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An Update on the ‘Company Model’ and Other Anesthesia Kickback Schemes

Mark F. Weiss, JD
The Mark F. Weiss Law Firm, Dallas, TX, Los Angeles and Santa Barbara, CA

Kickbacks in healthcare are rarely (but *not* never) as blatant as an envelope of cash passed under the table. But they do exist in many forms and settings.

When asked why he robbed banks, the notorious criminal Willie Sutton reputedly responded, “Because that’s where the money is.” Referring physicians, quite often but not always the owners of facilities, and facilities themselves, might seek a share of anesthesia fees for the same reason. But instead of using a gun, they turn to less violent but still violative devices, one of which is the so-called “company model” of anesthesia services. Others include questionable management services deals and expense-shifting arrangements.

Warning: unlike a bank robbery, the compliance issues cut both ways. The intentional submission to kickback demands is a crime. So, too, are schemes in which anesthesia providers propose kickbacks to obtain referrals.

The Key Compliance Issue

The federal anti-kickback statute (AKS) prohibits the offer of, demand for, payment of, or acceptance of any remuneration for referrals of patients whose care is covered by federal healthcare programs such as Medicare, Medicaid and Tricare (among many others).

There are exceptions, known as “safe harbors,” that describe certain arrangements not subject to the AKS because they are unlikely to result in fraud or abuse. The ability to fit within a safe harbor is voluntary. In other words, the failure to qualify for a safe harbor is not fatal for the parties to the arrangement; rather, a detailed analysis of the statute itself and of the facts of the deal is then required.

Company Model Arrangements

Let’s begin with a quick primer on the company model. In its most direct form, the company model involves the formation, by the surgeon-owners of an ambulatory surgery center (ASC), of an anesthesia services company to provide all of the anesthesia services for the center.

In the typical scenario, prior to the formation of the company, all anesthesia services were provided by anesthesiologists, alone or in concert with CRNAs, either for their separate accounts or for the account of their anesthesia group. After the formation of the company, the anesthesiologists and CRNAs are employed or subcontracted by the company, with a significant share of the anesthesia fee being redirected to the company model’s owners, the surgeons.

There are other variants of the model, such as that in which the facility itself directly employs the anesthesia providers or controls the company that, in turn, employs them. However, for purposes of this discussion, the issues are relatively the same. For that reason, we’ll use the surgeon-owned “anesthesia company” as the avatar for a company model scheme.

Broad OIG Guidance

Two fraud alerts issued by the Office of Inspector General (OIG) of the Department of Health and Human Services, the agency charged with regulating and enforcing the AKS, are applicable to the analysis of company model deals: its 1989 Special Fraud Alert on Joint Venture Arrangements, which was republished in 1994, and a 2003 Special Advisory Bulletin on Contractual Joint Ventures.

Note that the term "joint venture," as used by the OIG in the alerts, is not limited to the creation of a legal entity; rather, it covers any arrangement, whether contractual or involving a new legal entity, between parties in a position to refer business and those providing items or services for which Medicare or Medicaid pays.

The OIG has made clear that compliance with both the form and the substance of a safe harbor is required in order for it to provide protection. The OIG demands that if one underlying intention is to obtain a benefit for the referral of patients, the safe harbor would be unavailable and the AKS would be violated.

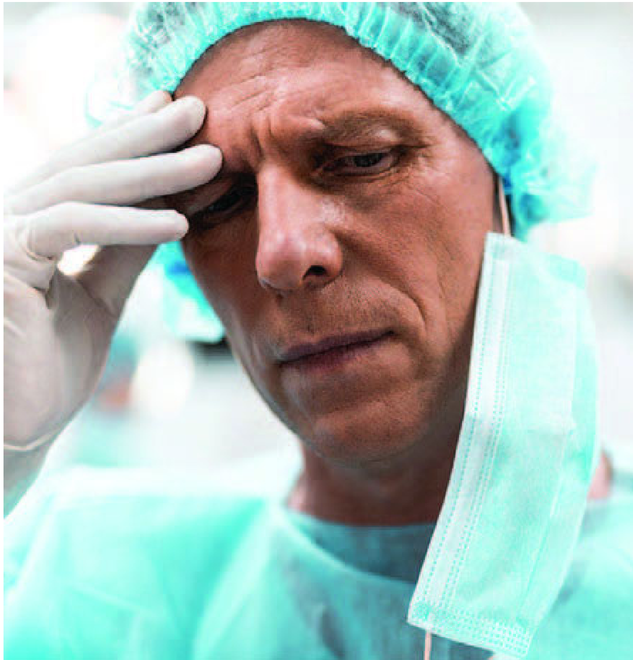
Although each alert illustrates the OIG's regulatory posture, the 2003 Special Advisory Bulletin is particularly on point in connection with analyzing company model structures. In it, the OIG focuses on arrangements in which a healthcare provider in an initial line of business (for example, a surgeon) expands into a related business (such as anesthesiology) by contracting with an existing provider of the item or service (anesthesiologists or CRNAs) to provide the new item or service to the owner's existing patient population.

The 2003 Special Bulletin lists some of the common elements of these problematic structures in general. Neither of the alerts are anesthesia-specific (or, for that matter, specific to any medical specialty). In the points that follow, I have substituted words such as "surgeon" and "anesthesiologist," all in brackets, for the broader terms used by the OIG.

- The surgeon expands into [an anesthesia business] that is dependent on direct or indirect referrals from, or on other business generated by, the owner's existing business [such as the surgeon's practice or ASC].
- The surgeon does not operate the [anesthesia] business—the [anesthesiologist] does—and does not commit substantial funds or human resources to it.
- Absent participation in the joint venture, the [anesthesiologist] would be a competitor [of the surgeon's anesthesia company], providing services, billing and collecting [for the anesthesiologist's own benefit].
- The [surgeon] and the [anesthesiologist] share in the economic benefit of the [surgeon's] new [anesthesia] business.
- The aggregate payments to the [surgeon] vary based on the [surgeon's] referrals to the new [anesthesia] business.

Advisory Opinion 12-06

The OIG's first direct pronouncement on the propriety of the company model came in June 2012, when it issued Advisory Opinion 12-06. The anesthesia group requesting the opinion presented two alternative proposed scenarios, one a management fee deal and the other a company model structure. We'll discuss the company model structure first and then, in the section below, relating to other types of kickback schemes, explore the proposed management fee arrangement.



In the proposed company model structure, the surgeons, or their ASC, would set up an anesthesia company to hold the exclusive anesthesia contract at the ASC. The anesthesia company would engage the anesthesia group at a negotiated rate as an independent contractor to provide the actual anesthesia care and certain related services. The anesthesia company would retain any profit.

In its Opinion 12-06, the OIG stated that no safe harbor was available in respect of the distributions that the surgeons would receive from their anesthesia company. The ASC investment safe harbor does not apply to protect distributions of anesthesia profits. Even if the safe harbor for payment to employees applied, or if the safe harbor for personal services contracts applied, those safe harbors would protect payments to the anesthesiologists. But they would not apply to the company model profits that would be distributed to the surgeons, and such remuneration would be prohibited under the AKS if one purpose of the remuneration is to generate or reward referrals for anesthesia services.

Because, as mentioned above, the failure to qualify for a safe harbor does not automatically render an arrangement a violation of the AKS, the OIG then turned to an analysis pursuant to the 2003 Special Advisory Bulletin and found that the physician- owners of the proposed company model entity would be in almost the exact same position as the suspect joint venture described in the bulletin: that is, in a position to receive indirectly what they cannot legally receive directly—a share of the anesthesiologists' fees in return for referrals.

Therefore, the OIG stated that the proposed company model venture could potentially generate prohibited remuneration under the AKS, and the OIG potentially could impose administrative sanctions on the requestor. In other words, the OIG declined to approve the arrangement.

Advisory Opinion 13-15

On November 12, 2013, the OIG released Advisory Opinion 13-15 dealing with a situation closely akin to a "company model" deal. [*Note to reader: In full disclosure, the author was counsel to the anesthesia group in its request for Advisory Opinion 13-15*.]

Underlying 13-15 was a proposed arrangement whereby a psychiatry group performing electroconvulsive therapy (ECT) procedures at a hospital would capture the difference between the amount it collected for

anesthesia for ECT patients and the per diem rate it would pay to the anesthesia provider.

Initially, an anesthesia group held the exclusive contact to provide all anesthesia services at a hospital (Hospital). Then, in late 2010, a psychiatry group with a practice centering on performing ECT procedures relocated to the Hospital. "Dr. X," board certified in both psychiatry and anesthesiology, is one of the psychiatry group's owners.

In 2011, the anesthesia group began negotiating with the Hospital for the renewal of its exclusive contract. The Hospital demanded an initial carve out: Dr. X would be allowed to independently provide anesthesia services to ECT patients.

The following year, when negotiating the 2012 renewal, the hospital demanded amendments to the carve-out provision:

- Dr. X would be allowed to provide anesthesia services to ECT patients and the anesthesia group would be required to provide coverage for Dr. X.
- Pursuant to what was called the "Additional Anesthesiologist Provision," the psychiatry group would determine if an additional anesthesiologist was needed for ECT anesthesia. If so, the anesthesia group would negotiate to provide those services. If the anesthesia group and the psychiatry group did not come to terms, then the psychiatry group or Dr. X could contract with an additional anesthesiologist.

Subsequently, the psychiatry group informed the anesthesia group that an additional anesthesiologist was needed. The parties began negotiating. Under the proposed arrangement presented to the OIG, the anesthesia group and the psychiatry group would enter into a contract pursuant to which the anesthesia group would provide the additional ECT anesthesia services. The anesthesia group would reassign to the psychiatry group its right to bill and collect for the services. The psychiatry group would pay the anesthesia group a per diem rate. The psychiatry group would retain the difference between the amount collected and the per diem rate.

OIG's Analysis

The OIG has stated on numerous occasions that the opportunity to generate a fee could constitute illegal remuneration under the AKS even if no payment is made for a referral. Under the proposed arrangement, the psychiatry group would have the opportunity to generate a fee equal to the difference between the amount it would bill and collect and the per diem rate paid to the anesthesiologists.

The OIG found that the proposed arrangement would not qualify for protection under the AKS's safe harbor for personal services and management contracts. That safe harbor protects only payments made by a principal (here, the psychiatry group) to an agent (here, the anesthesia group); *no safe harbor would protect the remuneration the anesthesia group would provide to the psychiatry group by way of the discount between the per diem rate their group would receive and the amount that the psychiatry group would actually collect*.

Because failure to comply with a safe harbor does not render an arrangement per se illegal, the OIG then analyzed whether, given the facts, the proposed arrangement would pose no more than a minimal risk under the AKS.

The OIG flatly stated that "*the proposed arrangement appears to be designed to permit the psychiatry group to do indirectly what it cannot do directly; that is, to receive compensation, in the form of a portion of the anesthesia group's revenues, in return for the psychiatry group's referrals of patients to the anesthesia group for anesthesia services*."

The OIG concluded that the proposed arrangement could potentially generate prohibited remuneration under the AKS and that the OIG could impose administrative sanctions in connection with the proposed arrangement. In other words, the OIG declined to approve the arrangement.

Advisory Opinion 13-15 demonstrates a fact lost to many when discussing company model deals: they generally do not fit into an available safe harbor—either the personal services and management contract safe harbor or the employee safe harbor. Not only is this because payment is not set in advance and will vary with the value or volume of referrals, but even more fundamentally, because those safe harbors apply only to payments from the principal to the agent, *not to payments, that is, remuneration, from the agent to the principal*. In 13-15, the discount that permits the referral source to profit from the arrangement is *remuneration to the principal*.

Second, although failure to fit within a safe harbor is not ipso facto fatal, the OIG has again illustrated that being put in a position to profit from one's referrals raises significant concerns of prohibited remuneration —that is, of violation of the AKS. Note that payment of so-called "fair market value," the supposed holy grail of anti-kickback analysis, is not a panacea. Deals that place the referral maker in the position of profiting from its referrals are highly suspicious even in the face of valuation studies and valuation opinions.

The Bottom Line on the Company Model

The term "company model" is an industry descriptor of certain types of arrangements. It's not the case that any specific law or regulation makes, in blanket fashion, company model deals illegal.

In similar fashion, although they give great insight into the minds of the federal enforcers of the AKS, that is, of the OIG, advisory opinions themselves are binding only on the specific requestor. As such, courts do not defer to the opinions as creating any sort of precedent. The AKS is a criminal statute, and, as such, intent to provide/accept remuneration to induce referrals must be proven. That means that the analysis is highly fact-specific.

In similar fashion, when an alleged company model scheme underlies a federal False Claims Act (i.e., whistleblower) lawsuit, specific facts relating to the kickback-tainted claims for payment must be pleaded with particularity, although there is some variance among the federal court circuits as to the required degree.

For example, in 2017, the False Claims action brought by the Florida Society of Anesthesiologists against a number of surgeons and facilities based on allegations of company model arrangements (U.S. ex rel.

Florida Society of Anesthesiologists v. Choudhry) was dismissed after the Florida Society failed three times to plead sufficient facts to withstand the defendants' attack on its pleadings.

The bottom line is that each arrangement within the rubric of the company model must be scrutinized extremely carefully. The "chance" of criminal conviction, or of civil judgment on the False Claims front, may be low, but the criminal penalties (jail time, civil monetary penalties, exclusion from participation in federal healthcare programs) and trebled civil damages judgments are high. Low odds times high penalties equal high risk.

Management Services/Expense- Shifting Arrangements

Let's turn to another category of often-seen, highly questionable arrangements: the imposition of management fees or other expenses on the anesthesia providers, or, as illustrated by the return, below, to Advisory Opinion 12-06, to the proposed *offer* to pay such fees.

Back to Advisory Opinion 12-06

As you'll recall from the discussion above, the anesthesia group requesting Advisory Opinion 12-06 presented a second scenario, one involving a management fee arrangement. In that arrangement, the anesthesiologists would not meld into a company model structure. Instead, the existing anesthesia group would continue to serve as the ASC's exclusive provider of anesthesia services. And accordingly, the group would continue to bill and collect for its own account.

However, the group would begin paying the ASCs for "management services," including preoperative nursing assessments; adequate space for all of the group's physicians, including their personal effects; adequate space for the group's physicians' materials, including documentation and records; and assistance with transferring billing documentation to the group's billing office.

Although both Medicare and private payers set their reimbursement to the ASCs taking into account the expenses of the type included within the management fee, the ASCs would continue to bill Medicare and private payers in the same amount as currently billed. The management fee would be at fair market value and determined on a per patient basis. No management fee would be charged in connection with federal healthcare program patients.

Consistent with its longstanding viewpoint, the OIG found that carving out federally-funded patients was ineffective to remove the proposed arrangement from within the purview of the AKS, because the payment of the fee in connection with private payers would influence the decision to refer all cases, thereby not reducing the risk that their payment is made to induce the referral of the federally-funded ones.

The OIG stated that the AKS seeks to ensure that referrals will be based on sound medical judgment, and competition for business based on quality and convenience, instead of paying for referrals. But under the management fee proposal, the ASCs would be paid twice for the same services: by Medicare or by the private payer via the facility fee, and then also by the anesthesiologists via the management fee. That double payment could unduly influence the ASCs to select the requestor as the ASCs' exclusive provider of anesthesia services. Therefore, the OIG concluded that the management fee arrangement could potentially generate prohibited remuneration under the AKS, and that the OIG potentially could impose administrative sanctions on the requestor.

Sweet Dreams

In August 2016, the U.S. Attorney for the Middle District of Georgia, joined by Georgia's Attorney General, announced a civil settlement with a series of anesthesia businesses collectively known as Sweet Dreams Nurse Anesthesia (Sweet Dreams).

In that settlement, Sweet Dreams agreed to pay $1,034,416 to the U.S. government and $12,078.79 to the State of Georgia to resolve allegations that it violated (*due to underlying AKS violations*) the False Claims Act and the Georgia False Medicaid Claims Act.

Sweet Dreams was alleged to have entered into arrangements with ASCs to provide the facilities with free anesthesia drugs in exchange for exclusive anesthesia agreements. Like the elements of the "management services" that the requestor anesthesia group proposed to provide to the surgery center in Advisory Opinion 12-06, anesthesia drugs are a part of the expenses covered by the facility fees paid by Medicare, Medicaid and other payers.

By either providing the drugs itself, or reimbursing the ASCs for the cost of drugs, an anesthesia group puts itself in the position of providing what is essentially double payment to the ASC: once from the anesthesia group and once from Medicare or the other payer. That double payment could unduly influence the ASC to select the group as the ASC's provider.

The allegations announced in connection with the Sweet Dreams settlement were, for the most part, similar to commonly observed kickback demand/offer situations: the demand or offer to provide personnel to work in the ASC, the provision of drugs, the provision of supplies, the provision of anesthesia machines and so on. However, another allegation may be one of a kind: That they agreed, through an affiliate, to fund the construction of an ASC in exchange for contracts as the exclusive anesthesia provider at that and a number of other ASCs.

Southern Crescent Anesthesiology

We've all probably seen them: unpaid medical directorships. Yes, sometimes they're demanded by a facility, from ASCs to hospitals, as a part of the "deal" for an exclusive contract. And sometimes they're offered by the anesthesia group to induce the facility to choose it as the exclusive provider.

But free isn't always free. Sometimes it costs millions, as in the 2018 settlement of allegations that CRNA David LaGuardia (LaGuardia) and his anesthesia entities Southern Crescent Anesthesiology, PC (SCA) and Sentry Anesthesia Management, LLC (Sentry) provided a free medical director to an ASC.

The portion of the settlement allocated to the free directorship wasn't specifically disclosed, because it was part of an overall $3.2 million settlement paid to the federal government by a medical practice (Georgia Bone & Joint), an ASC (Southern Bone & Joint, aka Summit Orthopaedic Surgery Center) and La Guardia, SCA and Sentry that also resolved allegations that Georgia Bone & Joint and LaGuardia submitted false claims to Medicare for non-FDA approved prescription drugs purchased outside the U.S.

The Bottom Line on Management Services/Expense-Shifting Arrangements

Although on the first level, they might appear to be commercially reasonable, arrangements by which anesthesia groups provide anything of value to or for a facility in connection with the right to provide services to patients is fraught with AKS danger. This is true whether the items or services are demanded by the facility or a surgeon . . . or offered by the anesthesia group. Same issue. Same bottom line. Same potential crime.

Just as in connection with the company model arrangements discussed above, the legal issues are highly complex and involve compliance with a *criminal* law statute, the AKS. Anyone confronted by, or designing, an arrangement that potentially violates the AKS must obtain counsel well versed in the issues.

Last, but not least, in answer to the question I suspect lurks in the minds of readers ("But Mark, how will I ever get caught?"), it pays to know that many cases come to light as the result of whistleblowers, whether actual whistleblowers under the FCA or just those who "drop the dime" by contacting the OIG or other federal or state authorities to report what they think might be a crime. You have to pay attention to the fact that many whistleblowers are insiders, including physicians and medical group or facility employees. Whistleblower Adam Nauss, who worked with Sweet Dreams for several years, received a portion of the settlement. So, too, did whistleblower Sharon Kopko, the former practice administrator at Georgia Bone & Joint and Summit Surgery Center.

Picture each of your employees and colleagues with a whistle around their neck.

Mark F. Weiss, JD, is an attorney who specializes in the business and legal issues affecting physicians and physician groups on a national basis. He served as a clinical assistant professor of anesthesiology at USC Keck School of Medicine and practices with the Mark F. Weiss Law Firm, a firm with offices in Dallas, Texas and Los Angeles and Santa Barbara, California, representing clients across the country. He can be reached by email at markweiss@advisorylawgroup.com.

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