[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-2016-01

Dear [name redacted]:

We write in response to your request for an advisory opinion regarding whether a hospital expansion project that would add outpatient observation 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 seek a determination that, because outpatient observation beds are not subject to licensure by [name of state department redacted] (the "Department"), the addition of new observation beds would not increase the number of beds for which the hospital was licensed on March 23, 2010.

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. In issuing this opinion, we relied solely on the facts and information presented to us. 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 or the regulations at 42 C.F.R. Part 411, Subpart J.

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 at 42 C.F.R. §§ 411.370 through 411.389.

I. FACTUAL BACKGROUND

Hospital is an acute-care hospital located in [state redacted] ("State"). Hospital is owned in part by physicians who make referrals for designated health services ("DHS") to Hospital.

Requestor certified that, on March 23, 2010, Hospital was licensed by the Department for 24 inpatient beds, and that it continues to have 24 licensed inpatient beds. Requestor certified that Hospital also has 12 short stay beds in addition to the 24 licensed inpatient beds. Requestor certified that the 12 existing short stay beds are not licensed by the

Department, and are not intended for use for patients admitted to Hospital as inpatients. According to Requestor, the short stay beds are in small rooms equipped with basic monitoring equipment only. In contrast, the 24 licensed inpatient beds are in large universal rooms that are equipped with all levels of patient monitoring and are capable of accommodating patients from admission to discharge.

Under the Proposed Arrangement, Hospital would add new observation beds to the existing facility. Requestor certified that, because observation beds are not licensed by the Department, the addition of new observation beds will not require additional licensing or revisions to Hospital's current license. Requestor further certified that it has confirmed this fact with the Program Director of the Department.

State requires hospitals to submit an annual license application. Hospital's application for the license that was in effect on March 23, 2010, and each annual application since that time indicate that the "[t]otal number of setup and staffed beds for inpatients in the hospital …" is 24. Requestor certified that, after the observation beds are added, Hospital's next annual license application will continue to list no more than 24 beds.

Requestor certified that the observation beds will not be used for inpatients, and that Hospital has procedures in place to ensure that the observation beds are not used for inpatients. Requestor also certified that the rooms housing the observation beds will not be used as operating rooms or procedure rooms, as defined in section 1877(i)(3)(G) of the Act and our regulations at 42 C.F.R. §411.362(a).

II. LEGAL ANALYSIS

A. Law and Regulations

a. Federal Law – Physician Self-Referral Law

Under section 1877 of the Act (42 U.S.C. § 1395nn), a physician may not refer a Medicare patient for DHS to an entity with which the physician (or an immediate family member of the physician) has a financial 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.

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, the ownership or investment interest is in the hospital itself (and not merely in a subdivision of the hospital), and additional restrictions added by Section 6001(a) of the Affordable Care Act (the "ACA") are satisfied. The corresponding regulation for the exception is found at 42 C.F.R.

§ 411.356(c)(3).

As amended by the ACA, the whole hospital exception imposes limitations on the expansion of facility capacity, requiring that:

> the 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.[1]

The term "licensed" is not defined in the Act or our 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, 2010 ….[2]

b. State Hospital Licensure Laws and Regulations

State does not require a certificate of need for new construction or facility expansion; however, any facility that meets State's statutory definition of a "hospital" must be licensed by the Department on an annual basis. The annual license fee for a hospital is based on the total operating expenses of the hospital, rather than the number or type of beds at the hospital. The license issued by the Department to a hospital does not specify the number or type of beds at the hospital.

Hospitals in State are required by statute to submit an annual license application on a form prepared by the Department. State's licensure statute lists certain information that must be provided in the license application. The licensure statute does not specifically require that an applicant hospital include on its license application the number or type of beds at the hospital, but does provide that "other information the [Department] requires" must be included in the license application.

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[1] 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).

[2] 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").

The Department develops the hospital license application form and issues licenses, pursuant to the authority granted to it by statute. The license application form developed by the Department includes an entry for beds, which requires the applicant to specify the "[t]otal number of setup and staffed beds for inpatients in the hospital (exclud[ing] pediatric visitors, newborn nursery cribs, maternity labor and delivery beds) as of the date of [the] application." The number of setup and staffed beds for inpatients is not included on the license issued to a hospital. However, the Department provides information to consumers online, including the "[n]umber of set up and available total beds under hospital licensure." The Department also maintains an online directory that lists the number of "set up/staffed inpatient beds" at each hospital in the State.

B. Analysis

We believe that State's hospital application and licensure process effectively is a system to license a specific number of beds in a hospital and that a hospital's "licensed" beds do not include any type of bed other than "setup and staffed inpatient beds." Therefore, we do not believe that observation beds are among the categories of beds that are licensed by the State. For this reason, we conclude that the addition of observation beds will not increase the number of beds for which Hospital was licensed on March 23, 2010.

In keeping with the statutory language of section 6001(a) of the ACA and our interpretation of the preamble to the final rule, where possible we will give effect to the phrase "for which the hospital is licensed" with respect to beds.[3] For the following reasons, we conclude that State, through the Department, "licenses" the number of beds in State hospitals. Applicants must provide certain information on the annual license application form developed by the Department pursuant to its statutory authority. Specifically, the Department requires license applicants to indicate the hospital's total number of "setup and staffed beds for inpatients." In addition, the Department publishes the number of beds "under licensure" in its report for consumers and hospital directory, which is available on the Department's website. This report indicates that Hospital has 24 beds "under licensure." Because we believe that State's application and licensure scheme results in the licensure of hospital beds, we conclude that Hospital is licensed by State for the number of beds listed on its application from.

In order to determine whether the addition of observation beds at Hospital would result in a violation of the prohibition on facility expansion, we evaluated whether State's licensure scheme establishes certain categories of beds that are subject to licensure and

[3] Requestor does not suggest—nor would we be inclined to accept the suggestion—that the State simply does not license the number of beds, and therefore there are no limitations on the expansion of bed capacity at physician-owned hospitals in the State. We believe such an argument would be inconsistent with the prohibition on facility expansion in the ACA.

other categories of beds that are not. As noted above, a hospital must indicate the total number of "setup and staffed inpatient beds" on its license application. Although the term "setup and staffed" is not defined clearly in State's regulations, "setup and staffed inpatient beds," as used on the State license application form, appears to exclude beds that are not designed and used solely for inpatient services. Because State's regulations classify observation services as outpatient services, we conclude that beds that are used exclusively for observation services are not "setup and staffed inpatient beds" and, therefore, are not subject to licensure in State.

Hospital's most recent licensure application and the licensure application that was in effect on March 23, 2010, both state that Hospital has 24 "setup and staffed inpatient beds."[4] Requestor certified that the licensure application it submits following the addition of the new observation beds will not reflect an increase in the number of "setup and staffed inpatient beds." Requestor further certified that the Program Director for the Department has confirmed that the observation beds will not be subject to licensing or require an amendment of the existing license. Finally, Requestor certified that the observation beds will not be used for inpatients, and that procedures will be put in place to ensure that misuse of the observation beds will not occur.

Based on our review and Requestor's certifications, we conclude that Hospital's addition of the observation beds described in its request for this advisory opinion will not cause Hospital to exceed the number of beds licensed at Hospital on March 23, 2010. In addition, the Requestor certified that the rooms housing the observation beds will not be used as operating rooms or procedure rooms. Thus, the Hospital's addition of 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, and our independent review of State's licensure process, 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.

[4] Moreover, all annual applications between March 23, 2010 and the date of this Advisory Opinion indicated 24 staffed and setup inpatient beds.

- 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.

- 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 U.S.C. section 1320a-7b(b)).

- 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,

Sean Cavanaugh
Deputy Administrator & Director
Center for Medicare

cc: [name redacted]