

AO-SH-2004-08-02

[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” or “Requestor”) 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 on the facts and information you presented to us. If material facts have not been disclosed or have changed since we accepted your request, 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 “under development” as of November 18, 2003, and is therefore exempt from the specialty hospital moratorium. We note that, although the Hospital is exempt from the specialty hospital moratorium, a referring physician’s ownership or investment interest in the Hospital must comply with the remaining terms of either the rural provider exception or the hospital ownership exception, as set forth in section 1877(d) of the Social Security Act (the Act) and as interpreted at 42 CFR section 411.356(c). We express no opinion regarding compliance with either of these exceptions.

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

I. STATUTORY BACKGROUND

A. The Physician Self-Referral Prohibition

Under section 1877 of the Act (42 USC section 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

¹ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, section 507.

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 punishable by denial of payment 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 USC sections 3729-3733.

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

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (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 a rural area.

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 percent 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 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

² In 1993, the physician self-referral prohibition was made applicable to the Medicaid program. 42 USC section 1396b(s).

hospital's failure to satisfy all of these considerations does not necessarily preclude us from determining that a specialty 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 party requesting this advisory opinion is [name redacted] ("the Partnership" or "the Requestor"), a limited partnership that was formed [in September 2002] for the purpose of developing the Hospital. At the time of its formation, the partnership was among the following: [name redacted] LLC (Partner 1); [name redacted] (Partner 2); and eleven physicians. Partner 2 had a 100 percent membership interest in Partner 1.

[In February 2003], Partner 2, through a wholly-owned subsidiary, purchased for [approximately \$2 million] the [acreage redacted] parcel upon which Requestor proposes to build the Hospital. [In January 2004], Partner 2 sold its interest in the Partnership, its interest in Partner 1, and the [acreage redacted] parcel to [name redacted] LLC (Partner 3) for [more than \$2 million.]³

The Requestor has certified that the Hospital would focus almost exclusively on pain management, bariatric, orthopedic and neurological patient surgical care. The proposed facility will be a one-story building with 38 surgical beds, five intensive care beds, six surgery suites, and associated ancillary support departments. All investor physicians will have medical staff privileges at the Hospital and will likely refer patients to, and treat patients at, the Hospital.

A. Architectural Plans

Detailed architectural plans for the hospital project were originally completed [in the spring of 2003]. The plans included the following: (i) a map of the proposed hospital site and adjacent area, including all landscape plans; (ii) architectural drawings, including structural, mechanical, electrical, plumbing, foundation and roof schematics; and (iii) detailed interior drawings, including building elevations. In addition, an engineering and survey firm prepared sewer, water, and drainage designs for the hospital site during June 2003.

B. Funding

The Hospital has certified that a substantial amount of funding was received and expended before November 18, 2003. In December 2002, the eleven physician investors in the specialty hospital project contributed [more than \$800,000] pursuant to a confidential partnership offering. As previously discussed, in [February 2003], Partner 2 (through a wholly-owned subsidiary) expended [approximately \$2 million] for the [acreage redacted] parcel upon which the Hospital would be built. Partner 3 purchased this property, as well as Partner 2's interest in the Partnership and Partner 1, for [more than \$2million].

³ Requestor has certified that this transaction did not increase the number of direct or indirect physician investors in the Partnership.

C. Zoning Requirements

[In June 2003], the local jurisdiction approved annexation of the land and rezoned it for use as a hospital. The U.S. Army Corps of Engineers required that a wetland mitigation permit be obtained for the chosen site. The required wetland permit was issued [in May 2003].

D. State Regulatory Approvals

The state in which the Hospital is located does not require certificate of need review prior to development or construction of a hospital. Applicable state law requires new hospitals to submit a complete set of architectural plans and specifications to the state for plan review and approval before construction begins. Specifically, applicable state law requires new hospitals to: (i) submit a copy of the floor plans and specifications for state approval; (ii) incorporate the state's comments into plan revisions; (iii) obtain review and approval of the plans by the [state fire marshal] prior to commencement of construction; and (iv) incorporate the [fire marshal's] comments into plan revisions. Successful completion of the plan review process is required to obtain hospital licensure.

The Requestor certified that it submitted plans to the state for review in July 2003. Requestor certified that a representative of the hospital met in July 2003 with officials from the [state health department] to review architectural plans for the Hospital. The [state health department] provided minor comments to the Requestor regarding the architectural plans. Requestor proceeded to incorporate those comments into its plans. As of November 18, 2003, however, the Requestor had not yet received formal approval from the [state health department] or the [fire marshal] as needed to begin construction of the Hospital.

In addition, the Requestor applied for and received a water quality certification from the state. Applicable state law required such a certification for before the Requestor could clear, grade, excavate, and fill the land where the proposed Hospital would be located. The state issued the water quality certification [in May 2003].

III. CONCLUSION

Based on the facts certified by the Requestor, we determine that the Hospital was under development as of November 18, 2003. Accordingly, the specialty hospital moratorium set forth in section 507 of the MMA does not apply to the Hospital.

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 Requestor. This advisory opinion may not be introduced 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. 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 USC section 1320a-7b(b)).

- This advisory opinion will not bind or obligate any agency other than the Department of Health and Human Services. Under 42 CFR section 411.382, the Centers for Medicare & Medicaid Services reserves the right to reconsider the issues posed in this advisory opinion and, where public interest requires, rescind or revoke this opinion.

- This opinion is limited to the proposed arrangement. We express no opinion regarding any other financial arrangements disclosed or referenced in your request letter. Moreover, we express no opinion regarding whether a referring physician's ownership or investment interest in 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 CFR section 411.370 et seq.

Sincerely,

Herb B. Kuhn
Director, Center for Medicare Management