DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Office of the Secretary  
Office of Inspector General  
42 CFR Parts 1001, 1003, 1005 and 1006  
RIN 0991–AA90  
Health Care Programs: Fraud and Abuse; Revised OIG Civil Money Penalties Resulting From Public Law 104–191  
AGENCY: Office of Inspector General (OIG), HHS.  
ACTION: Final rule; correction amendments.

SUMMARY: This document contains several corrections to the final regulations which were published in the Federal Register on Wednesday, April 26, 2000 (65 FR 24400). These regulations revised the OIG’s civil money penalty (CMP) authorities in conjunction with new or revised provisions set forth in the Health Insurance Portability and Accountability Act of 1996, and codified a number of technical corrections to the regulations governing OIG’s sanction authorities. In that final rule, several inadvertent errors appeared in the regulations text and are now being corrected.

CMP Knowledge Standard—§ 1003.102(a)(6)

In the preamble discussion regarding revisions to § 1003.102(a)(6), addressing the submission of claims for services that are medically unnecessary, we indicated that this paragraph was being amended to include the “knows or should know” standard found in the statute and in the revision to § 1003.102(a)(1) to ensure that it is not the OIG’s intent to subject providers to penalties for legitimate disagreements over the medical necessity of items and services or for honest mistakes or errors (65 FR 24403). As indicated in that discussion, while the knowledge standard in the statute requires that providers assume responsibility for appropriate billing of their services, the OIG intends to impose CMPs only after establishing that a provider knew that a billed item or service was not medically necessary, or that he or she deliberately ignored or recklessly disregarded such information. Accordingly, we indicated that we were revising § 1003.102(a)(6) by adding the words “knows or should know” to have the paragraph read as: “An item or service that a person knows or should know is medically unnecessary, and which is part of a pattern of such claims.” (emphasis added). This language was inadvertently omitted from the revised regulations text. In order to be consistent with the preamble discussion, we are correcting the omission that occurred in § 1003.102(a)(6).

Discovery—§ 1005.7

In summarizing the provisions of the final rule, we indicated that we were amending § 1005.7 to provide for motions to compel discovery once a request for production of documents has been received. The preamble stated that any objections to a request for the production of documents will have to be filed with the opposing party within 15 days of receiving the discovery request, and that the party seeking the production of documents may then file a motion to compel discovery within 15 days, unless a lengthier time frame is set by the administrative law judge (ALJ) (65 FR 24412–13). This discretion afforded to the ALJ to grant an extension was inadvertently omitted from the regulations text in § 1005.7(e). We are correcting this omission by redesignating existing paragraph (e)(3) in this section to read as (e)(4) and by adding a new paragraph (e)(3) to address the ALJ’s discretion in extending the appropriate time frames.

Preventive Care—§ 1003.101

In the definition for “preventive care” appearing in § 1003.101, the definition incorrectly cites § 1003.102(b)(13) as the applicable cross-reference. We are amending this definition to cite the correct cross-reference, which is to the term “remuneration” that is set forth in this same section.

Amendatory Language to § 1003.103(a)

Introductory Text and § 1003.105(a)(1)(i)

We are amending the language in the introductory text for § 1003.103(a) and
in paragraph (a)(1)(i) for §1003.105 to make the references consistent with the those provisions added in earlier final rulemaking published on April 7, 2000 (65 FR 18434), which addressed OIG CMP authority for unbundling hospital outpatient services.

List of Subjects
42 CFR Part 1001
Administrative practice and procedure, Fraud, Health facilities, Health professions, Medicaid, Medicare.

42 CFR Part 1003
Administrative practice and procedure, Fraud, Grant programs—health, Health facilities, Health professions, Maternal and child health, Medicaid, Medicare, Penalties.

42 CFR Part 1005
Administrative practice and procedure, Fraud, Penalties.

42 CFR Part 1006
Administrative practice and procedure, Fraud, Investigations, Penalties.

Accordingly, 42 CFR parts 1003 and 1005 are corrected by making the following correcting amendments:

PART 1003—CIVIL MONEY PENALTIES, ASSESSMENTS AND EXCLUSIONS

1. The authority citation for part 1003 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320–7, 1320a–7a, 1320a–7, 1320a–7, 1320a–7, 1320a–7a and 1320c–5.

2. Section 1003.101 is amended by revising the introductory text of paragraph (a) to read as follows:

§1003.101 Definitions.

(a) Preventive care, for purposes of the definition of the term Remuneration as set forth in this section and the preventive care exception to section 231(h) of HIPAA, means any service that—

3. Section 1003.102 is amended by revising the introductory text of paragraph (a) and by revising paragraph (a)(6) to read as follows:

§1003.102 Basis for civil money penalties and assessments.

(a) The OIG may impose a penalty and assessment against any person whom it determines in accordance with this part has knowingly presented, or caused to be presented, a claim which is for—

(6) An item or service that a person knows or should know is medically unnecessary, and which is part of a pattern of such claims.

4. Section 1003.103 is amended by revising the introductory text of paragraph (a) to read as follows:

§1003.103 Amount of penalty.

(a) Except as provided in paragraphs (b) through (k) of this section, the OIG may impose a penalty of not more than—

5. Section 1003.105 is amended by revising paragraph (a)(1)(i) to read as follows:

§1003.105 Exclusion from participation in Medicare, Medicaid and all Federal health care programs.

(a)(1) * * *

(i) Is subject to a penalty or assessment under §1003.102(a), (b)(1), (b)(4), (b)(12), (b)(13) or (b)(15); or

PART 1005—APPEALS OF EXCLUSIONS, CIVIL MONEY PENALTIES AND ASSESSMENTS

1. The authority citation for part 1005 continues to read as follows:

Authority: 42 U.S.C. 405(a), 405(b), 1302, 1320a–7, 1320a–7a and 1320c–5.

2. Section 1005.7 is amended by redesignating existing paragraph (e)(3) as (e)(4) and by adding a new paragraph (e)(3) to read as follows:

§1005.7 Discovery.

(e) * * *

(3) The ALJ may extend any of the time frames set forth in paragraph (e)(1) of this section.


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44 CFR Part 65

FEDERAL EMERGENCY MANAGEMENT AGENCY

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