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Developing an OBL: Key Considerations Before Spending a Dime Or Too Much Time

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The office-based laboratory (OBL) industry has proliferated over the past decade as surgical cases have increasingly migrated from inpatient to outpatient surgical settings, including OBLs, ambulatory surgery centers and infusion centers. Although many physicians and patients prefer to provide and receive care in an OBL setting because it provides a high quality, lower cost and convenient alternative to receiving care in a hospital, the OBL industry is nonetheless under attack on a variety of fronts. Governmental and commercial payor reimbursement for OBL procedures has declined substantially over time, and there have been lawsuits, governmental investigations and news articles that have been critical of care provided in OBLs. These issues have generated headwinds for this young but growing industry. It is therefore important for physicians and investors alike interested in developing an OBL to be aware of the complex landscape of laws and regulations that apply to OBLs. This article provides an overview of key legal, corporate, tax, financial and structural considerations for operators to be aware of before opening an OBL.
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The office-based laboratory (OBL) industry is under attack on a variety of fronts, but there are steps that operators can take to mitigate legal risk associated with healthcare-related lawsuits and investigations. In July 2022, the U.S. Attorney's Office for the Eastern District of New York filed a civil complaint against Fresenius Vascular Care, Inc. (FVC) alleging that the company performed unnecessary procedures on dialysis patients at nine centers and billed federal health care programs for those procedures in violation of the Federal False Claims Act.[1] In October 2023, the New York State Attorney General jointly filed with the attorneys general of Georgia and New Jersey an additional complaint alleging that FVC knowingly subjected end-stage renal disease patients, including elderly people, people of color, and low-income individuals, to unnecessary and invasive procedures to increase its revenues.[2]

In December 2022, the United States intervened in a Federal False Claims Act whistleblower case in the Southern District of Arizona against Modern Vascular and many of its principals, affiliates and investor physicians and podiatrists.[3] The government alleged 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 OBLs.

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[1]U.S. ex. rel. John Pepe, M.D. and Richard Sherman, M.D. v. Fresenius Vascular Care, Inc. (complaint available athttps://www.justice.gov/usao-edny/pr/united-states-files-claims-alleging-fresenius-vascular-care-inc-defrauded-medicare-and).

[2]The States of Georgia, New Jersey and New York ex. rel. John Pepe, M.D. and Richard Sherman, M.D. v. Fresenius Vascular Care, Inc., American Access Care Physician, PLLC, Access Care Physicians of NJ, LLC, New Jersey Interventional Associates, LLC, Snapfinger Vascular Access Center, LLC, Fresenius Vascular Care Augusta, LLC, American Access Care of Atlanta, LLC, and Gregg Miller, M.D. (complaint available at https://ag.ny.gov/sites/default/files/court-filings/fresenius-complaint-in-intervention.pdf).

[3]U.S ex. rel. Radhakrishnan, et al., ex rel. Terry, et al., ex rel. Katherine Diggins, et al., v. Yury Gampel, Modern Vascular of Glendale, LLC Modern Vascular LLC (complaint available at https://www.justice.gov/opa/pr/united-states-files-false-claims-act-complaint-against-chiropractor-modern-vascular-office).

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In addition to these legal actions, certain news outlets have focused a critical eye on problematic practices in the OBL space. For example, the *New York Times* published an article in July 2023 highlighting alleged overuse of atherectomy devices in the treatment of patients with peripheral artery disease leading to amputations and other complications.[4] Further, *ProPublica* has published a series of articles critical of the shift to outpatient vascular care and accompanying concerns about physicians allegedly performing unnecessary, costly and risky procedures.[5] One recent *ProPublica* article commented that "experts fear patients are being caught up in a new era of profit-driven procedure mills, in which doctors can deploy any number of devices in the time it takes to drill a tooth and then bill for the price of a new car."[6]

Even though many patients prefer to receive surgical care in an OBL setting because it is often more convenient and cost effective than receiving care in an ASC or hospital outpatient department (HOPD), the OBL industry is currently under scrutiny from payors, other providers and the media. It is therefore more important than ever for OBLs to focus on providing high quality care in an ethical and compliant manner, and there are a variety of topics that prospective and current OBL owners should consider when structuring, syndicating and operating an OBL.

1. **Consider Building an OBL to ASC Standards**. Regardless of the specific care delivery setting, Medicare treats all OBLs the same for purposes of reimbursement. Services performed in an OBL are reimbursed by Medicare under the Medicare Physician Fee Schedule (MPFS) and claims are submitted using Place of Service (POS) code 11; while services performed in a Medicare-certified ambulatory surgery center (ASC) are reimbursed by Medicare under the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System (OPPS/ASC) using POS code 24. Although the Medicare reimbursement differential for surgical services performed in an OBL and ASC has been minimized over recent years, there remain notable differences in reimbursement for certain surgical services. Such site-specific payment differences, however, may be eliminated if the Centers for Medicare & Medicaid Service (CMS) implements site-neutral payment policies across outpatient care delivery settings.

For example, on April 26, 2023, the House Energy and Commerce Committee Health Subcommittee held a legislative hearing to consider a variety of bills directing CMS to implement site-neutral payments based on where services are most commonly provided.[7] The bills would direct CMS to identify whether items and services within an ambulatory payment classification (APC) are more commonly performed in the OBL, ASC or HOPD setting. Where items and services within an APC are most commonly performed in an ASC setting, the generally higher HOPD payment rates would be aligned to ASC payment rates. Services furnished in an OBL setting would continue to be paid under the MPFS. Where services within an APC are most commonly performed in an OBL setting, HOPD and ASC payment rates would be aligned with the typically lower MPFS non-facility rates.

Parties wishing to hedge against reimbursement uncertainty often consider building an OBL to ASC standard—including building, fire and life safety code requirement. However, doing so can be an expensive endeavor and can cost upwards of four times the cost of building an similarly-sized OBL. It also may not be possible to build to ASC standards in some buildings due to structural considerations, while other states may limit the number and type of ASCs in a given geography under certificate of need laws. However, the incremental costs of building to ASC standards from the start can be trivial when compared against later retrofitting a space to ASC standards.

2. **Consider Your Strategic Goals**. OBLs are frequently organized either as a department of a "group practice" as defined under 42 C.F.R 411.352 or as a separate stand-alone clinic. Although there is not a "correct" way to structure an OBL, it is important to understand the benefits and drawbacks associated with each organizational structure, including the following (Table 1):
3. **Proforma Planning Produces Profits**. Prior to purchasing land or a building, or entering into expensive long-term space or equipment leases, investors should generate a business plan and financial pro forma to model projected business growth over time. The proforma should be conservative and based upon easily achievable case volumes. It should also take into account historical and anticipated payor mix, anticipated commercial payor reimbursement rates, a ramp up period during which time the OBL would attempt to obtain commercial payor contracts, and considerations related to certain types of diagnostic imaging services that some OBLs may be limited in providing in compliance with the Federal Stark Law (see section 9 below). A realistic and well thought out proforma can be an investor's best tool when evaluating an OBL's size and the number of surgical suites that may be needed. Most commercial lenders will require applicants to present these materials as a condition of obtaining financing. Finally, although patients wish to receive care in a modern and well-appointed office suite, investors should consider whether their patients

[4]See *They Lost Their Legs. Doctors and Health Care Giants Profited*, New York Times (available at https://www.nytimes.com/2023/07/15/health/atherectomy-peripheral-artery-disease.html).

[5]See *Arterial Motives. The Big Business of Clogged Arteries*, ProPublica (article series available at https://www.propublica.org/series/arterial-motives).

[6]See In *the "Wild West" of Outpatient Vascular Care, Doctors Can Reap Huge Payments as Patients Risk Life and Limb*, ProPublica (available at https://www.propublica.org/article/maryland-dormu-minimally-invasive-vascular-medicare-medicaid).

[7]Society of Interventional Radiology (SIR) Open Forum, eviCore Clinical Guidelines Peripheral Vascular Intervention – Version: 1.0.23.

Table 1 Common Organizational Structures for OBLs

	OBL Organized as a Group Practice	OBL Organized as a Clinic
Strategic Goal	Used by group practices to foster revenue enhancement, group independence, succession planning and to support physician recruitment	Used as a collaborative tool by physicians in a geographic market to provide complimentary surgical services (e.g., dialysis vascular access, peripheral arterial disease, venous embolization, etc. . .).
Corporate Organizational Structure	Often organized as a professional corporation or professional limited liability company	Often organized as a professional corporation or professional limited liability company; alternatively may be structured using an MSO-friendly PC structure to allow for non-physician investment in an affiliated management services organization
Start-Up	If a group practice has been established, then starting up an OBL may be simple if operated under the group practice's tax identification number	Time-consuming to organize a new entity, syndicate equity and enter into new organizational documents
Commercial Payor Contracting	If an established group practice already has commercial payor contracts, then a group practice can typically either perform surgical services under its existing payor contract or enter into limited payor negotiations to add new codes (typically takes 0-3 months)	Clinics will typically need to engage in payor contracting with commercial payors, which may take longer in some states and/or may be very difficult if a panel is closed to certain provider types (typically takes 3-9 months)
Working Capital Requirements	Limited, due to ease of payor contracting and existing organizational and equity structure	Extensive, due to payor contracting challenges
Fair Market Value Investment	With certain exceptions, investors are not required to purchase equity in a group practice in exchange for fair market value consideration	Investors are required to purchase equity in an OBL that does not qualify as a group practice in exchange for fair market value consideration
Performing Stark Law Designated Health Services (DHS) (e.g., diagnostic imaging)	May be performed and billed within the group practice, subject to satisfying the Stark Law in-office ancillary services exception or another exception	Difficult for an entity to perform or bill for DHS since a clinic typically can't satisfy the Stark Law in-office ancillary services exception
Non-Physician Investment	Challenging to structure to allow non-physicians to directly invest in a group practice, particularly in corporate practice of medicine (CPOM) states. May require significant restructuring of a practice that can result in adverse income tax consequence for a practice's owners	Direct non-physician investment may be permitted in non-CPOM states; management service organization-" friendly physician" model may be used to allow non-physician investment in an affiliated management services organization in CPOM states

may prefer to receive care in a space that looks like the Taj Mahal or their local Target, since an appearance of opulence may scare away some patients, and unnecessary frills could strain an OBL's financial performance.

4. **Understand Your Competition**. It is important to understand the competitive landscape for surgical services in a geographic area. For example, are there other hospitals, ASCs, OBLs, urgent care centers, HOPDs, freestanding emergency departments, or physician practices providing the types of procedures that a new OBL wishes to provide? Competition for a "slice of the pie" can be fierce, and competitors often have a vested interest in excluding new market entrants. For example, a hospital may (i) refuse to enter into a patient transfer agreement with a new ASC, (ii) implement onerous conflict of interest policies preventing physicians on their medical staff from holding interests in competitive healthcare facilities, (iii) engage in "economic credentialing" by refusing to credential, or re-credential physicians, who have competitive economic interests, or (iv) enter into exclusive arrangements with physicians or physician groups to that can indirectly prevent certain types of physicians, particularly interventional radiologists, from being able to obtain

commercial payor contracts. Competitors have also been known to take even more aggressive approaches to squelch competition, including filing lawsuits and whistleblower actions, and encouraging commercial payors not to contract for services with new providers. Additionally, as lending standards have tightened, banks are increasingly requiring applicants to perform a feasibility study analyzing the competitive landscape and potential patient population likely to use the OBL as a lending condition.

5. **Syndicate Before Spending**. Some investors believe that if they build an OBL, then others will quickly line up to invest or provide professional services at a center. Such a Field of Dreams — "if you build it they will come" — development approach can cause project delays and can lead to financial failure. It is therefore important to finalize an OBL's investment structure before breaking ground, and understand whether its investors and physician service providers may be subject to non-compete or other contractual restrictions that could prevent them from investing in, or providing professional services at, an OBL.
6. **Overcome Investment Reluctance**. When physicians who have not previously worked together are interested in developing an OBL, one or more physicians may wish to gain comfort with the other potential investors by initially entering into a professional services agreement to perform surgical services at a center before investing. This is an appropriate strategy for allowing parties to gain familiarity with one another. However, it is also important for potentially interested investors to understand that federal and state fraud and abuse laws require investors to purchase equity in an OBL (that is not otherwise organized as part of a physician group practice) or an ASC in exchange for fair market value and commercially reasonable compensation at the time of purchase. When organizing a de novo outpatient center, each investor should contribute a pro-rata share of startup expenses, costs and working capital in proportion to such investor's ownership percentage. When an investor purchases equity in an OBL or ASC after it has become profitable, then an investor may be required to pay a higher purchase price (possibly up to eight times a center's EBITDA). A physician who wishes to delay investment could miss an opportunity to purchase equity in exchange for de novo pricing.
7. **Maximize Interventionalist Investment**. CMS, the Office of Inspector General, U.S. Department of Health and Human Services and governmental enforcement agencies have expressed concern about non-interventionalists profiting (in the form of profits distributions) from referrals made to outpatient healthcare facilities where they do not perform surgical services or use such facilities as an extension of their physician practice. The government believes that such investment can create a financial conflict of interest that can cloud a physician's clinical decision-making, lead to overutilization of resources and result in depletion of the Medicare Trust Fund. Although certain prophylactic safeguards may be implemented to decrease the degree of fraud and abuse risk associated with non-interventionalist investment, a variety of facts are critically important when analyzing the degree of regulatory risk associated with non-interventionalist investment. Additionally, non-interventionalist investment in an ASC will preclude an ASC from being able to satisfy the federal Anti-Kickback Statute safe harbor for ownership in an ASC. Violation of this statute is a felony punishable by imprisonment of up to 10 years, fines or both. Violations may also result in civil and administrative penalties, exclusion from participation in federal healthcare programs and administratively imposed civil monetary penalties of and treble damages. It is therefore important to consult with knowledgeable healthcare counsel to help evaluate the degree of fraud and abuse risk associated with non-interventionalist investment in outpatient facilities, and to pursue prophylactic measures to help decrease the degree of fraud and abuse risk.
8. **Execute Organizational Documents**. Did you date your spouse before getting married? Presumably you did, and during that time you likely spent time determining your joint priorities. Entering into a business arrangement with other investors to develop an OBL shares many of the same characteristics as dating. In particular, it is important for investors to have a shared financial, operational, organizational and managerial vision. It is therefore helpful for investors to enter into a contractual arrangement that addresses these, and other material, issues before investing significant capital on development. These types of issues are frequently addressed in an OBL's organizational documents such as an entity's bylaws, buy-sell agreement, partnership agreement, shareholders' agreement or joint venture operating agreement. A lender will almost always insist upon receiving signed copies of an OBL's organizational documents as a lending condition.
9. **Understand Whether Your OBL May Provide Stark Law Designated Health Services**. Subject to certain exceptions, the Stark Law prohibits a physician from referring a patient to an entity with which a physician or immediate family member has a direct or indirect financial relationship for the furnishing of DHS for which payment may be made under Medicare or Medicaid. Certain surgical services, including but not limited to, a variety of diagnostic imaging services commonly performed by vascular surgeons and interventional radiologists in OBLs, may qualify as DHS and therefore must be performed in compliance with an applicable Stark Law exception—most often the in-office ancillary services (IOAS) exception. This exception is commonly used to protect referrals of DHS made by physicians within a "group practice." However, in most cases where a stand-alone OBL entity is organized, the IOAS exception generally cannot be satisfied because the newly organized entity is unable to qualify as a group practice. As a result, Stark Law DHS

often times cannot be performed in many OBLs established outside of a physician group practice.

10. **States and Payors Often Have Additional Rules to Follow**. In addition to federal law considerations, state-specific fraud and abuse laws should be analyzed. Additionally, some states have certificate of need laws limiting the development of new outpatient service locations, including OBLs and ASCs, absent a demonstrated community need. Some states have corporate practice of medicine laws designed to limit non-physician investment in entities providing physician services, which may require investors to explore using a management services organization "friendly PC" model to accommodate non-physician investment in an affiliated management services organization.

State-specific rules and regulations applicable to OBLs should also be followed, including anesthesia rules, medical board rules, rules related to performing percutaneous coronary interventions (which at this time may generally only be performed in ASCs in some states), and rules requiring third-party accreditation by organizations such as the Accreditation Association for Ambulatory Health Care. Finally, a growing number of states, including Florida and New York, have implemented rules and regulations specific to the ownership and operation of OBLs, which represents a growing trend that has accelerated in response to certain recent news stories critical of OBLs and state and federal enforcement actions against select OBLs.

Finally, a growing number of commercial payors are implementing stringent reimbursement rules for commonly performed OBL procedures. Earlier this summer, Aetna announced that it would require prior authorizations for a variety of commonly performed peripheral vascular interventions effective September 1, 2023, including atherectomy, thrombectomy, embolectomy, thrombolysis and PTA or stent placement.[8] Aetna indicated that it would also likely deny many atherectomy cases moving forward, citing a lack of clinical evidence to support the use of atherectomy in the treatment of peripheral artery disease.

11. **Implement Prophylactic Measures and Best Practices to Guard Against Legal Scrutiny**. In light of heightened industry and the potential individual civil and criminal liability that can arise from a fraud and abuse investigation, stakeholders should consider implementing a variety of prophylactic measures in an effort to mitigate fraud and abuse risks. Below is a summary of these considerations (Table 2):
12. **The Hybrid Model Presents Unique Operational Considerations**. Under federal law, distinct entities may share space so long as they maintain temporal separation. CMS defines a "distinct entity" in the State Operations Manual as one that is "wholly separate and clearly distinguishable from any other healthcare facility or office-based physician practice" either physically or temporally. Under these rules, an ASC and OBL may share space so long as each entity uses the space at different times and has its own hours of operation. Most "hybrid" facilities operate their ASC and OBL on different days in order to satisfy the temporal separation requirement. A small percentage of hybrids operate their ASC and OBL on the same day. Hybrids that operate an ASC and OBL on the same day must ensure that all patients have exited the facility (including the waiting room and recovery suite) prior to converting the space to the opposite type of use in order to achieve temporal separation.

In addition, some states do not permit hybrid arrangements, so an operator must evaluate state laws before implementing a hybrid model. In addition, an ASC and OBL involved in a hybrid model must ensure that their respective prescription drugs and medical records are separately maintained and are not accessible to each other. If a unified electronic medical records system is used to operate both an ASC and OBL, each entity should ensure that there are sufficient firewalls and safeguards in place to prevent access to medical records of the respective ASC and OBL patients, and staff should have different system logon credentials for each electronic medical records system. Signage in waiting areas should also clearly indicate to patients the days and hours of ASC and OBL operations, and patients should be advised that the amount of their copays, coinsurance and deductibles may be different depending upon the care settings.

13. **Engage Experienced Consultants**. Many physicians spend far more than planned when building their OBL because they do not use a management company, general contractor and/or architect with significant experience building OBLs. It is therefore important to work with companies that have completed a variety of similar types of projects, preferably in the state where an OBL will be located, since stricter state and local building and fire codes may apply in certain areas. Reputable consultants should be able to provide at least three references for completed projects, and it is also a good practice to check Better Business Bureau and online reviews before engaging such companies. Some trade organizations, including the Outpatient Endovascular and Interventional Society, the Society of Interventional Radiology and the Renal Physicians Association, may be able to direct their members to reputable consultants.

Please contact one of the authors if you have questions about the information contained in this article

[8] Aetna Office Link Update June 2023, available at: https://www.aetna.com/content/dam/aetna/pdfs/olu/officelink-updates-june-2023-olu.pdf (see p. 10)

Table 2 Prophylactic Measures to Help Reduce Fraud and Abuse Risk

Risky Behavior	Prophylactic Measure
Lack of corporate oversight of compliance with applicable fraud and abuse laws and other applicable legal and regulatory requirements.	Develop and implement an effective compliance program that promotes monitoring of compliance with all applicable federal statutory, regulatory, and Medicare and Medicaid program requirements and state laws and regulations. Specifically, implement policies promoting preventative screenings, ensuring referrals to an OBL are based upon peer-reviewed literature, medical necessity, and local and national coverage determinations.
Lack of patient transparency regarding referrals to facilities owned by a referring physician.	Include a disclosure containing a list of all facilities with which the patient's treating physician has a financial relationship with intake paperwork. Note that this disclosure may be required by state law and may require the notice to provide alternative treatment settings where a referring physician does not have an ownership or financial relationship.
Building an ownership model that focuses on 1 interventionalist.	Consider maximizing the number of interventionalist owners and the percentage of equity held by such owners in an OBL equity syndication.
Conditioning equity participation upon a physician's future referrals.	Ensure the terms of an investment are unrelated 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 patterns before offering that person an opportunity to invest. Additionally, ensure that 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 not be based upon an investor's history of referrals. Finally, offer investment opportunities in an OBL to the general community, not only to those who are in a position to make referrals or use the OBL as an extension of practice.
Providing services solely to the physician owners' patients	Implement a plan to market the OBL's services more broadly to the general community.
Relieving physician investors' financial "skin in the game."	Require each investor to make a substantial pro-rata capital investment and ensure that investment represents a bona fide business risk for all investors. All investors should also be responsible for their share of any loans made to the OBL. OBLs and management companies should also avoid making loans to investors to finance buy-in contributions.

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