

or other comparable officer of the hospital.

(5) *Community input and timing of complete request.* Upon submitting a request for an exception and until the hospital receives a CMS decision, the hospital must disclose on any public Web site for the hospital that it is requesting an exception and must also provide actual notification that it is requesting an exception, in either electronic or hard copy form, directly to hospitals whose data are part of the comparisons in paragraphs (c)(2)(ii) and (c)(3)(ii) of this section. Individuals and entities in the hospital's community may provide input with respect to the hospital's request no later than 30 days after CMS publishes notice of the hospital's request in the FEDERAL REGISTER. Such input must take the form of written comments. The written comments must be either mailed or submitted electronically to CMS. If CMS receives written comments from the community, the hospital has 30 days after CMS notifies the hospital of the written comments to submit a rebuttal statement.

(i) If only filed Medicare hospital cost report data are used in the hospital's request, the written comments, and the hospital's rebuttal statement—

(A) A request will be deemed complete at the end of the 30-day comment period if CMS does not receive written comments from the community.

(B) A request will be deemed complete at the end of the 30-day rebuttal period, regardless of whether the hospital submits a rebuttal statement, if CMS receives written comments from the community.

(ii) If data from an external data source are used in the hospital's request, the written comments, or the hospital's rebuttal statement—

(A) A request will be deemed complete no later than 180 days after the end of the 30-day comment period if CMS does not receive written comments from the community.

(B) A request will be deemed complete no later than 180 days after the end of the 30-day rebuttal period, regardless of whether the hospital submits a rebuttal statement, if CMS receives written comments from the community.

(6) A permitted increase under this section—

(i) May not result in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed exceeding 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds; and

(ii) May occur only in facilities on the hospital's main campus.

(7) *Publication of final decisions.* Not later than 60 days after receiving a complete request, CMS will publish the final decision in the FEDERAL REGISTER.

(8) *Limitation on review.* There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the process under this section (including the establishment of such process).

[75 FR 72260, Nov. 24, 2010, as amended at 76 FR 74581, Nov. 30, 2011; 79 FR 67029, Nov. 10, 2014; 80 FR 71378, Nov. 16, 2015]

§411.370 Advisory opinions relating to physician referrals.

(a) *Period during which CMS accepts requests.* The provisions of §411.370 through §411.389 apply to requests for advisory opinions that are submitted to CMS during any time period in which CMS is required by law to issue the advisory opinions described in this subpart.

(b) *Matters that qualify for advisory opinions and who may request one.* Any individual or entity may request a written advisory opinion from CMS concerning whether a physician's referral relating to designated health services (other than clinical laboratory services) is prohibited under section 1877 of the Act. In the advisory opinion, CMS will determine whether a business arrangement described by the parties to that arrangement appears to constitute a "financial relationship" (as defined in section 1877(a)(2) of the Act) that could potentially restrict a physician's referrals, and whether the arrangement or the designated health services at issue appear to qualify for any of the exceptions to the referral prohibition described in section 1877 of the Act.

(1) The request must relate to an existing arrangement or one into which

§411.372

42 CFR Ch. IV (10–1–20 Edition)

the requestor, in good faith, specifically plans to enter. The planned arrangement may be contingent upon the party or parties receiving a favorable advisory opinion. CMS does not consider, for purposes of an advisory opinion, requests that involve the activities of third parties.

(2) The requestor must be a party to the existing or proposed arrangement.

(c) *Matters not subject to advisory opinions.* CMS will not address through an advisory opinion—

(1) Whether the fair market value was, or will be, paid or received for any goods, services, or property; and

(2) Whether an individual is a *bona fide* employee within the requirements of section 3121(d)(2) of the Internal Revenue Code of 1986.

(d) *Facts subject to advisory opinions.* The requestor must include in the advisory opinion request a complete description of the arrangement that the requestor is undertaking, or plans to undertake, as described in §411.372.

(e) *Acceptance of requests.* (1) CMS does not accept an advisory opinion request or issue an advisory opinion if—

(i) The request is not related to a named individual or entity;

(ii) The request does not describe the arrangement at issue with a level of detail sufficient for CMS to issue an opinion, and the requestor does not timely respond to CMS requests for additional information;

(iii) CMS is aware, after consultation with OIG and DOJ, that the same course of action is under investigation, or is or has been the subject of a proceeding involving the Department of Health and Human Services or another governmental agency;

(iv) CMS believes that it cannot make an informed opinion or could only make an informed opinion after extensive investigation, clinical study, testing, or collateral inquiry; or

(v) CMS determines that the arrangement or course of conduct at issue is or would be in violation of applicable State or Federal law or regulation.

(2) CMS may elect not to accept an advisory opinion request if it determines, after consultation with OIG and DOJ:

(i) The course of action described is substantially similar to a course of

conduct that is under investigation or the subject of a proceeding involving the Department or other law enforcement agencies; and

(ii) Issuing an advisory opinion could interfere with the investigation or proceeding.

(f) *Effects of an advisory opinion on other Governmental authority.* Nothing in this part limits the investigatory or prosecutorial authority of the OIG, the Department of Justice, or any other agency of the Government. In addition, in connection with any request for an advisory opinion, CMS, the OIG, or the Department of Justice may conduct whatever independent investigation it believes appropriate.

[69 FR 57227, Sept. 24, 2004, as amended at 72 FR 51098, Sept. 5, 2007; 84 FR 63191, Nov. 15, 2019]

§411.372 Procedure for submitting a request.

(a) *Format for a request.* A party or parties must submit a request for an advisory opinion to CMS according to the instructions specified on the CMS Web site.

(b) *Information CMS requires with all submissions.* The request must include the following:

(1) The name, address, telephone number, and Taxpayer Identification Number of the requestor.

(2) The names and addresses, to the extent known, of all other actual and potential parties to the arrangement that is the subject of the request.

(3) The name, title, address, and daytime telephone number of a contact person who will be available to discuss the request with CMS on behalf of the requestor.

(4) A complete and specific description of all relevant information bearing on the arrangement, including—

(i) A complete description of the arrangement that the requestor is undertaking, or plans to undertake, including:

(A) The purpose of the arrangement; the nature of each party's (including each entity's) contribution to the arrangement; the direct or indirect relationships between the parties, with an emphasis on the relationships between physicians involved in the arrangement