

More Bad News For the Company

Model and its Sponsors

BY MARK F. WEISS, JD

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

"Everyone is doing it" is no more of a defense to a federal Anti-Kickback Statute (AKS) violation, than the fact that dozens of people are selling crack on street corners is a defense to drug charges.

A recent OIG Advisory Opinion serves as a stark reminder that deals in which "anesthesia management companies" sponsor and manage captive anesthesia groups owned by surgeons, aka "company model deals," come fraught with danger of criminal prosecution.

Although OIG Advisory Opinion 23-05, made public on August 18, 2023, addresses a proposed business arrangement involving intraoperative neuromonitoring (IONM), the scheme it shot down is completely analogous to the sponsored form of the company model of anesthesia services.

Whether prosecutions and whistleblower actions will follow is anyone's guess, but an educated guess is that it's simply a matter of time.

A PRIMER ON THE COMPANY MODEL

Let's begin with a quick primer on the company model.



Although it can take various forms, the most prevalent are a direct model and a sponsored model.

The direct model involves the formation of an anesthesia services company by the surgeon-owners of an ambulatory surgery center (ASC). The purpose of the company is to provide all of the anesthesia services for the center. Prior to the company's formation, all anesthesia services were provided by anesthesiologists (working 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.

In the sponsored model, a so-called anesthesia management company fosters the creation of an anesthesia company for the surgeons, who become its owners. The management company continues to provide operational support from a menu including recruiting, credentialing, managed care contracting, billing and collection—in many cases providing a turnkey management solution to the surgeon-owners. As in the direct model, 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.

The Proposed Arrangement

The entity requesting the Advisory Opinion 23-05 (Monitoring Company) contracts with various hospitals and ASCs for IONM, which involves a technical component performed by a neurophysiologist and a "live," but often remote, monitoring of the test results and waveforms by a neurologist.

Currently, the Monitoring Company employs neurophysiologists and has a management services agreement with a physician practice (Practice)

More Bad News For the Company

Continued from page 11

that employs and/or subcontracts with neurologists. Surgeons schedule IONM services for their surgical cases by making a referral to the Monitoring Company. The Monitoring Company then schedules one of its neurophysiologists to perform the technical component and contacts with Practice to assign a neurologist to perform the professional component. Generally, the Monitoring Company bills the hospital or ASC at which the case is performed for the technical component, and Practice bills the surgical patient or insurer, as applicable, for the professional component.

The “Proposed Arrangement” involves a contractual joint venture in which the referring surgeons would profit from their referrals. Specifically, the Monitoring Company would assist surgeons (Surgeon Owners) who request IONM monitoring with the formation and operation of a turnkey physician-owned entity (Newco) that would perform IONM services.

The Surgeon Owners would form the Newco and would set the terms of their respective ownership interests and the methodology for the distribution of profits amongst themselves. Neither the Monitoring Company nor the Practice would have ownership in Newco.

After formation, the Surgeon Owners would have limited participation in Newco’s day-to-day business operations and would instead contract with the Monitoring Company and Practice for the

performance of the following business operations:

1. Pursuant to a billing services agreement between the Monitoring Company and Newco, the Monitoring Company would provide to Newco billing, collection and certain other administrative services in exchange for a fee from Newco (the “Billing Services Agreement”).
2. Pursuant to a personal services agreement between Practice and Newco, Practice would provide to Newco the services of its neurologists and the services of neurophysiologists (which Practice would lease from the Monitoring Company under the management services agreement between the Monitoring Company and Practice) in exchange for a fee from Newco (the Personal Services Agreement).

The Monitoring Company certified that the services provided by the Monitoring Company and Practice under these contracts would constitute virtually all of the day-to-day requirements of an IONM business. The Monitoring Company does not expect that Newco would need to hire any dedicated employees because the Monitoring Company and Practice would provide all necessary services for Newco.

Newco would contract with various hospitals and ASCs under an IONM services agreement that would govern Newco’s provision (or arranging for the provision) of the technical and professional components of IONM



services for surgeries at such facilities. Generally, Newco would bill the hospital or ASC for the technical component and would bill the surgical patient or insurer, as applicable, for the professional component.

Although Newco’s billing would be handled by the Monitoring Company under the Billing Services Agreement, the Monitoring Company would take direction from the Surgeon Owners regarding the amounts to be billed for services.

Why Would Monitoring Company Do This?

Why would the Monitoring Company want to do this? It’s because other IONM companies are engaging in the scheme, and surgeons, seeking to profit from IONM referrals, are demanding it.

In its request to the OIG, the Monitoring Company stated that it seeks to retain business from its existing surgeon clients that otherwise would be lost to competing IONM companies willing to engage in the scheme, and certified that it would adopt the Proposed

Arrangement only as required in specific situations where its existing surgeon clients wish to own their own IONM company and may not continue to do business with Requestor otherwise.

Although Newco would pay a fee to the Monitoring Company under the Billing Services Agreement and would pay a fee to Practice under the Personal Services Agreement, the Monitoring Company anticipates that Newco would achieve substantial profits from the Proposed Arrangement (i.e., the difference in fees paid to the Monitoring Company and Practice under the services agreements and reimbursement received from third parties) and anticipates that Monitoring Company and Practice would earn substantially less profit under the Proposed Arrangement than under their current business model.

This is primarily because, as the Monitoring Company certified: (i) reimbursement for the professional component of IONM can far exceed the cost of providing the service; and (ii) Practice would charge Newco less than it could bill a third-party payor for the same services under the Monitoring Company's and Practice's current business model because competing IONM companies marketing similar arrangements to surgeons have aggressively discounted their charges for such services.

The Underlying Law

The federal anti-kickback statute (AKS) prohibits the offer of, demand for, payment of or acceptance of any remuneration for referrals of Medicare or Medicaid patients. There are exceptions, most notably regulatory "safe harbors," that describe certain arrangements not

subject to the AKS because they are unlikely to result in fraud or abuse.

Broad OIG Guidance

The OIG has issued two fraud alerts applicable to the analysis of joint venture 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.

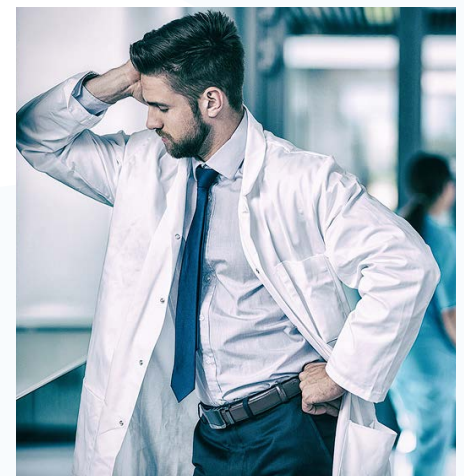
The OIG has made clear that compliance with both the form and the substance of a safe harbor is required in order for it to provide protection. The OIG demands that if even one underlying intention is to obtain a benefit for the referral of patients, the safe harbor would be unavailable, and the AKS 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 structures such as presented in regard to IONM as well as other "popular" arrangements designed to capture referral profits.

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 (e.g., IONM or anesthesiology) by contracting with an existing provider of the item or service (e.g., neurophysiologist, neurologists, anesthesiologists or nurse anesthetists) to provide the new item or service to the owner's existing patient population.

The 2003 bulletin lists some of the common elements of these problematic structures in general terms, with bracketed examples inserted by the author:

- >>> The surgeon expands into [IONM or 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 [IONM or anesthesia] business—the [IONM provider or anesthesiologist] does—and does not commit substantial funds or human resources to it.



More Bad News For the Company

Continued from page 13

- »» Absent participation in the joint venture, the [IONM provider or anesthesiologist] would be a competitor [of the surgeon's IONM or anesthesia company], providing services, billing and collecting [for the IONM company's or the anesthesiologist's own benefit].
- »» The [surgeon] and the [IONM company or anesthesiologist] share in the economic benefit of the [surgeon's] new [IONM or anesthesia] business.
- »» The aggregate payments to the [surgeon] vary based on the [surgeon's] referrals to the new [IONM or anesthesia] business.

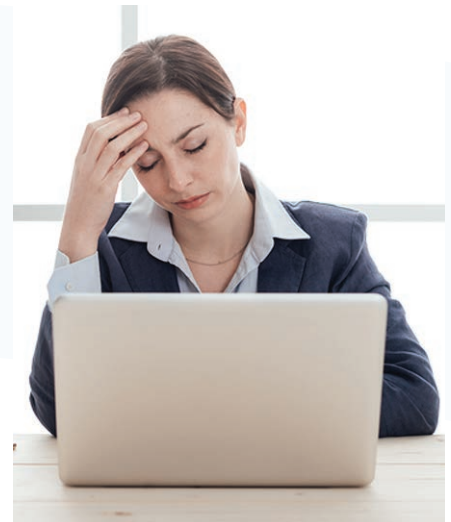
The OIG's Opinion

The OIG determined that the Proposed Arrangement would involve several forms of remuneration, including, but not limited to: (i) discounts under the Personal Services Agreement provided by Practice to Newco; (ii) the

opportunity for Newco to generate a profit through the difference between the fees paid by Newco to each of the Monitoring Company and Practice under the services agreements and the reimbursement Newco would receive for such services from third parties; and (iii) returns on investment interests in Newco to the Surgeon Owners. These streams of remuneration could induce the Surgeon Owners to make referrals of IONM services for which payment could be made by a federal healthcare program.

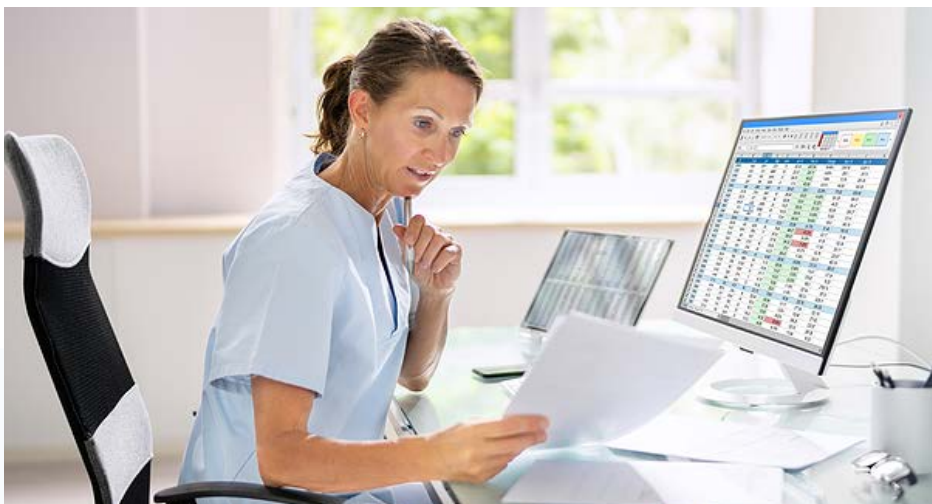
The OIG found that there was no safe harbor protection for the Proposed Arrangement's streams of remuneration, and that it would have many of the indicia of suspect contractual joint ventures about which the OIG has longstanding and continuing concerns.

The Proposed Arrangement would present a host of risks of fraud and abuse under the federal AKS, including patient steering, unfair competition,



inappropriate utilization and increased costs to federal healthcare programs. The OIG stated that it is possible that the Proposed Arrangement could enable the Monitoring Company and Practice to do indirectly what they could not do directly: pay the Surgeon Owners a share of the profits from their referrals for IONM services that could be reimbursable by a federal healthcare program.

Even if the Monitoring Company could ensure that no IONM services reimbursable by a federal healthcare program would ever be referred to Newco, the remuneration to Newco under the Proposed Arrangement could induce the Surgeon Owners to refer their IONM services reimbursable by a federal healthcare program to the Monitoring Company and Practice, thereby disguising remuneration for federal healthcare program beneficiary referrals through the payment of amounts purportedly related to non-federal health care program business.



TAKE HOME THESE ESSENTIAL POINTS

1. 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.
2. Just because the facts of Advisory Opinion 23-05 involve IONM and neurologists doesn’t lessen the value of the opinion as an indication of the OIG’s position *vis-à-vis* other joint venture arrangements, such as the role played by so-called anesthesia management companies in helping surgeons, e.g., gastroenterologists, set up and manage captive anesthesia companies for their ASCs.
3. 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. 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.
4. 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.
5. 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 equals high risk.



MARK F. WEISS, JD

Mark F. Weiss, JD, is an attorney specializing in the business and legal issues affecting anesthesia groups and healthcare facilities on a national basis, practicing at The Mark F.

Weiss Law Firm, with offices in Dallas, Texas and Los Angeles and Santa Barbara, California. He served as a clinical assistant professor of anesthesiology at USC Keck School of Medicine. He can be reached by email at markweiss@weisspc.com.