OHIO—SO₂—Continued

Designated area	Does not meet primary standards	Does not meet secondary standards	Cannot be classified	Better than national standards
Washington County:				.,
Waterford Township				Х
The remainder of Washington County				X
All other counties in the State of Ohio				X

- ¹ This area remains undesignated at this time as a result of a court remand in PPG Industries, Inc. v. Costle, 630 F.2d 462 (6th Cir. 1980).
- ²This area was affected by the Sixth Circuit Court remand but has since been designated.
- ³ This area was not affected by the court remand in PPG Industries, Inc. v. Costle 630 F.2d 462 (6th Cir. 1980).

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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 the OIG's sanction authorities. Inadvertent errors appeared in the text of the regulations concerning the knowledge standard in § 1003.102 (a)(6), and in § 1005.7 with respect to discovery. In addition, an incorrect cross-reference was cited in the definition for the term "preventive care," as set forth in part 1003. As a result, we are making corrections to 42 CFR 1003.101, 1003.102(a) and 1005.7 to assure the technical correctness of these regulations.

EFFECTIVE DATE: June 5, 2000.

FOR FURTHER INFORMATION CONTACT: Joel Schaer, (202) 619–0089, OIG Regulations Officer.

SUPPLEMENTARY INFORMATION: The HHS Office of Inspector General (OIG) issued final regulations on April 26, 2000 (65 FR 24400) that revised the OIG's CMP authorities, in conjunction with new and revised provisions set forth in the Health Insurance Portability and Accountability Act of 1996, Public Law 104–191. Among other provisions, this final rulemaking codified new CMPs for excluded individuals retaining ownership or control interest in an entity; upcoding and claims for medically unnecessary services; offering inducements to beneficiaries; and false certification of eligibility for home health services. The rule also 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 $\S 1003.103(a)$ 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-7e, 1320a-10, 1395u(j), 1395u(k), 1395cc(g), 1395dd(d)(1), 1395mm, 1395nn(g), 1395ss(d), 1396b(m), 11131(c) and 11137(b)(2).

2. Section 1003.101 is amended by republishing the introductory text, and by revising the introductory paragraph for the definition of the term Preventive care to read as follows:

§ 1003.101 Definitions.

For purposes of this part:

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 republishing 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.

Dated: May 26, 2000.

Michael Carelton,

Deputy Director for Information Resource Management.

[FR Doc. 00–13994 Filed 6–2–00; 8:45 am]
BILLING CODE 4152–01–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 65

[Docket No. FEMA-7320]

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Interim rule.

SUMMARY: This interim rule lists communities where modification of the base (1-percent-annual-chance) flood elevations is appropriate because of new scientific or technical data. New flood insurance premium rates will be calculated from the modified base flood elevations for new buildings and their contents.

DATES: These modified base flood elevations are currently in effect on the dates listed in the table and revise the Flood Insurance Rate Map(s) in effect prior to this determination for each listed community.

From the date of the second publication of these changes in a newspaper of local circulation, any person has ninety (90) days in which to request through the community that the Associate Director for Mitigation reconsider the changes. The modified elevations may be changed during the 90-day period.

ADDRESSES: The modified base flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Matthew B. Miller, P.E., Chief, Hazards Study Branch, Mitigation Directorate, 500 C Street SW., Washington, DC 20472, (202) 646–3461, or (e-mail) matt.miller@fema.gov.

SUPPLEMENTARY INFORMATION: The modified base flood elevations are not listed for each community in this interim rule. However, the address of the Chief Executive Officer of the community where the modified base flood elevation determinations are available for inspection is provided.

Any request for reconsideration must be based upon knowledge of changed conditions, or upon new scientific or technical data.

The modifications are made pursuant to Section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR Part 65.