

## **Exploring Potential Business Ventures**

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As physicians struggle to stay independent and remain profitable in this tumultuous health care environment, vascular surgeons are among the types of specialists well-positioned to expand their existing practices to include an in-office vascular surgical suite (“In-Office Suite”) or establish a free-standing ambulatory surgery center (“ASC”) individually or in partnership with a hospital or complementary specialty group (e.g., interventional radiologists).

With the development of minimally invasive surgical technologies and new forms of anesthesia, many vascular surgical procedures can be safely and efficiently performed outside a hospital setting. For example, common vascular surgical procedures performed in an In-Office Suite include, but are not limited to, diagnostic arteriography, venography, venous ablation, balloon angioplasty, atherectomy, vena caval filters, filter extraction, and stenting.

Whether you are considering expanding your existing practice to include an In-Office Suite or establish an ASC (either independently or in partnership with other health care providers) may be largely depend on the regulatory environment of the state in which you operate. Many states have certificate of need (“CONs”) laws that limit the ability for physicians to open an ASC. Other states have rigorous office-based surgery guidelines and requirements that push physicians towards development of an ASC.

Additionally, there are other legal, financial, and operational considerations to keep in mind when exploring potential business venture opportunities, which are generally discussed in this article. Moreover, the decision to maintain independence through the establishment of an In-Office Suite versus an ASC jointly owned by other health care providers must be weighed against the implementation of Medicare Access and CHIP Reauthorization Act and continued push towards consolidation and integration (assuming this movement does not change with the new presidency).

### **Legal Considerations**

#### ASC

Many states like Illinois<sup>1</sup> require ASCs to be separately licensed. Additionally, as noted above, many states like Kentucky<sup>2</sup> have regulatory schemes that require CONs prior to establishing an ASC.

Moreover, if you choose to establish an ASC and want to be participate in the Medicare program, certain standards and requirements must be met and achieved in order to participate in, and be certified by, the Medicare program<sup>3</sup> that are not applicable to In-Office Suites. For example, the ASC must be a distinct entity, comply with specific building and construction requirements, and cannot mix functions and operations in common space with another entity

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<sup>1</sup> See 210 ILCS 5/4, §4.

<sup>2</sup> K.R.S. §216B.020.

<sup>3</sup> See 42 C.F.R. Part 416.

such as an adjacent physician's office during hours of operation.<sup>4</sup> ASCs are also routinely subject to on-site surveys by CMS to ensure quality assurance and safe operating environments.

Additionally, in the event you elect to partner with other health care providers to form a free-standing ASC such as a hospital and/or specialty group that are potential referrals sources, the joint venture must be properly structured from a fraud and abuse standpoint. Specifically, if the physician owner of the joint venture entity refers any "designated health services" ("DHS")<sup>5</sup> to the health care provider joint venturer for which such entity bills Medicare for such DHS (e.g., inpatient hospital services if the joint venture partner is a hospital), the direct and indirect financial relationships (ownership and compensation) among the parties must comply with an applicable exception to the Stark Law.

Similarly, if the parties are in a position to refer any federal health care program business to each other, the direct and indirect financial relationships among the parties should be structured to fit within an applicable federal Anti-Kickback Statute safe harbor. Moreover, many states have similar fraud and abuse laws which must be reviewed to ensure compliance.

Further, keep in mind that many third party payors require ASCs to be accredited by a third party accreditation agency such as The Joint Commission, Accreditation Association for Ambulatory Health Care, American Association for Accreditation of Ambulatory Surgery Facilities, Inc.

#### *In-Office Suites*

In most states, unlike ASCs, because an In-Office Suite is generally considered to be an extension of the physician practice, separate licensure, CON approval, and separate Medicare certification is not required. However, many states impose specific office-based surgery guidelines and requirements that must be followed when performing any in-office based surgeries. For example, Illinois law requires the office-based operating physician to have training and experience in anesthesia services in order to administer anesthesia, enter into a practice agreement with a certified registered nurse anesthetist to provide anesthesia services, or engage an anesthesiologist to administer the anesthesia in the physician's office.<sup>6</sup>

As with ASCs, many states such as Indiana<sup>7</sup> and New York<sup>8</sup> require In-Office Suites to be accredited by a third party agency. Additionally, accreditation may be required to be reimbursed for office-based surgery by third party payors.

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<sup>4</sup> *Id.* at Subpart C.

<sup>5</sup> As defined under 42 C.F.R. §411.351.

<sup>6</sup> See 68 Ill. Adm. Code 1285.340 (a).

<sup>7</sup> See 844 I.A.C. §5-5-20 (after January 1, 2010, a practitioner may not perform or supervise a procedure that requires anesthesia in an office-based setting unless the office-based setting is accredited by an accreditation agency approved by the board under the rules).

<sup>8</sup> See McKinney's Public Health Law §230-d (3); *but see* Georgia Composite Medical Board Office-Based Anesthesia and Surgery Guidelines (achieving accreditation by an appropriate agency is one method to demonstrate facility preparedness and staff competency to provide office-based surgery).

## **Financial Considerations**

### *Build-Out Costs*

Generally, the cost to build-out an In-Office Suite is less than the cost to purchase or rent a separate space to operate an ASC. To off-set the costs of a free-standing ASC, you may consider joint venturing with a hospital or other specialty group to jointly own the ASC. However, as noted above, the ownership structure of the joint venture and financial relationships among the parties must be appropriately structured from a regulatory standpoint to avoid implicating the federal Anti-Kickback Statute and Physician Self-Referral Law and applicable state laws (e.g., mini-kickback and mini-Stark laws; fee-splitting; corporate practice of medicine).

Overhead costs such as office staff, ancillary clinical personnel, and medical equipment and supplies likely will be similar whether you establish an In-Office Suite or ASC.

### *Reimbursement*

Traditionally, when surgeries or procedures are performed in a facility setting such as outpatient hospitals or ASCs not owned by the physicians, the physician is only paid for the professional services he/she renders.

Thus, one of the primary benefits to establishing an In-Office Suite or ASC is that the physician owner will have the ability to globally bill for the surgical procedures. Meaning, you will be able to bill and collect for the professional component for the professional vascular surgical services rendered and bill and collect for the technical component related to the surgery.

However, the reimbursement rates differ when surgeries are performed in an In-Office Suite versus an ASC, which could drive, in large part, the decision on whether to establish an In-Office Suite or ASC. The professional fees for surgeries performed in a physician office (billed as POS 11 – “Non-Facility”) are, on average, reimbursed at a significantly higher rate than surgeries performed in a facility setting such as a hospital outpatient facility or ASC (rates vary somewhat depending on geographic location). See e.g., Table 1.

**Table 1. 2016 Medicare Rates**

<b>Procedure</b>	<b>Non-Facility Fee</b>	<b>Facility Fee</b>	<b>Difference</b>
<b>CPT 37227</b> (revascularization, endovascular, open or percutaneous, femoral/popliteal artery(s), unilateral; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed)	\$15,186.38	\$785.19	\$14,401.19
<b>CPT 36475</b> (venous ablation)	\$1,568	\$293.95	\$1,274.05

Clearly having an In-Office Suite may result in the potential for increased revenue for a practice. And, in turn, results in cost savings to the patients and the health care system at-large by performing surgeries in a less costly setting without compromising the quality of care delivered. That being said, many third party payors may not reimburse for office-based surgeries and, thus, third party payors agreements should be reviewed to ensure that office-based surgeries are reimbursed.

### **Operational Considerations**

A primary operational advantage to establishing an In-Office Suite or independently creating and operating an ASC is a physician's ability to retain autonomy, control, and independence. The In-Office Suite and/or ASC offers a more convenient and efficient location for your patient, which, in turn, results in increased patient satisfaction, continuity of care, increased patient comfort, and better personalized care. You also have the ability to control your patient flow, workload, schedule, and create more work-life balance for yourself.

Moreover, to the extent that you are not business-savvy and want to focus solely on the clinical aspects of your practice rather than the day-to-day management of the In-Office Suite or ASC, you may consider engaging an experienced third party management company. Any such management services arrangement entered into must, however, be properly structured from a health care regulatory standpoint, including, but not limited to, compliance with the Stark Law, Anti-Kickback Statute, state fee-splitting and corporate practice of medicine prohibitions, and other applicable laws.

### **Questions to Consider Before Moving Forward**

Below are some questions to consider when determining whether an In-Office Suite or ASC is a feasible business venture for you:

1. Does my state have CON and/or office-based surgery guidelines/requirements that may make it difficult for me to establish an In-Office Suite or ASC?
2. Have I run the numbers (e.g., projected revenue and expenses for each model) to determine which model – In-Office Suite or ASC – will be most beneficial for me?
3. Do I have the capital to build an ASC and/or In-Office Suite? If I am considering an ASC, is there a specialty group or other health care provider with which I may consider partnering with to establish a joint venture entity? If yes, does my proposed joint venture model comply with applicable federal and state health care regulatory laws?
4. Can I perform the types of surgical services I typically provide my patients in an In-Office Suite (e.g., surgical services primarily include minimally invasive procedures that can be safely performed in an In-Office Suite versus more complicated procedures or large patient base who would not be ideal candidates for office-based surgeries (e.g., severe anxiety; severe dye allergies; low pain tolerance; high risk for complications))?

5. Do applicable state requirements limit the type of procedures I can perform in an In-Office Suite?
6. Do I want to consider engaging a third party management company to handle the day-to-day non-clinical operations of the In-Office Suite or ASC?
7. Do the private payors I contract with reimburse for In-Office Suite procedures? Is the reimbursement structure similar to Medicare such that a financial benefit to the practice will result?

Although there are obvious benefits to establishing an In-Office Suite or ASC, as you can see from this brief summary, careful planning, consideration, and legal counsel is required.

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<sup>i</sup> The author gratefully acknowledges the contributions of Peter Critikos (J.D. Candidate 2018 at Emory University School of Law).