AO-SH-2004-11-05

[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. The Hospital will change its name to [name redacted] before it begins operations.

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 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.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 Social Security 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 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 (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 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

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

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 of the MMA 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 "Partnership" or the "Requestor"). The Partnership was formed in September 2000 and was among the following parties as of November 18, 2003: (i) [name redacted] ("General Hospital"), a nonprofit hospital; (ii) [name redacted] ("Consulting Group,"), a consulting group that provides business and financial advice to health care industry clients; (iii) [name redacted] ("Physician Group"), a medical practice owned by seven urologists; and (iv) 33 other individual physicians.

In December 2000, the Requestor acquired and has continuously operated an ambulatory surgery center ("ASC"). The Partnership originally planned to open a second ASC, but ultimately decided to develop and operate a specialty hospital instead. Further, it decided to cease operating the existing ASC after the specialty hospital became operational.

The Hospital will be located in part of a new medical office building that is located on the campus of the General Hospital. The land is owned by General Hospital's parent company ("Parent Company"), which has leased the land to [name redacted] ("Development Company") pursuant to a long-term ground lease dated January 1, 2001.[4] Development Company built a medical office building on this land.

In April 2001, the Requestor leased from Development Company approximately 18,000 square feet of space in the medical office building. In August 2003, after the parties agreed to convert the project from an ambulatory surgery center to a specialty hospital, the lease was amended to increase the amount of space leased to 50,000 square feet. Within the leased space, the Hospital will occupy 3 floors to be used for the provision of health care services, plus space on another floor for administrative services. 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 Development Company or Parent Company.

will have 9 inpatient beds, 9 operating suites, 3 treatment rooms, 12 pre-op beds, 18 recovery beds, emergency and urgent care area and related ancillary services.[5] 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

Requestor has certified that a full set of architectural plans was developed and presented to the Requestor for approval in August 2003. In October 2003, Requestor submitted detailed architectural plans to the state health department as part of the state's "plan review" process for new hospitals. Requestor has certified that these plans included garden and floor plans and construction-ready structural, mechanical, electrical, plumbing, and engineering plans.

B. Funding

The Requestor certified that a substantial amount of funding had been received and expended before November 18, 2003. For example, through a private limited offering that was conducted from September to November 2000, the Partnership raised [more than $2,300,000], which was set aside for construction of a new facility. Under the lease arrangement between Development Company and the Partnership, Development Company will pay approximately [$4,300,000] and the Partnership will pay approximately $2,500,000 in build-out costs to construct the Hospital.

No other financing was received as of November 18, 2003. Although the Partnership's Board of Managers approved a proposal on November 17, 2003 for a $1,000,000 working capital line of credit and an equipment loan, the loan documents were not executed until March 2004.

C. Zoning Requirements

The Requestor provided certified documentation that the Hospital will be located on the campus of General Hospital. The Requestor has certified that the use of the chosen site for a hospital is an allowable use and therefore did not require any zoning approval by the local jurisdiction. The Requestor received the necessary building permits to construct the Hospital on September 12, 2002 and November 3, 2003.

[5] 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.

D. State Regulatory Approvals

The state in which the Hospital is located does not require certificate of need review prior to development and construction of a hospital. Applicable state law requires new hospitals to submit preliminary and final architectural plans, a functional program narrative and outline specifications to the state health department for "plan review" and approval before construction begins. The state health department 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.

In August 2003, Requestor filed with the state health department an application for plan review, including preliminary architectural plans for the hospital. The Requestor also certified that on November 13, 2003, it received notice from the state health department that a complete plan submittal had been received.

In addition to plan review and approval, the state mandates accessibility in publicly and privately funded buildings and facilities. Applicable state law requires the submission of construction documents for review and approval. The Requestor had received approval for the construction plans involving the building of the second ambulatory surgery center, but submitted a new request for approval on November 6, 2003 due to changes made after the project was converted to the development of a specialty hospital. On November 12, 2003, Requestor received notice that it filed a complete submittal for the accessibility review.

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 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 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 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 advisory 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 Kuhn
Director, Center for Medicare Management