[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-2019-01

Dear [name redacted]:

We write in response to the request by [name redacted] (the "Requestor") for an advisory opinion regarding whether certain operating rooms that were not in use on March 23, 2010 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).

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.[1] 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 were not disclosed or were 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 operating rooms that are subject of this opinion when determining the aggregate number of licensed beds, procedure rooms, and operating rooms for which Requestor was licensed on March 23, 2010 (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 other than [name redacted], the requestor of this opinion, 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

Since October 22, 2002, physicians have held ownership or investment interests in Requestor. On June 18, 2007, [name redacted] ("Merged Hospital"), merged with and into Requestor, terminated its Medicare provider agreement, was licensed as part of Requestor, and became a "remote location" of Requestor as defined at 42 C.F.R. §413.65. Prior to June 18, 2007, Merged Hospital was a physician-owned, freestanding acute care

[1] Requestor also certified to the truthfulness and accuracy of information related to agreements among the parties related to one or more transactions that are not the subject of this advisory opinion.

hospital with eight licensed beds and four operating rooms, all of which were in active use. Subsequent to June 18, 2007, but prior to March 23, 2010, all four of the operating rooms from the Merged Hospital (the "Remote Location ORs") ceased to be used for surgical procedures, although they remained structurally unchanged.

Requestor certified that, on March 23, 2010, the Remote Location ORs were not used for clinical activities, but were structurally unmodified, fully operational, and remained on standby to be used as operating rooms if necessary. That is, the Remote Location ORs were equipped to support patient care, including the necessary medical gases, vacuum, electrical, mechanical, and lighting systems. In addition, the Remote Location ORs were in compliance with all Federal and state requirements, such as fire and environment of care. The facility at the remote location also had a fully operational pre-operative assessment area and post-anesthesia care unit, and was fully accredited by the Joint Commission.

Requestor certified that it discontinued use of the Remote Location ORs due to a low volume of surgical services. However, for all of calendar year 2010, aside from the need for sterilization, there were no modifications necessary in order for the Remote Location ORs to be converted to "full use" hospital operating rooms. Essentially, during all of calendar year 2010, including on March 23, 2010, Requestor had two campuses where surgeries could be performed, although there was not adequate volume to warrant the use of operating rooms at both campuses.

In late 2011, Requestor was required to update outdated lighting in all of the operating rooms on its main campus. Because the Remote Location ORs were not being used, the lighting in those operating rooms was removed and used to replace the lighting in the operating rooms on Requestor's main campus. As a result, as of late 2011, the unused Remote Location ORs were no longer fully equipped for surgical procedures.

Currently, the Remote Location ORs are used for therapy services. However, Requestor certified that, if needed, the Remote Location ORs could be converted to full-service operating rooms within a few days, with the primary modifications being the addition of the required lighting and sterilization of the rooms. According to Requestor, the [state agency redacted] ("State") confirmed that Requestor may replace the lighting and begin using the Remote Location ORs as operating rooms upon validation that their air exchanges meet current State requirements.

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), 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, unless an exception applies. 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 March 23, 2010.[2] 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.

B. Analysis

Requestor seeks a determination whether it may count the Remote Location 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 <u>existed</u> at the hospital and were <u>operational</u> on March 23, 2010 (or December 31, 2010, if applicable)."[3] Thus, in order for Requestor to count the Remote Location ORs in the Hospital's Baseline, the Remote Location ORs must have <u>existed</u> at the Requestor's remote location (*i.e.*, Merged Hospital) and been <u>operational</u> on March 23, 2010. We conclude that the four Remote Location ORs existed at Merged Hospital 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."[4]

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:

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[2] Section 1877(i)(1)(B) of the Act; see also, 42 CFR §411.362(b)(2).
[3] 75 Fed. Reg. 226, 72240 (Nov. 24, 2010) (emphasis added).
[4] *See* English Oxford Dictionary, found at https://en.oxforddictionaries.com (last accessed January 2, 2019).

> *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." According to Requestor, the Remote Location ORs were available for use, built out and equipped as operating rooms as required by 42 C.F.R. §482.51(b)(3), and they were ready to be used as operating rooms if necessary on March 23, 2010. Further, as of March 23, 2010, the Remote Location ORs were not used for other clinical activities, were structurally unmodified from their use as operating rooms prior to the merger, and remained fully equipped to support surgical care, with the necessary medical gases, vacuum, electrical, mechanical, and lighting systems. Also important to our analysis is Requestor's certification that the Remote Location ORs were in compliance with all Federal and state operational requirements and the facility was fully accredited by the Joint Commission.

Finally, our analysis turns only on the status of the Remote Location ORs on March 23, 2010. The fact that the Remote Location ORs did not have lighting necessary to operate as surgical suites for a short period in late 2011 or that they are currently used to provide therapy services does not impact our determination whether the Remote Location ORs "existed" and were "operational" on March 23, 2010, and should be included in the Hospital's Baseline. A physician-owned hospital may reduce the number of its licensed beds, procedure rooms, or operating rooms and subsequently increase that number by returning the licensed beds, procedure rooms, or operating rooms to service, as long as the aggregate number of licensed beds, procedure rooms, and operating rooms does not exceed the Hospital's Baseline.[5]

[5] See 75 Fed. Reg. 71800, 72242 (Nov. 24, 2010) for a similar analysis regarding changes in the number or composition of physician owners or investors in a physician-owned hospital.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that you may include the four Remote Location ORs 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. CMS reserve the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, rescind, modify or terminate 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