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New Cases, New Tools in the Fight Against the "Company Model" Kickback Scheme

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It was a morning like any other.

That is, until Pat, the president of Some City Anesthesia Group, Inc., got the call from Tracy, the president of Local G.I. Medical Group and its affiliate, Last G.I. Center Before Freeway, the ASC owned by Local G.I.'s seven gastroenterologists.

"Pat, your team does great work. I mean, you've covered every single one of our cases for the past seven years. The few times that there were problems, you solved them almost immediately," Tracy said.

"Thanks," Pat replied. "I really appreciate that. What can I do for you?"

"Well, we had our monthly meeting last night at the center, and the guys decided they need more control over anesthesia. You know, to make sure we have the right coverage from the right providers. Our management company told us that's the right move. They've helped us set up Kick Back and Relax Gastrothesia, *our own anesthesia group."*

"I don't understand," Pat said. "You just told me that we've provided great coverage for the past seven years."

"Uh, yeah. Look, I'm not saying that your guys can't keep working at the center. They can subcontract under Kick Back and Relax. It'll pay Some City Anesthesia $1,100 a day for each of your guys on the schedule. Does that work? Heck, it's win-win!"

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"But Tracy, Pat stammered, "that's less than it costs us to staff the facility."

"Sorry, Pat, but that's more than what Kick Back and Relax has contracted to pay some independent contractors," Tracy replied. "So, I'm just letting you know that the end of the month is your group's last day. That's when Kick Back and Relax takes over."

You wake up sweaty and startled. What a nightmare!

Your cell phone rings. You glance at the screen. It's that G.I., Tracy. You wonder what he wants.

The Company Model

As in the nightmare above, in its most direct form, the so-called "company model of anesthesia services" involves the formation, by the surgeon-owners of an ASC, sometimes in concert with others such as a hospital or a management company, of an anesthesia services company to provide all of the anesthesia at the facility.

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, *i.e.*, 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.

New Tools to Fight Back

In general terms, we can divide the fight against the company model into two major battlegrounds. The first is the litigation-focused battleground, chiefly False Claims Act (*i.e.*, "whistleblower") lawsuits and governmental action, including, but not limited to, criminal prosecution. We'll call that "Domain 1."

Anesthesiologists can certainly participate in Domain 1 as whistleblowers. However, for most groups the more fertile goal is to prevent, as opposed to prosecute, which leads us to the second battleground, "Domain 2." It occurs at the scheme's infancy. That's when well thought out, smart and strategic attacks can quash the planned company model arrangement *before* it's implemented, preserving the group's business opportunity, professional independence and patient relationships.

Of course, the strategies involved in Domain 2 are largely, although in truth not completely, based on the happenings in Domain 1.

This article focuses on the import of two relatively recent events, two new tools in the battle against the company model. The first is the situation that I'll refer to as "Daitch and Frey" involving millions paid in settlement and prison time. The second is an announced $66 million settlement by Tenet Healthcare.

But, first, it's essential that you understand the key compliance issues underlying an attack on the company model, as well as some of the prior, foundational events.

The Key Compliance Issues

For most anesthesia groups, the key compliance issue in the fight against the company model centers on its violation of the federal anti-kickback statute (AKS) and its state law counterparts.

The 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 with 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.

The AKS is a criminal statute. Violation can, and does, lead to fines and imprisonment. The submission of claims to federal healthcare programs in violation of the AKS serves as the trigger for violation of the False Claims Act. Additionally, in the situation in which a hospital is a co-owner of a facility at which a company model scheme is deployed, the same fact pattern can trigger a Stark Law violation by the hospital and the participating surgeons.

Broad OIG Guidance

The Office of Inspector General (OIG) of the U.S. Department of Health and Human Services is the agency charged with regulating and enforcing the AKS.

The OIG has issued broad guidance applicable to the analysis of company model deals: its 1989 Special Fraud Alert on Joint Venture Arrangements, which was republished in 1994, and its 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 is illustrative of the regulatory posture of the OIG, 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.

Specific OIG Guidance

In addition to broad industry guidance such as fraud alerts, the OIG also issues specific guidance, that is, advisory opinions, upon request of parties to an actual or actually planned arrangement.

Technically speaking, advisory opinions are binding only on the specific party requesting the opinion, called the "requestor." However, they are used in the compliance context, including in connection with Domain 2 strategy, for their

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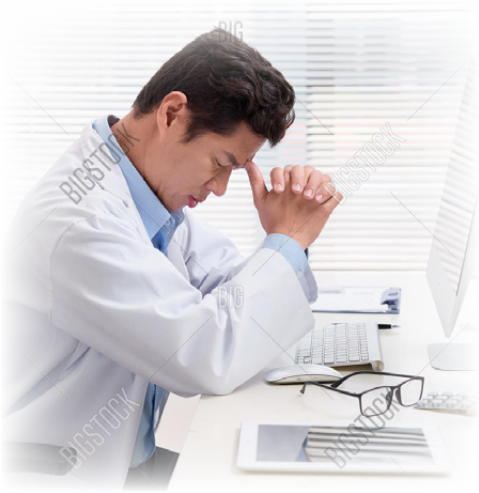

insight into the thinking of the federal enforcers of the AKS, that is, of the OIG.

Advisory Opinion 12-06

The OIG's first pronouncement directly 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 of which was a company model structure in which surgeons, or their ASC, would set up an anesthesia company to hold the exclusive anesthesia contract at the surgeons' 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 there was no safe harbor 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, failure to qualify for a safe harbor does not automatically render an arrangement in 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 to 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 anti-kickback statute.

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 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.

New Cases. New Tools.

With that background, let's turn to our focus on the import of two relatively recent events, two new tools in the battle against the company model.

The first is the situation concerning two Florida pain medicine physicians, Drs. Daitch and Frey and their related entities, including an anesthesia "company." The second is an announced $66 million settlement by Tenet Healthcare of a whistleblower action that involved a company model entity deployed at a surgical hospital.

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Daitch and Frey

Jonathan Daitch, MD, an interventional pain management specialist, and Michael Frey, MD, a physiatrist and pain medicine physician, co-owned both a professional practice in Fort Myers, Florida, Advanced Pain Management Specialists, P.A. (Advanced Pain), and a facility, Park Center for Procedures, LLC (Center).

The two also formed a company model entity, Anesthesia Partners of SWFL, LLC (Anesthesia Partners), to be the exclusive provider of anesthesia services for Advanced Pain. Anesthesia Partners contracted with CRNAs to provide the anesthesia services.

In 2015, a CRNA at the Center filed a False Claims Act lawsuit, *U.S. ex rel. Christine H. Oha, et al. v. Advanced Pain Management, etc., et al.*, alleging that Daitch, Frey and other defendants had engaged in various kickback schemes. Among the allegations were that Daitch and Frey unnecessarily ordered, and Anesthesia Partners unnecessarily performed, MAC and general anesthesia on patients undergoing pain management procedures.

Subsequently, the U.S. Government, via the Department of Justice, intervened in the case for the purposes of settlement.

Dr. Daitch got off *relatively* lightly. That is, lightly only in the sense the resolution involved a financial *civil* settlement, not criminal prosecution or the loss of his freedom. And, note that civil settlements are just that, settlements—they are not an admission of guilt.

According to the Department of Justice's December 2018 press release, the government entered into a $1.718 million civil settlement with Daitch, *which included the additional allegation that Anesthesia Partners contracted with CRNAs at contracted rates and then profited by billing the full amount to Medicare and Tricare.*

Of course, that's the same analysis as the OIG used in Advisory Opinion 13-15. If we substitute "the surgeon" (in other words, Daitch) for "psychiatry group" as used in that advisory opinion, the government's position is that the company model is "*designed to permit the [surgeon] to do indirectly what [the surgeon] cannot do directly; that is, to receive compensation, in the form of a portion of the anesthesia group's revenues, in return for the [surgeon's] referrals of patients to the anesthesia group for anesthesia services.*"

In the words of the Department of Justice, "this arrangement resulted in improper remuneration to Dr. Daitch as one of the owners of Anesthesia Partners. The United States contends that Dr. Daitch's ownership interest in Anesthesia Partners, and the remuneration he received through this ownership interest, induced him to refer his patients for anesthesia services to Anesthesia Partners."

Frey was not as lucky as his partner.

In a pre-packaged set of *criminal* charges and a simultaneous plea agreement, Frey pleaded guilty to two of the allegations against him. In return for his admitting guilt as to two counts of conspiracy to receive healthcare kickbacks, the U.S. government agreed not to charge him with additional criminal offenses relating to, among other things, *"kickbacks related to his ownership of Anesthesia Partners"*—in other words, for his involvement in the company model scheme.

In February 2019, Frey was sentenced to 18 months in federal prison and ordered to pay $472,112.88 in restitution, plus other fines and penalties.

In addition to the above mention of consistency with Advisory Opinion 13-15, the combined facts of the settled civil case against Daitch and the guilty plea in the criminal case against Frey are entirely consistent with the OIG's position in Advisory Opinion 12-06. In that opinion, the OIG stated that there was no safe harbor available in respect of distributions that the surgeons would receive from their anesthesia company, and such remuneration would be prohibited under

the AKS if one purpose of the remuneration is to generate or reward referrals for anesthesia services.

Tenet

In Tenet Healthcare Corporation's November 2019 10-Q filing with the SEC (for the quarter ended 9/30/19), it disclosed that it reached an agreement in principle with the United States Department of Justice to pay $66 million and other costs to settle a whistleblower suit involving, among other serious allegations, its participation in a company model arrangement. Again, as mentioned above, civil settlements are not an admission of guilt.

The underlying False Claims Act lawsuit, entitled *U.S. ex rel. Wayne Allison, etc., et al. v. Southwest Orthopaedic Specialists, PLLC, et al.*, centers around numerous Oklahoma orthopedic surgeons, their practice, Southwest Orthopaedic Specialists (SOS), the surgical hospital they created, Oklahoma Center for Orthopaedic and Multispecialty Surgery (OCOM) and the corporate entities that purchased and/or control the surgical hospital, Tenet Healthcare and its subsidiary, USPI.

Among other things, the suit alleges that SOS and other defendants, including Tenet and USPI, entered into an anesthesia company scheme under which they formed and operated an entity called Anesthesia Partners of Oklahoma, LLC, to which OCOM granted the exclusive anesthesia contract. The complaint alleges that, as a result, anesthesia company profits were distributed to those owners in a manner directly related to the volume and value of referrals by the SOS surgeons.

These allegations are of additional interest because they're not along the traditional line of company model scheme attack. The common attack involves an allegation that there's an inherent, forced kickback in the relationship between the surgeon or facility-controlled anesthesia company and the anesthesiologists and/or CRNAs it employs or engages. That's the "discount" analysis discussed above in regard to Advisory Opinion 13-15 and Drs. Daitch and Frey.

Here, however, the allegations essentially attack the *existence* of the exclusive contract with the captive anesthesia company as an AKS violation (the SOS surgeons controlled approximately 2/3 of the OCOM's revenue—their anesthesia company got the contract).

They also attack the fact that the surgeons' referrals to OCOM were referrals to their anesthesia company; the surgeons' profit distributions from the anesthesia company depended directly on the volume and value of their referrals to OCOM, another theory of AKS violation.

Today's 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 renders the company model *per se* illegal.

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.

However, those are Domain 1 issues, that is, challenges on the litigation and enforcement battlefront. The battle to be played out in Domain 2, that is, in connection with the strategy of defeating proposed company model arrangements into which surgeons or facilities attempt to force you, is not as unforgiving.

That's because even if the "chance" of criminal conviction, or of civil judgment on the False Claims front, may be low, the criminal penalties (jail time, civil monetary penalties and debarment from participation in federal healthcare programs) and trebled civil damages judgments pursuant to the False Claims Act are high. Low odds, times high penalties, equals high risk.

Daitch and Frey and Tenet, combined with OIG pronouncements and other support, form a potent set of Domain 2 tools that, in the right hands, can be used to defeat a proposed company model scheme *before* it's implemented, preserving your group's business opportunity, professional independence and patient relationships.

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