CLIENT ALERTS & INSIGHTS

Modern Vascular is the Latest Defendant in a Growing Trend of Qui Tam Relator Cases against Office-based Lab Companies

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Earlier this month a federal judge unsealed a federal qui tam relator complaint originally filed in January 2020 by Dr. Jay Radhakrishnan and Dr. William Julien against Arizona-based Modern Vascular and certain of its principals, affiliates and unnamed investor physicians accusing the defendants of violating certain federal fraud and abuse laws, including the Anti-Kickback Statute, the Stark Law and the False Claims Act, by paying illegal kickback to referring physicians and performing medically unnecessary procedures on patients at the company's office-based laboratories (OBLs). The Department of Justice has indicated it plans to join the lawsuit by December 2022. Modern Vascular operates fourteen OBLs across the country that provide minimally-invasive surgical procedures focusing on the treatment of peripheral arterial disease (PAD), uterine fibroids and varicose veins.

The complaint alleges that Modern Vascular's founder Yury Gampel pressured doctors providing services at the OBLs to "perform invasive procedures on as many referred patients as possible." The complaint also alleges that the company's OBLs treated patients based upon which procedures received the highest Medicare reimbursement and without regard to medical necessity. The complaint focuses, in large part, on the opening of a Modern Vascular clinic in San Antonio in 2019. The complaint describes a conference call held by Mr. Gampel that included 16 potential podiatrist investors where he explained the terms of the investment, promised the participants that the investment was lawful and that an initial $15,000 investment would yield in excess of $1 million in profits in less than five years. Gampel also allegedly told the potential investors they would receive "as much as $80,000 to $100,000 per year" in profits distributions in exchange for their initial $15,000 investment for a 2% equity stake in an OBL. The complaint also states that "Gampel repeatedly explained to the San Antonio potential investors that this was not a passive investment, and that the money they were investing was not important, but that the only important thing was that the investors refer patients and influence other doctors to refer patients to the OBL..."

OBL physician investment remains common, and is growing in popularity as a means for physicians to ensure that their patients receive timely, cost-effective and convenient outpatient care instead of seeking treatment in a hospital outpatient department or surgery center. OBLs typically are either organized as a department of a physician's medical practice, or as an independent freestanding OBL clinic. OBLs operating as freestanding clinics that are owned by physicians attempt to ensure that their ownership structure satisfies the elements of the Investment Interest Safe Harbor under the federal Anti-Kickback Statute (AKS). The AKS is a criminal statute that prohibits the exchange, or offer to exchange, of anything of value in an effort to induce or reward the referral of federal health

care program business. The Office of Inspector General ("OIG") has adopted safe harbors to protect certain business and financial practices and relationships from criminal and civil prosecution. Failure to satisfy all of the elements of a safe harbor does not necessarily make a specific ownership structure, conduct or a practice illegal, but instead makes it subject to increased scrutiny and individualized review. There are eight elements to the Investment Interest Safe Harbor, some of which many OBLs have difficulty satisfying:

1. Offer on Equal Terms: The terms of investment offered to a passive investor, if any, who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be no different from the terms offered toother passive investors.

2. Treat Non-Investors Equally: The entity or investor must not market or furnish the entity's items or services (or those of another entity as part of a cross referral agreement) to passive investors differently than to non-investors.

3. Pay Equal Returns: The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

4. Exceed 40% Investment Interest: Investors who are in a position to make or influence referrals to, otherwise furnish items or services to, or otherwise generate business for the entity must not hold more than 40% of value of investment interest of each class of investment interests during the previous fiscal year or 12 months. This element can be difficult for physician-owned OBLs to satisfy since physician owners often times account for a large percentage of patient referrals.

5. Offer Terms Related to Referral Volume: The terms on which an investment interest is offered to an investor who is in a position to make or influence referrals, to, furnish items or services to, or otherwise generate business for the entity must not be related to the previous or expected volume of referrals, items or services furnished, or the amount of business otherwise generated from that investor to that entity.

6. Condition Upon Referral: Must not require a passive investor to make referrals to, be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity as a condition for remaining as an investor.

7. Exceed 40% of Gross Revenue: No more than 40% of entity's gross revenue related to the furnishing of health care items and services in the previous fiscal year or previous 12-month period may come from referrals or business otherwise generated from investors. This 40% standard can also be difficult for physician-owned OBLs to satisfy since physician owners often times account for a large percentage of patient referrals.

8. Loan Funds to Obtain Investment Interest: The entity or any investor (or other individual or entity acting on behalf of the entity or any investor in the entity) must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity.

The complaint alleges that various elements of the safe harbor were not satisfied, that Modern Vascular would condition continued ownership upon a physician's referral of patients to an OBL and that profits distributions were outsized and not commensurate with a physician's pro-rata ownership interest in an OBL.

This lawsuit follows on the heels of another recently unsealed *qui tam* relator lawsuit against Fresenius and its vascular access affiliate Azura, which makes similar allegations to those contained in the Modern Vascular complaint. In the Fresenius lawsuit, two relator physicians allege that Fresenius centers provided medically unnecessary care and regularly entered into unlawful arrangements with nephrologists in order to secure patient referrals for Fresenius' dialysis centers, and that Fresenius entered into unlawful arrangements with physician referral sources in violation of federal fraud and statutes. There have been other governmental investigations and settlements in the OBL space implicating similar theories of violations of federal fraud and abuse laws, including against Philadelphia-based Vascular Access Centers L.P. and 23 affiliates that resulted in that company entering into a settlement with the Department of Justice where it agreed to enter into a corporate integrity agreement and pay $3.825 million to resolve claims that it violated the False Claims Act by billing Medicare for non-reimbursable vascular access procedures.

Benesch's Healthcare+ team monitors the development of this area of the law and may provide additional updates as they become available. For additional questions about the importance of this case and similar cases in the OBL industry to your business, please contact the authors of this article.

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