[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-2025-1

Dear [name redacted]:

We write in response to your request for an advisory opinion from the Centers for Medicare & Medicaid Services ("CMS") regarding [name redacted]'s ("Hospital" or "Requestor") proposal to relocate the entire Hospital eight miles from Hospital's current location and add an emergency department (the "Proposed Relocation"). Specifically, you seek a determination that, following the Proposed Relocation, Hospital would meet the requirement under section 1877(i)(1)(A) of the Social Security Act ("the Act") and 42 C.F.R. § 411.362(b)(1) that the hospital had physician ownership or investment on December 31, 2010 and a provider agreement under section 1866 of the Act in effect on that date.

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 submission, we conclude that following the Proposed Relocation, if effectuated, Hospital would satisfy the requirement under section 1877(i)(1)(A) of the Act and 42 C.F.R. § 411.362(b)(1) that the hospital had physician ownership or investment on December 31, 2010 and a provider agreement under section 1866 of the Act in effect on that date. Therefore, referrals of designated health services to Hospital by physicians who have (or whose immediate family members have) ownership or investment interests in Hospital would not be prohibited, provided that all of the other requirements of the exception at sections 1877(d)(3) and (i)(1) of the Act and 42 C.F.R. § 411.356(c)(3) are satisfied. We express no opinion regarding whether the Proposed Relocation, 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.

I. FACTUAL BACKGROUND

Requestor certified that it is enrolled in the Medicare program as a hospital located in [redacted] ("State") and that it qualifies as a "hospital" under section 1861 of the Act. Hospital is owned in part by physicians who make referrals for designated health services to Hospital.

Requestor certified that, as of December 31, 2010, Hospital had physician ownership and a Medicare provider agreement, and that the aggregate percentage of ownership held by physicians

has not increased from the aggregate percentage held by physicians as of March 23, 2010. Requestor certified that, as of March 23, 2010, Hospital's aggregate number of operating rooms, procedure rooms, and beds was 48, and that Hospital currently has an aggregate number of 48 operating rooms, procedure rooms, and beds.

Under the Proposed Relocation, Hospital would relocate the entire hospital approximately eight miles from its current location and add an emergency department at the new location. After the Proposed Relocation, Hospital would not continue operations at its current location. Requestor certified that Hospital's aggregate number of operating rooms, procedure rooms, and beds would remain the same after the Proposed Relocation. Requestor also certified that the services provided by Hospital would remain the same following the Proposed Relocation and that the Proposed Relocation would not cause an interruption in services to patients. In addition, Requestor certified that, after the Proposed Relocation, Hospital would continue to use its existing name, logo, and branding and maintain its existing Federal Tax Identification Numbers, and Requestor would seek to continue participating in the Medicare program under the same Medicare provider agreement currently in place.

Requestor certified that the Proposed Relocation would not change the community or the patient base that is currently served by Hospital. In particular, Requestor certified that approximately three quarters of Hospital's patients do not reside in the metropolitan area where Hospital is currently located. Requestor added that this percentage has been relatively steady over the last few years.

Requestor certified that there would not be a change of Hospital ownership as a result of the Proposed Relocation and, other than its physical location, Hospital would not make any other substantial changes. Requestor certified that Hospital does not anticipate any leadership changes because of the Proposed Relocation and intends to relocate some of its existing physical assets to the new location and purchase other new assets to outfit the space.

Requestor certified that State does not require a certificate of need for new construction or expansion. However, State does require that Hospital submit to its Department of Health any proposed change due to new construction, remodeling, or change of use of an area and any change must have the approval of the Department of Health before it is made.[1] State also mandates that licenses are not assignable or transferable.[2] Requestor certified that, after discussions with State's Department of Health, Requestor believes that Hospital will be able to maintain its same health care facility license after the Proposed Relocation.

II. LEGAL ANALYSIS

A. Law and Regulations

[1] [redacted].
[2] [redacted].

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. We refer to this prohibition as the referral prohibition. The physician self-referral law also prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third-party payor) for any improperly referred designated health services. We refer to this prohibition as the billing prohibition. There are numerous statutory and regulatory exceptions to the physician self-referral law. The referral and billing prohibitions do not apply if all requirements of an applicable exception are satisfied.

Section 1877(d)(3) of the Act provides an exception, commonly referred to as the "whole hospital exception," for ownership or investment interests in a hospital located outside Puerto Rico.[3] The whole hospital exception is codified in regulation at 42 C.F.R. § 411.356(c)(3). To satisfy the requirements of the whole hospital exception and avoid the physician self-referral law's referral and billing prohibitions, the referring physician must be authorized to perform services at the hospital, the ownership or investment interest must be in the hospital itself (and not merely in a subdivision of the hospital), and the hospital must meet the requirements of section 1877(i)(1) of the Act (codified at 42 C.F.R. § 411.362) no later than September 23, 2011. Section 1877(i)(1)(A) of the Act, which is codified in our regulations at 42 C.F.R. § 411.362(b)(1), requires that the hospital submitting the claim for designated health services referred by a physician who has (or whose immediate family member has) an ownership or investment interest in the hospital had physician ownership or investment on December 31, 2010, and a provider agreement under section 1866 of the Act on that date.

In the FY 2024 Inpatient Prospective Payment Systems final rule ("FY 2024 IPPS final rule"), we stated that the physician self-referral law does not prohibit a hospital with physician ownership from relocating some or all of the operating rooms, procedure rooms, or beds for which the hospital was licensed on March 23, 2010 (or December 31, 2010, if the hospital did not have a provider agreement in effect as of March 23, 2010).[4] We emphasized that,

> [T]o avoid the physician self-referral law's referral and billing prohibitions under the rural provider exception or the whole hospital exception, an ownership or investment interest must satisfy the requirements of the applicable exception at the time of the physician's referral, and the hospital must meet the requirements of section 1877(i)[(1)] of the Act and [42 C.F.R.] § 411.362 no later than September 23, 2011. Section 1877(i)(1)(A) of the Act and [42 C.F.R.] § 411.362(b)(1) require that *the* hospital had physician ownership or investment on December 31, 2010, and a provider agreement under section 1866 of the Act on that date. Put another way, for a hospital to bill Medicare (or another individual, entity, or third-

[3] Section 1877(d)(2) of the Act provides an exception for ownership or investment interest in a rural provider. Hospital certified that it does not qualify as a rural provider, as the term is defined at 42 C.F.R. § 411.356(c)(1). Therefore, the rural provider exception is not applicable to Hospital, and the following discussion pertains only to the whole hospital exception.

[4] 88 Fed. Reg. 58640, 59302 (Aug. 28, 2023).

> party payor) for a designated health service furnished as a result of a physician owner's referral following the relocation of … operating rooms, procedure rooms, or beds to a location other than the main campus of a hospital, the hospital (including all of its provider-based locations) must remain the *same hospital* that had both physician ownership or investment and a Medicare provider agreement on December 31, 2010.[5]

The FY 2024 IPPS final rule referred readers to the CY 2023 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems ("CY 2023 OPPS/ASC") proposed rule for a complete discussion of the requirement that a hospital must remain the *same* hospital after relocation in order to satisfy section 1877(i)(1)(A) of the Act and 42 C.F.R. § 411.362(b)(1).[6]

In the CY 2023 OPPS/ASC proposed rule, we detailed some of the factors that we consider to be relevant when determining whether a hospital that bills Medicare (or another individual, entity, or third-party payor) for a designated health service furnished as a result of a physician owner's referral following a relocation (the "relocated hospital") is the *same* hospital as the pre-relocation hospital that had physician ownership or investment on December 31, 2010, and a provider agreement under section 1866 of the Act on that date (the "original hospital"). These factors include, but are not limited to: status of, type of, and party to the state license for both the relocated hospital and the original hospital, including any lapses in state licensure or operation of either the relocated hospital or the original hospital; status of and party to the Medicare provider agreement, including any lapses in Medicare participation of either the relocated hospital or the original hospital; whether the relocated hospital has the same Medicare provider number as the original hospital; the location and structure of the relocated hospital's building(s) and those of the original hospital; whether the relocated hospital is under the same state's licensure regime as the original hospital; whether the relocated hospital serves the same community as the original hospital; whether the relocated hospital provides the same scope of services as the original hospital; the relocated hospital's ownership and that of the original hospital; and the number of

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[5] 88 Fed. Reg. at 59302. In the FY 2024 IPPS final rule, we drew a distinction between the relocation of "original" operating rooms, procedure rooms, or beds that a hospital had as of March 23, 2010 (or December 31, 2010, if the hospital did not have a provider agreement in effect as of March 23, 2010) and any operating rooms, procedure rooms, or beds that a hospital may have added after that date pursuant to a decision from CMS granting the hospital permission to expand. Hospital is not seeking to expand its facility; therefore, this distinction is not relevant for this Advisory Opinion, and the term "original" has been replaced in this quotation with an ellipsis.

[6] 88 Fed. Reg. 59302 *citing* the CY 2023 OPPS/ASC proposed rule (87 Fed. Reg. 44502, 44798 (Jul. 26, 2022)). In the CY 2023 OPPS/ASC proposed rule, we proposed an exception to the physician self-referral law that would have excepted ownership or investment interests in a rural emergency hospital (REH) (the "proposed REH exception"). In that rulemaking, we discussed how we considered, but did not propose, an alternative to the proposed REH exception, under which REHs would have been permitted to use the whole hospital and rural provider exceptions. In the context of our discussion of the alternative to the proposed REH exception, we explained our interpretation of the whole hospital exception requirement at section 1877(i)(1)(A) of the Act and 42 C.F.R. § 411.362(b)(1). Although we did not finalize the REH exception, the interpretation of the whole hospital requirement at section 1877(i)(1)(A) of the Act and 42 C.F.R. § 411.362(b)(1) was incorporated by reference in the FY 2024 IPPS final rule.

operating rooms, procedure rooms, and beds operated by the relocated hospital and that of the original hospital. We added that no one factor would be dispositive to the determination.[7]

B. Analysis

The question presented by Requestor is whether, following the Proposed Relocation, referrals by physicians who have (or whose immediate family members have) ownership or investment interests in Hospital would be prohibited because Hospital would fail to satisfy the requirement at section 1877(i)(1) of the Act and 42 C.F.R. § 311.362(b)(1) that Hospital had physician ownership or investment on December 31, 2010 and a provider agreement under section 1866 of the Act in effect on that date. As explained above, the focus of our analysis is whether Hospital, following the Proposed Relocation, will be the same hospital that had physician ownership or investment and a provider agreement on December 31, 2010. In making this determination, we look to the factors detailed in the CY 2023 OPPS/ASC proposed rule.

Requestor certified that, based on discussion with the State Department of Health, it believes that Hospital's licensure would remain the same after completion of the Proposed Relocation. Requestor also certified that Hospital will seek to continue participating in the Medicare program under the same Medicare provider agreement currently in place. Requestor certified that it would maintain its existing Federal Tax Identification Number following the Proposed Relocation. Requestor certified that that the Proposed Relocation would not alter the community or patient base served by Hospital due to the size of the surrounding geographic area served by Hospital. Requestor also certified that Hospital would not change its existing name, logo, or branding. According to Requestor, Hospital would continue to provide the same services apart from adding emergency services as the result of the addition of an emergency department at Hospital's new location.[8] Requestor certified that Hospital would not exceed the number of operating rooms, procedure rooms, and beds for which the hospital was licensed on March 23, 2010 following the Proposed Relocation. Lastly, Requestor certified that the Proposed Relocation would not affect Hospital's ownership.

Given these facts, we conclude that, after completing the Proposed Relocation, Hospital will remain the same hospital that had physician ownership and a Medicare provider agreement on December 31, 2010.

C. CONCLUSION

Based on the facts certified by Requestor, we conclude that, following completion of the Proposed Relocation, Hospital would remain the same hospital that had physician ownership and a Medicare provider agreement on December 31, 2010, and Hospital would therefore continue to satisfy the requirement at section 1877(i)(1) of the Act and 42 C.F.R. § 411.362(b)(1), as

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[7] 87 Fed. Reg. at 44799.

[8] We do not believe that the addition of an emergency room would substantially alter the overall scope of services furnished by Requestor, and we reiterate that no one factor is dispositive in our analysis of whether Hospital would remain the same hospital that had physician ownership and a provider agreement on December 31, 2010 after the Proposed Relocation.

incorporated in the whole hospital exception at 42 C.F.R. § 411.356(c)(3), that it had physician ownership and a provider agreement under section 1866 of the Act on December 31, 2010. Thus, the physician self-referral law would not prohibit referrals to Hospital by physicians who have (or whose immediate family members have) ownership or investment interests in Hospital due solely to a failure to satisfy the requirements of 42 C.F.R. § 411.362(b)(1), as incorporated in the whole hospital exception. We express no opinion regarding whether the Proposed Relocation, 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.

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,

Ing Jye Cheng
Deputy Director
Center for Medicare

cc: [name redacted]