Valuation of Ambulatory Surgery Centers

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National Association of Certified Valuators and Analysts

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Regulatory (Part IV of V)

As noted in the first installment of this five-part series, an ambulatory surgery center (ASC) is a distinct entity that primarily provides outpatient surgical procedures to patients who do not require an overnight stay after the procedure. ASCs typically provide relatively uncomplicated surgical procedures in a non-hospital, outpatient setting, and most ASC cases are non-emergency, noninfected, and elective. This fourth installment will discuss the regulatory environment in which ASCs operate.

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As noted in the first installment of this five-part series, an ambulatory surgery center (ASC) is

a distinct entity that primarily provides outpatient surgical procedures to patients who do not require an overnight stay after the procedure.[1] ASCs typically provide relatively uncomplicated surgical procedures in a non-hospital, outpatient setting, and most ASC cases are non-emergency, noninfected, and elective.[2] This fourth installment will discuss the regulatory environment in which ASCs operate.

Federal Fraud and Abuse Laws

The Anti-Kickback Statute (AKS) and the Stark Law are generally concerned with the same issue: the financial motivation behind patient referrals. However, while the AKS is broadly applied to payments between any healthcare industry actor and relates to any item or service that may be paid for under any federal healthcare program, the Stark Law specifically addresses the referrals from physicians to entities with which the physician has a financial relationship for the provision of defined services that are paid for by Medicare or Medicaid.[3] Additionally, while violation of the Stark Law carries only civil penalties, violation of the AKS carries both criminal penalties (up to a five-year prison term per violation) and civil penalties.[4] It is also important to note that many states also have âbabyâ Stark and AKS laws, which are more restrictive than their federal counterparts.[5]

AKS

The AKS makes it a felony for any person to âknowingly and willfullyâ solicit or receive, or to offer or pay, any âremuneration,â directly or indirectly, in exchange for the referral of a patient for a healthcare service paid for by a federal healthcare program.[6] Of note, interpretation and application of the AKS under case law has created a precedent for a regulatory hurdle known as the âone purposeâ test, under which test healthcare providers violate the AKS if even one purpose of the arrangement in question is to offer remuneration deemed illegal under the AKS.[7]

The Patient Protection and Affordable Care Act (ACA) made two additional changes to the intent standards related to the AKS. First, the legislation amended the AKS by stating that a person need not have actual knowledge of the AKS or specific intent to commit a violation of the AKS for the government to prove a kickback violation.[8] However, the ACA did not remove the requirement that a person must âknowingly and willfullyâ offer or pay remuneration for referrals in order to violate the AKS.[9] Therefore, in order to prove a violation of the AKS, the government must show that the defendant was aware that the conduct in question was âgenerally unlawful,â but not that the conduct specifically violated the AKS.[10] Second, the ACA provided that a violation of the AKS is sufficient to state a claim under the False Claims Act (FCA).[11] The amended AKS points out that liability under the FCA is â[i]n addition to the penalties provided for in [the AKS]â¦â[12] This suggests that in addition to civil monetary penalties paid under the AKS, violation of the AKS would create additional liability under the FCA, which itself carries civil monetary penalties of over $21,500 plus treble damages.[13]

Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited.[14] Â In response to these concerns, Congress created a number of statutory exceptions and delegated authority to the U.S. Department of Health and Human Services (HHS) to protect certain business arrangements by means of promulgating several safe harbors,[15] 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.[16] Failure to meet all of the requirements of a safe harbor does not necessarily render an arrangement illegal.[17]

Under the AKS, ASCs are treated differently. ASCs must meet specific AKS safe harbor provisions: the entity must be certified in accordance with applicable regulations; the entityâs 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 investorâs ownership interest; and, all the following applicable standards must be met within one of the following categories set forth in the table below.**Â**

Table: ASC Exceptions to the AKS[18]

	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

4					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,
	A	B	C	D	E
	Category	Surgeon-Owned ASC	Single-Specialty ASC	Multi-Specialty ASC	Hospital/Physician ASC
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
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 12-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 12-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 12-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
			Single-Specialty		Hospital/Physician

	Category	Surgeon-Owned ASC	ASC	Multi-Specialty ASC	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;
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.

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).[19] DHS encompasses the following items and services:

- Clinical laboratory services;
- Physical therapy services;
- Occupational therapy services;
- Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services;
- Radiation therapy services and supplies;
- Durable medical equipment and supplies;
- Parenteral and enteral nutrients, equipment, and supplies;
- Prosthetics, orthotics, and prosthetic devices and supplies;
- Home health services;
- Outpatient prescription drugs;
- Inpatient and outpatient hospital services; and,
- Outpatient speech-language pathology services.[20]

ASCs are generally not subject to Stark Law restrictions, because they typically do not furnish DHS. However, in the event that the ASC is performing DHS (e.g., radiology services), and that DHS is not reimbursed by Medicare as part of a composite rate,[21] then any financial relationship between the physicians and the hospital, and their connection to the ASC, 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).

Certificate of Need

Certificate of Need (CON) laws present market entry barriers for potential ASCs.[22] CON programs have the major goal of controlling costs by restricting provider capital expenditures.[23] The rationale behind CON laws mainly originates from the belief that healthcare does not operate like other markets to correct excess supply, and healthcare is plagued by market failures resulting in excess supply and needless duplication of some services, causing overall costs to rise.[24]

ASCs located in a state with a CON law must complete a regulatory review process in order to obtain a certificate.[25] Currently, 27 states have CON laws relating to the opening of an ASC.[26] Of note, states without CON laws restricting the formation of ASCs have slightly more ASCs per 100,000 individuals on average than states with CON laws restricting ASCs.[27]

Future Regulatory Trends

In October 2019, the Centers for Medicare and Medicaid Services (CMS) published proposed rules related to the Stark Law and AKS,[28] outlining significant modernization and clarification of these fraud and abuse laws. While the timeline for finalizing these rule

changes remain unclear, their impact on ASCs may be minimal as the Stark Law generally does not apply to ASCs, and the AKS proposed rule did not modify the exceptions related to ASCs.

It is important to note that, despite the stance of the current presidential administration toward de-regulating healthcare,[29] the regulatory scrutiny of healthcare entities (especially regarding fraud and abuse violations) has generally increased in recent years. Due to the nature of AKS, and its criminal and civil penalties, disregarding federal and state regulation of the ASC industry may result in more than an unassuming fine. With the level of regulation of the ASC industry intensifying,[30] ASC operators increasingly need to pay heed to current regulations and understand how future regulatory developments may affect the industry going forward.

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[1] âChapter 5: Ambulatory Surgical Center Servicesâ in âReport to Congress: Medicare Payment Policyâ Medicare Payment Advisory Commission, March 2019, p. 127â129.

[2] âAmbulatory surgical centers: Development and managementâ By Thomas R. O'Donovan, Aspen Systems Corp, 1976, p. xiv.

[3] âCOMPARISON OF THE ANTI-KICKBACK STATUTE AND STARK LAWâ Office of Inspector General, 2019, https://oig.hhs.gov/compliance/provider-compliance-training/files/StarkandAKSChartHandout508.pdf (Accessed 10/16/19).

[4] Ibid.

[5] *See* âState Health Care Fraud Law: An AHLA 50-State Survey with Summaries and Linksâ American Health Lawyers Association Fraud and Abuse Practice Group: Washington, D.C., September 9, 2018, available at: https://www.healthlawyers.org/store/Pages/Product-Details.aspx?productid=%7B3B609F69-E8B1-E811-80DF-0050569E287F%7D (Accessed 12/3/19).

[6] âCriminal Penalties for Acts Involving Federal Health Care Programsâ 42 U.S.C. Â§ 1320a-7b(b)(1).

[7] âRe: OIG Advisory Opinion No. 15-10â 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 10/15/19), p. 4-5; âU.S. v. Greberâ 760 F.2d 68, 69 (3d Cir. 1985).

[8] âHealth Care Reform: Substantial Fraud and Abuse and Program Integrity Measures Enactedâ McDermott Will & Emery, April 12, 2010, p. 3; âPatient Protection and Affordable Care Act,â Pub. L. No. 111-148, Â§ 6402, 124 Stat. 119, 759 (March 23, 2010).

[9] âHealth Care Fraud and Abuse Laws Affecting Medicare and Medicaid: An Overviewâ By Jennifer A. Staman, Congressional Research Service, September 8, 2014, https://www.fas.org/sgp/crs/misc/RS22743.pdf (Accessed 10/16/19), p. 5.

[10] Ibid.

[11] âHealth Care Reform: Substantial Fraud and Abuse and Program Integrity Measures Enactedâ McDermott Will & Emery, April 12, 2010, p. 3; âPatient Protection and Affordable Care Act,â Pub. L. No. 111-148, Â§ 6402, 124 Stat. 119, 759 (March 23, 2010).

[12] âLiability under subchapter III of chapter 37 of title 31â 42 U.S.C. Â§ 1320a-7b(g) (2013).

[13] âFalse claimsâ 31 U.S.C. Â§ 3729(a)(1) (2013).

[14] âRe: OIG Advisory Opinion No. 15-10â 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 10/15/19), p. 5.

[15] Ibid.

[16] âMedicare 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 Ruleâ Federal Register, Vol. 64, No. 223 (November

19, 1999), p. 63518-63520.

[17] âRe: Malpractice Insurance Assistanceâ 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 10/15/19), p. 1.

[18] âExceptions: Ambulatory Surgery Centersâ 42 C.F.R. Â§ 1001.952(r) (2015).

[19] âLimitation on Certain Physician Referralsâ 42 U.S.C. Â§ 1395nn(a).

[20] âLimitation on Certain Physician Referralsâ 42 U.S.C. Â§ 1395nn(h)(6)(A).

[21] The regulations specifically note that âDHS 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 Â§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).â âDefinitionsâ 42 C.F.R. Â§ 411.351.

[22] âIBISWorld Industry Report 0D5971 Ambulatory Surgery Centers in the USâ By Dmitry Diment, IBISWorld, August 2019, p. 22.

[23] âChapter 8: Miscellaneous Subjectsâ Department of Justice, June 25, 2015, https://www.justice.gov/atr/chapter-8-miscellaneous-subjects#1a (Accessed 10/15/19).

[24] Ibid.

[25] âIBISWorld Industry Report 0D5971 Ambulatory Surgery Centers in the USâ By Dmitry Diment, IBISWorld, August 2019, p. 22.

[26] âCON-Certificate of Need State Lawsâ National Conference of State Legislatures, February 28, 2019, http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx (Accessed 10/11/19).

[27] âCON versus non-CON states: Which regions boast more Medicare-certified ASCs?â By Mary Rechtoris, Beckerâs ASC Review, June 15, 2017, https://www.beckersasc.com/asc-coding-billing-and-collections/con-versus-non-con-states-which-regions-boast-more-medicare-certified-ascs.html (Accessed 10/15/19).

[28] For more information, see: âProposed Stark Law Changes: Healthcare Valuation Implicationsâ Health Capital Topics, Vol. 12, Issue 10 (October 2019), available at: https://www.healthcapital.com/hcc/newsletter/10_19/PDF/STARK.pdf (Accessed 12/16/19).

[29] âExecutive Order Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repealâ The White House, January 20, 2017, Federal Register Vol. 82, No. 14, p. 8351â8352.

[30] âIBISWorld Industry Report 0D5971 Ambulatory Surgery Centers in the USâ By Dmitry Diment, IBISWorld, August 2019, p. 29.