

§ 411.373

of the business (products and services) and, if relevant, their Medicare and Medicaid provider numbers. The requestor must also include a brief description of any other entities that could affect the outcome of the opinion, including those with which the requestor, the other parties, or the immediate family members of involved physicians, have any financial relationships (either direct or indirect, and as defined in section 1877(a)(2) of the Act and § 411.351), or in which any of the parties holds an ownership or control interest as defined in section 1124(a)(3) of the Act.

(6) A discussion of the specific issues or questions the requestor would like CMS to address including, if possible, a description of why the requestor believes the referral prohibition in section 1877 of the Act might or might not be triggered by the arrangement and which, if any, exceptions to the prohibition the requestor believes might apply. The requestor should attempt to designate which facts are relevant to each issue or question raised in the request and should cite the provisions of law under which each issue or question arises.

(7) An indication of whether the parties involved in the request have also asked for or are planning to ask for an advisory opinion on the arrangement in question from the OIG under section 1128D(b) of the Act (42 U.S.C. 1320a-7d(b)) and whether the arrangement is or is not, to the best of the requestor's knowledge, the subject of an investigation.

(8) The certification(s) described in § 411.373. The certification(s) must be signed by—

(i) The requestor, if the requestor is an individual;

(ii) The chief executive officer, or comparable officer, of the requestor, if the requestor is a corporation;

(iii) The managing partner of the requestor, if the requestor is a partnership; or

(iv) A managing member, if the requestor is a limited liability company.

(9) A check or money order payable to CMS in the amount described in § 411.375(a).

(c) *Additional information CMS might require.* If the request does not contain

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all of the information required by paragraph (b) of this section, or, if either before or after accepting the request, CMS believes it needs more information in order to render an advisory opinion, it may request whatever additional information or documents it deems necessary. Additional information must be provided in writing, signed by the same person who signed the initial request (or by an individual in a comparable position), and be certified as described in § 411.373.

[69 FR 57227, Sept. 24, 2004]

§ 411.373 Certification.

(a) Every request must include the following signed certification: “With knowledge of the penalties for false statements provided by 18 U.S.C. 1001 and with knowledge that this request for an advisory opinion is being submitted to the Department of Health and Human Services, I certify that all of the information provided is true and correct, and constitutes a complete description of the facts regarding which an advisory opinion is sought, to the best of my knowledge and belief.”

(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) *Initial payment.* Parties must include with each request for an advisory opinion submitted through December 31, 1998, a check or money order payable to CMS for \$250. For requests submitted after this date, parties must include a check or money order in this

amount, unless CMS has revised the amount of the initial fee in a program issuance, in which case, the requestor must include the revised amount. This initial payment is nonrefundable.

(b) *How costs are calculated.* Before issuing the advisory opinion, CMS calculates the costs the Department has incurred in responding to the request. The calculation includes the costs of salaries, benefits, and overhead for analysts, attorneys, and others who have worked on the request, as well as administrative and supervisory support for these individuals.

(c) *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.

(d) *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]

§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 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]