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12 Business and Legal Considerations for Successfully Developing a “Hybrid” Office-Based Laboratory—Ambulatory Surgery Center

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In recent years, changes to Centers for Medicare and Medicaid Services' (CMS) reimbursement policies for outpatient interventional procedures has both expanded the scope of surgical services that may safely be performed in outpatient non-hospital based settings (such as a Medicare-certified ambulatory surgery centers (ASC) and office-based laboratories), while simultaneously adjusting reimbursement in these settings to align with CMS "site-neutral" payment policies that reimburse providers the same amount for the same clinical services regardless of the setting in which the services are provided. The transition to site-neutrality has been a slow and uneven process as CMS considers the appropriateness of select reimbursement adjustments for services, and as providers push back against reimbursement cuts intended to achieve site-neutrality. For example, in a recent win for hospitals, on September 17, 2019 a federal judge overturned a CMS rule that cut Medicare reimbursement for some hospital clinic visits beginning January 1, 2019. U.S. District Judge Rosemary Collyer ruled in favor of hospitals that sued to prevent an expansion of CMS site-neutral payment policy to evaluation and management services at off-campus hospital-based clinics.

Since it is presently unclear how Medicare reimbursement rates and site-neutral payment policies will unfold in outpatient non-hospital based settings, many providers are evaluating the benefits of a "hybrid" office-based laboratory—ASC model to provide outpatient interventional procedures to guard against this uncertainty. Under the hybrid model, a center is operated as an office-based laboratory, catheterization laboratory or vascular access center (these settings are collectively referred to in this article as an "OBL") on certain days, and as a Medicare-certified ASC on other days. Although a hybrid model can be an attractive means to ensure continuity of care for patients and reduce the need for costly inpatient admissions, there are various potential business and legal considerations that should be evaluated before developing a hybrid center.

1. **Consider Building the OBL to ASC Standards.** Regardless of the specific care delivery setting, Medicare treats all OBLs in the same manner 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 ASC are reimbursed by Medicare under the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System (OPPS/ASC) using POS code 24. Medicare reimbursement for surgical services performed in an OBL is generally less than when identical services are performed in an ASC where providers are reimbursed for both a professional and technical/facility fee component.

However, some types of clinical services (e.g., certain peripheral arterial disease and endovascular procedures) continue to be reimbursed by Medicare at higher rates when performed in an OBL. Many commentators believe that CMS may eliminate such site-specific payment differences as it implements site-neutral payment policies. However, since it is presently unclear how Medicare reimbursement rates and site-neutral payment policies will unfold in coming years, building an OBL to ASC-specific standard—including building, fire and life safety codes—may help guard against ever-changing Medicare

reimbursement policies. Brandon Scanlon, Image Guided Therapy Solutions Business Leader with [Philips Healthcare](#) has noticed that “many facilities start as an OBL and then grow into a hybrid ASC model. The incremental costs in building to ASC standards from the start are minimal when compared to a retrofit after-the-fact.”

2. **Engage Experienced Consultants.** Many physicians spend far more than their original estimate to build an ASC, OBL or hybrid because they do not to use a management company, general contractor and/or architect with significant experience building these types of facilities. It is therefore important to work with companies that have completed a variety of similar types of projects, preferably in the state where a facility will be located, since stricter state and local building codes may apply in certain areas. A reputable management company, general contractor and/or architect should be able to provide three to five references for completed projects, and it is also a good practice to check Better Business Bureau and online reviews before engaging such companies. When ready to engage a contractor or architect, it is advisable to use an American Institute of Architects-approved form of contract to ensure that both parties’ interests are thoroughly protected.
3. **Build to Accommodate Growth, but Avoid Overbuilding.** Prior to purchasing land or a building, investors should consider creating a financial pro forma to model projected business growth over the initial investment period. According to Marc Toth, President of [ACA Cardiovascular](#), this model is “typically conservative, based upon achievable case volumes and should take into account historical and anticipated payor mix, reimbursement rates and Stark Law considerations” (see section 10 below). Investors may choose to work with an ASC or OBL management company experienced in developing such pro formas to help ensure that a facility is “right sized” for growth.
4. **Syndicate Before Spending.** Some investors believe that if they build an ASC, OBL or hybrid then others will quickly line up to become investors or provide professional services at these centers. Such a *Field of Dreams* — “if you build it they will come” — investment approach can cause project delays or failures. Prior to beginning development, it is important to understand which other physicians may be interested in investing and performing services at a center, whether they may be subject to non-compete or other restrictions that could prevent them from investing, and their ability to timely provide capital for a development project.
5. **Enter Into a Letter of Intent.** Did you date your spouse before getting married? Presumably you did, and during that time you may have spent a significant amount of time determining your joint priorities and developing strategies for resolving disputes. Entering into an ASC, OBL or hybrid joint venture shares many of the same characteristics as dating. In particular, it is important for investors to have a shared financial, operational and managerial vision for a project. It is therefore helpful for investors to develop a letter of intent that

addresses these and other, material issues before spending significant financial resources on development.

- 6. Overcoming Investment Reluctance.** When physicians who have not previously worked together are interested in developing an OBL, ASC or hybrid, 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, including federal and state Anti-Kickback Statutes, require investors to purchase equity in an ASC or freestanding OBL in exchange for fair market value and commercially reasonable compensation at the time of purchase.

When organizing a *de novo* ASC, freestanding OBL or hybrid, each investor should contribute a *pro rata* share of startup expenses, costs and working capital in proportion to such investor's equity ownership percentage. When an investor purchases equity in an ASC, OBL or hybrid after it has become profitable, then an investor may be required to pay a higher purchase price (often two to seven times a center's EBITDA, depending upon a variety of factors). A physician who wishes to delay investment could miss an opportunity to purchase equity in exchange for *de novo* pricing.

- 7. Don't Underestimate the Competition.** It is important to understand the competitive landscape for surgical services in a geographic area. For example, are there other hospitals, ASCs, OBLs or physician practices providing the types of procedures that a new ASC, OBL or hybrid intends to provide? Competition for a "slice of the pie" is fierce in certain markets, and competitors often have a vested financial interest in excluding new market entrants. For example, a hospital may refuse to enter into a patient transfer agreement with a new ASC in certain markets, which is presently required by the federal ASC Conditions of Participation. Competitors have also been known to take other more aggressive approaches to squelch competition, including filing lawsuits and whistleblower actions, and encouraging commercial payors not to contract for services with new providers.
- 8. Non-Interventional Physician Investment Generally Increases Fraud and Abuse Risk.** CMS, the Office of Inspector General, U.S. Department of Health and Human Services and governmental enforcement agencies have consistently expressed concern about non-interventionalists profiting (in the form of profits distributions) from referrals made to ASCs and other 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 reduce (but not eliminate) the degree of fraud and abuse risk associated with non-interventionalist investment in ASCs, OBLs and hybrids, 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 investors' ability 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 of up to \$100,000 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 up to \$100,000 per kickback and three times the amount of illegal remuneration received. 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 ASCs, OBLs and hybrids.

9. **Consider Long-Term Goals When Structuring an OBL.** OBLs are frequently organized either as a department of a group practice or as a separate stand-alone company. Although there is not a 'correct' way to structure OBL or hybrid investment entities, it is important to understand the legal implications of a structure up front and the key benefits and drawbacks associated with organizing each structure, including the following:

	OBL as Practice Department	OBL as Stand-Alone Entity
Ease of Organization	Already set up, as it will be operated under the practice’s tax ID and payor contracts	Time-consuming to organize a new entity, syndicate investment, obtain a new tax ID and payor contracts
Fair Market Value Investment	Investors are not required to purchase equity in a practice in exchange for fair market value consideration	Investors are required to purchase equity in an OBL in exchange for fair market value consideration
Performance of Stark Law Designated Health Services (DHS)	May be performed within the group practice, subject to satisfying the Stark Law in-office ancillary services exception	Unlikely that such an entity would qualify as a group practice, and therefore DHS should not be performed
Non-Physician, Private Equity or Management Company Investment	Challenging to structure to allow non-physicians to invest in a practice department, particularly in corporate practice of medicine (CPOM) states	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 CPOM states
Sale of OBL to Third Party	Sale would result in either a sale of the entire practice, or could potentially result in a taxable sale of OBL assets to a new entity; may produce a lower sale multiple	Sale process is simpler; may be accomplished through a sale of assets or equity; may produce a higher sale multiple

Additionally, according to [David Cutler](#), CPA, an accountant who regularly works with physicians to organize healthcare entities in a tax efficient manner, “it is important to consider all aspects related to income and estate tax planning, asset protection, succession and retirement planning, as well as realizing the highest after tax rate of return on such investment before proceeding with organizing an entity.”

10. Stark Law DHS Should Not Be Performed in Non-Group Practice OBLs.

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 commonly performed in an OBL may qualify as DHS and therefore must be performed in compliance with an applicable Stark Law exception—namely 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 generally should not be performed in many OBLs established outside of a physician group practice, which may impact a newly-formed OBL’s financial performance.

11. The Hybrid Model Presents Certain 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 hybrids 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, a number of states do not permit hybrid ASC/OBL arrangements so an operator must evaluate state licensure, certificate of need, and other rules and regulations applicable in a state in which a hybrid intends to operate.

In addition, an ASC and OBL involved in a hybrid model must ensure that their respective 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.

12. State-Specific Legal Considerations. In addition to federal law considerations, state-specific fraud and abuse laws and other limitations should also be evaluated. Some states have certificate of need laws that limit the development of new outpatient service locations, including ASCs, absent a demonstrated

community need. Some states have corporate practice of medicine laws designed to prevent non-physician investment in an OBL or physician practice, which may require investors to explore using a management services organization-“friendly PC” model to accommodate non-physician investment. State-specific regulations, anesthesia rules and medical board rules may also limit the types of services that may be provided in an ASC or OBL. Janet Dees, President of [American Vascular Associates](#) notes that “in some states, the board of medicine will not allow percutaneous coronary intervention (PCI) or coronary procedures to be performed in an ASC, or for coronary diagnostic procedures to be performed in an OBL or ASC. Although there is movement in many states to re-evaluate these restrictions, it is important to examine these restrictions early in the planning and development phase.”

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