[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-2020-01

Dear [name redacted]:

We write in response to your request for an advisory opinion on behalf of [name redacted] ("Requestor" or the "Hospital"), regarding whether two operating rooms and 12 inpatient beds, which were added to the Hospital as part of an expansion initiated in 2008 ("Expansion ORs" and "Expansion Beds," respectively), may be counted when determining the aggregate number of licensed beds, procedure rooms, and operating rooms that the physician-owned hospital may not exceed under section 1877(i)(1)(B) of the Social Security Act (the "Act") and 42 C.F.R. § 411.362(b)(2).[1] For purposes of this advisory opinion, we refer to this as the "Hospital's Baseline."

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 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 on the specific facts certified in the request for an advisory opinion and supplemental submissions, we conclude that Requestor may count the Expansion ORs and Expansion Beds in the Hospital's Baseline. We express no opinion regarding 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 or entities other than Requestor 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

The Hospital is licensed by the [state agency redacted] ("Department of Health") to operate in [state redacted] ("State") as an acute care hospital, and it had both physician ownership and a Medicare provider agreement on March 23, 2010. The Department of Health issues licenses on a

[1] Following the issuance of CMS-AO-2019-01, we revisited our analysis of the Requestor's original advisory opinion request to ensure that our analysis remains consistent across requests involving similar issues. On [date redacted], we rescinded our original advisory opinion pertaining to the addition of the Expansion ORs and Expansion Beds, pursuant to CMS' authority at § 411.382 to rescind or revoke an advisory opinion if doing so is in the public interest. This advisory opinion supersedes the rescinded advisory opinion. We note that our original advisory opinion inadvertently was omitted from inclusion on the CMS website.

yearly basis. Pursuant to State's hospital licensure rules, the Department of Health issued the Hospital a license for calendar year 2010 on December 22, 2009. The Department of Health's December 22, 2009 letter issuing the license to the Hospital does not state the number of beds or operating rooms in the Hospital, nor does the physical license issued by the Department of Health for 2010 state the number of beds or operating rooms in the Hospital.

In 2008, the Hospital initiated an expansion of the Hospital, including the addition of the Expansion ORs, the Expansion Beds, and other renovations to the existing floors of the Hospital. State's hospital licensure rules do not require a certificate of need or a similar pre-approval process for new construction or the expansion of an existing facility. According to Requestor, for an expansion of an existing licensed hospital, State's licensure rules require only the following approvals: (1) design release from State's building commissioner; (2) completion of a plan review by the Department of Health; and (3) documentation from State's building commissioner that the hospital complies with State's fire and safety rules. According to Requestor, once a hospital receives the required approvals, the Department of Health has no discretion to deny or withhold the addition of inpatient beds to a hospital's license, and licensure follows as a matter of ministerial formality.[2]

The Hospital received the required design release from State's building commissioner on August 6, 2009, and the Department of Health completed its plan review of the proposed expansion on October 6, 2009. On December 23, 2009, the Hospital received the last of the required approvals, a certificate of occupancy issued by State's building commissioner, confirming that the Hospital complied with State's fire and safety rules. The Hospital utilized the Expansion ORs prior to March 23, 2010.

By letter to the Department of Health dated September 1, 2009, the Hospital's Chief Operating Officer requested that the Department of Health add the Expansion Beds to the Hospital's license. The September 1, 2009 letter also stated that the Hospital intended to add two operating rooms. On December 21, 2009, the Hospital sent another letter to the Department of Health, requesting the addition of the Expansion ORs and Expansion Beds to the Hospital's license. According to Requestor, counsel for the Hospital reached out to the Department of Health by telephone, email, and in person in the ensuing months to ensure that the Department of Health added the Expansion ORs and Expansion Beds to the Hospital's license.

By letter dated June 16, 2010, the Department of Health informed the Hospital that State had updated its state and federal computer database to reflect the addition of the Expansion Beds to the Hospital, effective June 16, 2010. The June 16, 2010, letter does not refer to the Hospital's license or to State's licensure rules generally.

---

[2] State's licensure rules provide that, after the design release and plan review are complete, the hospital shall submit an application to the Department of Health, and the application shall include documentation that the hospital is in compliance with State's fire safety rules. The Requestor confirmed with the Department of Health's staff, and certified for purposes of this advisory opinion, that a license application is not required for a hospital's expansion. According to the Requestor, the license application is only required for newly constructed hospitals. We accept and rely upon the Requestor's certification, and express no independent opinion on the requirements of State's licensure laws and regulations.

II. LEGAL ANALYSIS

A. Law and Regulations

Under section 1877 of the Act and the regulations in 42 C.F.R. § 411.350 et seq. (collectively, the "physician self-referral law"), unless an exception applies and its requirements are satisfied, 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 relationship. The physician self-referral law also prohibits the entity from presenting or causing to be presented claims to Medicare, the beneficiary, or any other entity for DHS that are furnished as a result of a prohibited referral.

Section 1877(d)(3) of the Act provides an exception for physician ownership or investment interests in a hospital located outside Puerto Rico. The exception, often referred to as the "whole hospital" exception, requires that the physician is authorized to perform services at the hospital, the physician's ownership or investment interest is in the hospital itself (and not merely in a subdivision of the hospital), and the additional restrictions added by Section 6001(a) of the Affordable Care Act (the "ACA") are met. 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 DHS to the hospital, and the hospital may submit claims for the referred DHS.

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] Put another way, in order to satisfy this requirement of the whole hospital exception, the number of operating rooms, procedure rooms and beds for which the physician-owned hospital is licensed at the time it wishes to utilize the whole hospital exception may not exceed the Hospital's Baseline.

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, while operating rooms or procedure rooms must have been in existence and operational as of March 23, 2010:

> 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

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

> operating and procedure rooms that existed at the hospital and were operational on March 23, 2010 . . . .[4]

In interpreting and applying the physician self-referral law, CMS considers a bed to be licensed if the state considers it to be licensed as of a certain date.

B. Analysis

1. Expansion Beds

Requestor seeks a determination whether it may count the Expansion Beds in the Hospital's Baseline. With respect to the addition of beds, CMS interprets the limitation on expansion as applying to the number of beds for which a hospital was licensed on March 23, 2010.[5] Thus, in order for Requestor to count the Expansion Beds in the Hospital's Baseline, the Expansion Beds must have been licensed on March 23, 2010. In interpreting and applying the physician self-referral law, CMS considers a bed to be licensed if the state considers it to be licensed as of a certain date. However, CMS may also consider additional beds appropriate for inclusion in the Hospital's Baseline for purposes of the physician self-referral law, depending on the facts and circumstances.[6] We conclude that, for purposes of the physician self-referral law, the Expansion Beds were licensed on March 23, 2010.

In State's hospital licensure scheme, any facility that meets State's statutory definition of a "hospital" must be licensed by the Department of Health on an annual basis. However, there is no provision in State's hospital licensure rules pertaining to the licensing of the number of beds in a hospital. The license issued to a hospital by the Department of Health does not specify the number of beds at the hospital, and the annual license fee for a hospital is based on the total operating expenses of the hospital, rather than the number of inpatient (or other) beds at the hospital.

In advisory opinion CMS-AO-2016-01, which pertains to the licensure of beds in State, we looked to the Department of Health's license application process to guide our analysis of the number and types of beds that are licensed by State. We noted that hospitals in State are required by statute to submit an annual license application on a form prepared by the Department of Health. Although State's licensure statute does not require an applicant to submit information regarding the number of its beds in a license application, the Department of Health is authorized by statute to collect other information that it requires as part of the licensure process. Pursuant to this grant of authority, the Department of Health has developed a hospital license application form, and the form requests information regarding the total number of "set up and staffed beds for inpatients" at a hospital. The Department of Health also maintains an online directory that

---

[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] 75 Fed. Reg. 71800, 72244 (Nov. 24, 2010).
[6] The focus of our legal analysis and conclusion is whether the Expansion Beds are considered to be licensed on March 23, 2010, for purposes of the physician self-referral law. We do not express an opinion on, and our advisory opinion in no way affects, the State's independent determination as to whether it would consider the Expansion Beds to be licensed on that date for purposes of state law.

lists the number of "set up/staffed inpatient beds" at each hospital in State. In light of this license application process, we concluded that a hospital is licensed by State for the number of beds listed on its annual application form and State's online directory.

We affirm the conclusion of CMS-AO-2016-01 regarding State's licensure rules, but believe that the facts presented by Requestor raise a more specific and nuanced question. Specifically, Requestor seeks a determination as to the precise date that beds are considered to be "licensed" for purposes of the physician self-referral law when a State-licensed hospital adds beds to an existing facility outside of State's annual license application cycle.[7]

Requestor certified that, under State's licensure rules, the Hospital was required to obtain three approvals for the Expansion: (1) design release from State's building commissioner; (2) completion of a plan review by the Department of Health; and (3) documentation from State's building commissioner that the Hospital complies with State's fire and safety rules. Requestor certified that it had received all three approvals as of December 23, 2009.[8] Requestor further certified that it had provided timely notification to the Department of Health of its desire to add the Expansion Beds to its license by this date. According to Requestor, once these approvals are received, the Department of Health has no legal discretion to deny the addition, and licensure would automatically follow as a ministerial formality.

Requestor's characterization of the addition of beds as a "ministerial formality" is consistent with the language used in the Department of Health's June 16, 2010 letter to Requestor. The June 16, 2010 letter does not state that the beds had been approved by State or licensed effective June 16, 2010. Rather, the letter states that the Department of Health had updated information regarding the Hospital's bed count in its state and federal computer database, effective June 16, 2010. In contrast, the Department of Health's December 22, 2009 letter to Requestor, which was sent as part of State's annual licensing cycle, explicitly states that the Department of Health "hereby issue[s]" the Hospital's 2010 license, pursuant to the authority granted by State's licensure statute.

Based on Requestor's certification that, as of December 23, 2009, all of the required approvals were received, and that the Department of Health at that point had no legal authority to deny or withhold the addition of the Expansion Beds to the Hospital's license, we conclude that the beds were "licensed" on December 23, 2009 for purposes of the physician self-referral law and, thus, can be included in the Hospital's Baseline. To be sure, the Department of Health did not notify the Requestor until June 16, 2010 that it had updated its database to include the Expansion Beds, and the Department of Health's letter explicitly states that the update is "effective June 16, 2010." Nonetheless, based on Requestor's certification that licensure follows automatically as a ministerial formality after the three required approvals are received—a certification that is consistent with the plain language of the Department of Health's June 16, 2010 letter—we view the June 16, 2010 letter as an acknowledgement by the Department of Health that its records had

[7] The Hospital received its license for calendar year 2010 on December 22, 2009, one day before the Hospital secured all the required approvals for the Expansion Beds.
[8] Requestor certified that it was not required to submit a hospital license application for expansion of an existing facility.

been updated to reflect the Expansion Beds, as opposed to the formal issuance of a license for the Expansion Beds that would not be effective until June 16, 2010.

2. Expansion ORs

Requestor seeks a determination whether it may count the Expansion ORs in the Hospital's Baseline. With respect to operating rooms, CMS interpreted the limitation on expansion as applying to "the number of operating . . . rooms that existed at the hospital and were operational on March 23, 2010 (or December 31, 2010, if applicable)."[9] Thus, in order for Requestor to count the Expansion ORs in the Hospital's Baseline, the Expansion ORs must have existed and been operational on March 23, 2010. We conclude that the Expansion ORs existed and were operational on March 23, 2010.

The term "existed" is not defined in the statute or applicable regulation. For purposes of this advisory opinion, we attribute the dictionary (and common) meaning to the term "exist"; that is, the Remote Location ORs "existed" on March 23, 2010 if they "occurred or were found, especially in a particular place."[10]

The term "operational" is defined at 42 C.F.R. § 424.502. This regulation is applicable to both providers, such as Requestor, and suppliers and states:

> *Operational* means the provider or supplier has a qualified physical practice location, is open to the public for the purpose of providing health care related services, is prepared to submit valid Medicare claims and is properly staffed, equipped, and stocked (as applicable, based on the type of facility or organization, provider or supplier specialty, or the services or items being rendered), to furnish these items or services.

In addition, 42 C.F.R. § 482.51(b)(3) states that the following equipment must be available to all operating room suites:

- Call-in system;
- Cardiac monitor;
- Resuscitator;
- Defibrillator;
- Aspirator; and
- Tracheotomy set

We believe that the presence of this equipment is required for operating rooms to "exist" and be "operational."

---

[9] 75 Fed. Reg. 226, 72240 (Nov. 24, 2010) (emphasis added).
[10] *See* English Oxford Dictionary, found at https://www.lexico.com/en/definition/exist (last accessed November 25, 2019).

Requester received a Certificate of Occupancy for the Expansion ORs on December 23, 2009, confirming that the Expansion ORs existed and were available for occupancy as of that date. Requestor certified that the equipment listed in 42 C.F.R. § 482.51(b)(3) was available for use in the Expansion ORs as of December 23, 2009. Finally, Requestor certified that the Hospital, in fact, began using the Expansion ORs to provide services, including services billable to Medicare, before March 23, 2010 and that the Expansion ORs have been in continuous use since that date. Based on Requestor's certifications, we conclude that the Requestor may count the Expansion ORs in the Hospital's Baseline.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that Requestor may include the two Expansion ORs and the 12 Expansion Beds in the Hospital's Baseline for purposes of section 1877(i)(1)(B) of the Act and 42 C.F.R. § 411.362(b)(2). We express no opinion regarding any other provision of section 1877 of the Act or the regulations at 42 C.F.R. Part 411, Subpart J.

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.

- 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 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. 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. §§ 411.370 through 411.389.

Sincerely,

Elizabeth Richter
Deputy Director, Center for Medicare

CC: [name redacted]