AO-SH-2004-12-07

[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, as set forth in section 1877(d)(3) of the Social Security Act (the "Act"), as interpreted at 42 C.F.R. § 411.356(c)(3).[2] We express no opinion regarding compliance with this exception.

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 C.F.R. §§ 411.370 through 411.389.

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

[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, 42 C.F.R. § 411.356(c)(1)) is not applicable.

may wish to consult their website (http://oig.hhs.gov//fraud/advisoryopinions.html). Issuance of this CMS advisory opinion is not intended to, and should not be construed to, address the propriety of your arrangement under the anti-kickback statute.

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, 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 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 ("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 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

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

"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 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 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 party requesting this advisory opinion is [name redacted] (the "Requestor"), a limited liability company formed in October 2002 for the purpose of operating the Hospital. Requestor is owned by [name redacted] ("Partner 1") and [name redacted] ("Partner 2"). Partner 1 is owned by 40 physicians, and Partner 2 is owned by 36 physicians and one non-physician investor. Because some of the physicians possess ownership interests in both Partner 1 and Partner 2, the total number of physician investors in both partners is 49. All of the physician owners practice in one of the following specialties: orthopedic medicine; orthopedic surgery; physical medicine; or anesthesiology.

[Name redacted] ("Real Estate Company") is a limited liability company owned by 47 physicians and one non-physician investor. All physician investors in Real Estate Company possess ownership interests in Partner 1, Partner 2, or both. Pursuant to a lease agreement executed in September 2003, Real Estate Company agreed to construct at its sole cost and expense the building in which Hospital would be located, and Requestor agreed to lease approximately [130,000] square feet in the building for an initial 20-year term for purposes of operating the Hospital.[4] Pre-construction site preparation began in July 2003 and construction began in August 2003.

Requestor certified that the Hospital would focus almost exclusively on orthopedic surgery. All physician investors in the Hospital will be members of the Hospital's active medical staff and will refer patients to, and treat patients at, the Hospital.

A. Architectural Plans

[4] We express no opinion regarding any direct or indirect financial relationship that may exist between the Hospital and any referring physician that has a financial relationship with the Real Estate Company.

Requestor certified that all architectural plans were completed before November 18, 2003. We note that architectural plans (including electrical, mechanical, plumbing and structural plans) were completed and furnished to the state in three separate submissions delivered in July, August, and October 2003.

B. Funding

Requestor certified that a substantial amount of funding had been received and expended for the Hospital project before November 18, 2003. For example, an initial capital contribution of [more than $3.0] million was raised by June 2003, [between $2.5 and 3] million of which was spent on development of the Hospital prior to November 18, 2003. In September 2003, Real Estate Company closed on a [between $40 and $45] million construction loan, secured with a mortgage security agreement. [More than $30] million of this loan was for purposes of constructing the Hospital as required under Real Estate Company's Lease Agreement with Requestor. By November 18, 2003, approximately $10 million of the construction loan had been disbursed, over [$7.0]million of which was expended prior to November 18, 2003 for land acquisition, loan fees and other closing costs, taxes, professional services, and various construction costs.

C. Zoning Requirements

In February 2003, the local jurisdiction rezoned the location of the hospital property as a special use hospital district. Requestor certified that no other zoning approval was necessary to construct the Hospital on the chosen site. We note that in August 2003, the local jurisdiction approved the Hospital's site and development plan and issued the required construction permit for the Hospital.

D. Regulatory Approvals

The state in which the Hospital would be located does not require certificate of need review prior to development or construction of a hospital. Applicable state law requires new hospitals to submit detailed architectural and operational plans to the state Department of Fire and Building Services (DFBS) and the state Department of Health (DOH) for review and approval. After the DFBS issues a construction design release, construction may proceed, and an application for licensure must be filed with the DOH. All required approvals from the DFBS and DOH must be obtained before a certificate of occupancy is issued.

Requestor certified that the architectural and operational plans for the project were submitted to the DFBS and DOH in three separate packages by November 3, 2003. Requestor certified that the construction design release was issued by the DFBS on November 6, 2003. Requestor had not received DOH approval as of November 18, 2003.

III. CONCLUSION

Based on the facts certified by 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 MMA does not apply to the Hospital.

IV. LIMITATIONS OF THIS OPINION

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

- This opinion shall be without force and effect if the 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 entirely 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 which 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 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 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 ownership or investment interest 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