

**[Names and addresses of Requestors have been redacted]
Re: Proposed Ambulatory Surgical Treatment Center for [Material redacted]. Advisory Opinion No. CMS-AO-98-001.**

Dear Dr. [material redacted]:

We are writing in response to your recent request for an advisory opinion (“AO”) concerning whether a physician’s referrals for certain services are prohibited under section 1877 of the Social Security Act (the “Act”). In your request, you posed the following questions:

1. Would the investment in and ownership of an Ambulatory Surgical Treatment Center (“ASTC”) by physicians, who will refer patients to the ASTC and who will perform surgeries at that ASTC, violate the prohibition in section 1877 of the Act against certain physician referrals?
2. Is the proposed location of the ASTC a rural area under the rural provider exception in section 1877(d)(2) of the Act (referencing the rural definition in section 1886(d)(2)(D) of the Act)?
3. Would the rural exception in section 1877(d)(2) of the Act apply to the proposed ASTC arrangement?
4. Under section 1877 of the Act, can non-surgeon physician investors in the ASTC refer patients there without violating the Federal prohibition against referring patients to an entity with which a physician has a financial relationship?

You have certified that all of the information you have provided in your request, including all supplementary materials and letters, is true and correct and constitutes a complete description of the parties, relationships and facts regarding the proposed arrangement (the “Arrangement”).

In issuing this opinion, we have relied solely upon the information that you have presented to us. We have not undertaken an independent investigation of this information. If material facts have not been disclosed, or have changed since we accepted your request, those differences would nullify the validity of this AO.

Based upon the information provided, we conclude that the Arrangement would qualify for the rural provider exception to the prohibition against physician referrals, provided that the designated health services for which Medicare patients are referred to the ASTC by the owner physicians are actually furnished in a rural area and that substantially all of the designated health services furnished by the ASTC are furnished to individuals residing in a rural area.

FACTUAL BACKGROUND

[Material redacted], a newly formed limited liability company in [Material redacted], is proposing to build and operate the ASTC. [Material redacted] indicates that the ASTC will provide outpatient ambulatory surgery as well as ancillary services such as clinical laboratory services, radiology services, ultrasound, parenteral nutrients, and outpatient prescription drugs. We expect that physician investors will refer some patients for services furnished by the ambulatory surgical center located within the ASTC. These ambulatory surgical services will be furnished by the part of the facility that meets the ambulatory surgical center conditions and requirements in section 42 CFR part 416. In addition, physician investors will also refer patients for other services to parts of the facility that are not included within the ambulatory surgical center.

The ASTC will be located in [Material redacted], [Material redacted], which is in [Material redacted] County. [Material redacted] expects that substantially all of the designated health services provided by the ASTC will be furnished to individuals residing in a rural area. [Material redacted] indicates that, upon completion, the ASTC will be the first such center located in [Material redacted] County.

In order to finance the construction and operation of the ASTC, [Material redacted] will sell shares of the company to investors. The investors will be physicians who will refer patients to the ASTC. Further, some of these physicians will perform medical and surgical procedures at the ASTC. [Material redacted] expects that physician investors will refer Medicare beneficiaries to the ASTC.

LEGAL ANALYSIS

A. The Referral Prohibition

Section 1877 of the Social Security Act prohibits a physician from referring a Medicare patient to an entity for certain designated health services if the physician has a financial relationship with the entity, unless an exception applies. Specifically, Section 1877(a)(1) of the Act states that:

[I]f a physician (or an immediate family member of such physician) has a financial relationship with an entity . . . , then (A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this title, and (B) the entity may not present or cause to be presented a claim under this title or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).

Under section 1877(g) of the Act, the statutory sanctions for violating this prohibition can include denial of payment to an entity furnishing services under a prohibited referral, refunds of billed amounts to any individual who has paid for a service furnished under a prohibited referral, assessment of civil money penalties, or exclusion from the Medicare program.

B. Financial Relationship

The statute specifies two categories of financial relationship: (1) an ownership or investment interest in an entity and (2) a compensation arrangement between a physician and an entity. An ownership or investment interest can be through debt, equity, or other means. [Material redacted]'s Proposed Private Offering Memorandum (the "POM") indicates that, in exchange for capital contributions to the limited liability company, [Material redacted] proposes to offer investor physicians up to 49 percent of the company's interest in profits, losses and cash flow. Units are being offered to individual physicians licensed to practice medicine in [Material redacted] and who are residents of [Material redacted]. Also the physician investors are expected to maintain medical staff privileges at the ASTC. The remaining 51 percent of the equity of [Material redacted] will be owned and controlled by Dr. [Material redacted]. We conclude that the Arrangement as described to us between [Material redacted] and the investors fits within the definition of an ownership or investment interest under section 1877(a)(2) of the Act. [Material redacted] has not presented any issues regarding compensation relationships between the physicians and [Material redacted]. Therefore, this AO applies to just the ownership or investment interest.

The POM indicates that the investment offer is being made to "individual physicians licensed to practice medicine in [Material redacted] and who are residents of [Material redacted]." [Material redacted] indicates that the investors will include physicians who practice in the same vicinity as the ASTC. [Material redacted] plans that during the course of their respective practices local physician investors will refer some of their patients to the ASTC for services. Section 1877(h)(5) of the Act defines a referral to include: (1) the request by a physician for an item or service for which payment may be made under Medicare part B, including the request by a physician for a consultation with another physician and (2) the request or establishment of a plan of care by a physician which includes the provision of a designated health service.

The Act prohibits referrals for designated health services. Designated health services include: clinical laboratory services, radiology services (including magnetic resonance imaging, computerized axial tomography scans and ultrasound services), radiation therapy services and supplies, durable medical equipment and supplies, prosthetics, orthotics, and prosthetic devices and supplies, physical and occupational therapy services, home health services, parenteral and enteral nutrients, equipment and supplies, inpatient and outpatient hospital services and outpatient prescription drugs. [Material redacted] indicates that it anticipates providing some of these designated health services. Unless an exception applies, a physician investor in [Material redacted] who refers Medicare patients for a designated health service to the ASTC would be making a prohibited referral.

Some of the exceptions to the physician referral prohibition apply both to ownership and compensation relationships while others apply only to ownership or only to

compensation arrangements. The rural provider exception, discussed below, is available to parties that are involved in an ownership arrangement.

C. Rural Provider Exception

The rural provider exception is potentially appropriate for designated health services furnished by the ASTC. The rural provider exception in section 1877(d)(2) of the Act applies “. . . [i]n the case of designated health services furnished in a rural area (as defined in section 1886(d)(2)(D)) by an entity, if substantially all of the designated health services furnished by such entity are furnished to individuals residing in such a rural area.” In essence, a rural area is defined in section 1886(d)(2)(D) of the Act as what an urban area is not:

the term “urban area” means an area within a Metropolitan Statistical Area (as defined by the Office of Management and Budget) or within such similar area as the Secretary has recognized . . . by regulation . . . and the term “rural area” means any area outside such area or such similar area.

We refer you to Table 4A of the FY 1999 PPS Hospital Update Final Rule, (63 FR 41052; July 31, 1998 (copy enclosed)) for the list of urban areas and their constituent counties. Since [Material redacted] County, [Material redacted] is not listed as an urban area or a constituent county of an urban area, it is considered to be a rural area. If the designated health services referred by the owner physicians are actually furnished in [Material redacted] County, the first part of the rural provider test will be met.

The rural provider exception involves a two part test, however. In addition to the requirement that designated health services be furnished in a rural area, substantially all designated health services furnished by the provider must be furnished to individuals residing in a rural area. By regulation regarding referrals involving clinical laboratory services, we have interpreted “substantially all” to mean at least 75 percent in 42 CFR 411.356(c)(1). In terms of referrals for the other designated health services, we have proposed to apply this same definition in a proposed rule published in the Federal Register on January 9, 1998 at 63 FR 1659. Although the 75 percent standard is not included in a final regulation governing referrals for the other designated health services, it reflects our current interpretation of the “substantially all” standard. At this time we do not anticipate changing this standard.

Because [Material redacted] has not begun to operate the ASTC, it is not possible to make a final determination whether substantially all of the ASTC’s designated health services are provided to the residents of rural areas. However, [Material redacted] has certified that essentially all of the patients who will be utilizing the [Material redacted] facility reside in the [Material redacted] area and [Material redacted] County, [Material redacted] and that more than 99 percent of the population who will be utilizing the facility reside in the non-Metropolitan Service area of [Material

redacted] County. If, as [Material redacted] certifies, substantially all of the designated health services furnished by the ASTC are furnished to individuals residing in a rural area, the ASTC will meet the second element of the rural provider exception. We caution, however, that the “substantially all” test is an ongoing requirement. Therefore, to remain within the rural provider exception on an ongoing basis, it is necessary that substantially all of the designated health services be furnished to patients who reside in a rural area.

D. Physician Specialty and Referral Prohibition

You have also raised the question of whether the non-surgeon physician investors in the ASTC can refer patients to the ASTC without violating the referral prohibition. The referral prohibition in section 1877(a) of the Act applies to any individual who meets the definition of a “physician” under section 1861(r) of the Act and who has an unexcepted financial relationship with an entity, regardless of the physician’s specialty. However, section 1877(h)(5)(C) excepts from the term “referral” a pathologist’s request for clinical diagnostic laboratory tests and pathological examination services, a radiologist’s request for diagnostic radiology services, and a radiation oncologist’s request for radiation therapy. The provision applies if two conditions are met: (1) the request results from a consultation initiated by another physician and (2) the tests or services are furnished by, or under the supervision of, the pathologist, radiologist, or radiation oncologist. Since it appears that the ASTC will meet the rural provider exception, however, we see no reason at this time to consider the application of section 1877(h)(5)(C).

LIMITATIONS OF THIS OPINION

The limitations that apply to this AO include the following:

- This AO and the validity of the conclusions reached in it are based entirely upon the accuracy of facts and information that you have presented to us.
- This AO is only relevant to the specific questions posed at the beginning of this opinion. This AO is limited in scope to the specific Arrangement described in this letter and has no application to other arrangements, even those which appear to be similar in nature or scope.
- This AO does not apply to nor can it be relied upon by any individual or entity other than the requester. This AO may not be introduced in any matter involving an entity or individual that is not a requester to this opinion.
- This AO applies only to the statutory provisions specifically noted above. No opinion is herein expressed or implied with respect to the application of any other Federal, State, or local statute, rule, regulation, ordinance or other law that may apply to the Arrangement.
- This AO will not bind or obligate any agency other than the U.S. Department

of Health and Human Services. Under 42 CFR 411.382, CMS reserves the right to reconsider the issues posed in this AO and where public interest requires, rescind or revoke this opinion.

- This AO is also subject to any additional limitations set forth at 42 CFR 411.370 et seq.

Very truly yours,

/S/

Robert A. Berenson, M.D.
Director
Center for Health Plans and Providers
Enclosure
cc [Material redacted]