

(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 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]

**§ 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

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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 any request for an advisory opinion, documents and information submitted to it under these procedures, and to use them for any governmental purposes.

## **Subpart E—Obligations and Responsibilities of the OIG**

### § 1008.41 **OIG acceptance of the request.**

(a) Upon receipt of a request for an advisory opinion, the OIG will promptly make an initial determination whether the submission includes all of the information the OIG will require to process the request.

(b) Within 10 working days of receipt of the request, the OIG will—

(1) Formally accept the request for an advisory opinion,

(2) Notify the requestor of what additional information is needed, or

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(3) Formally decline to accept the request.

(c) If the requestor provides the additional information requested, or otherwise resubmits the request, the OIG will process the resubmission in accordance with paragraphs (a) and (b) of this section as if it was an initial request for an advisory opinion.

(d) Upon acceptance of the request, the OIG will notify the requestor by regular U.S. mail of the date that the request for the advisory opinion was formally accepted.

(e) The 60-day period for issuance of an advisory opinion set forth in §1008.43(c) of this part will not commence until the OIG has formally accepted the request for an advisory opinion.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38326, July 16, 1998]

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

(a) An advisory opinion will be considered issued once payment is received and it is dated, numbered, and signed by an authorized official of the OIG.

(b) An advisory opinion will contain a description of the material facts provided to the OIG with regard to the arrangement for which an advisory opinion has been requested. The advisory opinion will state the OIG's opinion regarding the subject matter of the request based on the facts provided to the OIG. If necessary, to fully describe the arrangement, the OIG is authorized to include in the advisory opinion the material facts of the arrangement, notwithstanding that some of these facts could be considered confidential information or trade secrets within the meaning of 18 U.S.C. 1905.

(c)(1) The OIG will issue an advisory opinion, in accordance with the provisions of this part, within 60 days after the request for an advisory opinion has been formally accepted;

(2) If the 60th day falls on a Saturday, Sunday, or Federal holiday, the time period will end at the close of the next business day following the weekend or holiday;

(3) The 60 day period will be tolled from the time the OIG—