[We redacted 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: CMS Advisory Opinion No. CMS-AO-2014-01

Dear [name redacted]:

We write in response to your May 20, 2013 request for an advisory opinion regarding a proposed arrangement under which an entity would invest in [name redacted] (Requestor), an organization with physician investors that owns and operates [name redacted] (Hospital) located in [state redacted]. Specifically, you seek a determination as to whether, in calculating the aggregate percentage of physician-held ownership or investment interests in Hospital (or an entity whose assets included the hospital) as of March 23, 2010 (Baseline Physician Ownership), you must include the value of any interests of individuals or entities that agreed prior to March 23, 2010 to contribute assets to Hospital (or an entity whose assets would include Hospital) on a date after March 23, 2010 in exchange for ownership or investment interests in Hospital.

You 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 and arrangements between the parties. In issuing this opinion, we relied solely on the facts and information you presented to us and certified as true, accurate, and complete. 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 facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Hospital's Baseline Physician Ownership does not include the value of any ownership or investment interests attributable to assets that were committed for contribution but not transferred to Hospital (or an entity whose assets would include Hospital) on or before March 23, 2010.

This opinion may not be relied on by any persons 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

Hospital is an acute care hospital licensed by the State of [state redacted] and located in [city and state redacted]. Requestor began developing Hospital in January 2009 on land owned by Requestor. At that time, physicians owned, in the aggregate, 88 percent of Requestor's outstanding shares, and the remainder was owned by [name redacted], a limited liability company that had no physician ownership (Non-physician Investor). As part of the development process, Requestor entered into a preliminary design and build agreement (Design-Build Agreement) in January 2009. In addition, Requestor procured a [amount redacted] bank loan in March 2009. In October 2009, Requestor filed a building permit application for the planned hospital facility.

As part of Requestor's development efforts in late 2009 and early 2010, Requestor entered into discussions with owners of two ambulatory surgery centers (ASCs) regarding their potential investment in the Hospital. One ASC was a publicly-traded entity (Public ASC). The other ASC was physician-owned (Physician-owned ASC) and located adjacent to the land owned by Requestor and reserved for Hospital construction. In the aggregate, physicians owned 80 percent of the outstanding shares of Physician-owned ASC; many of them also had an ownership interest in Requestor. As a result of these discussions, it was contemplated that Hospital would be owned and operated by a newly formed business entity (NEWCO) that would be owned by Non-physician Investor, the physicians who had ownership interests in either Physician-owned ASC or Requestor or both (Physician Owners), and Public ASC.

On March 1, 2010, the Requestor, Non-physician Investor, both ASCs, and the Physician Owners entered into an agreement (the Contribution Agreement) under which the Requestor and both ASCs agreed to contribute certain assets to NEWCO in exchange for Physician Owners, Non-physician Investor, and Public ASC receiving ownership interests in NEWCO. At the time the Contribution Agreement was executed, NEWCO had no assets or operations and no physician ownership. Requestor certified that on March 23, 2010, prior to the transfer of assets to NEWCO, the physicians held, in the aggregate, 88 percent of the total value of the ownership and investment interests in Requestor.

All asset contributions occurred April 30, 2010 (the Closing Date), at which time Requestor contributed the real estate upon which Hospital would be built, the associated building permit, the bank loan proceeds and borrowing capability (Loan-Promissory Note), and the Design-Build Agreement. As of the Closing Date, taking into account the exercise of certain options to purchase additional interests in NEWCO, the Physician Owners obtained a collective ownership interest in NEWCO of 62.21 percent; Non-physician Investor obtained an ownership interest of 17.5 percent; and Public ASC obtained a 20.29 percent ownership interest.

On September 29, 2010, Public ASC withdrew from the joint venture, and its ownership interest was distributed proportionally to Physician Owners and Non-physician Investor. Requestor certified that, as of September 29, 2010, Physician Owners had a 78.04 percent ownership interest in NEWCO, and Non-Physician Investor had a 21.96 percent ownership interest in NEWCO.

On October 7, 2010, NEWCO merged into Requestor pursuant to an Agreement and Plan of Merger with Requestor as the surviving entity succeeding all of the assets and liabilities of NEWCO. After the merger, Requestor wholly owned Hospital. Requestor certified that, upon the merger and until May 17, 2011, Physician Owners had a 78.04 percent ownership interest in Requestor, and Non-Physician Investor had a 21.96 percent ownership interest in Requestor. Requestor also certified that, following a May 17, 2011 offering through which Non-Physician Investor sold a 1.96 percent interest in Requestor to physician investors, the aggregate percentage of physician ownership in Requestor was 80 percent.

After the merger, Requestor oversaw the completion of Hospital's construction, applied and received the facility license from the [state agency redacted] on [date redacted], and enrolled

Hospital in the Medicare program. Hospital entered into a Medicare provider agreement with CMS that became effective on December 22, 2010. The physician owners of Requestor are on the medical staff at Hospital and refer patients to Hospital for designated health services reimbursed by the Medicare program.

II. LEGAL ANALYSIS

A. Law

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.[1]

Section 1877(d)(3) of the Act provides an exception for physician ownership or investment interests in a hospital if certain conditions are met. Section 6001(a) of the Patient Protection and Affordable Care Act (the ACA), enacted on March 23, 2010, amended the hospital ownership exception to prevent new physician-owned hospitals from utilizing the exception and to impose additional restrictions on existing physician-owned hospitals. Under the revised exception, a physician-owned hospital must, among other things, have a provider agreement that was in effect no later than December 31, 2010. 42 U.S.C. § 1395nn(i)(1)(A)(ii). Thus, hospitals under development when the ACA was enacted had several months to complete construction and obtain a Medicare provider agreement. In addition, the revised exception requires that the "percentage of the total value of the ownership or investment interests held in the hospital, or in an entity whose assets include the hospital, by physician owners or investors in the aggregate [must] not exceed such percentage as of [March 23, 2010]." Id. at § 1395nn(i)(1)(D)(i). Thus, among other requirements, a physician-owned hospital must not, at the time of a physician owner's referral, have an aggregate physician ownership or investment percentage greater than the Baseline Physician Ownership.

B. Analysis

We do not believe that the ACA amendments to the hospital ownership exception were intended to disrupt physician investment in entities developing hospitals that were close to completion at the time of the enactment of the ACA. The statute specifically recognizes that, as of the date of enactment, the relevant physician ownership or investment may be in an entity "whose assets include the hospital." Moreover, neither such entity nor the "hospital" whose assets it holds must be authorized to operate as a Medicare participating hospital until December 31, 2010. See 42 U.S.C. § 1395nn(i)(1)(A).

[1] In 1993, the physician self-referral prohibition was made applicable to the Medicaid program, effective January 1, 1995. 42 U.S.C. § 1396b(s).

For purposes of section 1877(i)(1)(D)(i), Requestor is the entity whose assets included Hospital as of March 23, 2010. Requestor certified that, as of March 23, 2010, it held all of the existing assets and liabilities of what would become Hospital, including the Design-Build Agreement; the Loan-Promissory Note; the building permit; and the real property on which Hospital would be built. Thus, for purposes of determining Hospital's Baseline Physician Ownership, we look to the direct and indirect physician ownership and investment interests held in Requestor on March 23, 2010.

We do not believe that the Contribution Agreement modified any ownership or investment interests that were held in Requestor as of March 23, 2010. Although the Contribution Agreement was signed on March 1, 2010, the parties to the agreement did not transfer any assets or ownership interests until closing on April 30, 2010. Relying on Requestor's certifications, we have determined that Hospital's Baseline Physician Ownership was 88 percent on March 23, 2010.

For purposes of determining the percentage of physician ownership and investment interests in Hospital after March 23, 2010, we look to physician ownership in Requestor for the period from March 23, 2010 through and including April 29, 2010; in NEWCO for the period from April 30, 2010 through and including October 6, 2010; and in Requestor on and after October 7, 2010. Requestor certified that the aggregate physician ownership or investment percentage in Requestor from March 23, 2010 through and including April 29, 2010 was 88 percent; that the aggregate physician ownership or investment percentage in NEWCO from April 30, 2010 through and including October 6, 2010 was 62.21 percent; that the aggregate physician ownership or investment percentage in Requestor on October 7, 2010 was 78.04 percent; and that the aggregate physician ownership or investment percentage in Requestor since October 7, 2010 has never exceeded 88 percent. Thus, based on Requestor's certifications, we have determined that the aggregate direct and indirect physician ownership in NEWCO, and the subsequent merger of NEWCO into Requestor, did not cause the aggregate percentage of physician ownership and investment in the entity whose assets included Hospital to exceed the Baseline Physician Ownership.

III. CONCLUSION

Based on the specific facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Contribution Agreement entered into on March 1, 2010 did not affect any ownership or investment interests in the entity whose assets included Hospital. Therefore, we believe that, as of March 23, 2010, Hospital's Baseline Physician Ownership was 88 percent. Based on the facts you certified, we also conclude that the subsequent transactions described in Section I of this opinion did not cause the aggregate percentage of direct and indirect physician ownership and investment interests in Hospital to exceed Hospital's Baseline Physician Ownership. We make no determination regarding the applicability of, or compliance with, any other criteria in the hospital ownership exception or any other exception to the physician self-referral law.

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 Requestor or Referring Physicians, including, without limitation, the Federal anti-kickback statute, section 1128(B)(b) of the Act.

- 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, 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 in 42 C.F.R. §§ 411.370 through 411.389.

Sincerely,

/s/

Sean Cavanaugh
Director, Center for Medicare

cc: [name redacted]