CLIENT ALERTS & INSIGHTS

Top 10 Lessons Learned from the Government's Complaint Against Modern Vascular

JANUARY 11, 2023

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Last month, the United States formally joined in the *qui tam* relator case against Arizona-based Modern Vascular. The action, originally filed in 2020 by relators Dr. Jay Radhakrish and Dr. William Julien, and since joined by a number of others, accuses Modern Vascular and many of its principals, affiliates and investor physicians and podiatrists of violating a variety of fraud and abuse laws, including the federal False Claims Act and the Anti-Kickback Statute. Modern Vascular operates fourteen office-based laboratories (OBLs) across the country providing minimally invasive surgical procedures.

The government alleges that Modern Vascular and its founder, Yury Gampel, engaged in a fraudulent scheme whereby physicians and podiatrists were encouraged or permitted to invest in OBLs, or affiliated management service organizations, in exchange for making referrals to an OBL. Notably, the government alleges that Modern Vascular conditioned investment in a center upon a prospective investor first achieving certain minimum referral volumes. Referral source investors were also allegedly able to invest in these entities for consideration that may have been inconsistent with fair market value standards, while the company allegedly paid outsized distributions to its investors. Referral source investors were allegedly told that the purchase price was intentionally low, and that they should focus on bringing in a steady stream of referrals. The company also allegedly engaged in forced redemptions of the equity of referral source investors when the volume of their referrals decreased. The government also alleges that the company created and implemented a questionable peripheral arterial disease screening policy intended to increase referrals to its OBLs as a means of increasing profits.

The government's complaint focuses on actions allegedly taken by Modern Vascular and its principals contrary to the central policy behind the AKS-namely that financially incentivizing physicians to make referrals to a business in which they have a financial interest can corrupt their professional judgment, result in the provision of unnecessary medical care and result in excessive spending by federal healthcare programs and taxpayers. Below are some key prophylactic measures that outpatient businesses could consider implementing to mitigate fraud and abuse risks, many of which are discussed in the government's complaint:

1. Focus on quality of care, not volume of cases. Implementing policies promoting preventative screenings and referrals to an OBL that are not based upon peer-reviewed literature, medical necessity and local and national coverage determinations can result in risk of overuse and abuse;
2. Maximize the number of interventionalist owners and the percentage of equity held by such owners;

3. Require each investor to make a substantial pro-rata capital investment, and ensure that investment represents a bona fide business risk for all investors;
4. Ensure that the terms of an investment are not related to the prior or expected volume or value of referrals to, items or services furnished to, or the amount of business otherwise generated for an OBL. For example, an OBL should not utilize a "trial period" to evaluate a potential investor's referral volume or patters before offering that person an opportunity to invest;

5. Ensure there is no express or implied requirement for investors to make referrals to an OBL as a condition of remaining an investor. Investor equity redemption decisions should never be based upon an investor's history of referrals. Additionally, offer investment opportunities in an OBL to general community, not only to those who are in a position to make referrals;

6. OBLs should not track a physician investor's referrals;

7. OBLs should consider entering into risk-bearing reimbursement contracts, where possible;

8. OBLs should consider implementing a charity and discounted care policy;

9. OBLs should implement a compliance plan and engage in regular compliance training of fraud and abuse issues; and

10. OBLs should take seriously patient, payor and investor complaints about quality of care and fraud and abuse issues, and engage in a fair, impartial, and thorough investigation.

This case and related governmental investigation marks at least the fifth action brought against OBLs, vascular access centers and physicians operating in this industry. Some of these cases have resulted in millions of dollars' of fines and penalties and exclusion from participation in governmental healthcare programs. Benesch's Healthcare+ team monitors legal developments and trends occurring in OBLs, ambulatory surgery centers, vascular access centers and other outpatient care arenas. Please contact the authors for additional information about the information contained in this article or its impact on your business.

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