

## **The Anesthesia Company Model: Frequently Asked Questions**

### **Florida-specific Issues**

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#### **1. What is the situation in Florida?**

For several years, FSA members have been contacting the society with reports of company model arrangements throughout the state. Questions have been raised about important patient safety issues and the legality of these entities given the Federal Anti-Kickback Statute, the False Claims Act, and similar Florida law.

#### **2. What has been the FSA's response to the company model?**

The FSA decided in 2011 to form a formal task force to begin to understand the company model and its impact on patients and its membership. FSA leadership became concerned that company model arrangements could compromise patient care and safety by corrupting the professional judgment of the captive anesthesiologists. Another concern became the financial impact on the system and individual patients with the overutilization of health care resources. Finally, it was recognized that there were a growing number of FSA members that were adversely affected by the scheme in a number of aspects.

As a result, the FSA pursued several tracks, including meeting with and educating US Congressional members, State legislators, and state regulators, including officials from the Florida Attorney General's office.

In addition, the FSA has been active in bringing this matter to the attention of key members of the ASA leadership in order to raise awareness of the threat that the company model poses to patient safety. The ASA, in turn, has repeatedly petitioned the Office of the Inspector General, brought the issue up with Congressional leaders and executive branch regulators, and provided information and legal resources to its members.

#### **3. What legal action has the FSA taken?**

After several years of pursuing non-legal options, the membership of the FSA authorized the Executive Committee to explore solutions and take action to counter the company model.

In the spring of 2013 the FSA consulted an external law firm with extensive experience in health care fraud issues and qui tam ("whistleblower") actions. After reviewing the

situation in Florida, consulting with legal counsel, and seeing no good alternative to stem the rise of the company model, the FSA proceeded forward as the relator in such a lawsuit.

In October of 2013, the FSA filed a complaint in the United States District Court for the Middle District of Florida, as a co-plaintiff with the United States of America and the State of Florida. The defendants were Florida corporations and physicians who are alleged through their ownership and participation in company model arrangements to have violated Federal and State law related to the Anti-Kickback Statute and the False Claims Act, among other laws. The demand was for a jury trial.

#### **4. What has happened since then?**

The Federal and State governments have proceeded to investigate the allegations against these corporations and individuals under “seal”, meaning without full disclosure to the defendants or the public. This investigation continues to this day and includes interviewing of witnesses and demands for relevant documents. The presiding judge extended the time period of the seal on several occasions to allow these investigations to proceed. The FSA’s legal counsel has been in constant contact with Federal and State authorities throughout this process.

#### **5. Why is this public knowledge now?**

In March of 2016 the presiding judge decided that the seal was not to be extended again and the defendants and public had a right to know of the presence of the case.

#### **6. What happens next?**

The case proceeds along parallel tracks, with the government continuing its discovery of documents and interviews of witnesses, and the FSA’s legal counsel initiating formal legal proceedings against the defendants

#### **7. What if I am involved as the anesthesiologist in a company model?**

If you think you may be involved in one of these arrangements, it would be prudent to consult legal counsel now to assess your situation and determine your next steps. If you are involved in a problematic arrangement, legal counsel may advise you that you need to unwind – terminate – the arrangement and address your potential exposure for overpayments. If so, you would need to act quickly because the deadline to return an overpayment and avoid further liability is 60 days once and the overpayment is identified by your legal counsel.

#### **8. What can I do if I am considering entering one of these arrangements?**

It is imprudent to proceed without consulting your lawyer about next steps.

**9. What if I think I am involved in a problematic arrangement and the referring physicians take the position that the arrangement is legal?**

In consultation with an attorney, you need to make your own assessment about the legality or illegality of your situation. If you are involved in an arrangement that you want to terminate and the referring physicians will not agree to unwind the arrangement, while it is possible to request an HHS-OIG Advisory Opinion, doing so could expose you to possible enforcement action, as a request for an Advisory Opinion must disclose all of the underlying facts. You should consult your lawyer about your options and the risks associated with the different options.

**10. Can I contact the FSA's attorney for more questions on this matter?**

Yes, Monica Navarro can be reached at (248) 558-2702 or via email at [mnavarro@vezinalaw.com](mailto:mnavarro@vezinalaw.com)

**11. As an FSA member, what should I say if asked about the whistleblower lawsuit by another physician?**

“My professional organization believes that the company model compromises the independent judgment of the physician anesthesiologist and could jeopardize safe patient care. The FSA consulted experienced legal counsel who advised us that in all likelihood these arrangements were in violation of several Federal and State self-referral statutes, and due to the profit motive involved, it was unlikely that these entities would cease and desist if requested.”

“For these reasons and seeing no alternative, the FSA proceeded with a qui tam (whistleblower) law suit. If there are entities or individuals who have decided to voluntarily participate in company model arrangements, they may be subject to penalties for violating the relevant statutes.”

**12. What if I am approached for information by someone in my hospital or ambulatory surgery center?**

Relay the information as noted above, and refer them to the FSA by having them email the society by calling 786-300-3183 or emailing [executiveoffice@fsahq.org](mailto:executiveoffice@fsahq.org) .

**13. What if I am approached by someone from the media?**

This is an ongoing and complicated legal matter and our attorneys strongly recommend that FSA members do not interact with the media but refer them to the FSA's public relations consultants, VancoreJones Communications, by calling 850-681-8530 or emailing [svancore@vancorejones.com](mailto:svancore@vancorejones.com)

## **14. What if I want more information or have further questions?**

Contact the FSA office by calling 786-300-3183 or emailing [executiveoffice@fsahq.org](mailto:executiveoffice@fsahq.org).

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## **Background Information on the Company Model from the ASA**

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### **1. What is the “company model”?**

Under the “company model,” referring physicians, who typically also own the facility where surgical procedures are performed, form a separate anesthesia company in order to share in anesthesia revenue. The referring physicians pay the anesthesiologists a portion of the anesthesia revenues (the anesthesia professional fee) and retain the balance as profit.

### **2. What is the purpose of an anesthesia company in a company model?**

The anesthesia company is set up to provide anesthesia services to the referring physicians’ patients, usually at ambulatory surgery centers (ASCs) and offices where the payer mix is more favorable, rather than at inpatient facilities where there are higher proportions of government payer patients. The referring physicians bill for the anesthesia services and share in anesthesia revenues. Consultants have touted the “company model” and variations on the “company model” as a way for referring physicians to offset their declining professional fees by retaining some portion of the professional fees paid for anesthesia services.

### **3. Why should I be concerned?**

The “company model” has serious financial and legal consequences for anesthesiologists.

### **4. What has ASA been doing about the “company model”?**

ASA has repeatedly brought this issue to the attention of the Department of Health and Human Services Office of Inspector General (HHS-OIG). Again in February of this year, ASA sent a formal communication to Inspector General Levinson outlining concerns with the “company model.”

### **5. What is the Federal Government doing about the “company model”?**

On June 1, 2012, HHS-OIG issued an Advisory Opinion (No. 12-06) on a “company model” arrangement and expressed the view that it could violate the Federal Anti-Kickback Statute.

## **6. Why did HHS-OIG issue this Advisory Opinion?**

HHS-OIG issued this Advisory Opinion in response to a request submitted by an anesthesia practice (the “Requestor”) regarding two different proposed arrangements, both of which represented a departure from the current practice between the Requestor and the Centers at which the Requestor provided services.

## **7. What are the proposed arrangements described in the Advisory Opinion?**

Under Proposed Arrangement A, the Requestor would begin paying the Centers a per-patient fee, excluding Federal health care program patients, for “Management Services,” such as paying for space in the referring physician’s facility and paying for the services of Center personnel to transfer billing documentation to the anesthesiologists’ billing office.

Under Proposed Arrangement B, the physician-owners would establish an anesthesia company and engage the Requestor as an independent contractor to provide anesthesia services, paying the Requestor a negotiated rate and retaining the balance of the professional fees paid for anesthesia services.

## **8. What did HHS-OIG conclude about the proposed arrangements?**

The HHS-OIG concluded that both arrangements posed regulatory concern.

- a. With regard to Proposed Arrangement A, the HHS-OIG stated: Based on the facts presented here, we think there is risk that the Requestor would be paying the Management Services fees with regarding to non-Federal health care program patients to induce the Centers’ referral of all of its patients, including Federal health care program beneficiaries.
- b. With regard to Proposed Arrangement B, the HHS-OIG concluded: Based on the facts presented here, it appears that Proposed Arrangement B is designed to permit the Centers’ physician-owners to do indirectly what they cannot do directly; that is, to receive compensation, in the form of a portion of the Requestor’s anesthesia services revenues, in return for their referrals to the Requestor. This conclusion is consistent with, and supported by, the Requestor’s representation that it is under competitive pressures to enter into the Proposed Arrangements to stem the loss of its business.

Significantly, under the “company model” (Proposed Arrangement B), even though the regulatory “safe harbors” might protect the payments to the Requestor (the anesthesiologists), the safe harbors would *not* protect the distribution of profits to the referring physicians.

## **9. Are there limitations to HHS-OIG Advisory Opinion 12-06?**

As is true of all Advisory Opinions the HHS-OIG issues, Advisory Opinion 12-06 applies only to the facts listed in the Advisory Opinion. Nonetheless, it still is considered to be very important guidance regarding the HHS-OIG's views of these types of arrangements. Because the HHSOIG addressed only the two scenarios the Requestor posed, the Advisory Opinion does not provide complete guidance regarding all types of problematic arrangements (such as referring physicians directly employing anesthesiologists).

## **10. Where can I find a copy of the recent HHS-OIG Advisory Opinion?**

You may click [HERE](#) to see a copy of the Advisory Opinion.

## **11. What legal issues are raised by the “company model”?**

- a. Federal Anti-Kickback Statute
- b. Federal False Claims Act
- c. State laws – including prohibitions against (1) fee-splitting, (2) physician self-referrals, and kickbacks, as well as disclosure requirements

## **12. What does the Anti-Kickback Statute prohibit?**

The Anti-Kickback Statute prohibits knowingly and willfully offering, paying, soliciting, or receiving any remuneration to induce referrals of items or services reimbursable by federal health care programs. “Remuneration” covers the transfer of anything of value no matter what form, whether it be cash, services, assuming the referral source's costs, and other items of value, regardless of whether paid directly or indirectly.

## **13. What does the Anti-Kickback Statute say about intent?**

The health care reform law (PPACA) amended the intent standard under the Anti-Kickback Statute to provide that you need not have actual knowledge that an activity violates the Anti-Kickback Statute and you need not have specific intent to violate the Anti-Kickback Statute in order to be convicted. The transaction is illegal if even one purpose of the remuneration is to induce referrals or to pay for referrals even though funds may be paid for legitimate services provided.

As it relates to “company model,” if the referring physicians intend to get something in return for allowing anesthesiologists to work at an ASC or office, the Anti-Kickback Statute is implicated. In the case of Proposed Arrangement A where the anesthesiologists would have paid for “Management Services,” the Anti-Kickback Statute is violated if any part of the compensation is intended as a *quid pro quo* for the

right to work at the ASC or office, even if the anesthesiologists were paying for legitimate services.

#### **14. What is a “Suspect Contractual Joint Venture”?**

The HHS-OIG has long been concerned with arrangements between those in a position to refer business, such as physicians, and those providing items and services for which Medicare or Medicaid pays. The HHS-OIG first issued a Special Fraud Alert on “Joint Venture Arrangements” in 1989. In 2003, the HHS-OIG issued a Special Advisory Bulletin on “questionable” or “suspect” joint venture arrangements, which it defined as an arrangement in which:

- a. a health care provider in one line of business (the “Owner” or referring physicians in a “company model”)
- b. expands into a related health care business □ by contracting with an existing provider of an item or service (the “Supplier” or the anesthesiologists in a “company model”)
- c. to provide the new item or service to the Owner’s existing patient population, including federal health care program patients.

Just as in a “company model” arrangement, in a suspect contractual joint venture, the Owner contracts out substantially the entire operation of the related line of business to the Supplier, who otherwise would be a potential competitor, and receives in return the profits of the business as remuneration for its referrals. Among the many concerns the HHS-OIG noted was that the payments to the Supplier typically would vary with the value or volume of business that the Owner generates for the new business and that the Owner’s payments to the Supplier also would vary based on the Owner’s referrals to the new business.

Significantly, the HHS-OIG noted that, even if safe harbor protection might be available for the money flowing from the Owner (referring physicians) to the Supplier for actual services provided, the illegal remuneration is the difference between the money paid by the Owner to the Supplier and the reimbursement received from the federal health care programs. “By agreeing effectively to provide services it could otherwise provide in its own right for less than the available reimbursement, the Manager/Supplier is providing the Owner with the opportunity to generate a fee and a profit. The opportunity to generate a fee is itself remuneration that may implicate the Anti-Kickback Statute.”

#### **15. How does the False Claims Act fit in?**

The health care reform law (PPACA) provides that claims arising out of violations of the anti-kickback law are false claims for purposes of False Claims Act. If a “company model” anesthesia company involves a violation of the Anti-Kickback Statute, then all claims submitted by the anesthesia company would violate the False Claims Act.

## **16. Does the “company model” violate state Anti-Kickback Statutes?**

The “company model” could violate state Anti-Kickback Statutes:

- a. Many states and DC have some form of Anti-Kickback Statute.
- b. These state Anti-Kickback Statutes vary widely and are not necessarily modeled on federal law.
- c. Some are general in application; others are Medicaid-specific.
- d. The intent standard may be different under state law.
- e. State laws do not necessarily have the safe harbors available under federal law.

## **17. What are the potential penalties for Federal Anti-Kickback Statute violations?**

- a. Felony - Maximum fine of \$25,000 and/or imprisonment up to 5 years.
- b. Conviction means automatic exclusion from Federal health care programs.
- c. Civil Monetary Penalties: \$50,000/violation + damages up to 3 times total remuneration.

## **18. Are there other possible penalties I should be concerned about?**

Yes. As noted in Q&A 15, claims arising out of violations of the Anti-Kickback Statute are false claims for purposes of the False Claims Act. Penalties for violation of the False Claims Act include civil penalties of \$5,500 to \$11,000 plus three times the government’s damages *per false claim*. The False Claims Act also contains “whistleblower” provisions under which individuals can recover between 15-30% of the amount recovered. The damages add up quickly because the penalties are per claim.

## **19. But can I be liable if I did not prepare the claims?**

Yes. Physicians are responsible for claims filed in their names, even if they do not prepare claims and even if others profited from receiving the proceeds.

The HHS-OIG recently reminded physicians of this potential liability in a February 2012 HHS-OIG Alert on reassignment. The HHS-OIG Alert titled “OIG ALERTS PHYSICIANS TO EXERCISE CAUTION WHEN REASSIGNING THEIR MEDICARE PAYMENTS: *Physicians May Be Liable for False Claims Submitted by Entities Receiving Reassigned Medicare Payments*” can be viewed by clicking [HERE](#).

Whether you are an employee or independent contractor, if you reassign your right to Medicare payment, Medicare requires (42 C.F.R. § 424.80(d)) that you have open access to claims filed on your behalf and imposes joint and several liability on you and the assignee for overpayments. “Several” liability means that you alone can be 100% responsible for all Medicare overpayments.



## **20. Is there any time limit on returning overpayments?**

Yes. The health care reform law (PPACA) requires providers, including physicians, to report and return a government overpayment within 60 days of identifying the overpayment. Under the proposed rule issued in February 2012, an overpayment is “identified” when a person has actual knowledge that an overpayment exists or acts in reckless disregard or deliberate ignorance of an overpayment. It is possible that the issuance of the HHS-OIG Advisory Opinion on June 1, 2012 will serve as the date on which physicians should have “identified” overpayments resulting from “company model” arrangements.

## **21. What must I do, if I suspect I may be involved in one of these arrangements?**

If you are involved, or if you think you may be involved, in one of these arrangements, you should contact your lawyer now to assess your situation and determine your next steps. If you are involved in a problematic arrangement, you will need to unwind – terminate – the arrangement and address your potential exposure for overpayments. You need to act quickly, as you must act to report and return overpayments within 60 days of identifying them.

## **22. What can I do if I am considering entering one of these arrangements?**

Do not proceed further until you consult your lawyer about next steps.

## **23. What if I think I am involved in a problematic arrangement and the referring physicians take the position that the arrangement is legal?**

You need to make your own assessment about the legality or illegality of your situation. If you are involved in an arrangement that you want to terminate and the referring physicians will not agree to unwind the arrangement, while it is possible to request an HHS-OIG Advisory Opinion, doing so could expose you to possible enforcement action, as a request for an Advisory Opinion must disclose all of the underlying facts. You should consult your lawyer about your options and the risks associated with the different options.

## **24. What if I am involved in an arrangement that is not a “company model,” but is similar to either of the two proposed arrangements considered in HHS-OIG Advisory Opinion 1206?**

See the answer in Q&A 23. Seeking an HHS-OIG Advisory Opinion may be an option, but may involve the risks noted in Q&A 23. Again, your lawyer can best counsel you on your course of action and whether or not the arrangement implicates the Anti-Kickback Statute.

**25. Since there appear to be many examples of violations of the law inherent in the "company model" and its many variations, how vigorously have prosecutions been pursued? What jurisdictions would prosecute these cases? Do these cases need to be reported by "whistle blowers" to be prosecuted?**

We are not aware of enforcement action that has been taken on the company model. The Advisory Opinion is relatively new, so it is possible that such action is yet to come. In this regard, it is worth noting that regulatory agencies usually take enforcement action after they have issued guidance regarding application of the law.

There was anecdotal discussion of a whistleblower or "*qui tam*" action that may have been filed by an employee of an anesthesia company several years ago, though it is uncertain if that action is still pending. ASA also has heard of at least one meeting with regional enforcement authorities seeking to obtain information about company model arrangements to bring before a grand jury.

**26. Has the ASA presented these concerns to the national organizations which represent the physicians who are responsible for these questionable relationships?**

ASA went directly to the HHS Office of Inspector General to obtain guidance from the Federal Government as to the legality or illegality of the company model. There have not been any formal communications with the national physician organizations representing referring physicians. ASA has taken every opportunity in public forums and the trade press and on the ASA website to communicate its concerns. That said, there have been informal discussions with some of the leaders of the national physician organizations representing the referring physicians now that an Advisory Opinion on the subject has been issued.

**27. If both parties to an arrangement enter into an agreement similar in some aspects to either of the arrangements discussed in the Advisory Opinion with the advice of counsel recommending the exact model proposed, who would be liable? Would legal counsel on both sides of the contract formation shield the parties involved in any way?**

The answer would depend upon the specific facts. In scenarios that may implicate the Anti-Kickback Statute, attorneys usually discuss whether or not safe harbor treatment is available and the risks involved in a transaction. If the attorneys qualify their advice by saying that safe harbor treatment *may* be available, but that there are certain risks, such advice would not necessarily shield the parties from liability.

**28. Will State Attorneys General (“AGs”) have authority here? Will AGs aggressively pursue company model arrangements as fraud?**

Whether or not a State AG would pursue an arrangement would depend upon what state law provides, as State AGs have authority to enforce their state laws. ASA is aware that anesthesiologists in several states have met or are planning to meet with their State Attorneys General to discuss this issue. Some States have very broad state anti-kickback laws or self-referral laws that may apply. State Medicaid programs also may take enforcement action, whether through a Medicaid Integrity Contractor or otherwise.

**29. If an anesthesiologist is a substantial owner along with referring physicians, of an ASC engaged in the "company model" with non-owner anesthesiologists, is any protection afforded to the parties involved?**

If there is a violation of the Federal Anti-Kickback Statute, having an anesthesiologist involved as an owner of the facility does not avoid the problem that the referring physicians are profiting from their referrals for anesthesia services.

**30. In order to be in violation, as under Arrangement B, does "intent" have to be present?**

The Federal Anti-Kickback Statute is a criminal statute, so the Government would have to demonstrate intent in order to establish a violation. But intent can be inferred from the facts. For example, intent could be inferred from the referring physician being paid twice for the same service or from statements made by the referring physician. It also is worth noting that the Patient Protection and Affordable Care Act clarified the intent standard for violations of the federal Anti-Kickback Statute and makes clear that a person need not have actual knowledge of the law or specific intent to commit a violation of the law in order to violate the Anti-Kickback Statute.

**31. If several years ago a group entered into a contract unknowingly relating to the company model, and now it is quite concerned about the legality, it seems there is no safe retreat. How would an anesthesia group go about raising concern on the ASC or referring physician side of the contract?**

There are two ways, you can approach the subject:

1. Ask if the referring physicians have seen the Advisory Opinion and if they have discussed it with their counsel.
2. If the referring physicians do not believe that there is a concern, it may be appropriate to bring in your own lawyer and to have counsel for the parties discuss the legal issues. If the referring physicians are not persuaded that a problem exists, the anesthesiology practice would need to make its own decision regarding continuing or terminating the relationship and other steps it might need to take (see FAQs 15 and 18-20, above).