

§ 411.378

42 CFR Ch. IV (10–1–10 Edition)

§ 411.378 **Withdrawing a request.**

The party requesting an advisory opinion may withdraw the request before CMS 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. CMS 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.

[69 FR 57229, Sept. 24, 2004]

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

(a) Upon receiving a request for an advisory opinion, CMS 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, CMS—

(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 CMS has requested, or otherwise resubmits the request, CMS 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, CMS notifies the requestor by regular U.S. mail of the date that CMS formally accepted the request.

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

[69 FR 57229, Sept. 24, 2004]

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

(a) CMS 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 CMS official.

(b) An advisory opinion contains a description of the material facts known to CMS that relate to the arrangement that is the subject of the advisory opinion, and states CMS's opinion about the subject matter of the request based on those facts. If necessary, CMS includes in the advisory opinion material facts that could be considered confidential information or trade secrets within the meaning of 18 U.S.C. 1095.

(c)(1) CMS 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 CMS 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 CMS—

(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 CMS receives written notice from the requestor to continue processing the request;

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

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

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

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

[69 FR 57229, Sept. 24, 2004]

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

Any advice CMS 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. CMS 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. CMS does not proceed against the requestor with respect to any action the requestor and the involved parties have taken in good faith reliance upon CMS's advice under this part, provided—

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

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

[69 FR 57229, Sept. 24, 2004]

§ 411.384 Disclosing advisory opinions and supporting information.

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

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

(c) Any predecisional document, or part of such predecisional document, that is prepared by CMS, 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 CMS 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 CMS's obligation, under applicable laws, to publicly disclose the identity of the requesting party or parties, and

the nature of the action CMS has taken in response to the request.

[69 FR 57230, Sept. 24, 2004]

§ 411.386 CMS's advisory opinions as exclusive.

The procedures described in this subpart constitute the only method by which any individuals or entities can obtain a binding advisory opinion on the subject of a physician's referrals, as described in § 411.370. CMS has not and does not issue a binding advisory opinion on the subject matter in § 411.370, in either oral or written form, except through written opinions it issues in accordance with this subpart.

[69 FR 57230, Sept. 24, 2004]

§ 411.387 Parties affected by advisory opinions.

An advisory opinion issued by CMS does not apply in any way to any individual or entity that does not join in the request for the opinion. Individuals or entities other than the requestor(s) may not rely on an advisory opinion.

[69 FR 57230, Sept. 24, 2004]

§ 411.388 When advisory opinions are not admissible evidence.

The failure of a party to seek or to receive an advisory opinion may not be introduced into evidence to prove that the party either intended or did not intend to violate the provisions of sections 1128, 1128A or 1128B of the Act.

[69 FR 57230, Sept. 24, 2004]

§ 411.389 Range of the advisory opinion.

(a) An advisory opinion states only CMS's opinion regarding the subject matter of the request. If the subject of an advisory opinion is an arrangement that must be approved by or is regulated by any other agency, CMS's advisory opinion cannot be read to indicate CMS's views on the legal or factual issues that may be raised before that agency.

(b) An advisory opinion that CMS issues under this part does not bind or obligate any agency other than the Department. It does not affect the requestor's, or anyone else's, obligations to