

§ 411.382

42 CFR Ch. IV (10–1–20 Edition)

formally accepts the advisory opinion request.

(i) In the case of a request for a determination that an arrangement or course of conduct is indistinguishable in all material aspects from another arrangement or course of conduct that was the subject of a prior opinion, CMS issues an advisory opinion within 30 working days after the date on which it formally accepts the advisory opinion request.

(ii) In the case of a request that CMS determines, in its discretion, involves complex legal issues or highly complicated fact patterns, CMS issues an advisory opinion within a reasonable time period after the date on which it formally accepts the advisory opinion request.

(iii) If the last day of the 60-working day or 30-working day time period falls on a Saturday, Sunday, or Federal holiday, CMS may issue the advisory opinion at the close of business on the first business day following the weekend or holiday.

(2) The applicable time period for issuing an advisory opinion 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, as amended at 84 FR 63192, Nov. 15, 2019]

§ 411.382 CMS' right to rescind advisory opinions.

(a)(1) Any advice CMS gives in an advisory opinion does not prejudice its

right to reconsider the questions involved in the opinion, and CMS may rescind or revoke the opinion if it determines that there is good cause to rescind or revoke the opinion.

(2) Good cause shall exist where—

(i) There is a material change in the law that affects the conclusions reached in an opinion; or

(ii) A party that has received a negative advisory opinion seeks reconsideration based on new facts or law.

(b) CMS provides advance notice to the requestor and to the public of its decision to rescind or revoke the opinion so that the requestor and other parties may discontinue any course of action they have taken in accordance with, or in good faith reliance on, the advisory opinion.

(c) 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' advice under this part, provided—

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

(2) 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.

[84 FR 63193, Nov. 15, 2019]

§ 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 on the 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