

[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-2021-2

Dear [name redacted]:

We write in response to your request for an advisory opinion from the Centers for Medicare and Medicaid Services (“CMS”) regarding whether the addition of 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 or registration by the [name of state department redacted] (the “Department”), the addition of new observation beds by [name redacted] (“Requestor” or “Hospital”) would not increase the number of beds for which Hospital was licensed on March 23, 2010. Although you certified facts similar to those described in CMS advisory opinion CMS-AO-2016-01,¹ the Proposed Arrangement, including the state statutory and regulatory scheme governing the Proposed Arrangement, is not indistinguishable in all material respects from the arrangement that was the subject of CMS-AO-2016-01.² Therefore, we provide an independent review and analysis of the Proposed Arrangement here.

You certified that the information provided in the 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. 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.

¹ <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2016-01.pdf>

² 42 CFR § 411.380 (c)(1)(i). For example, unlike state in CMS-AO-2016-01, the State in the Proposed Arrangement does not license hospitals. Rather, hospitals are required to submit an annual registration to the Department.

I. FACTUAL BACKGROUND

Hospital is a short-term acute care hospital located in [state redacted] (“State”). Hospital is owned in part by physicians who make referrals for designated health services to Hospital.

Requestor certified that, on March 23, 2010, Hospital was registered with the Department for 12 inpatient beds, and that it continues to have 12 inpatient beds registered with the Department. Requestor also certified that it has two observation beds used solely for providing outpatient care that are not registered with the Department. Requestor certified that the observation beds are located in small rooms equipped with basic monitoring equipment only. In contrast, Hospital’s 12 registered inpatient beds are located in large 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 that would be used solely for providing outpatient care. Requestor certified that, because the observation beds are neither licensed nor registered by the Department, the addition of new observation beds will not require additional licensing, registration, or revisions to the Hospital’s current registration. Requestor further certified that it has confirmed this fact with an employee of the Department.

Requestor certified that State requires hospitals to submit an annual registration to the Department, but does not license hospitals or hospitals beds. Hospital’s application for the registration that was in effect on March 23, 2010, and each annual application since that time indicate that the total number of beds in use for inpatients in the adult medical/surgical hospital is 12. Requestor certified that, after the new observation beds are added, Hospital’s next annual registration report will continue to list no more than 12 inpatient beds.

Requestor identified provisions in State’s administrative rules that define “hospital bed,” “inpatient,” and “outpatient” for purposes of hospital registration and reporting.

Requestor certified that, despite certain language in these definitions, it confirmed with the Department that, if a patient is not admitted to a hospital as an inpatient with a length of stay of at least the number of hours set forth in the definition of “inpatient,” the bed utilized by the patient would not be registered with the Department. Thus, if a patient remains in an observation bed for outpatient care beyond the number of hours set forth in the definition of “outpatient,” the patient does not automatically convert to an “inpatient,” and the observation bed does not automatically convert to an inpatient “hospital bed” for purposes of hospital registration and reporting.

Requestor certified that the new observation beds will not be used for inpatients, are not equipped for use as inpatient beds, and that Hospital has a policy and procedures in place to ensure that the new observation beds are not used for inpatients. Requestor also certified that the rooms in which the new observation beds will be located 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

Section 1877 of the Act and the regulations at 42 C.F.R. § 411.350 et seq. (collectively, the “physician self-referral law”) prohibit a physician from making a referral for certain designated health services payable by Medicare to an entity with which the physician (or an immediate family member of the physician) has a financial relationship unless all requirements of an applicable exception are satisfied. The physician self-referral law also prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third-party payer) for any improperly referred designated health services. There are numerous statutory and regulatory exceptions to the physician self-referral law.

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. The exception requires 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). If all of these requirements are satisfied, the physician may make referrals for designated health services to the hospital, and the hospital may submit claims for the referred designated health services.

As amended by the ACA, the whole hospital exception limits the expansion of facility capacity and, among other things, requires 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 was licensed as of March 23, 2010.³

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

³ Section 1877(i)(1)(B) of the Act; see also, 42 CFR § 411.362(b)(2).

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. State Hospital Licensure Laws and Regulations

State does not require a certificate of need for new construction or facility expansion, nor does State license hospitals or hospital beds. However, any facility that meets State’s statutory definition of a “hospital” must be registered and must report certain information to the Department each calendar year.⁵

Hospitals in State are required to submit an annual registration to the Department that reports, among other things, the hospital’s total number of beds listed by category of inpatient care provided.⁶ State administrative rules define “bed” (or “hospital bed”) as “a bed in a hospital with the attendant physical space, fixtures, and equipment for use in care primarily for inpatients.”⁷ State administrative rules define “inpatient” as a patient whose length of stay is 24 hours or more.⁸

The Department issues a letter to a hospital that has successfully completed the necessary hospital registration requirements as mandated by State law. The letter issued by the Department notifies the subject hospital that its registration requirement is complete and provides a list of the total number of beds reported by the subject hospital by category of inpatient care provided. The notification letter does not address beds used for outpatient care or other outpatient services. The Department also maintains an online directory of hospitals and hospital annual registration reports approved by the Department each year, both of which include the number of inpatient beds at each reporting hospital.

B. Analysis

State’s hospital registration process meets the standards for the licensing of hospitals in State, and beds registered in State do not include any type of bed other than inpatient beds. Observation beds, which Requestor certified are used solely for the provision of care to outpatients, are not among the categories of beds that are registered by State. For

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”).

⁵ [citation redacted]. Under State statute, a “hospital” means an institution classified as a hospital under State’s administrative rules in which are provided to inpatients diagnostic, medical, surgical, obstetrical, psychiatric, or rehabilitation care for a continuous period longer than 24 hours or a hospital operated by a health maintenance organization. [citation redacted]. State’s administrative rules define a “hospital” as a facility that is engaged primarily in providing to inpatients, by or under the supervision of an organized medical staff of physicians licensed by State, diagnostic services and therapeutic services for medical diagnosis and treatment or rehabilitation of injured, disabled, or sick persons. [citation redacted].

⁶ [citation redacted].

⁷ [citation redacted].

⁸ [citation redacted].

this reason, we conclude that the addition of observation beds will not increase the number of beds for which Hospital was licensed, registered, or authorized 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.⁹ For the following reasons, we conclude that State’s registration process effectively “licenses,” through the Department, the number of beds in State hospitals. Hospitals in State are required to register with the Department by providing certain information to the Department on the annual registration form developed by the Department pursuant to its statutory authority. Specifically, the Department requires hospitals to report the hospital’s total number of beds with the attendant physical space, fixtures, and equipment for use in caring primarily for inpatients that are in use for certain categories of inpatient care provided. The Department issues letters to hospitals that satisfactorily complete the hospital registration process, listing the number of inpatient beds reported by the subject hospital, and publishes the number of registered beds in its hospital directory, which is available on the Department’s website. This directory indicates that Hospital has 12 registered beds. Because we believe that State’s registration scheme results in the licensure of hospital beds, we conclude that Hospital is licensed by State for the number of beds listed on its registration form and in the letter issued to Hospital by the Department.

In order to determine whether the addition of observation beds at Hospital would result in a violation of the prohibition of facility expansion, we evaluated whether State’s registration scheme establishes certain categories of beds that are subject to registration and other categories of beds that are not. As noted above, a hospital is required to report its total number of beds by category of inpatient care provided, and only beds for use in caring primarily for inpatients are subject to registration. Requestor confirmed with the Department that even an extended stay in an observation bed used solely for providing outpatient care—in other words, in a bed that is not used to care primarily for inpatients—will not result in the conversion of the observation bed to a bed that is subject to State’s registration requirement. Because State does not classify observation beds used solely for outpatient services as “beds” that must be reported on a hospital’s registration, we conclude that observation beds used solely for providing outpatient care are not subject to registration in State.

Hospital’s most recent registration report and the registration report that was in effect on March 23, 2010, both state that Hospital has 12 beds for use in caring primarily for inpatients. Requester certified that the registration report it submits following the addition of the new observation beds will not reflect an increase in the number of beds for use in caring primarily for inpatients. Requestor further certified that the new observation beds will be used solely for providing outpatient care and that Hospital has

⁹ Requestor does not suggest—nor would we be inclined to accept the suggestion—that State simply does not license the number of beds, and therefore there are no limitations of the expansion of bed capacity at physician-owned hospitals in State. We believe such an argument would be inconsistent with the prohibition on facility expansion in the ACA.

procedures in place to ensure that the observation beds are not used for caring for inpatients.

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, Requestor certified that the rooms housing the observation beds will not be used as operating rooms or procedure rooms. Thus, 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).

C. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, and our independent review of State's registration 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 Requestor and any other individual or entity.

D. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued to the Requestor of this opinion. The U.S. Department of Health and Human Services will not impose sanctions under section 1877(g) of the Act with respect to Requestor and all individuals and entities that are parties to the arrangement described in this opinion. Individuals and entities other than the parties to the arrangement may rely on this advisory opinion as an illustration of the application of the physician self-referral law and regulations to the specific facts and circumstances described in the advisory opinion in accordance with 42 C.F.R. § 411.387(c).
- 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, except as permitted under 42 C.F.R. § 411.387(a)(2) and (b).
- 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 Requestor, including, without limitation, the Federal anti-kickback statute, section 1128B(b) of the Act (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.

- CMS reserves the right to reconsider the questions involved in this advisory opinion and, for good cause (as defined at 42 C.F.R. § 411.382 (a)(2)), may rescind or revoke this opinion.
- This advisory opinion is limited in scope to the specific arrangement described in this letter.
- 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. §§411.370 through 411.389.

Sincerely,

Elizabeth Richter
Deputy Director
Center for Medicare

CC: [name redacted]