

§411.382

42 CFR Ch. IV (10–1–99 Edition)

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.

[63 FR 1657, Jan. 9, 1998]

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(b) The parties promptly discontinue the action upon receiving notice that HCFA had rescinded or revoked its approval, or discontinue the action within a reasonable "wind down" period, as determined by HCFA.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