[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-2021-01

Dear [name redacted]:

We write in response to your request for an advisory opinion on behalf of [name redacted] ("Requestor" or "Group Practice") regarding how the regulation at 42 C.F.R. § 411.352(a) limits the provision of designated health services by a group practice. Specifically, you asked whether a physician practice would fail to qualify as a "group practice" for purposes of section 1877(h)(4) of the Social Security Act (the "Act") and 42 C.F.R. § 411.352 if it furnishes designated health services through a wholly-owned subsidiary entity that is a physician practice but does not itself qualify as a group practice.

You certified that 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 did not undertake 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 facts certified in your request for an advisory opinion and supplemental submissions, we conclude that furnishing designated health services through a wholly-owned subsidiary entity that is a physician practice but does not itself qualify as a group practice under 42 C.F.R. § 411.352 would not preclude Requestor's compliance with the requirement at 42 C.F.R. § 411.352(a) that a group practice is a single legal entity.

I. FACTUAL BACKGROUND

Requestor is a [state redacted] professional limited liability company operating as a physician practice in the state of [state redacted] ("Group Practice State"). [name redacted] (Owner) is the sole owner of Requestor. Requestor furnishes health care services to patients in Group Practice State, including designated health services to Medicare beneficiaries. Requestor certified that it currently satisfies all the requirements of 42 C.F.R. § 411.352 to qualify as a group practice for purposes of the physician self-referral law.

Owner is also the sole owner of [name redacted] ("Subsidiary A"), a [state redacted] professional corporation operating as a physician practice in the state of [state redacted] (State A) and [name redacted] ("Subsidiary B"), an [state redacted] professional limited liability company operating as a physician practice in the state of [state redacted] (State

B). Group Practice, Subsidiary A, and Subsidiary B are managed by [name redacted] (Manager). Requestor is proposing to acquire Subsidiary A and Subsidiary B from Owner. Requestor certified that, following the acquisition: (1) Requestor would be the sole owner of Subsidiary A and Subsidiary B (collectively, the "Subsidiaries"); (2) all clinical employees and contractors of the Subsidiaries would become employed or contracted by Requestor; (3) all material assets and business functions of the Subsidiaries would be transferred to Requestor or Manager; and (4) Manager would continue to provide management and other non-clinical services to Requestor and the Subsidiaries.

Following the acquisition of the Subsidiaries, Requestor would continue to furnish health care services, including designated health services, to its patients directly and through the Subsidiaries. Requestor certified that, because many payors and health plans prohibit assignment of their payor contracts to a successor organization, the Subsidiaries would continue to remain credentialed and contract directly with payors and health plans, and use billing numbers assigned to the Subsidiaries to bill such payors and health plans for items and services furnished to their enrollees. The Subsidiaries would also remain enrolled in Medicare under tax identification numbers assigned to the Subsidiaries, and use billing numbers assigned to them as participating suppliers to bill Medicare for items and services, including designated health services, furnished to beneficiaries.

Patients to whom health care services are furnished by the Subsidiaries would be considered patients of the Group Practice. The health care services furnished to Group Practice patients would be furnished or supervised by clinical personnel that are employed or contracted by Requestor and designated to work at the Group Practice State office site, the State A office site, or the State B office site. Manager would provide all nonclinical support personnel to the Group Practice and the Subsidiaries under the terms of the management agreement among the parties. All revenues of the Subsidiaries would be remitted to and be treated as revenues of the Group Practice.

Requestor certified that it would meet all other requirements to qualify as a group practice under section 1877(h)(4) of the Act and 42 C.F.R. § 411.352, including, but not limited to, the requirements that Requestor is a unified business with centralized decision making and that all revenues received by and expenses incurred by Requestor, Subsidiary A, and Subsidiary B are treated as revenues and expenses of Requestor.

II. LEGAL ANALYSIS

A. Law and Regulations

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. One of these exceptions, the exception for in-office ancillary services, is available to a physician practice consisting of two or more physicians only if the physician practice qualifies as group practice.[1] Section 1877(h)(4) of the Act defines the term "group practice," and the regulations at 42 C.F.R. § 411.352 set forth the requirements for qualifying as a group practice for purposes of the physician self-referral law. Under 42 C.F.R. § 411.352(a), a group practice must consist of a single legal entity operating primarily for the purpose of being a physician group practice.[2] A group practice that is otherwise a single legal entity may itself own subsidiary entities through which it provides services to the group practice.

In an August 1995 final rule (the "1995 Final Rule"),[3] we addressed qualification as a group practice in the context of a professional corporation that owns subsidiaries for the provision of equipment, billing services, or ancillary services. Although the requirement that a group practice must consist of a single legal entity precludes two or more groups of physicians each organized as separate legal entities from qualifying as a group practice, we interpreted the statute to permit a single group practice (that is, one single group of physicians) to own other legal entities for the purpose of providing services to the group practice.[4] We noted that the exception for in-office ancillary services at section 1877(b)(2)(B) of the Act appears to anticipate that a group practice may wholly own separate legal entities for billing or providing ancillary services. In a 2001 final rule with comment period ("Phase I"),[5] we responded to a similar inquiry requesting clarification whether a group practice could own subsidiaries that, for example, own real estate or equipment, provide billing services, or operate ancillary services.[6] There, citing the 1995 Final Rule, we reiterated our belief that the statute does not preclude a single group practice from owning other legal entities for the purposes of providing services to the

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[1] *See* 63 Fed. Reg. 1659, 1685-86 (Jan. 9, 1998).
[2] Using form CMS-855B, a physician group practice enrolls in the Medicare program as a unique supplier, referred to as a "clinic/group practice" for enrollment purposes. If an enrolling organization provides services as more than one type of supplier (for example, the legal entity is a clinic/group practice and also an ambulatory surgical center), it must submit a separate application for each type of supplier. See https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855b.pdf. A clinic/group practice may bill the Medicare program for services provided to beneficiaries by a physician or practitioner who has reassigned to the practice his or her right to bill and receive payment from the Medicare program using form CMS-855R. See https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855r.pdf. Most physician services provided to Medicare beneficiaries and billed by a physician or clinic/group practice are paid according to the Medicare Physician Fee Schedule, with special rules for billing and payment of physician services that are radiology services, laboratory services, drugs, and preventive and services and screening tests. See Pub. 100-04, Medicare Claims Processing Manual, Chapter 12, Section 10 at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf.
[3] 60 Fed. Reg. 41914 (Aug. 14, 1995).
[4] *Id*. at 41935-36.
[5] 66 Fed. Reg. 876 (Jan. 4, 2001).
[6] *Id*. at 899.

group practice.[7] In both the 1995 Final Rule and Phase I, we cited the example of a wholly-owned laboratory facility that provides laboratory services to a group practice, but did not provide an exhaustive list of the types of services a wholly-owned subsidiary may provide to a group practice.[8]

B. Analysis

The question presented by Requestor is whether it could satisfy the requirement at 42 C.F.R. § 411.352(a) that a group practice must consist of a single legal entity if Requestor furnishes designated health services through a wholly-owned legal entity that operates as a physician practice but does not itself qualify as a group practice. Our analysis focuses on whether the regulation at 42 C.F.R. § 411.352(a) precludes a group practice from furnishing services (including designated health services) through a wholly-owned subsidiary physician practice.

As we explained in the preambles to the 1995 Final Rule and Phase I, a group practice may furnish services to group practice patients, including designated health services, through wholly-owned subsidiaries. The regulation at 42 C.F.R. § 411.352(a) expressly states that a group practice that is otherwise a single legal entity may itself own subsidiary entities. It does not dictate or limit the types of subsidiary entities that a group practice may own. The example in the 1995 Final Rule and Phase I of a laboratory facility that is wholly-owned by a group practice and provides services to group practice patients is illustrative only, and we do not consider it to preclude a group practice from furnishing other types of services to its patients through other types of wholly-owned subsidiaries. However, in order for the group practice to satisfy the requirement at 42 C.F.R. § 411.352(a) that it is a single legal entity operating primarily for the purpose of being a physician group practice, it must primarily provide services of the type provided by a supplier that is enrolled in Medicare as a clinic/group practice and billed to Medicare in accordance with the claims processing instructions for physician services in the Medicare Claims Processing Manual (Pub. 100-04).[9]

Requestor certified that, following its acquisition of the Subsidiaries, all clinical employees and contractors of the Subsidiaries would become employed or contracted by Requestor. Such personnel would be designated to work at either the Group Practice State office site, the State A office site, or the State B office site. Although Subsidiary A and Subsidiary B would maintain their respective enrollments in Medicare, remain credentialed and contract directly with payors and health plans, and use billing numbers assigned to the Subsidiaries to bill Medicare and other payors and health plans for services furnished to their beneficiaries and enrollees, all revenues and expenses of the Subsidiaries would be treated as revenues and expenses of Group Practice.

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[7] *Id.*
[8] 60 Fed. Reg. 41936; 66 Fed. Reg. 899.
[9] See footnote 2 *supra*.

Based on the facts certified by Requestor, we conclude that the regulation at 42 C.F.R. § 411.352(a) and the related interpretation of the physician self-referral law in the 1995 Final Rule and Phase I do not preclude Requestor from qualifying as a single legal entity if Requestor furnishes designated health services through the Subsidiaries, provided that Requestor is the sole owner of the Subsidiaries. We note that, as wholly-owned subsidiaries of Requestor—which is an operating physician practice—neither of the Subsidiaries would qualify as a group practice for purposes of the physician self-referral law.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that furnishing designated health services through a wholly-owned subsidiary entity that is a physician practice but does not itself qualify as a group practice under 42 C.F.R. § 411.352 would not preclude Requestor's compliance with the requirement at 42 C.F.R. § 411.352(a) that a group practice is a single legal entity. We express no opinion regarding whether any other aspect of your current organizational structure or operations, or whether your proposed acquisition of Subsidiary A and Subsidiary B, if effectuated, would comply with any other provision of section 1877 of the Act or 42 C.F.R. Part 411, Subpart J. We also express no opinion regarding whether any designated health services referred by physicians employed or contracted by Requestor and furnished by Subsidiary A or Subsidiary B would satisfy the requirements of the exception for in-office ancillary services at section 1877(b)(2) of the Act and 42 C.F.R. § 411.355(b).

IV. 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 Social Security Act with respect to Requestor and all individuals and entities that are parties to the arrangement described therein. 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)) and Federal or State law governing not-for-profit corporations or entities.

- 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,

Carol W. Blackford
Acting Deputy Director
Center for Medicare