

(b) If the advisory opinion relates to a proposed arrangement, in addition to the certification required by paragraph (a) of this section, the following certification must be included and signed by the requestor: “The arrangement described in this request for an advisory opinion is one into which [the requestor], in good faith, plans to enter.” This statement may be made contingent on a favorable advisory opinion, in which case the requestor should add one of the following phrases to the certification:

(1) “if CMS issues a favorable advisory opinion.”

(2) “if CMS and the OIG issue favorable advisory opinions.”

[69 FR 57227, Sept. 24, 2004]

§411.375 Fees for the cost of advisory opinions.

(a) *Hourly rate.* CMS will charge an hourly rate of \$220. Parties may request an estimate from CMS after submitting a complete request. Before issuing the advisory opinion, CMS will calculate the final fee for responding to the request.

(b) *Agreement to pay all costs.* (1) By submitting the request for an advisory opinion, the requestor agrees, except as indicated in paragraph (c)(3) of this section, to pay all costs the Department incurs in responding to the request for an advisory opinion.

(2) In its request for an advisory opinion, the requestor may designate a triggering dollar amount. If CMS estimates that the costs of processing the advisory opinion request have reached or are likely to exceed the designated triggering dollar amount, CMS notifies the requestor.

(3) If CMS notifies the requestor that the actual or estimated cost of processing the request has reached or is likely to exceed the triggering dollar amount, CMS stops processing the request until the requestor makes a written request for CMS to continue. If CMS is delayed in processing the request for an advisory opinion because of this procedure, the time within which CMS must issue an advisory opinion is suspended until the requestor asks CMS to continue working on the request.

(4) If the requestor chooses not to pay for CMS to complete an advisory opinion, or withdraws the request, the requestor is still obligated to pay for all costs CMS has identified as costs it incurred in processing the request for an advisory opinion, up to that point.

(5) If the costs CMS has incurred in responding to the request are greater than the amount the requestor has paid, CMS, before issuing the advisory opinion, notifies the requestor of any additional amount that is due. CMS does not issue an advisory opinion until the requestor has paid the full amount that is owed. Once the requestor has paid CMS the total amount due for the costs of processing the request, CMS issues the advisory opinion. The time period CMS has for issuing advisory opinions is suspended from the time CMS notifies the requestor of the amount owed until the time CMS receives full payment.

(c) *Fees for outside experts.* (1) In addition to the fees identified in this section, the requestor also must pay any required fees for expert opinions, if any, from outside sources, as described in §411.377.

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

[69 FR 57228, Sept. 24, 2004, as amended at 84 FR 63192, Nov. 15, 2019]

§411.377 Expert opinions from outside sources.

(a) CMS may request expert advice from qualified sources if CMS believes that the advice is necessary to respond to a request for an advisory opinion. For example, CMS 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 CMS determines that it needs to obtain expert advice in order to issue a requested advisory opinion, CMS notifies the requestor of that fact and provides the identity of the appropriate expert and an estimate of the

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costs of the expert advice. As indicated in § 411.375(d), the requestor must pay the estimated cost of the expert advice.

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

[69 FR 57229, Sept. 24, 2004]

§ 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 contains a level of detail sufficient for CMS to process the request.

(b) If CMS determines that the request submitted lacks details necessary for CMS to process the request, CMS will provide notification to the requestor within 15 working days of receiving 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) CMS formally accepts a request when CMS determines that the request (inclusive of any supplemental submissions) describes the arrangement at

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issue with sufficient detail and that the grounds for rejection of a request listed at § 411.370(e) do not apply. Upon accepting the request, CMS notifies the requestor by regular U.S. mail of the date that CMS formally accepts the request.

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

[69 FR 57229, Sept. 24, 2004, as amended at 84 FR 63192, Nov. 15, 2019]

§ 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) Except as set forth in paragraph (c)(2) of this section, CMS issues an advisory opinion in accordance with the provisions of this part within 60 working days after the date on which it 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.