

**AO-SH-2004-06-01**

[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”).<sup>1</sup> Specifically, you seek a determination that [name redacted] (“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 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).<sup>2</sup> We express no opinion regarding compliance with this exception.

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-.389.

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<sup>1</sup> Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 507.

<sup>2</sup> 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.<sup>3</sup> 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

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

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: architectural plans were completed; funding was received; zoning requirements were met; and 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 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**

Hospital represented that it would focus almost exclusively on orthopedic and neurological surgical care, thus satisfying the section 507 definition of a specialty hospital. The Hospital has requested that the Centers for Medicare & Medicaid Services (CMS) determine if its proposed specialty hospital would be considered “under development” as of November 18, 2003. We discuss the relevant facts below.

The Hospital is a joint venture between [20 to 30] orthopedic surgeons and neurosurgeons currently practicing in [city redacted] and [name redacted (“Company A”)], an established national operator of ambulatory surgery centers and specialty hospitals. The Hospital was formed [in July 2001] and capitalized in 2002 pursuant to a confidential offering that raised [more than \$675,000]. With the addition of two physician investors in January 2003, equity funding totaled [more than \$750,000]. Collectively, the physician investors own xx% of the Hospital stock, and Company A owns the remaining xx%.<sup>4</sup> Company A received its ownership interest as compensation for its hospital development services provided to the Hospital.

The proposed facility will be a four-story building of approximately [xxx,xxx] square feet with [between 60 and 70] private beds, 10 surgery suites, and associated ancillary support departments. The Hospital will focus almost exclusively on inpatient and outpatient orthopedic and neurological surgical care.

### **A. Completion of Architectural Plans**

Architectural and design work for the hospital initially was drafted in 2002 and the first half of 2003 by several architecture firms. [In late summer 2003], a single architecture firm was hired to design the hospital and to develop final architectural plans. [In September 2003], Stage 1 preliminary construction plans were submitted for review by the [state name redacted] Department of Health (DOH). On November 13, 2003, the following documents had been completed and were submitted for DOH review: (i) civil engineering documents, including a

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<sup>4</sup>We express no opinion with respect to the legality of this venture under the Federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b).

map of the proposed hospital site and adjacent area, as well as all drainage, paving, storm sewer, utility plans, and relevant specifications for same; (ii) preliminary architectural plans, foundation plans, under-floor mechanical, electrical, plumbing, and steel superstructure plans, and related specifications for under-floor and structural work; and (iii) completed architectural drawings governing the exterior pre-cast concrete and glass/aluminum skin of the building, and related specifications.

## **B. Funding**

The Hospital certified that a substantial amount of funding had been received and expended before November 18, 2003. For example, by January 2003, physician investors in the specialty hospital project contributed [more than \$750,000] in equity funding. In February 2003, the Hospital acquired the site through a wholly-owned real estate holding partnership, [name redacted].<sup>5</sup> The [\$6,xxx,xxx] purchase price of the land was funded by a bank loan guaranteed by the physician investors and Company A. Over \$1.8 million in [additional] expenses had been incurred and paid by November 18, 2003, including architect and engineering fees, management fees, fees for geotechnical surveys and other reports, state and local fees, and demolition expenses. [In May 2003], the Hospital secured and received working capital financing from a bank [in excess of \$1,000,000].

## **C. Zoning Requirements**

In late 2000 and early 2001, the Hospital founders conducted feasibility analyses, selected a location for the hospital, and obtained an option to purchase the land on which the proposed specialty hospital could be built. For approximately eight to twelve months, the Hospital founders, in conjunction with the then-owner of the site, worked to resolve environmental issues, and to acquire preliminary city and state approvals for construction of a hospital on the site. In February 2002, the land was purchased by a developer engaged by the Hospital. The Hospital has certified that it obtained a special use permit from the local zoning commission [in May 2002], and that this permit is the only zoning approval required for development and construction of the hospital at the chosen site. Demolition of [more than 70,000] square feet of existing structures began [in April 2003]. Demolition and grading of the site were completed before November 18, 2003.

## **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 DOH for “plan review” and approval before construction begins. The DOH conducts intermediate and final 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. A new

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<sup>5</sup> In March 2003, the Hospital engaged a real estate investment trust (REIT) to be the exclusive developer of the specialty hospital project. The parties agreed that the REIT would complete development of the project, own the hospital building, and lease the building to the Hospital.

hospital's application for an initial license may not be submitted earlier than 60 days prior to the opening of the hospital.

The Hospital filed an application for plan review with the DOH on September 10, 2003. The application included preliminary construction documents. As permitted under state regulations, the Hospital requested accelerated review of its application. As noted above, the Hospital submitted to DOH detailed architectural and engineering plans and specifications on November 13, 2003. On November 17, 2003, DOH acknowledged receipt of a "complete plan submittal" for the project, although final construction documents had not yet been submitted.

### **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 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