

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Part 422**

[CMS-4041-IFC]

RIN 0938-AK71

Medicare Program; Modifications to Managed Care Rules**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Interim final rule with comment period.**SUMMARY:** This interim final rule with comment period corrects a technical error made in the August 22, 2003 final rule "Modifications to Medicare Rules" (68 FR 50840).**DATES:** This interim final rule with comment period is effective January 31, 2005.*Comment date:* To ensure consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on February 28, 2005.**ADDRESSES:** In commenting, please refer to file code CMS-4041-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments to <http://www.cms.hhs.gov/regulations/ecomments> or to www.regulations.gov (attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word).

2. *By mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4041-IFC, P.O. Box 8010, Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7197 in advance to schedule your arrival with one of our staff members. Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue,

SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244-1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Tony Hausner, (410) 786-1093.**SUPPLEMENTARY INFORMATION:**

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS-4041-IFC and the specific "issue identifier" that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. After the close of the comment period, CMS posts all electronic comments received before the close of the comment period on its public website. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (410) 786-7197.

I. Background

[If you choose to comment on issues in this section, please include the caption "BACKGROUND" at the beginning of your comments.]

On August 22, 2003, we published a final rule titled, "Modifications to Managed Care Rules" (68 FR 50840), which implemented the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), which included certain

changes to the intermediate sanctions regulations at 42 CFR 422.758.

In that final rule, we made limited organizational changes to the intermediate sanctions regulations (68 FR 50841); however, when making those organizational changes, we made technical errors in § 422.752 and § 422.758. Specifically, the \$25,000 Civil Money Penalty (CMP) that had been described at § 422.758(a) was inadvertently omitted in the revised version of the intermediate sanctions regulation. We note that these CMPs are set forth at section 1857(g)(3)(A) of the Social Security Act (Act) and provide authority for the Secretary to apply up to a \$25,000 penalty for each determination under section 1857(c)(2) that a deficiency not otherwise described in section 1857(g)(1) of the Act exists and has directly and adversely affected (or has the substantial likelihood of adversely affecting) one or more Medicare Advantage (MA) enrollees.

The omission of the \$25,000 CMP from § 422.758(a) occurred because we included language in § 422.758(a) that was intended to replace the first two sentences of § 422.752(a). This language clarifies that CMS does not have CMP authority in the case of the violations set forth in § 422.752(a). The OIG has CMP authority in the case of these violations. In the preamble to our August 22, 2003 final rule, we noted that we were changing § 422.752(a) for this purpose (68 FR 50851). However, the regulatory text was inadvertently placed at § 422.758(a).

We also have determined that the reference to § 422.756(f)(3) in existing § 422.758(b) more appropriately belongs in the introductory text of § 422.758 because our authority to impose CMPs in the amounts set forth in all of § 422.758 is described in § 422.756(f)(3). Section § 422.758(b) also contains a redundant reference to § 422.752(b), which we are eliminating, in this interim final rule with comment period, to avoid confusion.

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA also states that the timelines for these regulations may vary but shall not exceed 3 years after publication of the preceding proposed or interim final

regulation except under exceptional circumstances.

This interim final rule finalizes provisions set forth in the August 22, 2003 final rule. We will publish the final rule within the 3-year time limit imposed by section 902 of the MMA. Therefore, we believe that the interim final rule is in accordance with the Congress' intent to ensure timely publication of final regulations.

II. Provisions of the Interim Final Rule

[If you choose to comment on issues in this section, please include the caption "PROVISIONS OF THE INTERIM FINAL RULE" at the beginning of your comments.]

To ensure that the Medicare regulations are an accurate reflection of our current statutory authority to impose CMPs, in this interim final rule with comment period, we are correcting § 422.758 to state that if we make a determination under § 422.752(b), based on any determination under § 422.510(a) except a determination under § 422.510(a)(4), we may impose civil money penalties, pursuant to § 422.756(f)(3), in the following amounts:

- If the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more MA enrollees—up to \$25,000 for each determination.
- For each week that a deficiency remains uncorrected after the week in which the MA organization receives CMS' notice of the determination—up to \$10,000.
- If we make a determination, based on a determination under § 422.510(a)(1), that an MA organization has terminated its contract with us in a manner other than as described under § 422.512—\$250 per Medicare enrollee from the terminated MA plan or plans at the time the MA organization terminated its contract, or \$100,000, whichever is greater.

In addition, we are correcting § 422.752(a) to incorporate the changes that we intended to make in the August 22, 2003 final rule (and which currently appear at § 422.758(a)) to provide that for the violations listed in § 422.752(a), we may impose the sanctions specified in § 422.750(a)(2), (a)(3), or (a)(4) on any MA organization that has a contract in effect. The MA organization may also be subject to other applicable remedies available under law.

III. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them

individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IV. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

We find for good cause that it is unnecessary to undertake notice and comment procedures because this correcting amendment does not make any substantive policy changes. This correcting amendment sets forth self-implementing provisions of the Act (as described above) with respect to the imposition of CMPs. Because the rule directly conforms to the statute and does not articulate new requirements, we believe that pursuing notice and comment is unnecessary. Moreover, because that process could introduce confusion regarding our current authority to impose CMPs, we find that pursuing that process would be both impracticable and contrary to the public interest. Therefore, for good cause, we waive notice and comment procedures under 5 U.S.C. 553(b)(B).

With respect to the requirement of a 60-day delay in the effective date of any final rule under the Congressional Review Act (CRA) (see U.S.C. section 801), the CRA provides that the 60-day delayed effective date shall not apply to any rule "which an agency for good cause finds that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." (See 5 U.S.C. section 808(2).) For the reasons set forth above, we believe that additional notice and comment rulemaking on this subject would be impracticable, unnecessary, or contrary to the public interest. Therefore, we do not believe that the CRA requires a 60-day delay in the effective date of this final rule.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

VI. Regulatory Impact

[If you choose to comment on issues in this section, please include the caption "REGULATORY IMPACT" at the beginning of your comments.]

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 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 government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 million to \$29 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 will not have a significant economic impact on a substantial number of small entities.

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 for final rules 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 will 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 that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This interim final rule with comment period does not have any costs associated with this requirement and will not approach the Unfunded Mandates Reform Act threshold.

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 does 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 422

Administrative practice and procedure, Health facilities, Health Maintenance Organizations (HMO), Medicare+Choice, Penalties, Privacy, Provider-sponsored organizations (PSO), Reporting and recordkeeping requirements.

■ Accordingly, 42 CFR chapter IV is corrected by making the following correcting amendments:

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 422.752(a) introductory text is revised to read as follows:

§ 422.752 Basis for imposing sanctions.

(a) All intermediate sanctions. For the violations listed in this paragraph (a), we may impose the sanctions specified in § 422.750(a)(2), (a)(3), or (a)(4) on any MA organization that has a contract in effect. The MA organization may also be

subject to other applicable remedies available under law.

* * * * *

■ 3. Section 422.758 is revised to read as follows:

§ 422.758 Maximum amount of civil money penalties imposed by CMS.

If CMS makes a determination under § 422.752(b), based on any determination under § 422.510(a) except a determination under § 422.510(a)(4), CMS may impose civil money penalties, pursuant to § 422.756(f)(3), in the following amounts:

(a) If the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more Medicare Advantage enrollees—up to \$25,000 for each determination.

(b) For each week that a deficiency remains uncorrected after the week in which the Medicare Advantage organization receives CMS' notice of the determination—up to \$10,000.

(c) If CMS makes a determination, based on a determination under § 422.510(a)(1) that a Medicare Advantage organization has terminated its contract with CMS in a manner other than as described under § 422.512—\$250 per Medicare enrollee from the terminated Medicare Advantage plan or plans at the time the Medicare Advantage organization terminated its contract, or \$100,000, whichever is greater.

Dated: June 23, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: September 8, 2004.

Tommy G. Thompson,

Secretary.

[FR Doc. 04-28155 Filed 12-29-04; 8:45 am]

BILLING CODE 4120-01-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 0, 4 and 63

[ET Docket No. 04-35; FCC 04-188]

Disruptions to Communications

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: The Federal Communications Commission announces the effective date for Part 4, Disruptions to Communications, and the amendments to § 63.100, Notification of service outage, which also contain information

collection requirements subject to approval by OMB. Furthermore, the Federal Communications Commission has received approval from the Office of Management and Budget (OMB) for the new and/or revised information collection requirements contained in the information collection 3060-0484, "New Part 4 of the Commission's Rules Concerning Disruptions to Communications."

DATES: Part 4 and the amendments to § 63.100, published at 69 FR 70316 (December 3, 2004), and the information collection requirements contained therein are effective January 3, 2005.

FOR FURTHER INFORMATION CONTACT: Charles Iseman at (202) 418-2444, charles.iseman@fcc.gov, Office of Engineering and Technology, TTY (202) 418-2989.

SUPPLEMENTARY INFORMATION: The FCC published a document in the **Federal Register** of December 3, 2004 (69 FR 70316) that set forth an effective date of January 3, 2005, except for part 4 and the amendments to § 63.100, which contain information collection requirements that had not been approved by the Office of Management and Budget. The document stated that the Commission will publish a document in the **Federal Register** announcing the effective date for part 4 and the amendments to § 63.100, and the information collection requirements contained therein. On December 21, 2004, OMB approved the information collection requirements for 3060-0484, "Part 4 of the Commission's Rules Concerning Disruptions to Communications." Therefore, by this Notice, the Commission announces that the effective date for part 4 and the amendments to § 63.100, and the information collection requirements contained therein (3060-0484), will be January 3, 2005. The expiration date for the information collection requirements will be December 31, 2007.

Under OMB's terms of clearance, OMB's approval of the information collection is based on the Commission's Order Granting Partial Stay, FCC 04-291, adopted December 20, 2004 and released December 22, 2004. That Order grants an immediate partial stay of the provisions of paragraph 134 of the Report and Order (summarized as 69 FR 70316, December 3, 2004) insofar as it requires the reporting as outages of DS3 simplex events that are not corrected within five days of their discovery. At this time, the duration of the partial stay is unknown and the Commission continues discussions with both homeland security officials and impacted industry representatives. The