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Something Ventured: The Continued Scrutiny of ASC-Anesthesia Joint Ventures

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It has been over four years since the U.S. Department of Health and Human Services' (HHS) Office of Inspector General (OIG) issued its landmark advisory opinion pertainin to the Anti-Kickback Statute (AKS) implications of various joint ventures between anesthesia providers and physician-owned ambulatory surgical centers (ASCs). In that advisory opinion, the OIG called into question (and for all intents and purposes, prohibited) the "company model" of ASC-anesthesia revenue sharing, a model that hac long been blessed by experienced healthcare attorneys nationwide. The advisory opinic not only initiated a shift in the advice provided by healthcare regulatory attorneys to their ASC and anesthesia client but also resulted in an increased level of scrutiny by both the OIG and the Department of Justice (DOJ), a trend that has continued through today with no obvious end in sight. As a result, many anesthesia companies and their ASC partners now find themselves in the government's crosshairs due to various types of revenue-sharing ventures.

This increased attention from the government stems, at least in part, from the fact that those in the anesthesiology business rely heavily on patient referrals – that is, unlike the services provided by other types of healthcare provide (e.g., hospitals, physician groups, or ASCs), the need for anesthesia services typically arises only in conjunction witl services performed by another provider. Because anesthesia providers are so reliant on referrals, almost any monet arrangement between an anesthesia provider and the entity for which the anesthesia provider performs services cou implicate the AKS and elicit government scrutiny.

This article provides a brief overview of the regulatory framework surrounding these ASC-anesthesia joint ventures and revenue-sharing models. Moreover, the article serves to provide guidance as to what the government considers suspect agreement for anesthesia services.

I. Background: ASCs and Anesthesia

As defined in the Medicare regulations, an ASC is "a distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission."[1] Prior to 1970, when the first ASC opened in Phoenix, Arizona, physicians performed nearly all surgeries in hospitals.[2] As noted by the Ambulatory Surgery Center Association, on t Phoenix center's first day, five physicians performed five procedures, four of which required general anesthesia.[3] By 1973, the American Medical Association had adopted a resolution endorsing the performance of certain surgical procedures under general anesthesia in the outpatient setting, and the American Society of Anesthesiologists had released "Guidelines for Ambulatory Surgical Facilities" to set some initial industry standards.[4] By 2011, the number ASCs had grown to 5,300 nationwide, and Medicare had granted approval for ASCs to perform over 3,500 procedure

ASCs participating in the Medicare program receive payment under Medicare Part B for services furnished to Medica beneficiaries at the ASC in connection with Medicare-covered surgical procedures.[6] Under the ASC payment system,

Medicare makes packaged facility payments to ASCs for the specific ASC covered surgical procedures on the ASC list covered surgical procedures, and separately pays ASCs "for certain covered ancillary services that are provided integral to a covered ASC surgical procedure."[7] Importantly, pursuant to Chapter 14 of the Centers for Medicare & Medicaid Services' (CMS) Medicare Claims Processing Manual, "ASCs must accept Medicare's payment as payment in full for services with respect to those services defined as ASC services."[8] However, both the physician and the anesthesiologist can bill for the professional component of their respective services.[9]

The regulations provide a specific (albeit non-exhaustive) list of ASC services intended to be included in and covered by Medicare's ASC facility fee payment, as well as a list of ancillary services for which separate payment may be allowed.[10] In addition to, *inter alia*, items and services such as laboratory testing, equipment, surgical dressings, nursing and technician services, and administrative, recordkeeping, and housekeeping services, the prospectively-determined bundled facility fee covers "[m]aterials, including supplies and equipment for the administration and monitoring of anesthesia."[11]

II. Previous OIG Guidance Regarding Joint Ventures and the AKS

The AKS makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a federal healthcare program, and defines "remuneration" broadly to include the transfer of anything of value.[12] A violation of the AKS can also lead to liability under the False Claims Act (FCA)[13] and the Civil Monetary Penalties Law (CMPL),[14] as well as exclusion from federal healthcare programs.[15] Despite any past or ongoing scrutiny on the part of the government, however, joint venture arrangements between various healthcare providers are often permissible and do not automatically implicate (much less violate) the AKS.

The term "joint venture" does not have an express definition in statute or regulation; however, in a 1989 Special Fraud Alert (published in the Federal Register in 1994), the OIG noted that "[a] joint venture may take a variety of forms: it may be a contractual arrangement between two or more parties to cooperate in providing services, or it may involve the creation of a new legal entity by the parties, such as a limited partnership or closely held corporation, to provide such services."[16] Although the AKS does not expressly prohibit joint venture arrangements, the distinction between normal investment proceeds from the joint venture and prohibited remuneration often proves difficult. For that reason, the OIG established in the Special Fraud Alert certain factors that may assist in identifying a "suspect" arrangement:

1. Investors are chosen because they are in a position to make referrals;
2. Physicians who are expected to make a large number of referrals may be offered a greater investment opportunity in the joint venture than those anticipated to make fewer referrals;
3. Physician investors may be actively encouraged to make referrals to the joint venture, and may be encouraged to divest their ownership interest if they fail to sustain an "acceptable" level of referrals;
4. The joint venture tracks its sources of referrals, and distributes this information to the investors;
5. Investors may be required to divest their ownership interest if they cease to practice in the service area, for example, if they move, become disabled, or retire;
6. Investment interests may be non-transferable.[17]

Additionally, the OIG said it would also consider factors pertaining to the structure, financing, and profit distribution of the joint venture. Factors relevant to these aspects include:

1. Whether the joint venture business has its own separate location, distinct from the business location of any of the joint venture investors;
2. Whether the investment of capital is disproportionate, such that those investors who also make referrals to the venture have much less invested in the venture than other investors;
3. Whether the investors who can control patient referrals are allowed to "borrow" their investment capital from other investors or from the venture itself; and
4. Whether the investment returns are extraordinary.[18]

Thus, one of the key aspects of a well-structured healthcare joint venture is that payments to investors are directly proportional to their capital investments.

More recently, in 2003 the OIG issued a Special Advisory Bulletin relating to contractual joint ventures.[19] Citing to its previous Special Fraud Alert, the OIG recognized the continued proliferation of contractual joint venture arrangements between healthcare providers and the need for further guidance. The agency underscored certain "questionable contractual arrangements" in which "a health care provider in one line of business (hereafter referred to as the

'Owner') expands into a related health care business by contracting with an existing provider of related item or serv (hereafter referred to as the 'Manager/Supplier') to provide the new item or service to the Owner's existing patient population," including Medicare and Medicaid patients.[20]

As it had done previously, the OIG again noted the "common elements" typical of such problematic arrangements:

1. Owner expands into a related line of business, which is dependent on referrals from, or other business generated by, the Owner's existing business.[21]
2. Owner neither operates the new business itself nor commits substantial financial, capital, or human resources to the venture, and instead contracts out substantially all of the operations of the new business to the Manager/Supplier; however, while the Manager/Supplier essentially operates the business, the billing of insurers and patients is done in name of the Owner.
3. Manager/Supplier is an established provider of the same services as Owner's new line of business and would otherwise be a competitor of the new business, providing items ar services in its own right, billing insurers and patients in its own name, and collecting reimbursement.
4. Owner and Manager/Supplier share in the economic benefit of the Owner's new business; Manager/Supplier takes its share in the form of payments under the various contract with Owner, and Owner receives its share in the form of the residual profit from the new business.
5. Aggregate payments to the Manager/Supplier typically vary with the value or volume of business generated for the new business by the Owner. Although some arrangements certain fixed payments, other payments (such as payments for goods and services supplied by Manager/Supplier) will vary based on the number of goods and services provide thus, the aggregate payment to the Manager/Supplier from the whole arrangement will vary with referrals from the Owner.[22]

As discussed below, these factors play a critical role in the OIG's evaluation of agreements between ASCs and anesthesiologists.

III. OIG Advisory Opinion 12-06

In May 2012, the OIG issued Advisory Opinion 12-06, which specifically addressed certain concerns the requestors h with anesthesia arrangements in connection with ASCs.[23] The OIG concluded that each of the two anesthesia arrangements proposed by the requestors posed a heightened risk of fraud and abuse.[24]

The first proposed arrangement involved payment by the anesthesia group of a per-patient fee to the ASCs in retur for "management services" from the ASCs.[25] The fee would cover the cost of certain ASC expenses (e.g., preoperat nursing assessments, space for the requestor's physicians and records); however, the OIG concluded that such expenses were already included in the facility fees paid to the ASCs by private payors and Medicare.[26] As such, the OIG opined that the "management services" fee constituted double billing and was in violation of the AKS.[27]

The OIG then analyzed a second proposed arrangement whereby the anesthesia group would provide anesthesia services to a subsidiary established by each of the ASCs, which in turn would bill third-party payors for those same anesthesia services.[28] Under this arrangement, commonly referred to as the "company model," the subsidiaries wou either be owned directly by the ASCs or by the physician-owned LLCs or PCs that own the ASCs.[29] In turn, the subsidiary would engage the anesthesia group as an independent contractor to provide the anesthesia services to th ASCs or employ the anesthesiologists/CRNAs.[30] The anesthesia group would be paid a negotiated rate for its service out of the subsidiary's collections from Medicare/Medicaid and private payors for anesthesia-related services.[31] Importantly, the subsidiary would retain the profits from its anesthesia services business.[32]

In analyzing the company model, the OIG opined that the arrangement was designed to "do indirectly what [the parties] cannot do directly" – that is, permit the ASCs' physician owners "to receive compensation in the form of a portion of the [anesthesia group's] anesthesia services revenues, in return for their referrals to the [anesthesia group]."[33] Moreover, the OIG noted that no safe harbor would protect the remuneration the subsidiary would distribute to the ASCs' physician owners.[34]

The OIG also noted that the company model arrangement was substantially similar to the suspect "contractual joint ventures" described in its 2003 Special Advisory Bulletin (outlined above).[35] The OIG concluded that ASC physician owners would be in the same position as the Bulletin's hypothetical "Owner," and the anesthesia group would likewis be in the same position as the hypothetical "Manager/Supplier."[36] Like the Owner, the ASCs' physician owners woul seek to branch out into a related line of business (anesthesia services) with a minimum of risk and investment.[37] Meanwhile, the anesthesia group, otherwise in a position to compete with the physician owners and able to provide and bill for anesthesia services in its own right, would effectively operate and manage the anesthesia business of th subsidiaries.[38] Thus, because the anesthesia group is essentially giving up profits that would otherwise inure solely

its benefit, the OIG concluded that the only reason to give up such profits would be to exchange them for the ASCs' patient referrals, on which the anesthesia group is dependent for business.[39]

In sum, the OIG culled out the two major issues that should be avoided in all ASC-anesthesia relationships: (1) "pay to-play," wherein an anesthesia group pays an ASC for the exclusive right to provide anesthesia services; and (2) "double dipping," wherein the ASC requires the anesthesia group to incur the cost of drugs and other supplies that a intended to be covered by the ASC facility fee and for which the ASC is reimbursed.

IV. Continued Scrutiny of ASC-Anesthesia Arrangements after 12-06

a. *Anesthesia's Response*

In the years leading up to the OIG's publication of Advisory Opinion 12-06, the anesthesia community had been working diligently to get the OIG's attention regarding the company model, a model the anesthesia community was solidly against. The American Society of Anesthesiologists (ASA) wrote multiple letters to the OIG, concerned that th then-current trend was of physician-owned facilities moving away from the traditional fee-for-service model and "turning to the company model and related arrangements to capture the revenue stream from their referrals for anesthesia services."[40] Believing these arrangements to be "fraudulent and abusive," the ASA's letters requested th the OIG issue a Special Fraud Alert on the issue and to state outright that such practices would be subject to scrutin under the AKS.[41]

Even after the OIG issued 12-06, the ASA remained concerned. In February 2014, the organization again wrote to th OIG, this time requesting a Special Fraud Alert and modifications to existing safe harbors "to make clear that [the sa harbors] do not protect these elaborate schemes."[42] Alleging that "[t]hese 'fraudulent and abusive' practices continu unabated," the ASA cited data from its 2013 survey of some of its 52,000 anesthesiologist members.[43] Notably, the ASA informed the OIG that over half of the survey's respondents had received a "company model" request at a facili where the anesthesiologists were already providing services.[44] Moreover, said the ASA, of those that received such request and rejected it, 42.5 percent lost their contract to practice at that location.[45]

b. *U.S.* ex rel. *Florida Society of Anesthesiologists v. Choudhry*

In an October 2013 FCA *qui tam* complaint (unsealed in March 2016 after the federal government declined to intervene), the Florida Society of Anesthesiologists (FSA) accused more than 50 physicians, anesthesiology compani and ASCs of engaging in illegal kickback schemes by sharing revenues under a company model.[46] Citing directly to Advisory Opinion 12-06, the FSA stated in its complaint that "[t]he sharing of profits led to overutilization of anesthesia, as well as potential harm to the patients who would not normally have received anesthesia services."[47]

In a motion to dismiss filed in June 2016, one of the defendants summarizes the FSA's (and its own) position:

> The [FSA's] real grievance appears to be its belief that all the defendants "have a captive patient base as a result of their practices, unlike anesthesiologists who depend for their practice solely on referrals" and that this reality "threatens the independence of anesthesiology." . . . But a gripe about the way health care providers deliver anesthesia services in surgery centers does not amount to a violation of the FCA [].[48]

Citing to Advisory Opinion 12-06, the Motion to Dismiss argues that the FSA's complaint "is improperly premised on Advisory Opinion from the [OIG]. Consistent with being 'advisory,' the Advisory Opinion states on its face that it 'ma not be relied on' by anyone other than the requester who sought it."[49]

Although the defendants' motions to dismiss are still pending before the District Court for the Middle District of Flori and although the government declined to intervene, the outcome in *Choudhry* could prove to have a significant and lasting impact on the weight afforded to Advisory Opinion 12-06 and the government's decision whether or not to continue to target ASC-anesthesia company model arrangements moving forward.

c. *Sweet Dreams Nurse Anesthesia Settlement*

More recently, on August 5, 2016, the DOJ issued a press release announcing a more than $1 million settlement wit Sweet Dreams Nurse Anesthesia (Sweet Dreams) to resolve allegations that the anesthesia company had violated th AKS and, therefore, the FCA.[50] The press release described two kickback schemes alleged by the government. The first allegation concerned Sweet Dreams' "provision of free anesthesia drugs to [ASCs] in exchange for the ASCs

granting Sweet Dreams an exclusive contract to provide anesthesia services at those ASCs."[51] If true, the governme would likely view this arrangement as "double dipping," one of the OIG's main concerns outlined in Advisory Opinior 12-06. As discussed above, the Medicare regulations provide that drugs are included in the ASC facility fee payment Moreover, the Medicare Claims Processing Manual states that ASCs must accept the facility fee as payment in full.[53] Thus, if anesthesia drugs are needed, the government expects the ASC to use the facility fee money to purchase them; according to the government, if the anesthesia company pays for the drugs instead, this would constitute illeg remuneration under the AKS.

The second alleged scheme discussed in the DOJ's Sweet Dreams press release pertained to "the agreement of an affiliate of Sweet Dreams to fund the construction of an ASC . . . in exchange for contracts for Sweet Dreams' select as the exclusive anesthesia provider at that facility and a number of other podiatry-based ASCs affiliated with [the A funded by Sweet Dreams]."[54] Such an arrangement, if entered into by any anesthesia company with any ASC, woul be viewed by the government as a "pay-to-play" scenario – the second of the OIG's main concerns in Advisory Opin 12-06.

Settled four years after the issuance of Advisory Opinion 12-06, the Sweet Dreams matter serves as a strong indication that the federal government will continue to seek to target ASCs and anesthesiologists engaged in compa model or similar revenue-sharing model arrangements.

V. Avoiding Improper ASC-Anesthesia Arrangements

Despite the continued level of scrutiny over such arrangements, and despite the OIG's renouncement of the anesthe company model in Advisory Opinion 12-06, potential models still exist for ASCs seeking to enter into a mutually beneficial contractual arrangement with an anesthesia provider.

a. *Traditional Model*

Under the traditional model, the ASC bills for the facility fee, the ASC surgeons bill for their professional fees, and th anesthesia group bills for its professional anesthesia services. Here, the ASC has no interest in profiting from anesthesia services and is contracting for such services solely to create efficiencies and increase patient satisfaction, which may ultimately help to attract more business. Although this model does not entail any actual compensation, t ASC physician owners should still remain wary of double dipping – that is, the ASC should ensure that it is incurring of the costs for any anesthesia-related drugs and equipment reimbursed under the ASC facility fee.

This is the simplest ASC-anesthesia model in that, because no remuneration is passed between the parties, the arrangement does not implicate the AKS (absent the double dipping issue described above) and therefore does not require a safe harbor analysis.

b. *Employment/Independent Contractor Model*

Under this model, the ASC engages the anesthesiologists in either a direct employment or independent contractor arrangement. The anesthesia group reassigns to the ASC its right to bill and collect for professional anesthesia services, and the ASC enrolls in Medicare as a group practice and bills for anesthesia. This allows the ASC physician owners to have substantial flexibility in compensating the anesthesia provider, and allows the income from anesthes services to be distributed to all physician owners. Moreover, the AKS safe harbors for bona fide employment[55] or for personal services and management contracts[56] would apply to any compensation paid to the anesthesiologists if properly structured.

VI. Conclusion

Arrangements between ASCs and anesthesia providers have been heavily scrutinized in the last four years, no more than in the OIG's Advisory Opinion 12-06, and that trend shows no sign of ending any time soon. By challenging the validity of the ASC-anesthesia revenue-sharing models such as the company model, the OIG significantly changed t way that healthcare lawyers think about these arrangements. In the wake of 12-06, the DOJ, private *qui tam* litigan and anesthesia associations are working to enforce the OIG's opinion and do away with such practices. To avoid individual scrutiny, ASCs and anesthesiologists alike must remain wary of how they handle their relationships with o another moving forward.

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1 42 C.F.R. § 416.2; *see also* Centers for Medicare & Medicaid Services, Medicare Claims Processing Manual Ch. 14, Sec. 10.1 (Rev. 3031, Sept. 23, 2014), *available at* https://www.cms.gov/Regulations-and-Guida

2 Ambulatory Surgery Center Association (ASCA), "History of ASCs," http://www.ascassociation.org/advanc 26, 2016).

3 *Id.*

4 *Id.*

5 *Id.*

6 42 C.F.R. § 416 *et seq.*; Claims Processing Manual, *supra* note 1.

7 *See* 42 C.F.R. §§ 416.163, 416.164.

8 Claims Processing Manual, *supra* note 1.

9 *Id.*

10 42 C.F.R. § 416.164.

11 *Id.*

12 42 U.S.C. § 1320a-7b(b).

13 *Id.* § 1320a-7b(g).

14 42 U.S.C. § 1320a-7a(a)(7).

15 42 U.S.C. § 1320a-7(b)(7).

16 59 Fed. Reg. 65372, 65373 (Dec. 19, 1994).

17 *Id.*

18 *Id.*

19 68 Fed. Reg. 23148 (April 30, 2003).

20 *Id.* at 23148.

21 *Id.* at 23149 ("The new business line may be organized as a part of the existing entity or as a separate su Owner's existing patient base.").

[22] *Id.*

[23] OIG Advisory Opinion No. 12-06 (May 25, 2012).

[24] As with all Advisory Opinions, Advisory Opinion 12-06 did not conclude that the arrangements *did, in fact,* could. *Id.*

[25] *Id.*

[26] *Id.*

[27] *Id.*

[28] *Id.*

[29] *Id.*

[30] *Id.*

[31] *Id.*

[32] *Id.*

[33] *Id.*

[34] For example, because the subsidiary would not provide surgical services, the profits paid to the ASC phys harbor. *Id.*

[35] *Id.*

[36] *Id.*

[37] *Id.*

[38] *Id.*

[39] *Id.*

[40] Letter from Jane C.K. Fitch, M.D., President, American Society of Anesthesiologists, to Daniel R. Levinson, 2014) (citing to previous letters in footnote), *available at*

https://www.asahq.org/~/media/sites/asahq/files/public/resources/practice%20management/201

[41] *Id.*

[42] *Id.*

[43] *Id.*

[44] *Id.*

[45] *Id.*

[46] Case No. 8:13-cv-2603-T-27AEP (M.D. Fl.).

[47] *Id.*

[48] Defendants Jax Anesthesia Providers, LLC, Southpoint Anesthesia, LLC, and Borland-Groover Clinic, P.A.'s Complaint, Case No. 8:13-cv-2603-T-27AEP (M.D. Fl. June 17, 2016).

[49] *Id.*

[50] Department of Justice, "Sweet Dreams Nurse Anesthesia Group Pays More Than $1 Million to Resolve Kick https://www.justice.gov/usao-mdga/pr/sweet-dreams-nurse-anesthesia-group-pays-more-1-million-resol

[51] *Id.*

[52] 42 C.F.R. § 416.164.

[53] Claims Processing Manual, *supra* note 1.

[54] DOJ Press Release, *supra* note 50.

[55] 42 C.F.R. § 1001.952(i) ("'[R]emueration does not include any amount paid by an employer to an employ employer, for employment in the furnishing of any item or service for which payment may be made in wh health care programs.").

[56] *Id.* at § 1001.952(d) (stating that "remuneration" does not include "any payment made by a principal to a the parties; (2) the agreement covers all of the services to be provided by the agent for the term of the a for at least one year; (4) compensation to the agent is fair market value and does not take into account t generated between the parties; (6) the services performed under the agreement do not involve counselin the services contracted for are commercially reasonable).