

AO-SH-2004-09-04

[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 either the hospital ownership exception or the rural provider exception, as set forth in section 1877(d) of the Social Security Act (the “Act”), as interpreted at 42 C.F.R. § 411.356(c). We express no opinion regarding compliance with either of these exceptions.

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.

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

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.² 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 (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

² In 1993, the physician self-referral prohibition was made applicable to the Medicaid program. 42 U.S.C. § 1396b(s).

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 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 liability company formed in August 2002 for the purpose of operating the Hospital. The Requestor is owned by [between ten and fifteen physicians] and [name redacted], (“Management Company”), a national health care management company specializing in the development of ambulatory surgery centers and specialty hospitals. [Name redacted] (“Real Estate Company”) was created in August 2002 to acquire real estate and to develop and construct the Hospital. Some, but not all, of the Requestor’s members are also members of Real Estate Company.

Construction of the Hospital began in the spring of 2003, and the Hospital opened in early 2004.³ The Requestor leases from Real Estate Company the building in which the Hospital is located, and Management Company manages the Hospital’s daily operations.⁴ The Requestor certified that the Hospital focuses almost exclusively on surgical procedures. All physician owners of the Requestor are members of the Hospital’s active medical staff and regularly perform services at the Hospital.

A. Architectural Plans

Requestor has certified that all architectural, mechanical, electrical, and structural plans were completed by the end of March 2003.

³ The Requestor has certified that it has not submitted any Medicare or Medicaid claims relating to patients referred to the Hospital by physicians with ownership or investment interests in 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 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. For example, two securities offerings were held in 2002 to raise capital for the hospital development project. Pursuant to a confidential offering that closed in August 2002, Requestor raised [more than \$600,000] in capital contributions for the establishment and operations of the Hospital. Pursuant to a confidential offering that closed in November 2002, Real Estate Company raised [more than \$700,000] in capital contributions to fund the purchase of land and construction of the Hospital. The land was purchased by Real Estate Company for [approximately \$400,000] in March 2003. In addition, in May 2003, Real Estate Company obtained a construction loan [in excess of \$3,750,000] secured by a mortgage security agreement and assignment of rents. By November 18, 2003, [between \$2,500,000 to \$3,000,000 of this construction loan had been disbursed].

C. Zoning Requirements

The Requestor certified that the local jurisdiction rezoned the Hospital's property and approved the construction of a hospital building on that property in November 2002. The Requestor has also certified that no other zoning approval was necessary to construct the Hospital on 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 state health department and state fire marshal for approval before construction begins. The state health department and state fire marshal review the plans and 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.

Requestor has certified that the state fire marshal approved the drawings and specifications for the Hospital in March 2003 and that the state health department approved the Hospital's architectural plans in April 2003. In addition, the Requestor has certified that the state fire marshal approved the Hospital's fire alarm and fire suppression systems in July 2003 and August 2003, respectively.

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 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

FAHB5/J. Proctor/68852/final 9/17/04
Document:g/ppg/dids/flnrule/oaOuchitaOGC04.doc
Typist: T. Cox 60750