

§ 1008.37

(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 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 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]

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

42 CFR Ch. V (10-1-02 Edition)

§ 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.

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

[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;