AO-SH-2004-12-06

[Name redacted]

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion concerning the 18-month moratorium on physician 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] ("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 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 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 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 general 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 your arrangement under the anti-kickback statute.

This opinion may not be relied on by any persons other than the Requestor. This opinion is further qualified as set forth in section IV below and in 42 C.F.R. §§ 411.370 through 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 Hospital, the rural provider exception (section 1877(d)(2) of the Act, 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, 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 to Medicare 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 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 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 "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

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

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

In March 2001, the physician shareholders in a medical practice known as [name redacted] ("Medical Practice") began considering the viability of developing, owning, and operating a hospital devoted to spine surgery and pain management. In December 2002, the physicians formed two entities for purposes of developing the Hospital: (i) [name redacted] ("Real Estate Company"); and (ii) [name redacted] ("Operating Company"). The companies have identical investors; both are owned by [approximately 20 physicians] ([approximately 10] of whom are shareholders in Medical Practice) and one nonphysician individual who has provided development services on the project ("Developer").[4]

The land on which the Hospital is being built is owned by [name redacted] ("Property Owner"), an entity owned by Developer. Property Owner leases the land to Real Estate Company. Under the terms of the lease, a second Developer-owned entity is responsible for constructing the Hospital at Real Estate Company's expense. Real Estate Company, in turn, leases the land and the hospital facility to the Operating Company. The groundbreaking for the project occurred in June 2003, although the construction contract was not executed until August 2003. The Operating Company is the entity to which the hospital license will be granted.

Once construction is completed, the facility will be a two-story building of approximately 55,000 square feet with approximately 23 beds, four full-scale operating rooms and three treatment rooms. The Requestor certified that the Hospital will focus almost exclusively on surgical procedures. All investor physicians will have medical staff privileges at the Hospital and will likely refer patients to, and treat patients at, the Hospital.

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

A. Architectural Plans

The Requestor hired an architectural firm in January 2003. The architectural firm prepared architectural plans in March 2003, and final construction plans were completed and submitted to the state for approval in September 2003.

B. Funding

The Requestor certified that a substantial amount of funding had been received before November 18, 2003. The total project budget is estimated at [approximately 10 million dollars]. Both the Real Estate Company and the Operating Company provided some financing. Specifically, the Real Estate Company initially contributed [approximately $10,000] for Hospital construction, and the Operating Company contributed [approximately $10,000] to provide operating capital for the Hospital. In September 2003, a local bank agreed to provide a construction and short-term financing loan to the Real Estate Company in the amount of [approximately 10 million dollars]. The loan was secured by a multiple indebtedness mortgage, assignment of rents and leases, and security agreement executed by Property Owner, as well as personal guarantees executed by the physician investors and pursuant to which each physician guaranteed payment of all or a pro rata portion of the loan. [Approximately 4 million dollars] of the loan was disbursed as of November 18, 2003 for project-related expenditures.

C. Zoning Requirements

In June 2003, Requestor submitted the building plan for the Hospital to the local jurisdiction ("City") for review. The City issued a building permit for the Hospital in July 2003 and zoned the relevant property to permit construction of a hospital or medical center. The Requestor has certified that this zoning classification is the only zoning approval required for development and construction of the Hospital at the chosen site.

D. 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 preliminary and final architectural plans and specifications to the [name redacted] ("State Health Department") and the [name redacted] ("State Fire Marshal") for "plan review" and approval before construction begins. The State Health Department and the State Fire Marshal conduct inspections to verify compliance with approved construction documents and applicable rules and standards. Successful completion of the plan review process is required to obtain hospital licensure.

In May 2003, the Requestor received tentative plan review approval from the State Health Department, pending receipt of written approval from the State Fire Marshal. The State Fire Marshal granted new construction approval in October 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 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 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 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 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