

Commodity	Parts per million
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Cilantro, leaves .....	9.0
Leafy greens, subgroup 4A, except spinach .....	9.0
Mango .....	3.0
Okra .....	4.0
Papaya .....	3.0
Sapodilla .....	3.0
Sapote, black .....	3.0
Sapote, mamey .....	3.0
Star apple .....	3.0
Vegetable, fruiting, group 8, except tomato .....	4.0
* * * * *	*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Secretary**

**Office of Inspector General**

**42 CFR Part 1008**

**Medicare and State Health Care Programs: Fraud and Abuse; Issuance of Advisory Opinions by OIG**

**AGENCY:** Office of Inspector General (OIG), HHS.

**ACTION:** Interim final rule with comment period.

**SUMMARY:** In accordance with section 205 of the Health Insurance Portability and Accountability Act of 1996, this final rule amends the OIG regulations at 42 CFR part 1008 by (1) revising the process for advisory opinion requestors to submit payments for advisory opinion costs, and (2) clarifying that notices to the public announcing procedures for processing advisory opinion requests will be published on OIG's Web site.

**DATES:** *Effective Date:* These regulations are effective on April 25, 2008.

*Comment Period:* To assure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on April 25, 2008.

**ADDRESSES:** In commenting, please refer to file code OIG-223-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 on specific recommendations and proposals through the Federal eRulemaking Portal at <http://www.regulations.gov>. (Attachments should be in Microsoft Word, if possible.)

2. *By regular, express, or overnight mail.* You may send written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG-223-IFC, Room 5246, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201. 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 before the close period to Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201. Because access to the interior of the Cohen Building is not readily available to persons without Federal Government identification, commenters are encouraged to schedule their delivery with one of our staff members at (202) 358-3141.

For information on viewing public comments, please see section IV in the **SUPPLEMENTARY INFORMATION** section below.

**FOR FURTHER INFORMATION CONTACT:** Meredith Melmed, Office of Counsel to the Inspector General, (202) 619-0335.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

*A. Section 205 of Public Law 104-191*

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-101, specifically required the Department to provide a formal guidance process to requesting individuals and entities regarding the application of the anti-kickback statute, the safe harbor provisions, and other OIG health care fraud and abuse sanctions. In accordance with section 205 of HIPAA, the Department, in consultation with the Department of Justice, issues written advisory opinions to parties with regard to: (1) What constitutes prohibited remuneration under the anti-kickback statute; (2) whether an arrangement or proposed arrangement satisfies the criteria in section 1128B(b)(3) of the Social Security Act (the Act), or established by regulation, for activities which do not result in prohibited remuneration; (3) what constitutes an inducement to reduce or limit services to Medicare or Medicaid program beneficiaries under

section 1128A(b) of the Act<sup>1</sup>; and (4) whether an activity or proposed activity constitutes grounds for the imposition of civil or criminal sanctions under sections 1128, 1128A, or 1128B of the Act.

*B. OIG Final Regulations*

OIG published an interim final rule (62 FR 7350; February 19, 1997) establishing a new part 1008 in 42 CFR chapter V addressing various procedural issues and aspects of the advisory opinion process. In response to public comments received on the interim final regulations, we published a final rule (63 FR 38311; July 16, 1998) revising and clarifying various aspects of the earlier rulemaking. The rulemaking established procedures for requesting an advisory opinion. Specifically, the rule provided information to the public regarding costs associated with preparing an opinion and procedures for submitting an initial deposit and final payment to OIG for such costs.

**II. Provisions of the Interim Final Rule**

By statute, the Department must charge a fee equal to the costs incurred by the Department in responding to a request for an advisory opinion. (42 U.S.C. 1320a-7d(b)(5)(B)(ii)). Under the interim final and final advisory opinion rules, we directed requestors to make an initial payment to the U.S. Treasury by check or money order in the amount of \$250. The regulations have also allowed for the acceptance of final payment of the fee by check or money order.

Through this interim final rule, we are setting forth several revisions to the payment process for advisory opinion requests. Specifically, we are modifying our procedures for submitting an advisory opinion request by deleting the current requirements at §§ 1008.31(b) and 1008.36(b)(6) for an initial payment of \$250 for each advisory opinion request, and replacing the existing provision set forth in § 1008.31(b) with a requirement that payment for an advisory opinion be made directly to the Treasury of the United States, as directed by OIG. In addition, we are amending § 1008.43(d) to state that an advisory opinion will be issued following receipt by OIG of confirmation that payment in full has been remitted by the requesting party to the Department of Treasury as directed by OIG.

<sup>1</sup> Public Law 104-191 erroneously cited this provision as section 1128B(b) of the Act. Section 4331(a) of the Balanced Budget Act of 1997, Public Law 105-33, corrected this citation to section 1128A(b) of the Act.

### *A. Electronic Payment Directly to the U.S. Treasury*

As of the effective date of this rule, we will no longer accept checks or money orders from requesting parties and will require payments to be made directly to the United States Treasury through wire or other electronic funds transfer. Changing the requirement that payment be made by check or money order to provide for wire or other electronic funds transfers will create efficiencies in processing payments for advisory opinion requests, reduce the use of staff resources to process such payments, and reduce the burden on requesting parties.

### *B. Elimination of Initial Deposit*

We are also eliminating the initial deposit payment from the requirements for submitting an advisory opinion request. A deposit is not required by statute. We believe that deleting the initial deposit payment will further streamline the electronic payment process and will eliminate administrative burdens that may arise if an initial deposit must be returned. For instance, where parties erroneously submit requests that are wholly outside our authority to issue an advisory opinion, such as requests regarding issues arising under the physician self-referral law (42 U.S.C. 1395nn), returning funds submitted directly to the Department of Treasury would be cumbersome. In addition, eliminating the initial deposit requirement will reduce the burden on requesting parties by consolidating the parties' payment obligations into one final payment. We will provide additional instructions to the public on our Web site (<http://www.oig.hhs.gov>) for paying fees owed for advisory opinions via wire or other electronic funds transfer.

## **III. Regulatory Impact Statement**

### *A. Administrative Procedure Act*

OIG has determined that the public notice and comment requirements of the Administrative Procedure Act, 5 U.S.C. 553(b), do not apply to this rule because the rule is procedural in nature and does not alter the substantive rights of the affected parties. Therefore, this rule satisfies the exemption from notice and comment rulemaking in 5 U.S.C. 553(b)(A). OIG nevertheless invites comments on this rule and will consider all timely submitted comments.

The advisory opinion process is an established OIG program. This rule is limited to modifying the processing of payments received for advisory opinion requests. It does not modify eligibility of a party to request an advisory opinion, nor does it modify the standards under

which OIG will accept and/or analyze a request. OIG expects that this rule will further the public's interest in minimal burden by deleting the requirement for an initial payment of a deposit to be credited toward the final advisory opinion processing costs and by allowing the use of electronic transfers of funds. The rule will also provide greater efficiency in processing payments from requestors and will save staff time.

### *B. Regulatory Analysis*

We have examined the impact of this rule as required by Executive Order 12866, the Unfunded Mandates Reform Act of 1995, the Regulatory Flexibility Act (RFA) of 1980, and Executive Order 13132.

#### *Executive Order 12866*

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulations are 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 must be prepared for major rules with economically significant effects (*i.e.*, \$100 million or more in any given year).

This is not a major rule, as defined at 5 U.S.C. 804(2), and it is not economically significant since the overall economic effect of the rule is less than \$100 million annually. As indicated in Section II of this preamble, this rule deals exclusively with the procedural issues involved in the payment for advisory opinions issued by OIG. This rule does not address the substance of the anti-kickback statute or other sanction statutes. This rule does not change any costs associated with requesting an advisory opinion, but, rather, clarifies the procedures for submitting statutorily-mandated payment for costs incurred preparing an advisory opinion. We believe that the aggregate economic impact of this rule will be minimal and will have no effect on the economy or on Federal or State expenditures. To the extent that there is any economic impact, that impact will likely result in savings of Federal dollars through the improved efficiencies in the use of staff resources for processing advisory opinion requests and payments related to advisory opinion requests, as well as savings for parties that request advisory opinions.

#### *Unfunded Mandates Reform Act*

Section 202 of the Unfunded Mandates Reform Act of 1995, Public

Law 104-4, requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any one year by State, local or tribal governments, in the aggregate, or by the private sector, of \$110 million. Since the rule merely revises the process for paying for advisory opinions and creates greater efficiencies in processing payments, we believe that this rule that will not impose any mandates on State, local, or tribal governments or the private sector that would result in an expenditure of \$110 million or more (adjusted for inflation) in any given year, and that a full analysis under the Unfunded Mandates Reform Act is not necessary.

#### *Regulatory Flexibility Act*

The RFA and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, certain nonprofit organizations, and small governmental jurisdictions. Individuals and States are not included in the definition of a small entity. The RFA, as amended, requires an agency to prepare and make available to the public a regulatory flexibility analysis that describes the effect of a proposed rule on small entities when the agency is required to publish a general notice of proposed rulemaking for any proposed rule. Because this rule is being issued as an interim final rule, on the grounds set forth above, a regulatory flexibility analysis is not required under the RFA.

#### *Executive Order 13132*

Executive Order 13132, Federalism, establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirements or costs on State and local governments, preempts State law, or otherwise has Federalism implications. In reviewing this rule under the threshold criteria of Executive Order 13132, we have determined that this rule would not significantly limit the rights, roles, and responsibilities of State or local governments. We have determined, therefore, that a full analysis under Executive Order 13132 is not necessary.

The Office of Management and Budget (OMB) has reviewed this rule in accordance with Executive Order 12866.

### *C. Paperwork Reduction Act*

In accordance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we are required to solicit public comments, and receive

final OMB approval, on any information collection requirements set forth in rulemaking.

This rule will not impose any information collection burden or affect information currently collected by OIG.

#### IV. Inspection of Public Comments

All comments received before the end of the comment period are available for viewing by the public. All comments will be posted on <http://www.regulations.gov> as soon as possible after they have been received.

Comments received timely will also be available for public inspection as they are received at Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (202) 619-0089.

#### List of Subjects in 42 CFR Part 1008

Administrative practice and procedure, Fraud, Grant programs—health, Health facilities, Health professions, Medicaid, Medicare, Penalties.

■ Accordingly, 42 CFR chapter V, subchapter B is amended as set forth below:

#### PART 1008—[AMENDED]

■ 1. The authority citation for part 1008 continues to read as follows:

Authority: 42 U.S.C. 1320a-7d(b)

■ 2. Section 1008.31 is amended by revising paragraph (b) to read as follows:

#### § 1008.31 OIG fees for the cost of advisory opinions.

\* \* \* \* \*

(b) *Payment Method.* Payment for a request for an advisory opinion must be made to the Treasury of the United States, as directed by OIG.

\* \* \* \* \*

■ 3. Section 1008.36 is amended by removing paragraph (b)(6) and redesignating paragraphs (b)(7) and (b)(8) as (b)(6) and (b)(7) respectively.

\* \* \* \* \*

■ 4. Section 1008.43 is amended by revising paragraph (d) to read as follows:

#### § 1008.43 Issuance of a formal advisory opinion.

\* \* \* \* \*

(d) After OIG has notified the requestor of the full amount owed and OIG has determined that the full payment of that amount has been

properly paid by the requestor, OIG will issue the advisory opinion and promptly mail it to the requestor by regular first class U.S. mail.

Dated: January 30, 2008.

**Daniel R. Levinson,**  
*Inspector General.*

Approved: February 28, 2008.

**Michael O. Leavitt, Secretary.**

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**BILLING CODE 4152-01-P**

## OFFICE OF MANAGEMENT AND BUDGET

### Office of Federal Procurement Policy

#### 48 CFR Part 9903

#### Cost Accounting Standards Board; Contract Clauses

**AGENCY:** Cost Accounting Standards Board, Office of Federal Procurement Policy, OMB.

**ACTION:** Final rule.

**SUMMARY:** The Cost Accounting Standards (CAS) Board has adopted, without change, a final rule to add a clause for inclusion in CAS-covered contracts and subcontracts awarded to foreign concerns. The Board is taking this action to provide a standard clause for use by Government and contractor personnel in applying the CAS requirements to contracts and subcontracts awarded to foreign concerns.

**DATES:** *Effective Date:* April 25, 2008.

**FOR FURTHER INFORMATION CONTACT:** Laura Auletta, Manager, Cost Accounting Standards Board, 725 17th Street, NW., Room 9013, Washington, DC 20503 (telephone: 202-395-3256). Reference CAS-2007-01F.

#### SUPPLEMENTARY INFORMATION:

##### A. Background

The CAS Board published a proposed rule on June 14, 2007 (72 FR 32829) to provide a clause for use in contracts with foreign concerns. Prior to November 4, 1993, modified CAS coverage required a contractor to comply with only CAS 401 and CAS 402. Similarly, 9903.201-1(b)(4) required that foreign concerns comply with only CAS 401 and 402. Thus, prior to November 4, 1993, the contract clause at 9903.201-4(c) was used for both contracts with modified coverage and contracts with foreign concerns.

However, on November 4, 1993, the Board revised the definition of modified coverage to include CAS 405 and 406, so that modified coverage currently

includes CAS 401, 402, 405, and 406 (see 9903.201-2(b)). In conjunction with the revised definition of modified coverage, the Board also amended the clause at 9903.201-4(c) to include CAS 405 and 406. However, the Board did not change the requirement that foreign concerns comply with only CAS 401 and 402. As a result, the contract clause at 9903.201-4(c) could not be used for foreign concerns without modification by the parties.

This final rule provides a clause for use in contracts with foreign concerns that will not require modification. Except that it includes only CAS 401 and 402, this clause is identical to the clause currently applicable to contracts subject to modified coverage. To effect this change, this final rule amends 9903.201-4, Contract Clauses, to include the new clause at (f), Disclosure and Consistency of Cost Accounting Practices—Foreign Concerns.

The Board received no public comments in response to the proposed rule and has adopted the proposed rule as a final rule without change.

##### B. Paperwork Reduction Act

The Paperwork Reduction Act, Public Law 96-511, does not apply to this rulemaking, because this rule imposes no paperwork burden on offerors, affected contractors and subcontractors, or members of the public which requires the approval of OMB under 44 U.S.C. 3501, *et seq.*

##### C. Regulatory Flexibility Act, Unfunded Mandates Reform Act, Congressional Review Act, and Executive Orders 12866 and 13132

The Board certifies that this rule will not have a significant effect on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because small businesses are exempt from the application of the Cost Accounting Standards. For purposes of the Unfunded Mandates Reform Act of 1995, as well as Executive Orders 12866 and 13132, the final rule will not significantly or uniquely affect small governments, does not have federalism implications, and will not result in increased expenditures by State, local, and tribal governments, or by the private sector, of \$100 million or more. In addition, the Board has determined that this rule is not economically significant under the provisions of Executive Order 12866 or otherwise subject to Executive Order 12866 review. Finally, the final rule is not a “major rule” under 5 U.S.C. Chapter 8; the rule will not have any of the effects set forth in 5 U.S.C. 804(2).