

any, from outside sources, as described in § 411.377.

(2) The time period for issuing an advisory opinion is suspended from the time that HCFA notifies the requestor that it needs an outside expert opinion until the time HCFA receives that opinion.

[63 FR 1656, Jan. 9, 1998]

**§ 411.377 Expert opinions from outside sources.**

(a) HCFA may request expert advice from qualified sources if HCFA believes that the advice is necessary to respond to a request for an advisory opinion. For example, HCFA may require the use of accountants or business experts to assess the structure of a complex business arrangement or to ascertain a physician's or immediate family member's financial relationship with entities that provide designated health services.

(b) If HCFA determines that it needs to obtain expert advice in order to issue a requested advisory opinion, HCFA notifies the requestor of that fact and provides the identity of the appropriate expert and an estimate of the costs of the expert advice. As indicated in § 411.375(d), the requestor must pay the estimated cost of the expert advice.

(c) Once HCFA has received payment for the estimated cost of the expert advice, HCFA arranges for the expert to provide a prompt review of the issue or issues in question. HCFA considers any additional expenses for the expert advice, beyond the estimated amount, as part of the costs HCFA has incurred in responding to the request, and the responsibility of the requestor, as described in § 411.375(c).

[63 FR 1657, Jan. 9, 1998]

**§ 411.378 Withdrawing a request.**

The party requesting an advisory opinion may withdraw the request before HCFA issues a formal advisory opinion. This party must submit the withdrawal in writing to the same address as the request, as indicated in § 411.372(a). Even if the party withdraws the request, the party must pay the costs the Department has expended in processing the request, as discussed in

§ 411.375. HCFA reserves the right to keep any request for an advisory opinion and any accompanying documents and information, and to use them for any governmental purposes permitted by law.

[63 FR 1657, Jan. 9, 1998]

**§ 411.379 When HCFA accepts a request.**

(a) Upon receiving a request for an advisory opinion, HCFA promptly makes an initial determination of whether the request includes all of the information it will need to process the request.

(b) Within 15 working days of receiving the request, HCFA—

(1) Formally accepts the request for an advisory opinion;

(2) Notifies the requestor about the additional information it needs, or

(3) Declines to formally accept the request.

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

(d) Upon accepting the request, HCFA notifies the requestor by regular U.S. mail of the date that HCFA formally accepted the request.

(e) The 90-day period that HCFA has to issue an advisory opinion set forth in § 411.380(c) does not begin until HCFA has formally accepted the request for an advisory opinion.

[63 FR 1657, Jan. 9, 1998]

**§ 411.380 When HCFA issues a formal advisory opinion.**

(a) HCFA considers an advisory opinion to be issued once it has received payment and once the opinion has been dated, numbered, and signed by an authorized HCFA official.

(b) An advisory opinion contains a description of the material facts known to HCFA that relate to the arrangement that is the subject of the advisory opinion, and states HCFA's opinion about the subject matter of the request based on those facts. If necessary, HCFA includes in the advisory opinion material facts that could be

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considered confidential information or trade secrets within the meaning of 18 U.S.C. 1095.

(c)(1) HCFA issues an advisory opinion, in accordance with the provisions of this part, within 90 days after it has formally accepted the request for an advisory opinion, or, for requests that HCFA determines, in its discretion, involve complex legal issues or highly complicated fact patterns, within a reasonable time period.

(2) If the 90th day falls on a Saturday, Sunday, or Federal holiday, the time period ends at the close of the first business day following the weekend or holiday;

(3) The 90-day period is suspended from the time HCFA—

(i) Notifies the requestor that the costs have reached or are likely to exceed the triggering amount as described in § 411.375(c)(2) until HCFA receives written notice from the requestor to continue processing the request;

(ii) Requests additional information from the requestor until HCFA receives the additional information;

(iii) Notifies the requestor of the full amount due until HCFA receives payment of this amount; and

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

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

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**§ 411.382 HCFA's right to rescind advisory opinions.**

Any advice HCFA gives in an opinion does not prejudice its right to reconsider the questions involved in the opinion and, if it determines that it is in the public interest, to rescind or revoke the opinion. HCFA provides notice to the requestor of its decision to rescind or revoke the opinion so that the requestor and the parties involved in the requestor's arrangement may discontinue any course of action they have taken in accordance with the advisory opinion. HCFA does not proceed

against the requestor with respect to any action the requestor and the involved parties have taken in good faith reliance upon HCFA's advice under this part, provided—

(a) The requestor presented to HCFA a full, complete and accurate description of all the relevant facts; and

(b) The parties promptly discontinue the action upon receiving notice that HCFA had rescinded or revoked its approval, or discontinue the action within a reasonable "wind down" period, as determined by HCFA.

[63 FR 1657, Jan. 9, 1998]

**§ 411.384 Disclosing advisory opinions and supporting information.**

(a) Advisory opinions that HCFA issues and releases in accordance with the procedures set forth in this subpart are available to the public.

(b) Promptly after HCFA issues an advisory opinion and releases it to the requestor, HCFA makes available a copy of the advisory opinion for public inspection during its normal hours of operation and on the DHHS/HCFA web site.

(c) Any predecisional document, or part of such predecisional document, that is prepared by HCFA, the Department of Justice, 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 is exempt from disclosure under 5 U.S.C. 552, and will not be made publicly available.

(d) Documents submitted by the requestor to HCFA in connection with a request for an advisory opinion are available to the public to the extent they are required to be made available by 5 U.S.C. 552, through procedures set forth in 45 CFR part 5.

(e) Nothing in this section limits HCFA's obligation, under applicable laws, to publicly disclose the identity of the requesting party or parties, and the nature of the action HCFA has taken in response to the request.

[63 FR 1657, Jan. 9, 1998]

**§ 411.386 HCFA's advisory opinions as exclusive.**

The procedures described in this subpart constitute the only method by