

§ 1008.40

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 Regardless of whether the request is withdrawn, the requestor must pay the costs expended by the OIG in processing the opinion, as discussed in §1008.31(d) of this part.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

42 CFR Ch. V (10–1–06 Edition)

(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—

(i) Notifies the requestor that the costs have reached, or are likely to exceed, the triggering amount until the time when the OIG receives written notice from the requestor to continue processing the request;

(ii) Requests additional information from the requestor until the time the OIG receives the requested information;

(iii) Notifies the requestor of the full amount due until the time the OIG receives payment of the full amount owed; and

(iv) Notifies the requestor of the need for expert advice until the time the OIG receives the expert advice.

(d) After the OIG has notified the requestor of the full amount owed and the OIG has received full payment of that amount, the OIG will issue the advisory opinion and promptly mail it to the requestor by regular first class U.S. mail.

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

§ 1008.45 Rescission, termination or modification.

(a) Any advisory opinion given by the OIG is without prejudice to the right of the OIG to reconsider the questions involved and, where the public interest requires, to rescind, terminate or modify the advisory opinion. Requestors will be given a preliminary notice of the OIG's intent to rescind, terminate or modify the opinion, and will be provided a reasonable opportunity to respond. A final notice of rescission, termination or modification will be given to the requestor so that the individual or entity may discontinue or modify, as the case may be, the course of action taken in accordance with the OIG advisory opinion.

(b) For purposes of this part—

(1) To *rescind* an advisory opinion means that the advisory opinion is revoked retroactively to the original date of issuance with the result that the advisory opinion will be deemed to have been without force and effect from the original date of issuance. Rescission may occur only where relevant and material facts were not fully, completely and accurately disclosed to the OIG.

(2) To *terminate* an advisory opinion means that the advisory opinion is revoked as of the termination date and is no longer in force and effect after the termination date. The OIG will not proceed against the requestor under this part if such action was promptly, diligently, and in good faith discontinued in accordance with reasonable time frames established by the OIG after consultation with the requestor.

(3) To *modify* an advisory opinion means that the advisory opinion is amended, altered, or limited, and that the advisory opinion continues in full force and effect in modified form thereafter. The OIG will not proceed against the requestor under this part if such action was promptly, diligently, and in good faith modified in accordance with reasonable time frames established by the OIG after consultation with the requestor.

[63 FR 38326, July 16, 1998]

§ 1008.47 Disclosure.

(a) Advisory opinions issued and released in accordance with the provisions set forth in this part will be available to the public.

(b) Promptly after the issuance and release of an advisory opinion to the requestor, a copy of the advisory opinion will be available for public inspection between the hours of 10:00 a.m. and 3:00 p.m. on normal business days at the headquarter offices of the OIG and on the DHHS/OIG web site.

(c) Any pre-decisional document, or part of such pre-decisional document, that is prepared by the OIG, DoJ, or any other Department or agency of the United States in connection with an advisory opinion request under the procedures set forth in this part generally will be exempt from disclosure under 5 U.S.C. 552, and will not be made publicly available.

(d) Documents submitted by the requestor to the OIG in connection with a request for an advisory opinion may be available to the public in accordance with 5 U.S.C. 552 through procedures set forth in 45 CFR part 5.

(e) Nothing in this section will limit the OIG's right, in its discretion, to