medical review of claims, by nonclinical or clinical medical review staff, for a billed item or service identified by data analysis techniques or probe review to

have a likelihood of a sustained or high level of payment error.

Postpayment medical review means medical review of claims, by nonclinical or clinical medical review staff, for a billed item or service after a claim has been paid.

Provider-specific probe review means the complex medical review of a small sample of claims, generally 20 to 40 claims, from a specific provider or supplier for a specific billing code to confirm that or determine whether the provider or supplier is billing the program in error.

Random prepayment medical review means the prepayment medical review of claims, by nonclinical or clinical medical review staff, for a billed item or service that has not been identified by data analysis techniques or probe review to have a likelihood of a sustained or high level of payment error.

Quarterly error rate means the calculation of an error rate based on the results of non-random prepayment complex medical review for a specific billing code for a specific quarter.

Service-specific probe review means the complex medical review of a sample of claims, generally 100 claims, across the providers or suppliers that bill a particular item or service to confirm that or determine whether the item or service is billed in error.

Termination of non-random prepayment complex medical review means the cessation of non-random prepayment complex medical review.

§ 421.505 Termination and extension of non-random prepayment complex medical review.

(a) *Timeframe that a provider or supplier must be on non-random prepayment complex medical review.* There is no minimum timeframe that a provider or supplier must be on review. Except for cases described in paragraph (b) of this section, a contractor must terminate a provider or supplier from non-random prepayment complex medical review—

(1) No later than 1 year following the initiation of non-random prepayment complex medical review; or

(2) When calculation of the error rate indicates that the provider or supplier has reduced its initial error rate by 70 percent or more. A contractor must review claims for a specific billing code aberrancy for the quarter and calculate the quarterly error rate for those claims medically reviewed in that quarter. In order for this determination to be made, the provider or supplier must submit a copy of the medical records that indicate that the items or services billed are covered, correctly coded, and are

reasonable and necessary for the condition of the patient.

(3) When a provider or supplier is terminated from non-random prepayment complex medical review after 1 year of review and the contractor determines that the provider or supplier continues to have a high error rate despite educational interventions, the contractor must consider referring the provider or supplier to the contractor responsible for benefit integrity review. Contractors must also consider continuing educational interventions without performing further medical review or consider the need for post-payment medical review.

(b) *Extension of non-random prepayment complex medical review.*

(1) A contractor has the discretion to extend non-random prepayment complex medical review if a provider or supplier stops billing the code under review, shifts billing to another inappropriate code to avoid proper calculation of the error rate, fails to respond to requests for medical records, or engages in any other improper claims or billing-related activity to avoid non-random prepayment complex medical review. If the reduction in the error rate is attributed to a 25 percent or greater reduction in the number of claims submitted for the specific billing code under review, non-random prepayment complex medical review for that provider or supplier may be extended. However, if the number of claims submitted for a specific code was reduced because the provider or supplier began billing claims using a new appropriate code, or there is another legitimate explanation for the reduced number of claims billed, the contractor retains discretion to terminate from or extend a provider or supplier on non-random prepayment complex medical review.

(2) If extended medical review is necessary, contractors must notify providers and suppliers in writing the reasons for the need to perform additional prepayment complex review.

(c) *Quarterly termination evaluation.*

(1) Contractors, at a minimum, must evaluate the length of time a provider or supplier has been on non-random prepayment complex medical review on a quarterly basis.

(2) A determination as to whether the provider's or supplier's initial probe review error rate for a specific billing code has been reduced by 70 percent must also be evaluated quarterly. There is no minimum timeframe that a provider or supplier must be on review.

(3) The contractor's quarterly error rate evaluations must be for the discrete

quarter; a rolling error rate average over more than 1 quarter is not permitted.

(4) After the contractor determines that the provider or supplier must be terminated from non-random prepayment complex medical review, the claims processing system must be updated within 5 business days to ensure that a provider's or supplier's claims for a specific billing error are no longer suspended for non-random prepayment complex medical review.

(d) *Periodic re-evaluation.* (1) Once a provider or supplier is terminated from non-random prepayment complex medical review, contractors may periodically re-evaluate the provider or supplier's data and may place a provider or supplier that appears to have resumed a high level of payment error on non-random prepayment complex medical review.

(2) This review would only be initiated if a probe review confirms that there continues to be a high level of payment error.

(3) If there is a high level of payment error, a provider or supplier may be placed on non-random prepayment complex medical review no earlier than 6 months after termination of a previous non-random prepayment complex medical review. As set forth in § 421.505(a)(3) contractors may also refer the provider or supplier to the contractor responsible for benefit integrity review or place the provider or supplier on postpayment medical review.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: March 21, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: June 3, 2008.

Michael O. Leavitt,

Secretary.

[FR Doc. E8–22307 Filed 9–25–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 423

[CMS–4124–F2]

RIN–0938–AO78

Medicare Program; Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes; Correcting Amendment

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule; correcting amendment.

SUMMARY: In the December 5, 2007 issue of the **Federal Register**, we published a final rule finalizing the Medicare program provisions relating to contract determinations involving Medicare Advantage (MA) organizations and Medicare Part D prescription drug plan sponsors, including eliminating the reconsideration process for review of contract determinations, revising the provisions related to appeals of contract determinations, and clarifying the process for MA organizations and Part D sponsors to complete corrective action plans. In that final rule, we also clarified the intermediate sanction and civil money penalty provisions that apply to MA organizations and Part D sponsors, modified elements of MA organizations and Part D sponsors' compliance plans, retained voluntary self-reporting for Part D sponsors, implemented voluntary self-reporting for MA organizations, and revised provisions to ensure HHS has access to the books and records of MA organizations and Part D sponsors' first tier, downstream, and related entities. This correcting amendment corrects a limited number of technical and typographical errors identified in the December 5, 2007 final rule.

DATES: These correcting amendments are effective September 26, 2008, except for the amendment to § 423.505, which is effective on January 1, 2009. The correcting amendments for § 422.756(d) and § 423.756(d) are applicable beginning January 4, 2008.

FOR FURTHER INFORMATION CONTACT: Christine Reinhard (410) 786–2987. Stephanie Blaydes Kaisler (410) 786–0957.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 07–5946 (72 FR 68700 through 68741), the final rule entitled, “Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes,” there were technical errors that have been identified and corrected in the regulations text of this correcting amendment. We note that correcting two of these technical errors, found at § 422.756(d) and § 423.756(d), ensure that certain existing provisions which were never intended to be the subject of notice and comment rulemaking, remain in place for the benefit of all affected parties, including MA organizations and Part D sponsors. The provisions in this correcting amendment for § 422.756(d) and § 423.756(d) are effective as if they were included in the final rule published December 5, 2007.

Accordingly, the corrections are effective retroactive to January 4, 2008, the effective date of most of the provisions of the final rule. However, the provisions in this correcting amendment for § 423.505 are effective January 1, 2009 since these particular provisions in § 423.505 were not set to take effect until January 1, 2009.

II. Summary of Errors in the Regulations Text

On pages 68726 and 68735 of the December 5, 2007 final rule, there were technical errors made in the regulation text of § 422.756(d) and § 423.756(d). Specifically, a typographical error in our amendatory instructions caused us to inadvertently omit from the Code of Federal Regulations (CFR) existing paragraphs § 422.756(d)(3) and § 423.756(d)(3) regarding the duration of an MA and Part D intermediate sanction, respectively. We note that these existing provisions were not intended to be revised in the December 5, 2007 final rule (72 FR 68700 through 68741).

On page 68732 of the December 5, 2007 final rule, our amendatory instruction indicated that we were revising § 423.505(i)(2)(i). However, when we set out the changed regulations text, we inadvertently revised paragraph (i)(2)(ii) instead of paragraph (i)(2)(i). This typographical error, if not corrected, would have inadvertently deleted from the CFR the current paragraph at § 423.505(i)(2)(ii) regarding the 10-year record retention requirement as of January 1, 2009, the effective date of this provision as specified in the final rule. The correct § 423.505(i)(2)(i) should read “HHS, the Comptroller General, or their designees