

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]

BILLING CODE 4120-01-P

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

have the right to audit, evaluate and inspect any books, contracts, records, including medical records, and documentation of the first tier, downstream, and related entities involving transactions related to CMS' contract with the Part D sponsor." As stated above, the existing § 423.505(i)(2)(ii), which references the 10-year record retention requirements, remains in the CFR unchanged.

In § 423.505(i)(3)(iii) the term "related entity" is incorrectly used twice in the same sentence, so we have removed this duplication. In addition, we inadvertently included MA organization in § 423.505(i)(3)(iv) which only applies to Part D sponsors. We have revised the language accordingly.

III. Waiver of Proposed Rulemaking and Delay in Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide a period for public comment before the provisions of a rule take effect in accordance with section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). However, we can waive this notice and comment procedure if the Secretary finds, for good cause, that the notice and comment process is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons therefore in the notice.

Section 553(d) of the APA ordinarily requires a 30-day delay in effective date of final rules after the date of their publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued.

The provisions of this correcting amendment regarding the duration of sanctions at § 422.756(d) and § 423.756(d) make no substantive changes and are intended to restore provisions which were inadvertently removed from the CFR. These provisions were not revised in the final rule but were dropped because of a typographical error in our amendatory instructions. We must reinstate these provisions in the CFR to ensure that CMS may lift sanctions on MA and Part D plans as appropriate.

In addition, a typographical error in our regulations text would have inadvertently removed the current § 423.505(i)(2)(ii) from the CFR as of the effective date for these provisions on January 1, 2009. We are taking this opportunity to correct this error in the

CFR to ensure that the 10-year record retention requirements for Part D sponsors remains in the CFR unchanged. Without this correcting amendment, the Medicare Part D regulations could have been construed as being silent on the 10-year Part D recordkeeping requirement which could create confusion and uncertainty for affected parties regarding CMS' policy on this issue.

Finally, we are also taking this opportunity to correct typographical errors in § 423.505(i)(3)(iii) and (iv).

Because we are issuing this correcting amendment based on typographical errors, we find that undertaking further notice and comment procedures to incorporate these corrections into the December 5, 2007 final rule is unnecessary and contrary to the public interest.

For the same reasons, we are also waiving the 30-day delay in effective date for § 422.756(d) and § 423.756(d) in this correcting amendment. We believe that it is in the public interest to ensure that the December 5, 2007 final rule accurately state the current law and CMS policy. Thus, delaying the effective date of these corrections would be contrary to the public interest. Therefore, we also find good cause to waive the 30-day delay in effective date for § 422.756(d) and § 423.756(d).

List of Subjects

42 CFR Parts 422 and 423

- Accordingly, 42 CFR chapter IV is corrected by making the following correcting amendments to parts 422 and 423.

PART 422—MEDICARE ADVANTAGE PROGRAM

- 1. The authority citation for part 422 continues to read as follows:

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

- 2. Section 422.756 is amended by adding paragraph (d)(3) to read as follows:

§ 422.756 Procedures for imposing intermediate sanctions and civil money penalties.

* * * * *

(d) * * *

(3) *Duration of sanction.* The sanction remains in effect until CMS notifies the MA organization that CMS is satisfied that the basis for imposing the sanction has been corrected and is not likely to recur.

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

- 3. The authority citation for part 423 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh).

- 4. Section 423.505 is amended by—
- A. Revising paragraph (i)(2)(i).
- B. Revising paragraph (i)(2)(ii).
- C. Revising paragraph (i)(3)(iii).
- D. Revising paragraph (i)(3) (iv).

The revisions read as follows:

§ 423.505 Contract provisions.

* * * * *

(1) * * *

(2) * * *

(i) HHS, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any books, contracts, records, including medical records, and documentation of the first tier, downstream, and related entities involving transactions related to CMS' contract with the Part D sponsor.

(ii) HHS', the Comptroller General's, or their designee's right to inspect, evaluate, and audit any pertinent information for any particular contract period exists through 10 years from the final date of the contract period or from the date of completion of any audit, whichever is later.

(3) * * *

(iii) A provision requiring that any services or other activity performed by a first tier, downstream, and related entity in accordance with a contract or written agreement are consistent and comply with the Part D sponsor's contractual obligations.

(iv) A provision requiring the Part D sponsor's first tier, downstream, and related entities to produce upon request by CMS, or its designees, any books, contracts, records, including medical records and documentation of the Part D sponsor, relating to the Part D program, to either the sponsor to provide to CMS, or directly to CMS or its designees.

* * * * *

- 5. Section 423.756 is amended by adding paragraph (d)(3) to read as follows:

§ 423.756 Procedures for imposing intermediate sanctions and civil money penalties.

* * * * *

(d) * * *

(3) *Duration of sanction.* The sanction remains in effect until CMS notifies the Part D sponsor that CMS is satisfied that

the basis for imposing the sanction is corrected and is not likely to recur.

* * * *

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

Dated: September 16, 2008.

Ann C. Agnew,

Executive Secretary to the Department.

[FR Doc. E8-22592 Filed 9-25-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 455

[CMS-2271-F]

RIN 0938-AO97

Medicaid Integrity Program; Eligible Entity and Contracting Requirements for the Medicaid Integrity Audit Program

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

ACTION: Final rule.

SUMMARY: Section 1936 of the Social Security Act (the Act) (as added by section 6034 of the Deficit Reduction Act of 2005 (DRA) established the Medicaid Integrity Program to promote the integrity of the Medicaid program by requiring CMS to enter into contracts with eligible entities to: (1) Review the actions of individuals or entities furnishing items or services (whether on a fee-for-service, risk, or other basis) for which payment may be made under an approved State plan and/or any waiver of such plan approved under section 1115 of the Act; (2) audit claims for payment of items or services furnished, or administrative services rendered, under a State plan; (3) identify overpayments to individuals or entities receiving Federal funds; and (4) educate providers of services, managed care entities, beneficiaries, and other individuals with respect to payment integrity and quality of care.

This final rule will provide requirements for an eligible entity to enter into a contract under the Medicaid integrity audit program. The final rule will also establish the contracting requirements for eligible entities. The requirements will include procedures for identifying, evaluating, and resolving organizational conflicts of interest that are generally applicable to

Federal acquisition and procurement; competitive procedures to be used; and procedures under which a contract may be renewed.

DATES: This final rule is effective October 27, 2008.

FOR FURTHER INFORMATION CONTACT:

Barbara Rufo, 410 786-5589 or Crystal High, 410-786-8366.

SUPPLEMENTARY INFORMATION:

I. Background

A. Current Law

States and the Federal government share in the responsibility for safeguarding Medicaid program integrity. States must comply with Federal requirements designed to ensure that Medicaid funds are properly spent (or recovered, when necessary). CMS is the primary Federal agency responsible for providing oversight of States' Medicaid activities and facilitating their program integrity efforts.

B. Medicaid Integrity Program

Section 6034 of the Deficit Reduction Act (DRA) of 2005 (Pub. L. 109-171, enacted on February 8, 2006) added a new section 1936 to the Act that established the Medicaid Integrity Program, referenced as the "Program" hereafter, to combat Medicaid fraud and abuse. The Program is intended to identify, recover, and prevent Medicaid overpayments. It is also intended to support the efforts of the State Medicaid agencies through a combination of support and technical assistance.

Although individual States work to ensure the integrity of their respective Medicaid programs, the Program represents CMS' first national strategy to detect and prevent Medicaid fraud and abuse. The Program will provide CMS with the ability to more directly ensure the accuracy of Medicaid payments and to deter those who would exploit the program.

Section 6034 of the DRA amended title XIX of the Act by redesignating the former section 1936 as section 1937; and adding the new 1936 "Medicaid Integrity Program." The new section 1936 states the Secretary will promote the integrity of the Medicaid program by entering into contracts with eligible entities to carry out the following activities:

- Review of actions of individuals or entities furnishing items or services (whether on a fee-for-service, risk, or other basis) for which payment may be made under the State plan approved under title XIX (or under any waiver of such plan approved under section 1115 of the Act) to determine whether fraud, waste, or abuse has occurred, or is likely

to occur, or whether such actions have a potential for resulting in an expenditure of funds under title XIX in a manner which is not intended under the provisions of title XIX.

- Audit of claims for payment for items or services furnished, or administrative services rendered, under a State plan under title XIX, including cost reports, consulting contracts, and risk contracts under section 1903(m) of title XIX.

- Identification of overpayments to individuals or entities receiving Federal funds under title XIX.

- Education of providers of services, managed care entities, beneficiaries, and other individuals with respect to payment integrity and quality of care.

Section 1936 of the Act also mandates that the Secretary will, by regulation, establish procedures which will include the following:

- Procedures for identifying, evaluating, and resolving organizational conflicts of interest that are generally applicable to Federal acquisition and procurement.

- Competitive procedures to be used when entering into new contracts under this section; when entering into contracts that may result in the elimination of responsibilities under section 202(b) of the Health Insurance Portability and Accountability Act of 1996; and any other time considered appropriate by the Secretary.

- Procedures under which a contract under this section may be renewed without regard to any provision of law requiring competition if the contractor has met or exceeded the performance requirements established in the current contract.

CMS has determined not to address in this final rule the above bullet that references the Health Insurance Portability and Accountability Act of 1996 (HIPAA). We have determined that section 202(b) of HIPAA addressed certain Medicare contracting issues which, because of structural differences between the Medicare and Medicaid programs, such as the fact that the Federal Government does not utilize carriers or fiscal intermediaries in the Federal administration of the Medicaid program, do not pertain to the Medicaid contracting environment. Moreover, we have also determined that the provisions of the Act established by section 202(b) of HIPAA have since been repealed by section 911 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.