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HEALTHCARE INSIGHTS

ASCs and Office-Based Laboratories: Valuation Distinctions and Considerations Part I: Distinctions

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Until approximately forty years ago, virtually all surgery was performed in hospitals.[1] Since the 1970s, however, the outpatient services industry has grown at a steady pace, precipitated in part by the American Medical Association's (AMA) 1971 adoption of a resolution endorsing the concept of outpatient surgery under general and local anesthesia for selected procedures and patients.[2]

The resulting shift to outpatient care has led to a growing number of diverse outpatient office-based facilities tailored to meet the accelerated growth in demand for healthcare services, leading to the establishment of, among other enterprises, ambulatory surgery centers (ASCs), and, more recently, office-based laboratories (OBLs). Currently, there are over 9,280 ASCs,[3] and approximately 700 OBLs[4] in the U.S.

At the same time, this rapid increase has resulted in increased regulatory scrutiny of the formation, ownership, alignment, and transactions related to these outpatient entities. Consequently, those involved in any prospective transaction (or formation) need to understand the differences between these two types of outpatient facilities and the implications thereof.

This article is the first in a two-part series and will define ASCs and OBLs, and discuss their distinctions (regulatory and otherwise). Part II will identify valuation considerations emanating from those distinctions.

DEFINITIONS

ASCs

ASCs are distinct, Medicare-certified outpatient healthcare facilities that provide services to patients who do not require inpatient hospital admission and a stay lasting more than twenty-four hours.[5] ASCs may be classified as single-specialty or multi-specialty and may be owned by hospitals, physicians, or other healthcare enterprises. Medicare reimburses these enterprises under their own separate prospective payment system.[6]

Since their inception more than four decades ago, ASCs have played an increasingly crucial role in the medical community.[7] Physicians are attracted to ASCs due to the ability to set and maintain their schedule, customize their surgical environments, and use specialized staff, which minimizes turnaround time and maximizes the number of procedures efficiently and conveniently performed.[8] In short, physicians typically find greater professional autonomy over their work environment and the quality of care provided in ASCs.[9]

As noted above, ASCs have increased in number over recent years, due in part to the potential for a heightened quality

1. "History of ASCs," Ambulatory Surgery Center Association, https://www.ascassociation.org/advancingsurgicalcare/asc/historyofascs (Accessed 9/16/19).
2. *Ibid.*
3. "How Many Ambulatory Surgery Centers Are In The US?" By Alanna Moriarty, Definitive Healthcare, April 10, 2019, https://blog.definitivehc.com/how-many-ascs-are-in-the-us (Accessed 9/18/19).
4. "Outpatient Endovascular and Interventional Society," https://oeisociety.com/ (Accessed 9/18/19).
5. "Ambulatory Surgical Center Payment System, Centers for Medicare & Medicaid Services, MLN Fact Sheet, January, 2019", https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/AmbSurgCtrFeepymtfctsht508-09.pdf (Accessed 9/18/19).
6. *Ibid.*
7. "Ambulatory Surgery Centers: A Positive Trend in Health Care," Ambulatory Surgery Center Association, 2013, http://higherlogicdownload.s3.amazonaws.com/ASCACONNECT/142533d1-73af-4211-9238-7f136c02de93/UploadedImages/About%20Us/ASCs%20-%20A%20Positive%20Trend%20in%20Health%20Care.pdf (Accessed 9/18/19).
8. *Ibid.*
9. *Ibid.*

of care and efficiencies provided at these facilities, derived from technological and surgical procedure innovations.[10] In particular, improved anesthesia and utilization of safe, minimally invasive techniques have driven this migration toward ASCs.[11] Patients report a preference for ASCs due to their lower copays, convenient locations, short wait times, and ease of scheduling.[12]

OBLs

OBLs, also known as office-based endovascular centers, access centers, or interventional office suites, are physician offices wherein several services are offered. Similar to ASCs, OBLs can be single or multi-specialty and can have many ownership structures. However, unlike ASCs, OBL procedures (because they are located in a physician's office) are reimbursed under the Medicare Physician Fee Schedule.[13]

OBLs are typically operated and utilized by vascular surgeons, interventional radiologists, cardiologists, or other specialists, and services provided include: cardiovascular, endovascular, venous, and non-vascular services; cardiac procedures, such as diagnostic coronary angiograms, coronary stenting, and electrophysiology services; device implants, including pacemakers, defibrillators, loop recorders, and biventricular pacers; lower extremity endovascular revascularizations, such as chronic total occlusion and complex limb salvage procedures; renal and mesenteric revascularizations; and, subclavian stenting.[14]

While slower to materialize than ASCs, OBLs have increased rapidly over the past few years, for reasons similar to ASCs, e.g., opportunities for physician ownership, the "expedient patient experience,"[15] and "favorable outpatient procedural reimbursement."[16]

REGULATORY CONSIDERATIONS[17]

It should be noted that, in some cases, outpatient facilities are operated as a hybrid, wherein the facility is utilized for ASC procedures on some days, and for OBL procedures on other days. In these situations, the (more stringent) regulations related to ASCs would control processes.

Stark Law

The Stark Law governs those physicians (or their immediate family members) who have a financial relationship (i.e., an ownership investment interest or a compensation arrangement) with an entity, and prohibits those individuals from making Medicare referrals to those entities for the furnishing of designated health services (DHS).[18] DHS encompasses the following items and services:

1. Clinical laboratory services
2. Physical therapy services
3. Occupational therapy services
4. Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services
5. Radiation therapy services and supplies
6. Durable medical equipment and supplies
7. Parenteral and enteral nutrients, equipment, and supplies
8. Prosthetics, orthotics, and prosthetic devices and supplies
9. Home health services
10. Outpatient prescription drugs
11. Inpatient and outpatient hospital services
12. Outpatient speech-language pathology services[19]

10. "Chapter 5 Ambulatory Surgical Center Services" In "Report to the Congress: Medicare Payment Policy" Medicare Payment Advisory Commission, March 2019, http://medpac.gov/docs/default-source/reports/mar19_medpac_ch5_sec.pdf?sfvrsn=0 (Accessed 9/18/19), p. 134.
11. "Ambulatory Surgery Centers: A Positive Trend in Health Care," Ambulatory Surgery Center Association, 2013, http://higherlogicdownload.s3.amazonaws.com/ASCACONNECT/142533d1-73af-4211-9238-7f136c02de93/UploadedImages/About%20Us/ASCs%20-%20A%20Positive%20Trend%20in%20Health%20Care.pdf (Accessed 9/18/19), p. 5.
12 "Ambulatory Surgery Centers: A Positive Trend in Health Care," Ambulatory Surgery Center Association, 2013, http://higherlogicdownload.s3.amazonaws.com/ASCACONNECT/142533d1-73af-4211-9238-7f136c02de93/UploadedImages/About%20Us/ASCs%20-%20A%20Positive%20Trend%20in%20Health%20Care.pdf (Accessed 9/18/19); "Chapter 5 Ambulatory Surgical Center Services" In "Report to the Congress: Medicare Payment Policy" Medicare Payment Advisory Commission, March 2019, http://medpac.gov/docs/default-source/reports/mar19_medpac_ch5_sec.pdf?sfvrsn=0 (Accessed 9/18/19), p. 134.
13. See, e.g., "Future of vascular surgery is in the office," By Krishna M. Jain, MD, et al., Journal of Vascular Surgery, Vol. 51 (February 2010), pp. 509–514.
14. "Office-Based Labs: AN Evolving Healthcare Model," By Jeffrey G. Carr, Cath Lab Digest, Vol. 25, Issue 11 (November 2017), https://www.cathlabdigest.com/article/Office-Based-Labs-Evolving-Healthcare-Model (Accessed 9/17/19).
15. "Treatment outcomes and lessons learned from 5134 cases of outpatient office-based endovascular procedures in a vascular surgical practice," By PH Lin, et al., Vascular, Vol. 25, No. 2 (April 2017), available at: https://www.ncbi.nlm.nih.gov/pubmed/27381926 (Accessed 9/18/19), pp. 115–22.
16. The Need for Accreditation of Office-Based Interventional Vascular Centers," By Peter H. Lin, et al., Annals of Vascular Surgery, Vol. 38 (January 2017), available at: https://www.sciencedirect.com/science/article/abs/pii/S0890509616306689 (Accessed 9/18/19), pp. 332–338.
17. Please note that the information provided in this article does not, and is not intended to, constitute legal advice; instead, all information and content are for general informational purposes only.
18. "Limitation on Certain Physician Referrals," 42 U.S.C. § 1395nn(a).
19. "Limitation on Certain Physician Referrals," 42 U.S.C. § 1395nn(h)(6)(A).

OBLs and ASCs are generally not subject to Stark Law restrictions, because they typically do not furnish DHS. However, in the event that the ASC/OBL is performing DHS (e.g., radiology services), and that Medicare does not reimburse DHS as part of a composite rate,[20] then any financial relationship between the physicians and the hospital, and their connection to the ASC/OBL, may be subject to Stark, the application of which regulations (and any appropriate exceptions) would be determined by the structure of the financial relationship between the parties (e.g., direct/indirect, compensation/ownership investment).

Anti-Kickback Statute

The Anti-Kickback Statute (AKS) makes it a felony for any person to "knowingly and willfully" solicit or receive, or to offer or pay, any "remuneration," directly or indirectly, in exchange for the referral of a patient for a healthcare service paid for by a federal healthcare program.[21] Of note, interpretation and application of the AKS under case law has created a precedent for a regulatory hurdle known as the one purpose test, under which healthcare providers violate the AKS if even one purpose of the arrangement in question is to offer remuneration deemed illegal under the AKS.[22]

Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited.[23] In response to these concerns, Congress created a number of statutory exceptions and delegated authority to the HHS to protect certain business arrangements by means of promulgating several safe harbors,[24] which set forth regulatory criteria that, if met, shield an arrangement from regulatory liability, and are meant to protect transactional arrangements unlikely to result in fraud or abuse.[25] Failure to meet all of the requirements of a safe harbor does not necessarily render an arrangement illegal.[26]

Under the AKS, ASCs and OBLs are treated differently. Specifically, ASCs meet AKS safe harbor provisions, which state that "'remuneration' does not include any payment that is a return on investment interest, such as a dividend or interest income, made to an investor," under certain circumstances. For example, the operating and recovery room space must be exclusively dedicated to the ASC, all patients referred to the entity by an investor must be fully informed of the investor's ownership interest, and all of the following applicable standards must be met within one of the categories outlined in Table 1.

20. The regulations specifically note that "DHS do not include services that are reimbursed by Medicare as part of a composite rate (for example, SNF Part A payments or ASC services identified at §416.164(a)), except to the extent that services listed in paragraphs (1)(i) through (1)(x) of this definition are themselves payable through a composite rate (for example, all services provided as home health services or inpatient and outpatient hospital services are DHS)." "Definitions" 42 C.F.R. § 411.351.
21. "Criminal Penalties for Acts Involving Federal Health Care Programs," 42 U.S.C. § 1320a-7b(b)(1).
22. "Re: OIG Advisory Opinion No. 15-10," By Gregory E. Demske, Chief Counsel to the Inspector General, Letter to [Name Redacted], July 28, 2015, https://oig.hhs.gov/fraud/docs/advisoryopinions/2015/AdvOpn15-10.pdf (Accessed 9/18/19), pp. 4–5; "U.S. v. Greber" 760 F.2d 68, 69 (3d Cir. 1985).
23. "Re: OIG Advisory Opinion No. 15-10," By Gregory E. Demske, Chief counsel to the Inspector General, Letter to [Name Redacted], July 28, 2015, https://oig.hhs.gov/fraud/docs/advisoryopinions/2015/AdvOpn15-10.pdf (Accessed 9/18/19), p. 5.
24. *Ibid.*
25. "Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute; Final Rule," Federal Register, Vol. 64, No. 223 (November 19, 1999), pp. 63518–63520.
26. "Re: Malpractice Insurance Assistance," By Lewis Morris, Chief Counsel to the Inspector General, United States Department of Health and Human Services, Letter to [Name redacted], January 15, 2003, http://oig.hhs.gov/fraud/docs/alertsandbulletins/MalpracticeProgram.pdf (Accessed 9/18/19), p. 1.

TABLE 1: ASC EXCEPTIONS TO THE AKS [27]

	A	B	C	D	E
	Category	Surgeon-Owned ASC	Single-Specialty ASC	Multi-Specialty ASC	Hospital/Physician ASC
1	Investor	General surgeons or surgeons engaged in the same surgical specialty, who are in a position to refer patients directly to the ASC and perform surgery on such referred patients;	Physicians engaged in the same medical practice specialty who are in a position to refer patients directly to the entity and perform procedures on such referred patients;	Physicians who are in a position to refer patients directly to the entity and perform procedures on such referred patients;	A hospital; and,
2		Surgical group practices comprised exclusively of such surgeons; or,	Group medical practices composed exclusively of such physicians; or,	Group medical practices composed exclusively of such physicians; or,	General surgeons or surgeons engaged in the same surgical specialty, who are in a position to refer patients directly to the ASC and perform surgery on such referred patients;
3		Individuals not employed by the ASC or any other investor, not in a position to provide items or services to the entity or any other investors, and not in a position to make or influence referrals directly or indirectly to the ASC or any other investors;	Individuals not employed by the ASC or any other investor, not in a position to provide items or services to the entity or any other investors, and not in a position to make or influence referrals directly or indirectly to the ASC or any other investors;	Individuals not employed by the ASC or any other investor, not in a position to provide items or services to the entity or any other investors, and not in a position to make or influence referrals directly or indirectly to the ASC or any other investors;	Physicians engaged in the same medical practice specialty who are in a position to refer patients directly to the entity and perform procedures on such referred patients;
4					Physicians who are in a position to refer patients directly to the entity and perform procedures on such referred patients;
5					Surgical group practices comprised exclusively of such surgeons;
6					Group medical practices composed exclusively of such physicians; or,
7					Individuals not employed by the ASC or any other investor, not in a position to provide items or services to the entity or any other investors, and not in a position to make or influence referrals directly or indirectly to the ASC or any other investors;

27. "Exceptions: Ambulatory Surgery Centers," 42 C.F.R. § 1001.952(r) (2015).

	A	B	C	D	E
	Category	Surgeon-Owned ASC	Single-Specialty ASC	Multi-Specialty ASC	Hospital/Physician ASC
8	Standards	The investment terms offered to an investor may not be tied to the previous or expected number of referrals, services furnished, or the amount of business for the entity otherwise generated by the investor;	The investment terms offered to an investor may not be tied to the previous or expected number of referrals, services furnished, or the amount of business for the entity otherwise generated by the investor;	The investment terms offered to an investor may not be tied to the previous or expected number of referrals, services furnished, or the amount of business for the entity otherwise generated by the investor;	The investment terms offered to an investor may not be tied to the previous or expected number of referrals, services furnished, or the amount of business for the entity otherwise generated by the investor;
9		At least one-third of the surgeon investor's practice income for the prior fiscal year or the prior twelve-month period must come from the surgeon's performance of procedures;	At least one-third of the surgeon investor's practice income for the prior fiscal year or the prior twelve-month period must come from the surgeon's performance of procedures;	At least one-third of the surgeon investor's practice income for the prior fiscal year or the prior twelve-month period must come from the surgeon's performance of procedures;	Neither the entity nor any investor can loan funds or guarantee a loan for an investor if the investor uses any portion of the loan to acquire the investment interest;
10		Neither the entity nor any investor can loan funds or guarantee a loan for an investor if the investor uses any portion of the loan to acquire the investment interest;	Neither the entity nor any investor can loan funds or guarantee a loan for an investor if the investor uses any portion of the loan to acquire the investment interest;	At least one-third of the procedures performed by each physician investor must be performed at the investment entity;	An investor's payment in return for their investment must be directly proportional to the amount of capital they invested;
11		An investor's payment in return for their investment must be directly proportional to the amount of capital they invested;	An investor's payment in return for their investment must be directly proportional to the amount of capital they invested;	Neither the entity nor any investor can loan funds or guarantee a loan for an investor if the investor uses any portion of the loan to acquire the investment interest;	The ASC, the hospital and any physician investors, must treat patients receiving medical benefits or assistance under any healthcare program in a nondiscriminatory manner;

	A	B	C	D	E
	Category	Surgeon-Owned ASC	Single-Specialty ASC	Multi-Specialty ASC	Hospital/Physician ASC
12		Ancillary services performed for beneficiaries of federal healthcare programs must be related to the primary procedures performed at the ASC, and may not be billed separately to Medicare or other federal healthcare programs; and,	Ancillary services performed for beneficiaries of federal healthcare programs must be related to the primary procedures performed at the ASC, and may not be billed separately to Medicare or other federal healthcare programs; and,	An investor's payment in return for their investment must be directly proportional to the amount of capital they invested;	The ASC may not use (1) space, including operating and recovery room space located in or owned by any hospital investor, unless the space lease complies with the space rental safe harbor; (2) equipment provided by any hospital investor, unless the equipment lease complies with the equipment rental safe harbor; nor (3) services provided by any hospital investor, unless the services contract complies with the personal services and management contracts safe harbor;

	A	B	C	D	E
	Category	Surgeon-Owned ASC	Single-Specialty ASC	Multi-Specialty ASC	Hospital/Physician ASC
13	Standards	The ASC and any investors must treat patients receiving medical benefits or assistance under any healthcare program in a nondiscriminatory manner.	The ASC and any investors must treat patients receiving medical benefits or assistance under any healthcare program in a nondiscriminatory manner.	Ancillary services performed for beneficiaries of federal healthcare programs must be related to the primary procedures performed at the ASC, and may not be billed separately to Medicare or other federal healthcare programs; and,	Ancillary services performed for beneficiaries of federal healthcare programs must be related to the primary procedures performed at the entity, and may not be billed separately to Medicare or other federal healthcare programs;
14				The ASC and any investors must treat patients receiving medical benefits or assistance under any healthcare program in a nondiscriminatory manner.	The hospital's report, or any other claim for payment from a federal healthcare program, may not include any costs associated with the ASC unless the federal healthcare program requires their inclusion; and,
15					The hospital cannot directly or indirectly make or influence referrals to any investor or entity.

Additionally, the above safe harbors are only available to those ASCs that meet the following statutory definition:

> "any distinct entity that operates exclusively to provide surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed twenty-four hours following an admission. The entity must have an agreement with CMS [Centers for Medicare and Medicaid Services] to participate in Medicare as an ASC…"[28]

Because no federal licensing is required to operate an OBL,[29] they would not be considered an ASC under the AKS (as defined above). Consequently, the specific facts and circumstances related to a given transaction, such as the structure of the hospital-physician joint venture and the various financial relationships included (e.g., OBL space rental, information technology), will guide the applicability of AKS, and its associated safe harbors.

CONCLUSION

The number of healthcare services provided at ASCs and OBLs continues to increase due in part to the rapidly evolving technological advances that allow many services and procedures to be performed in a safe, high quality, and, often, less costly environment than at many inpatient providers. However, this growth potential may be inhibited by the complex healthcare regulatory scheme that governs the formation, ownership, alignment, and transactions related to these outpatient entities. Consequently, the potential exists for healthcare entities to become subject to substantial penalties arising from their entrance into transactions and arrangements that may subsequently be found to be legally impermissible.

This presents an opportunity for valuation professionals to work with healthcare providers considering a potential transaction, as well as healthcare legal counsel, to ensure that prospective transactions and arrangements comply with current laws, as well as satisfy applicable regulatory thresholds. Providers may feel more comfortable with also obtaining a certified opinion prepared in compliance with professional standards by an independent credential valuation professional (under the advice of legal counsel) and supported by adequate documentation as to whether each of the proposed elements of the transaction are both at fair market value and commercially reasonable, so as to establish a risk-averse, defensible position that the transactional arrangement can withstand regulatory scrutiny. VE

28. "Definitions," 42 U.S.C. § 416.2.
29. See "Facts about Office-Based Surgery Accreditation," The Joint Commission, February 16, 2018, https://www.jointcommission.org/facts_about_office-based_surgery_accreditation/ (Accessed 9/18/19).

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