

Recent Settlements May Indicate Increased Government Focus On The Stark Law’s “Group Practice” Requirements and Exception For “In-Office Ancillary Services”

Article By:

Gary W. Herschman

Joseph E. Lynch

Recent settlement agreements between the United States Department of Justice (the “DOJ”) and two urologist business partners suggests that the government may be focusing increased enforcement efforts on the Stark Law’s “group practice” requirements and the Stark exception for “in-office ancillary services.” The urologists agreed to pay over \$1 million to resolve the allegations.

In early January 2018, the DOJ entered into settlement agreements with Dr. Aytac Apaydin and Stephen Worsham to resolve allegations that the physicians submitted improper claims to Medicare for image-guided radiation therapy (“IGRT”) services provided between 2008 and 2014. IGRT uses imaging to improve the accuracy of radiation therapy during cancer treatment. IGRT is reimbursable by Medicare and is considered a “designated health service” under the Stark Law.

Drs. Apaydin and Worsham jointly owned two businesses: Salinas Valley Urology Associates (“SVUA”), a California medical practice, and Advanced Radiation Oncology Center (“AROC”), a facility where IGRT services were performed. The settlement agreements highlight two types of problematic arrangements involving these entities:

1. SVUA, the private medical practice, billed Medicare for IGRT services performed at AROC. However, the government contends that the financial relationship between SVUA and AROC failed to comply with an applicable Stark Law exception.
2. AROC entered into “lease arrangements” with other local urologists and urology practices (the “Lessee Urologists”) pursuant to which the Lessee Urologists billed Medicare for IGRT services performed at AROC on patients that were referred by the Lessee Urologists’ own practice. The government contends that providing the IGRT services at AROC did not meet the Stark Law “location requirements” applicable to the Lessee Urologists’ practices, and also contends that the lease arrangements violated the Anti-Kickback Statute.

The settlement agreements provide only brief descriptions of the allegedly improper arrangements

and do not specifically describe or explain the government's theory as to why the arrangements violated the Stark Law and AKS. However, the reference to the Stark Law "location requirements" provides a clue.

As a general matter, the Stark Law permits a physician to profit from the physician's referral of a designated health service if the service is performed within the referring physician's "group practice" and in a building that is used by the group practice for providing physician services or other centralized designated health services. These services are referred to as "in-office ancillary services" and are the subject of a statutory exception to the Stark Law, as well as a more detailed exception under the Stark Law regulations. By stating that AROC did not meet the "location requirements," the government appears to be alleging that the urology practices could not satisfy the requirements of the Stark "in-office ancillary services" exception, which was likely the only exception available to protect the arrangement from Stark Law liability.

Stark's "in-office ancillary services" requires compliance with the following three requirements (codified at 42 U.S.C. § 1395nn(b)(2)):

1. Performance. The services must be performed personally by:

- The referring physician;
- A physician who is a member of the same group practice as the referring physician; or
- Individuals who are directly supervised by the referring physician or by another physician in the group practice.

2. Location. The services must be furnished in one of the following locations:

- In a building in which the referring physician (or another physician who is a member of the same group practice) furnishes physicians' services unrelated to the furnishing of the designated health services; or
- In the case of a referring physician who is a member of a group practice, in another building which is used by the group practice: (a) for the provision of some or all of the group's clinical laboratory services, or (b) for the centralized provision of the group's designated health services.

3. Billing. The services must be billed by:

- The physician performing or supervising the services;
- A group practice of which such physician is a member under a billing number assigned to the group practice; or
- An entity that is wholly owned by such physician or such group practice.

Before a practice can take advantage of the "in-office ancillary services" exception, it must be structured to comply with Stark's comprehensive definition of a "group practice." The Stark regulations at 42 C.F.R. § 411.352 set forth detailed requirements related to how the practice is

owned and operated, covering topics such as:

- Corporate structure;
- The range of care provided by physicians within the group, as well as the amount of time such physicians spend providing services through the group;
- Distribution of the group's expenses and income;
- Centralized decision-making;
- Consolidated billing, accounting and financial reporting; and
- Physician compensation.

This settlement is significant because there have been very few enforcement actions or settlement agreements alleging violations of the Stark Law based on a group practice's failure to comply with the "in-office ancillary services" exception. If you are a physician or physician group that relies on the "in-office ancillary services" exception to share profits from ancillary services that you may refer, this settlement should be a wake-up call — make it a priority to review and confirm that: (i) your group meets the Stark definition of a "group practice" and all of its detailed requirements, and (ii) all ancillary services are provided in locations that meet the requirements of the Stark "in-office ancillary services" exception.

©2024 Epstein Becker & Green, P.C. All rights reserved.

National Law Review, Volumess VIII, Number 57

Source URL: <https://natlawreview.com/article/recent-settlements-may-indicate-increased-government-focus-stark-law-s-group>