AO-SH-2004-08-03

[Name redacted]

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion concerning the 18-month moratorium on physician referrals to specialty hospitals in which they have an ownership or investment interest (the "specialty hospital moratorium").[1] Specifically, you seek a determination that [name redacted] (the "Hospital") was "under development" as of November 18, 2003, thereby making the specialty hospital moratorium inapplicable to the Hospital.

You have certified that all of the information provided in your request, including all supplementary materials and documentation, is true and correct and constitutes a complete description of the relevant facts. In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of this information. If material facts have not been disclosed or have been misrepresented, this advisory opinion is without force and effect.

Based upon the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Hospital was not "under development" as of November 18, 2003, and therefore, it is subject to the specialty hospital moratorium.

This opinion may not be relied on by any persons other than the parties that requested it. This opinion is further qualified as set forth in section IV below and in 42 C.F.R. §§ 411.370 through 411.389.

I. STATUTORY BACKGROUND

A. The Physician Self-Referral Prohibition

Under section 1877 of the Social Security Act (42 U.S.C. § 1395nn), a physician cannot refer a Medicare patient for certain designated health services ("DHS") to an entity with which the physician (or an immediate family member of the physician) has a financial relationship unless an exception applies.[2] Section 1877 also prohibits the entity furnishing the DHS from submitting claims to Medicare, the beneficiary, or any other entity for Medicare DHS that are furnished as a result of a prohibited referral. Inpatient and outpatient hospital services are DHS. A financial relationship includes both ownership/investment interests and compensation arrangements. The statute enumerates various exceptions, including exceptions for physician ownership or investment interests in hospitals and rural providers. Violations of the statute are subject to denial of payment

[1] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 507.
[2] In 1993, the physician self-referral prohibition was made applicable to the Medicaid program. 42 U.S.C. § 1396b(s).

of all DHS claims, refund of amounts collected for DHS claims, and civil money penalties for knowing violations of the prohibition. Violations may also be pursued under the False Claims Act, 31 U.S.C. §§ 3729-3733.

B. Medicare Prescription Drug, Improvement, and Modernization Act of 2003

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA") amended the hospital and rural provider ownership exceptions to the physician self-referral prohibition. Prior to the MMA, the "whole hospital" exception allowed a physician to refer Medicare patients to a hospital in which the physician (or immediate family member of the physician) had an ownership or investment interest, as long as the physician was authorized to perform services at the hospital and the ownership or investment interest was in the whole hospital and not a subdivision of the hospital. Section 507 of the MMA added an additional criterion to the whole hospital exception, specifying that for the 18-month period beginning on December 8, 2003 and ending on June 8, 2005, physician ownership and investment interests in "specialty hospitals" would not qualify for the whole hospital exception. Section 507 further specified that, for the same 18-month period, the exception for physician ownership or investment interests in rural providers would not apply in the case of specialty hospitals located in rural areas.

For purposes of section 507 only, a "specialty hospital" is defined as a hospital in one of the 50 States or the District of Columbia that is primarily or exclusively engaged in the care and treatment of one of the following: (i) patients with a cardiac condition; (ii) patients with an orthopedic condition; (iii) patients receiving a surgical procedure; or (iv) patients receiving any other specialized category of services that the Secretary designates as being inconsistent with the purpose of permitting physician ownership and investment interests in a hospital. The term "specialty hospital" does not include any hospital determined by the Secretary to be in operation or "under development" as of November 18, 2003 and for which (i) the number of physician investors has not increased since that date; (ii) the specialized services furnished by the hospital has not changed since that date; and (iii) any increase in the number of beds has occurred only on the main campus of the hospital and does not exceed the greater of 5 beds or 50% of the beds in the hospital as of that date.

In determining whether a specialty hospital was "under development" as of November 18, 2003, section 507 of the MMA directs us to consider whether the following had occurred as of that date: (i) architectural plans were completed; (ii) funding was received; (iii) zoning requirements were met; and (iv) necessary approvals from appropriate State agencies were received. A specialty hospital's failure to satisfy all of these considerations does not necessarily preclude us from determining that the hospital was "under development" as of November 18, 2003. In addition, we may consider any other evidence that we believe would indicate whether a hospital was under development as of November 18, 2003.

II. FACTS

The parties to this advisory opinion request (collectively, the "Requestors") are [name redacted] (the "Partnership"), a limited partnership of approximately 100 physicians specializing in cardiology, cardiovascular surgery, or thoracic surgery; and [name redacted] (the "Medical Center"). The Requestors have certified that the Hospital would specialize in comprehensive cardiac and vascular screening, diagnostic services, and invasive and non-invasive therapeutic services.

Requestors have certified that the Partnership was formed in June 2003. In August 2003, the Partnership approached senior management of [name redacted] (the "System") concerning the potential location of the Hospital on the same campus as the Medical Center, a general acute care hospital wholly-owned by the System and that was under construction. At the time, the System did not have plans to construct a second, specialty hospital on the site.[3] In September 2003, the System's Board of Trustees voted to authorize continued discussions to explore the opportunity to collaborate with the Partnership to develop a specialty hospital on the Medical Center's campus.

As of November 18, 2003, however, there was no legally enforceable joint venture agreement in effect between the System and the Partnership. Rather, in November 2003, the System's Finance Committee arrived at a proposed agreement for a limited liability partnership with a 50/50 ownership by a tax-exempt entity related to the System and the Partnership. This proposed agreement was memorialized in a term sheet (i.e., letter of intent), which itself was not legally binding.

A. Architectural Plans

In November 2003, The Partnership engaged an architectural firm to provide pre-design services, including development of preliminary drawings, review of potential site configuration and location opportunities, and development of concept alternatives. In November 2003, the firm delivered a site plan for the Hospital.

The Requestors included a site plan with their advisory opinion request, but these documents do not exhibit a sufficient level of detail or development such that we can characterize them as "completed architectural plans." The Requestors acknowledge that the site plan documents are "preliminary." The Requestors did not engage in discussions with the architectural firm regarding the preparation of construction-ready plans until after November 18, 2003. No mechanical, engineering, or structurally detailed plans for the Hospital had been developed by November 18, 2003.

B. Funding

[3] A concept plan prepared by an architectural firm in February 2002 shows a hospital, medical office building, and parking structure on the site, with possible expansion at some unspecified time in the future. This plan was significantly revised in a preliminary site plan dated September 2002. The preliminary site plan includes a second hospital on the site; however, the site plan indicates that construction of the second hospital would not occur for at least five years. Not until the System began discussions with the Partnership was a plan proposed to accelerate building a second, specialty hospital on the site.

The certified facts show that, as of November 18, 2003, there was no significant financial commitment toward the development of the Hospital. According to the letter of intent memorializing the proposed agreement for a joint venture between the System and the Partnership, the anticipated cost of the Hospital was approximately $75 million. Yet, the approximately 100 physician investors in the Partnership had contributed less than $145,000 before November 18, 2003 toward the planning and development of the Hospital. That amount represents a modest investment of less than $1,600 from each physician investor and less than .2% of the total anticipated cost of the project.

No other financing was received as of November 18, 2003. Although the letter of intent proposed that the project be financed with approximately $10 million of equity capital (a portion of which the System would contribute) and the balance with debt financing, the System did not provide, and the Partnership did not receive, any financing on or before November 18, 2003.

C. Zoning Requirements

Although the Partnership was considering the possibility of developing the Hospital on land owned by the System, as of November 18, 2003, there was no commitment to build the Hospital on any particular site. Therefore, the Hospital itself was not the subject of any necessary zoning approval as of the relevant date.

D. State Regulatory Approvals

The state in which the Hospital would be located does not require certificate of need review prior to development and construction of a hospital. Applicable state law requires new hospitals to submit preliminary and final architectural plans, a functional program narrative and outline specifications to the state health department for review and approval before construction. The state health department conducts intermediate and final inspections to verify compliance with approved construction documents and applicable rules and standards. Preliminary architectural plans and outline specifications are to include the following information: floor area and bed distribution; a floor plan; construction type and fire rating; an area map of the hospital site with any hazardous and undesirable location identified; and a site plan. As of November 18, 2003, the Partnership had not obtained, or submitted an application to secure, approval from the state health department.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental information, we determine that, as of November 18, 2003, the Hospital was not "under development" within the meaning of section 507 of the MMA. Accordingly, the specialty hospital moratorium set forth in section 507 of the MMA applies to the Hospital.

We have based our conclusion on a variety of facts indicating that the project was still in an exploratory phase as of that date. In particular, the amount of the funding received as of November 18, 2003 was minimal in comparison to the projected cost of the project, and the project was not sufficiently developed to justify application for (much less receipt of) any necessary state approval. In addition, the Hospital's architectural plans were at an early stage of development, and the Hospital was not the subject of any necessary zoning approval.

IV. LIMITATIONS OF THIS OPINION

The limitations that apply to this advisory opinion include the following:

- This advisory opinion and the validity of the conclusions reached in it are based upon the accuracy of the information that you have presented to us.

- This advisory opinion is relevant only to the specific question(s) posed at the beginning of this opinion. This advisory opinion is limited in scope to the specific facts described in this letter and has no application to other facts, even those that appear to be similar in nature or scope.

- This advisory opinion does not apply to, nor can it be relied upon by, any individual or entity other than the Requestors. This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion applies only to the statutory provisions specifically noted above in the first paragraph of this opinion. No opinion is herein expressed or implied with respect to the application of any other Federal, State, or local statute, rule, regulation, ordinance, or other law that may apply to the facts, including, without limitation, the Federal anti-kickback statute (42 U.S.C. § 1320a-7b(b)).

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services. Under 42 C.F.R. § 411.382, CMS reserves the right to reconsider the issues posed in this advisory opinion and, where public interest requires, rescind or revoke this opinion.

- This advisory opinion is limited to the proposed arrangement. We express no opinion regarding any other financial arrangements disclosed or referenced in your request letter or supplemental submissions. Moreover, we express no opinion regarding whether a referring physician's financial relationship the Hospital satisfies the criteria of any exception under section 1877 of the Act or its implementing regulations.

- This advisory opinion is also subject to any additional limitations set forth at 42 C.F.R. § 411.370 et seq.

Sincerely,

Herb Kuhn
Director
Center for Medicare Management

cc: Dr. Jeffrey Gladden
Gary Brock