AO-SH-2005-06

[Name redacted]

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion concerning the 18-month moratorium on physician self-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 "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 the hospital ownership exception, set forth in section 1877(d) of the Social Security Act (the "Act"), as interpreted at 42 C.F.R. § 411.356(c)[2]. We express no opinion regarding compliance with this exception or with the physician self-referral prohibition generally.

The arrangement you described in your advisory opinion request may raise potential issues under the anti-kickback statute in section 1128B(b) of the Act (42 U.S.C. §1320a-7b(b)). The Office of Inspector General (OIG) is the agency with authority to issue opinions about the application of the anti-kickback statute. For additional information on the OIG's advisory opinion process, you may wish to consult their website (http://oig.hhs.gov//fraud/advisoryopinions.html). This CMS advisory opinion is not intended to, and should not be construed to, address the propriety of the Hospital's arrangement under the anti-kickback statute.

This opinion may not be relied on by any individual or entity other than the party 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.

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

[2] Based on the location of the Hospital, the rural provider exception (section 1877(d)(2) of the Act and 42 C.F.R. 411.356(c)(1) is not applicable.

I. STATUTORY BACKGROUND

A. The Physician Self-Referral Prohibition

Under section 1877 of the 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.[3] Section 1877 also prohibits the entity furnishing the DHS from submitting claims to Medicare, or billing 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 included as DHS. A financial relationship includes both ownership/investment interests and compensation arrangements. The statute and regulations enumerate 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 of all DHS claims that are the subject of the prohibited referrals, refund of amounts collected for such 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 an 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 entire hospital and not in only 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

[3] In 1993, the physician self-referral prohibition was made applicable to the Medicaid program. 42 U.S.C. § 1396b(s).

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 five 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 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 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 "Requestor"), a limited partnership formed in September 1999 for the purpose of operating the Hospital. The Requestor is owned by forty-four physicians and [name redacted] ("Management Company"), a health care management company specializing in the development of ambulatory surgery centers and specialty hospitals. The Management Company will manage the Hospital's daily operations. The Management Company is owned by 109 physicians and 9 non-physicians.[4]

[Name redacted] ("Real Estate Company") was formed in March 2002 to acquire real estate and to develop and construct a medical complex that will house the Hospital as well as medical offices. Real Estate Company is owned by [name redacted] ("Developer"); nineteen physician investors, fourteen of whom are also investors in the Hospital; and by thirty-one non-physician investors.[5] Real Estate Company agreed to construct the hospital under a "build to suit" arrangement. The Requestor leases the Hospital from Real Estate Company.

Construction of the Hospital began in December 2002. The Hospital, now constructed, is approximately 50,000 square feet with twenty-one beds, seven operating rooms, eight pre-operative rooms, and thirteen recovery bays. The Requestor certified that the Hospital would focus almost exclusively on surgical procedures. All physician investors in the Requestor will be members of the Hospital's active medical staff and will refer patients to, and treat patients at, the Hospital.

A. Architectural Plans

Requestor certified that all architectural plans (including mechanical, electrical, plumbing and structural plans) were completed and submitted for state approval in June 2001.

[4] Requestor has certified that none of the 109 physicians will refer patients to the Hospital.
[5] We express no opinion regarding any indirect financial relationship that may exist between the Hospital and any referring physician who has a direct or indirect financial relationship with Management Company or Real Estate Company.

B. Funding

The Requestor certified that a substantial amount of funding had been received and expended before November 18, 2003. The land was purchased for $3.3 million in July 1999. By December 2002, Requestor had raised over $6.3 million in equity funding for development and operation of the Hospital. In February 2003, Real Estate Company secured a construction loan in the amount of $18,550,000 to fund the construction of both the Hospital and the medical office building. By November 18, 2003, approximately $7.5 million of this loan had been disbursed.

C. Zoning Requirements

The Requestor certified that the local jurisdiction rezoned the Hospital property and approved the construction of a hospital building on that property in March 2000. The Requestor also certified that no other zoning approval was necessary to construct the Hospital on the chosen site.

D. Regulatory Approvals

The state in which Hospital is located does not require a certificate of need review prior to development or construction of a hospital. Applicable state law requires new hospitals to submit completed architectural plans and specifications to a state agency for approval before construction begins. To obtain a building permit from the state agency, a hospital must have secured funding and all local zoning and planning approvals. The state agency conducts inspections to verify compliance with approved construction documents and applicable rules and standards.

Requestor certified that an application for plan review was submitted to the state agency in April 2001. In October 2002, the state agency issued a building permit to begin construction. The state agency granted final construction approval in November 2002. The Requestor certified that it submitted its hospital license application to the state in November 2003, but was not licensed as of November 18, 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 shall be without force and effect if Hospital fails to (i) satisfy the definition of "hospital" in section 1861(e) of the Act; (ii) comply with the hospital conditions of participation set forth in 42 C.F.R. Part 482; or (iii) obtain, or comply with the terms of, a hospital provider agreement.

- 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 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 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 with 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 B. Kuhn
Director
Center for Medicare Management