

[We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.]

[name and address redacted]

Re: Advisory Opinion No. CMS-AO-2013-03

Dear [name redacted]:

We write in response to your request for an advisory opinion regarding whether a construction project that would add beds to an existing physician-owned hospital (the “Proposed Arrangement”) would violate the limitation on expansion of facility capacity set forth in section 1877(i)(1)(B) of the Social Security Act (the “Act”). Specifically, you assert that the new beds would be used solely for observation services, and that their addition to the hospital would involve a state approval process that will not result in any change to the number of beds for which the hospital is licensed.

You certified that 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 and agreements among the parties. In issuing this opinion, we relied solely on the facts and information presented to us. We did not undertake an independent investigation of this information. If material facts were not disclosed or were misrepresented, this advisory opinion is without force and effect.

Based on the specific facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement would not violate the limitation on expansion of facility capacity set forth in section 1877(i)(1)(B) of the Act. We express no opinion regarding whether the Proposed Arrangement, if effectuated, would comply with any other provision of section 1877 of the Act.

This opinion may not be relied on by any persons other than [name redacted], the requestor of this opinion (the “Requestor” or “Hospital”), and is further qualified as set forth in section IV below and in 42 C.F.R. §§ 411.370 through 411.389.

I. FACTUAL BACKGROUND

Hospital is a 61-bed acute care hospital located in [state redacted] (“State”). Hospital is jointly owned by a development company and by several individual physician owners.

Hospital is planning a construction project to add a new observation unit to the hospital with 14 beds designed and used specifically for observation services (“Observation Unit” and “Observation Beds,” respectively). Each Observation Bed will be located in a private room (“Observation Rooms”). Requestor certified that the Observation Rooms

will not be used as operating rooms or “procedure rooms,” as defined under 1877(i)(3)(G).

For the expansion of an existing hospital facility, the State’s rules and procedures for hospital licensing encompass two separate review processes: (1) architectural review and (2) facility licensing.

For the architectural review, the State’s hospital licensing rules impose requirements for new construction, including minimum floor area requirements for outpatient observation rooms and inpatient suites. To gain construction approval, a hospital must submit an application for plan review to the State’s architectural review group along with plan review fees, and certify that the plans meet the State’s new construction requirements. In the application for plan review, the hospital must also certify whether the construction project will change the design bed capacity of the hospital. The design bed capacity determines the number of beds in the hospital that must be licensed.

For facility licensing, the State’s hospital licensing rules require licensure for certain (but not all) categories of beds. If a construction project increases the design bed capacity of the hospital, upon completion of the project the hospital must submit a license application to the State’s facility licensing group for the new beds. The hospital must also pay a per-bed license fee for each new bed added to the hospital’s design bed capacity.

Requestor certified that the State does not license observation beds. Hospital designed the Observation Rooms to comply with the minimum requirements for outpatient observation rooms. The Observation Rooms were not designed to meet, and in fact will not meet, the requirements for inpatient suites. Requestor submitted an application for plan review to the State’s architectural review group, certifying that its plans meet the requirements for outpatient observation rooms, and the State gave the Hospital construction approval. Requestor’s application for plan review explicitly stated that the project will not change the design bed capacity of the hospital. Accordingly, Requestor certified that its hospital license renewal application will not reflect the addition of any beds requiring licensure as a result of the completion of the new observation unit.¹ For the 14 Observation Beds that are the subject of this Advisory Opinion, the State has not required the Hospital to pay the per-bed licensure fee, and the Hospital has not paid and will not pay the per-bed licensure fee.

II. LEGAL ANALYSIS

A. Law and Regulations

Under section 1877 of the Act (42 U.S.C. § 1395nn), a physician may not 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

¹ The State hospital license application requires hospitals to “provide the total number of licensed beds in each unit or area of service at this hospital location” for a number of categories. Observation beds are not included in the list of licensed bed types. *See* [citation redacted].

relationship, unless an exception applies. Section 1877 of the Act 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.²

The prohibition against physician self-referral does not apply if the requirements of an applicable exception are satisfied. Section 1877(d)(3) of the Act provides an exception, known as the “whole hospital” exception, for physician ownership or investment interests in a hospital located outside Puerto Rico, provided that the referring physician is authorized to perform services at the hospital and the ownership or investment interest is in the hospital itself (and not merely in a subdivision of the hospital). The corresponding regulation for the exception is found in 42 C.F.R. § 411.356(c)(3).

Section 6001(a)(3) of the Patient Protection and Affordable Care Act (“ACA”) amended the whole hospital exception to impose additional restrictions on physician ownership and investment in hospitals. As amended, the whole hospital exception imposes limitations on the expansion of facility capacity, stating that:

[T]he number of operating rooms, procedure rooms, and beds for which the hospital is licensed at any time on or after [March 23, 2010] is no greater than the number of operating rooms, procedure rooms, and beds for which the hospital is licensed as of such date.³

The term “licensed” is not defined by the statute or the regulations. In the preamble to the final rule implementing section 6001(a) of the ACA, we concluded that the statute’s reference to licensure applied only to beds, not to operating rooms or procedure rooms:

We recognize that States usually do not license the number of hospital operating and procedure rooms. ... [T]he limitation on expansion applies to operating rooms and procedure rooms, regardless of whether a State licenses these rooms. We interpret the statutory phrase “for which the hospital is licensed” as applying only to beds. In other words, we believe the statute limits a hospital’s ability to increase the number of beds for which it was licensed and the number of operating and procedure rooms that existed at the hospital and were operational on March 23, 2010⁴

B. Analysis

The Requestor seeks a determination from CMS regarding whether the construction of an Observation Unit containing 14 new beds violates the prohibition on facility expansion in section 1877(i)(1)(B) of the Act. As noted above, the prohibition against facility

² In 1993, the physician self-referral prohibition was made applicable to the Medicaid program. Section 1901 (42 U.S.C. § 1396).

³ Section 1877(i)(1)(B) (42 U.S.C. § 1395nn(i)(1)(B)); see also the corresponding regulation at 42 CFR § 411.362(b)(2).

⁴ 75 Fed. Reg. 71800, 72244 (Nov. 24, 2010); see also, *id.* at 72246 (“[w]e do not interpret the statutory reference to licensure as applying to operating and procedure rooms”).

expansion applies to beds for which a hospital is “licensed.” We believe that the State’s approval process for the Observation Unit will not result in the addition of 14 “licensed” beds.⁵

In this case, the Requestor certified that the 14 new Observation Beds are not subject to licensure in the State. Requestor submitted to the State’s architectural review group an application for plan review for the Observation Unit, and the State authorized the Hospital to begin construction. The application for plan review states that the construction project will not involve a change in the Hospital’s current licensed beds, nor its design bed capacity. Along with its application for plan review, Requestor paid plan review fees for the new Observation Unit. However, for the 14 Observation Beds, Requestor certified that it has not paid and will not pay any fees that are classified as “license fees” under the State’s regulatory regime. Specifically, because the State does not license observation beds, Requestor is not required to pay the per-bed license fee that applies to categories of beds requiring licensure.

Based on the Requestor’s certifications, we find that the State’s approval process for the Observation Unit will not result in the addition of new “licensed” beds at the Hospital. Therefore, the number of beds licensed on or after March 23, 2010 will not exceed the number of beds licensed before that date. In addition, the Requestor certified that the Observation Rooms will not be used as operating rooms or procedure rooms. Thus, the Hospital’s addition of 14 new Observation Beds will not violate the prohibition against expansion of facility capacity set forth at section 1877(i)(1)(B) of the Act and 42 C.F.R. § 411.362(b)(2).

III. CONCLUSION

Based on the specific facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement would not violate the limitation on expansion of facility capacity set forth in section 1877(i)(1)(B) of the Act. We have not considered, nor do we express an opinion about, any other relationship between the Requestor and any other individual or entity.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to the Requestor of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.
- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor of this opinion.

⁵ This opinion is based on a state regulatory scheme where certain categories of beds are licensed by the State and other categories of beds are not. A different analysis may be required for those states with a different licensing scheme.

- This advisory opinion is applicable only to the statutory and regulatory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, State, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Practice or the Requestor, including without limitation, the Federal anti-kickback statute (section 1128B(b) of the Act), 42 C.F.R. section 412.105(b) (determination of the number of hospital beds), and 42 C.F.R. section 412.106(a) (Special treatment: Hospitals that serve a disproportionate share of low-income patients; general considerations).
- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services. The Centers for Medicare & Medicaid Services reserve the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, rescind or revoke this opinion.
- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.
- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. section 411.370 through section 411.389.

Sincerely,

Elizabeth Richter
Acting Director
Center for Medicare

cc: [name redacted]