

the request. The calculation will include the costs of salaries and benefits payable to attorneys and others who have worked on the request in question, as well as administrative and supervisory support for such person. The OIG has the exclusive authority to determine the cost of responding to a request for an advisory opinion and such determination is not reviewable or waivable.

(d) *Agreement to pay all costs.* (1) By submitting the request for an advisory opinion, the requestor agrees, except as indicated in paragraph (d)(4) of this section, to pay all costs incurred by the OIG in responding to the request for an advisory opinion.

(2) In its request for an advisory opinion, the requestor may request a written estimate of the cost involved in processing the advisory opinion. Within 10 business days of receipt of the request, the OIG will notify in writing of such estimate. Such estimate will not be binding on the Department, and the actual cost to be paid may be higher or lower than estimated. The time period for issuing the advisory opinion will be tolled from the time the OIG notifies the requestor of the estimate until the OIG receives written confirmation from the requestor that the requestor wants the OIG to continue processing the request. Such notice may include a new or revised triggering dollar amount, as set forth in paragraph (d)(3) of this section.

(3) In its request for an advisory opinion, the requestor may designate a triggering dollar amount. If the OIG estimates that the costs of processing the advisory opinion request have reached, or are likely to exceed, the designated triggering dollar amount, the OIG will notify the requestor. The requestor may revise its designated triggering dollar amount in writing in its response to notification of a cost estimate in accordance with paragraph (d)(2) of this section.

(4) If the OIG notifies the requestor that the estimated cost of processing the request has reached or is likely to exceed the triggering dollar amount, the OIG will stop processing the request until such time as the requestor makes a written request for the OIG to continue processing the request. Any

delay in the processing of the request for an advisory opinion attributable to these procedures will toll the time for issuance of an advisory opinion until the requestor asks the OIG to continue working on the request.

(5) If the requestor chooses not to pay for completion of an advisory opinion, or withdraws the request, the requestor is still obligated to pay for all costs incurred and identified by the OIG attributable to processing the request for an advisory opinion up to that point.

(6) If the costs incurred by the OIG in responding to the request are greater than the amount paid by the requestor, the OIG will, prior to the issuance of the advisory opinion, notify the requestor of any additional amount due. The OIG will not issue an advisory opinion until the full amount owed by the requestor has been paid. Once the requestor has paid the OIG the total amount due for the costs of processing the request, the OIG will issue the advisory opinion. The time period for issuing advisory opinions will be tolled from the time the OIG notifies the requestor of the amount owed until the time full payment is received.

(e) *Fees for outside experts.* (1) In addition to the fees identified in this section, the requestor also must pay any required fees for expert opinions, if any, from outside sources, as described in § 1008.33.

(2) If the OIG determines that it is necessary to obtain expert advice to issue a requested advisory opinion, the OIG will notify the requestor of that fact and provide the identity of the appropriate expert and an estimate of the costs of the expert advice.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38324, July 16, 1998]

§ 1008.33 Expert opinions from outside sources.

(a) The OIG may request expert advice from qualified sources on non-legal issues if necessary to respond to the advisory opinion request. For example, the OIG may require the use of appropriate medical reviewers, such as quality improvement organizations, to obtain medical opinions on specific issues.

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(b) The time period for issuing an advisory opinion will be tolled from the time that the OIG notifies the requestor of the need for an outside expert opinion until the time the OIG receives the necessary expert opinion.

(c) Once payment is made for the cost of the expert opinion, as set forth in §1008.31(e) of this part, either directly to the expert or otherwise, the OIG will arrange for a prompt expert review of the issue or issues in question. Regardless of the manner of payment, the expert's work and opinion will be subject to the sole direction of the OIG.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38325, July 16, 1998]

Subpart D—Submission of a Formal Request for an Advisory Opinion

§ 1008.36 Submission of a request.

(a) A request for a formal advisory opinion must be submitted in writing. An original and 2 copies of the request should be addressed to the headquarter offices of the OIG.

(b) Each request for an advisory opinion must include—

(1) To the extent known to the requestor, the identities, including the names and addresses, of the requestor and of all other actual and potential parties to the arrangement, that are the subject of the request for an advisory opinion;

(2) The name, title, address, and daytime telephone number of a contact person who will be available to discuss the request for an advisory opinion with the OIG on behalf of the requestor;

(3) A declaration of the subject category or categories as described in §1008.5 of this part for which the advisory opinion is requested. To the extent an individual or entity requests an advisory opinion in accordance with §§1008.5(a)(3) or (a)(5) of this part, the requesting individual or entity should identify the specific subsections of sections 1128, 1128A or 1128B of the Act or the specific provision of §1001.952 of this chapter about which an advisory opinion is sought;

(4) A complete and specific description of all relevant information bear-

ing on the arrangement for which an advisory opinion is requested and on the circumstances of the conduct,¹ including—

(i) Background information,

(ii) For existing arrangements, complete copies of all operative documents,

(iii) For proposed arrangements, complete copies of all operative documents, if possible, and otherwise descriptions of proposed terms, drafts, or models of documents sufficient to permit the OIG to render an informed opinion,

(iv) Detailed statements of all collateral or oral understandings, if any, and

(v) If applicable, a designation of trade secrets or confidential commercial or financial information in the manner described in 45 CFR 5.65;

(5) Signed certifications by the requestor(s), as described in §1008.37 of this part;

(6) A check or money order payable to the Treasury of the United States in the amount of \$250, as discussed in §1008.31(b) of this part;

(7) A declaration regarding whether an advisory opinion in accordance with part 411 of this title has been or will be requested from CMS about the arrangement that is the subject of the advisory opinion request; and

(8) Each requesting party's Taxpayer Identification Number.

(Approved by the Office of Management and Budget under control number 0990-0213)

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38325, July 16, 1998]

§ 1008.37 Disclosure of ownership and related information.

Each individual or entity requesting an advisory opinion must supply full and complete information as to the identity of each entity owned or controlled by the individual or entity, and of each person with an ownership or control interest in the entity, as defined in section 1124(a)(1) of the Social

¹The requestor is under an affirmative obligation to make full and true disclosure with respect to the facts regarding the advisory opinion being requested.