

§ 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.

(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 ex-

tent 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 bearing 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 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

(7) 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; 73 FR 15939, Mar. 26, 2008]

§ 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

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

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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 Security Act (42 U.S.C. 1320a-3(a)(1)) and part 420 of this chapter.

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[67 FR 11936, Mar. 18, 2002]

§ 1008.38 Signed certifications by the requestor.

(a) Every request must include the following signed certification from all requestors: “With knowledge of the penalties for false statements provided by 18 U.S.C. 1001 and with knowledge that this request for an advisory opinion is being submitted to the Department of Health and Human Services, I certify that all of the information provided is true and correct, and constitutes a complete description of the facts regarding which an advisory opinion is sought, to the best of my knowledge and belief.”

(b) If the advisory opinion relates to a proposed arrangement, the request must also include the following signed certification from all requestors: “The arrangement described in this request for an advisory opinion is one that [the requestor(s)] in good faith plan(s) to undertake.” This statement may be made contingent on a favorable OIG advisory opinion, in which case, the phrase “if the OIG issues a favorable advisory opinion” should be added to the certification.

(c) The certification(s) must be signed by—

(1) The requestor, if the requestor is an individual;

(2) The chief executive officer, or comparable officer, of the requestor, if the requestor is a corporation;

(3) The managing partner of the requestor, if the requestor is a partnership; or

(4) The managing member, or comparable person, if the requestor is a limited liability company.

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

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§ 1008.39 Additional information.

(a) If the request for an advisory opinion does not contain all of the information required by § 1008.36 of this part, or the OIG believes it needs more information prior to rendering an advisory opinion, the OIG may, at any time, request whatever additional information or documents it deems necessary. The time period for the issuance of an advisory opinion will be tolled from the time the OIG requests the additional information from the requestor until such time as the OIG determines that it has received the requested information.

(b) The OIG may request additional information before or after the request for an advisory opinion has been accepted.

(c) Additional information should be provided in writing and certified to be a true, correct and complete disclosure of the requested information in a manner equivalent to that described in § 1008.38 of this part.

(d) In connection with any request for an advisory opinion, the OIG or DoJ may conduct whatever independent investigation they believe appropriate.

(e) Requesting parties are required to notify the OIG if they request an advisory opinion in accordance with part 411 of this title from CMS about the arrangement that is the subject of their advisory opinion request.

(f) Where appropriate, after receipt of an advisory opinion request, the OIG may consult with the requesting parties to the extent the OIG deems necessary.

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

§ 1008.40 Withdrawal.

The requestor of an advisory opinion may withdraw the request prior to the issuance of a formal advisory opinion by the OIG. The withdrawal must be written and must be submitted to the same address as the submitted request, as indicated in §§ 1008.18(b) and 1008.36(a) of this part. Regardless of whether the request is withdrawn, the requestor must pay the costs expended by the OIG in processing the opinion, as discussed in § 1008.31(d) of this part. The OIG reserves the right to retain