American Society of Anesthesiologists®

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February 26, 2013

Inspector General Daniel R. Levinson
Office of Inspector General
Congressional and Regulatory Affairs
United States Department of Health and Human Services
Room 5541C Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

Attention: OIG-121-N

Dear Mr. Levinson:

On behalf of the over 50,000 members of The American Society of Anesthesiologists (ASA), we appreciate the opportunity to submit comments in response to the Office of Inspector General (OIG) solicitation of proposals and recommendations for modifying existing safe harbor provisions and developing new Special Fraud Alerts. In our view, the economic model referred to as the "company model," and variations on that model, which enable referring physicians to profit from their referrals for anesthesia services, are "fraudulent and abusive." These arrangements negatively affect patients, competition, and the integrity of Federal health care programs. They never improve the quality of care or reduce the cost of care.

Despite OIG guidance in the 2003 Special Advisory Bulletin on Contractual Joint Ventures and the 1989 Special Fraud Alert on Joint Venture Arrangements, and issuance of Advisory Opinion 12-06, which addresses both a company model and management services arrangement, referring physicians continue to operate company model and similar arrangements, based upon misplaced reliance upon their consultants and advisors, claiming that there are no legal impediments to their implementation.

You already have recognized in Advisory Opinion 12-06 that company model arrangements allow referring physicians to do indirectly what they cannot do directly: profit from their referrals. Yet the problematic models continue in operation, with referring physicians emboldened by the lack of enforcement activity. When referring physicians make decisions regarding selection of anesthesiologists based upon who is willing to turn over substantial professional revenues in exchange for the referrals, patient care is jeopardized and the integrity of the Federal health care system is corrupted.

Unless you issue a Special Fraud Alert on these abusive arrangements and modify existing safe harbors to make clear that they do not protect these elaborate schemes, we fear that referring physicians and their consultants will continue to press these abusive and illegal models. (See Section C for ASA's specific requests.)

A. "Company Model" Arrangements and Variations

1. What is a "Company Model" Arrangement?

Consultants tout the company model as a way for referring physicians, such as gastroenterologists, ophthalmologists, orthopedists, and others, to offset their declining professional fees by skimming professional fees for anesthesia services. It is a form of fee-splitting whereby referring physicians create a separate "anesthesia company" that contracts with or hires anesthesiologists and/or nonphysician anesthetists to provide anesthesia services for the referring physicians' patients who are undergoing procedures or surgery. Typically, the referring physicians also own the facility where surgical/procedural and anesthesia services are provided, such as an ambulatory surgery center (ASC). The sole purpose of the anesthesia company is to provide anesthesia services to the referring physicians or the facilities they own. The referring physicians submit a bill for the procedure or surgery and also bill for the anesthesia services through the anesthesia company, as well as the facility fee through the ASC. The referring physicians then pay the anesthesia personnel and retain the balance (often the majority) of the anesthesia professional fees. This retained profit is in fact a kickback, compensation to the referring physicians for providing the referral for anesthesia services. The referring physicians share in three revenue streams: (1) the facility fee for the facility they own, (2) the procedural fee, and (3) the anesthesia services fee.

As stated in ASA's previous letters to the OIG,[1] physician-owned facilities have been moving away from the traditional fee-for-service model and turning to the company model and related arrangements to capture the revenue stream from their referrals for anesthesia services.

2. What are the Variations on Company Model Arrangements?

Advisors and consultants have offered referring physicians a variety of alternative arrangements to implement, with implementation often dependent upon how many groups of referring physicians and nonphysicians (such as ASC management companies) plan to share in the anesthesia revenue. We are aware of at least four variations on the company model.

a. Under what is called the "In-House Provider Model," the ASC, which is owned by the referring physicians, either employs or contracts with anesthesia personnel and bills for the anesthesia services. The consultants note that one advantage of that model is that anesthesia income is distributed to all referring physician owners.

[1] ASA has submitted letters to the OIG on company model issues, including a letter from ASA President Roger A. Moore, M.D. dated March 19, 2009; a letter from ASA President Alexander A. Hannenberg, M.D. dated June 16, 2010; a letter from ASA President Mark A. Warner, M.D. dated February 24, 2011; and a letter from ASA President Jerry A. Cohen, M.D. dated February 27, 2012.

In Advisory Opinion 12-06, the OIG stated that the safe harbor for ASC investments would not protect distribution of anesthesia revenues to referring physician owners of the ASC. As noted in Section C.2.b, below, we seek modification of the ASC safe harbor to clarify that only the profits from ASC services – the ASC facility fees – would be protected.

b. Under the so-called "Group Practice/Contracted Provider Model," the existing practice of the referring physicians employs anesthesia personnel and submits claims to payors for the anesthesia services. The consultants note that this approach is more practical when only one or two specialties own an ASC, and cite gastroenterology and ophthalmology as two examples.

As discussed below, we seek a modification to the safe harbors for investments in group practices and employees to avoid protection for arrangements that are thinly veiled efforts to enable referring physicians to profit from their referrals of anesthesia services.

c. Under the "Anesthesia Partner Model," the referring physicians establish a new company along with the anesthesiologists and/or nonphysician anesthetists. The new company contracts with anesthesia personnel and bills for their services. The consultants have commented that this arrangement can be customized to allow some or all referring physicians to profit from anesthesia fees. Essentially, this arrangement involves less profit for the referring physicians, as they share ownership of the new anesthesia company with the anesthesiologists and/or nonphysician anesthetists.

d. The "Anesthesia Practice Management Model" involves formation of two companies. First, the referring physicians and nonphysicians, such as the ASC management company, together form an anesthesia management company. The anesthesia management company provides administrative services to the ASC and receives a fee for these services, which is distributed to the equity owners of the company – the referring physicians and nonphysician managers.

The referring physicians also create a separate "anesthesia company" that is owned by the referring physicians who also own the ASC. This anesthesia company contracts with or employs the anesthesiologists and bills for the anesthesia services.

This model is touted as enabling nonphysician owners of the ASC, as well as referring physicians, the ability to profit from the revenues of the anesthesia management company.

Beyond these four models, consultants and businesses offer other variations of these models. These four are offered as examples of the focus on delivering profits to the referring physicians and the ASC management companies in exchange for the referral of anesthesia services to the anesthesiologists. (As used in this letter, the term "company model" references all variations on the original company model arrangement outlined in Section A.1, above.)[2]

[2] ASA is not suggesting that all models of physician employment, such as academic practices in which physicians are employed by a medical school or faculty practice plan and the deans and department chairs control salaries, are illegal. The focus of this comment letter is on structures owned in whole or in part by referring physicians.

3. The Role of Consultants: How Company Models Are Marketed

The raison d'être of company model arrangements is to enable referring physicians to "capture" the anesthesia revenue stream and offset declining professional revenues for the referring physicians' own services. Consultants market company model arrangements as additional revenue sources for ASCs and their physician owners or a way to "profit from anesthesia services."

Consultants fuel interest in these arrangements by presenting these models at ASC symposia and conferences and at professional medical specialty meetings, and by publishing articles in the trade press. The message of the presentations and articles is on the financial gain in exchange for the referrals of patients. These articles include *Can ASCs Share in Anesthesia Revenue?*, *Five Ways Your ASC Can Profit From Anesthesia Services*, and *Can Surgery Centers Profit From Anesthesia?*

The consulting firms that offer "turnkey" services and work with referring physicians to implement company model arrangements focus on the *volume* of the referring physicians' procedures and the payor mix for those procedures in order to calculate the *value* of the referrals for anesthesia services and, ultimately, the amount of revenue that referring physicians can realize from implementing these models. They offer "revenue forecasts" and other projections of how much money referring physicians can generate from implementation of a new arrangement.

In summary, the focus of these arrangements is on how much money the referring physicians can generate from their referrals for anesthesia services under Federal and private commercial health care programs. In the *pro formas* used to provide projections, consultants request information on the payor mix, including the percentage of Medicare, Medicaid, HMO Medicare, HMO Medicaid, Champus, Tricare, and other Federal health care programs.

4. Post-Advisory Opinion 12-06 Activity

The issuance of Advisory Opinion 12-06 has led to reexamination of the legality of some company model arrangements, but its effect has been limited.

The consulting firms (including law firms) that promote company model arrangements continue to offer services to implement models that allow referring physicians to profit from their referrals for anesthesia services. The sole business model of some of the consulting firms is to sell anesthesia management services to referring physicians. Those firms have an economic stake in giving comfort to those who have relied upon their aggressive "guidance" and they continue to market their services to referring physicians.

Business and legal consultants acknowledge Advisory Opinion 12-06, but choose to interpret it narrowly.

- Some claim that the Advisory Opinion result is based upon the fact that the request was submitted by an anesthesia practice.

- Others have sought to marginalize the Advisory Opinion, saying, for example, that it is not the "death knell" of anesthesia company model arrangements.
- Counsel for referring physicians sometimes take the position that company model arrangements do not violate the Anti-Kickback Statute, so long as the referring physicians divide the anesthesia profits equally.
- Some recommend that company model arrangements be "structured, and most importantly, actually implemented in a good faith manner and involve circumstances that reflect good intent, such as improving quality, efficiency and coordination of care or other permissible purposes."[3]
- Consultants point to the language in the Advisory Opinion about it not applying to anyone other than the requestor ("This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.") as the basis for differentiating other proposed company model arrangements.
- Finally, others have questioned the validity of the OIG's comments on the scope of the safe harbor for ASC investments.

A recent article (February 19, 2013) points to areas not addressed by Advisory Opinion 12-06 and suggests that the OIG may not prevail on its position on the unavailability of the safe harbor for ASC investments as applied to direct employment of anesthesiologists by ASCs.[4]

Some referring physicians who previously had implemented company model arrangements have simply dismissed Advisory Opinion 12-06 and have rejected efforts by the anesthesiologists to review the legality of the arrangement in light of the guidance in the Advisory Opinion. While the anesthesiologists can terminate their relationship with the referring physicians in those instances, the harm to Federal programs goes unchecked.

In summary, while Advisory Opinion 12-06 has garnered attention, it has not stemmed the efforts of referring physicians and their consultants to "capture the anesthesia revenue stream."

5. Expansion from ASCs and Offices to Hospitals

Company model arrangements are most often implemented in the ASC, single specialty center, or office environment for two reasons. First, referring physicians often own the ASCs or centers, and they certainly own their own offices, in which such an arrangement is implemented. Second,

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[3] *OIG Advisory Opinion 12-06: Insightful Guidance from the OIG For Structuring Company Model Arrangements*, ABA Health e-Source, June 2012, Volume 8, No. 10, available at http://www.americanbar.org/newsletter/publications/aba_health_esource_home/aba_health_law_esource_0612_kalmowitz.html.

[4] *22 Advisory Opinions Issues [sic] by the Office of Inspector General – 6 of Interest; Anesthesia ASC Arrangements – 7 Key Concepts; and ASC Anti-Kickback Safe Harbor issues -9 Key Concepts for 2013*, *Becker's ASC Review*, February 19, 2013, available at http://www.beckersasc.com/news-analysis/22-advisory-opinions-issues-by-the-office-of-inspector-general-6-of-interest-anesthesia-asc-arrangements-7-key-concepts-and-asc-anti-kickback-safe-harbor-issues-9-key-concepts-for-2013.html.

the payor mix for cases in the ASC or office environment tends to be more favorable than in the inpatient environment.

In the past several months, as hospitals acquire ASCs and single specialty centers, ASA has heard increasing numbers of reports of hospitals requesting or insisting that the exclusive anesthesia group agree to a carve-out from exclusivity for the ASC or center, so that the referring physicians, whose practices and centers are being acquired, can either implement or continue to operate a company model arrangement and can begin or continue to capture the anesthesia revenue stream. (An exclusive anesthesia group often has a right of first refusal to provide anesthesia services in all locations a hospital operates, which would be triggered by such an acquisition, absent the request to waive the right.)

To be clear, the requests by hospitals for a carve-out to exclusivity relate just to the ASC or center being acquired, where the referring physicians can expect to profit from anesthesia services. They do not relate to the standard inpatient cases the referring physicians perform, where there is generally less opportunity to profit from anesthesia services.

Apart from the legality of the company model arrangements in place at these locations, these requests by hospitals for the anesthesia group to forgo a valuable right in exchange for continuing to serve as the exclusive contractor raise separate Anti-Kickback and Stark law concerns. It is notable that these requests have occurred in different regions of the country and they post-date issuance of the Advisory Opinion.

B. Need for Further Guidance

ASA believes that further OIG guidance is needed on the legality of company model arrangements. ASA also urges you to modify existing safe harbors to limit their application to direct and indirect efforts by referring physicians to profit from their referrals of anesthesia services. (Specific requests appear in Section C, below.)

The continuing efforts of referring physicians to condition their referrals of anesthesia services on the willingness of anesthesiologists and nonphysician anesthetists to transfer a portion of their professional anesthesia fees to the referring physicians, or to an entity owned by the referring physicians, underscore the need for OIG guidance on the variety of legal structures that consultants market as an “additional revenue stream” for referring physicians.

There is a pressing need for guidance “on the ground.” ASA has heard from many of its members who are frustrated with what they view to be conflicting advice from attorneys as to the legality of company model arrangements. While the legality of an arrangement will depend upon the specific facts, the inconsistent advice from different attorneys leaves many anesthesiologists, and presumably referring physicians, confused as to what is, and is not, permissible.

It is against this backdrop of continued marketing efforts by those consultants who seek to profit from implementation of company model arrangements, continuing demands for anesthesiologists to turn over their anesthesia revenue to referring physicians, new requirements by hospitals for anesthesiologists to agree to turn over anesthesia profits to referring physicians, and conflicting legal advice regarding the legality of these arrangements under the Anti-Kickback Statute that ASA requests that you issue a Special Fraud Alert on these arrangements and modify existing safe harbors to limit protection for arrangements that are elaborately constructed, but in practice little more than naked efforts to enable referring physicians to profit from their referrals for anesthesia services in settings where the anesthesia services are profitable.

C. Specific Requests

1. Issuance of a Special Fraud Alert

Based upon the reasons outlined above, ASA believes that there is a pressing need for OIG guidance on the variety of company model arrangements that have been and continue to be implemented.

In prior discussions, OIG staff have indicated that the OIG prefers to provide guidance through the Advisory Opinion process, when it has specific facts on which to comment. Significantly, the advisory opinion process is not available to many anesthesiologists who are faced with requests (demands?) to participate in a company model arrangement. In particular, as explained below, anesthesiologists often are unable to satisfy the regulatory requirement in 42 C.F.R. § 1008.15(a) that the party requesting an advisory opinion certify that the facts relate to an arrangement "which the requestor in good faith plans to undertake."

In a seemingly deliberate and carefully choreographed effort, referring physicians frequently immediately cut off discussions with anesthesiologists who raise questions about the legality of a proposed arrangement, or who request information on the specific structure of a proposed arrangement, thereby depriving the anesthesiologists of the ability to file for an advisory opinion, as they are unable to represent that they will engage in the transaction, if approved. For the large majority of anesthesiologists facing requests to participate in a company model arrangement, the advisory opinion process is therefore unavailable.

ASA has heard of this pattern occurring in enough different locations and settings to be concerned that the advisory opinion process is not a realistic option for the large majority of anesthesiologists facing demands to participate in these arrangements.

Company model arrangements represent a specific trend that is abusive and illegal.

- They corrupt medical decision making, which can result in decreased quality of care for Federal health care program patients.
- They threaten the integrity of Federal health care programs.

- They result in overutilization of anesthesia services for certain procedures, resulting in increased cost to Federal health care programs.
- They are expanding to referring physicians in increasing numbers of medical specialties. They also are expanding beyond the ASC environment to single specialty centers, offices, and even hospitals.
- They are promoted by consultants who stand to benefit from management and other fees generated by the arrangement.

In a June 2001 Special Advisory Bulletin titled "Practices of Business Consultants," the OIG warned providers, suppliers, and others regarding the practices of business consultants who either engage in improper practices or encourage abuse of the Medicare and Medicaid programs. The efforts of business consultants who develop and implement company model arrangements for referring physicians to promote these arrangements occur in a marketplace in which legal experts disagree about the application of the Anti-Kickback Statute to these arrangements (and enforcement activity has not been observed).

OIG guidance is needed to promote compliance with the Anti-Kickback Statute and to minimize the potential for differing interpretations of the legality of, or risk associated with, particular arrangements.

We encourage you to use a Special Fraud Alert as a vehicle in which to provide guidance on the following points, among others:

- Does involvement by the referring physicians in the anesthesia company, or a focus on quality or efficiency, legitimize an otherwise suspect arrangement designed to allow referring physicians to profit from their referrals?
- How is the commercial reasonableness standard to be applied to company model arrangements? Is it necessarily not commercially reasonable (*i.e.*, inherently suspect) for anesthesiologists (the supplier) to enter into arrangements with referring physicians which, however packaged, result in transferring some portion of the anesthesiologists' professional fees to the referring physicians (or the facilities they own) in exchange for the opportunity to provide anesthesia services?
- Is it commercially reasonable for an anesthesia group to change an existing model, in which it provides services on a fee-for-service basis, bills and collects for its services, and retains its professional fees, and to enter into any of the company model variations, in which – whatever the structure – the result is that the referring physicians and/or the facilities they own profit from the referrals for anesthesia services?
- Is it inherently suspect for anesthesiologists to be forced into employment models, in which they are employed by ASCs owned (in whole or in part) by the referring physicians, in which the anesthesiologists in effect transfer a substantial portion – as much as fifty to seventy percent – of their revenues to the referring physicians as a condition of receiving referrals for anesthesia services?

- Does the same inherently suspect analysis apply when anesthesiologists are forced into employment models, in which they are employed directly by the referring physicians (or their professional practices), in which the anesthesiologists in effect transfer a substantial portion – as much as fifty to seventy percent – of their revenues to the referring physicians as a condition of receiving referrals for anesthesia services?
- Does the analysis differ if two or more groups of referring physicians seek to employ the same anesthesiologists through their professional practices?
- Does the safe harbor for employment protect arrangements in which the ASC directly employs anesthesiologists and in which the profit from anesthesia services is distributed to the referring physician owners of the ASC? (This point was addressed in the Advisory Opinion, but legal commentary has questioned this portion of the Advisory Opinion.)
- Does the safe harbor for investment in a group practice protect distribution of profits derived from an arrangement in which the group practice, consisting of referring physicians in one or more other medical specialties, employs or contracts with anesthesiologists, in order to capture the anesthesia revenues from their referrals?
- Are joint ventures involving referring physicians and anesthesiologists that result in the anesthesiologists receiving less than their full professional fee and the referring physicians receiving a portion of the profits of the joint venture, which include a portion of the anesthesiologists' professional fees, inherently suspect under the Anti-Kickback Statute?
- Are arrangements in which the referring physicians, or the facilities they own, compensate the anesthesiologists on a per-diem or per-annum basis inherently suspect, as the profit that the referring physicians (or the facilities that they own) will retain will necessarily correspond to the value of the referrals from the referring physicians for anesthesia services?

ASA stands ready to provide you with examples of the different types of company model arrangements that ASA members have faced and to assist in identifying additional points that can be covered in such a Special Fraud Alert.

2. Modification of Existing Safe Harbors

You recognized in Advisory Opinion 12-06 that the traditional company model arrangement posed the risk of violating the Anti-Kickback Statute in that it enabled referring physicians to do indirectly what they could do directly – profit from their referrals. You recognized the potential for corruption of Federal health care programs by these arrangements. Due to the nature of the advisory opinion process, Advisory Opinion 12-06 is limited to the facts presented. To apply the conclusion in the Advisory Opinion on a broader basis and to limit the ability of referring physicians to access safe harbor protection for arrangements that are designed to enable them to profit from their referrals, modifications to existing safe harbors are needed.

While we are listing proposed revisions to three existing safe harbors, we deem our first two proposals to be the most important ones.

a. ***Safe harbor for investments in group practices***. ASA requests that you modify the existing safe harbor for investments in group practices (42 C.F.R. § 1001.952(p)) to limit its applicability to variations of company model arrangements in which the referring physicians, through their group practices, employ or contract with anesthesiologists or other anesthesia personnel and thus are able to capture the anesthesia revenue stream.

This proposal can be accomplished in several ways. The most straightforward way to modify the safe harbor is to provide that it does not apply to revenues derived from the provision of anesthesia services if any equity owner of the group practice practices in a medical specialty other than anesthesiology or pain medicine (many pain medicine physicians are trained as anesthesiologists).

A second option, which may be susceptible to some abuse and is accordingly less preferable, is to limit application of the safe harbor to profits generated by the services provided by the equity owners of the group practice and from their employees who provide services in the same medical specialty as the equity owners of the group practice. This approach would not protect against the "joint venture"-type arrangements in which a group practice were to make a single anesthesiologist a "token" owner to try to access the safe harbor.

In addition, we request a modification to the safe harbor to provide that anesthesia services are not "in-office ancillary services" for purposes of the safe harbor for investments in group practices. The purpose of this revision is to clarify that referring physicians cannot try to justify the legality of company model arrangements by trying to characterize anesthesia services as in-office ancillary services.

b. ***Safe harbor for investments in ASCs***. ASA requests that you modify the existing safe harbor for investments in ASCs (42 C.F.R. § 1001.952(r)) to reflect in the regulation the OIG position articulated in Advisory Opinion 12-06, which is that the safe harbor for investments in ASCs does not protect distribution of profits from the provision of anesthesia services. This revision is important, as having anesthesia personnel employed by or under contract with the ASC has been particularly attractive to ASCs with referring physician owners in multiple specialties.

When referring physician ASC owners have separate group practices, they typically want to implement a model in which all of them can share in the profits from their referrals for anesthesia services.

- Direct employment or contracting by one group practice does not provide all ASC owners with the opportunity to share in the anesthesia profits.

- A traditional anesthesia company model, in which all of the ASC owners create and own a separate anesthesia company, is risky in light of the reasoning articulated in Advisory Opinion 12-06.
- Having the ASC directly employ or contract with anesthesia personnel would provide a mechanism for all owners of the ASC to share in the anesthesia profits, and would be particularly attractive if that arrangement were eligible for safe harbor protection.

Amending the safe harbor regulation will avoid abuse of the system by confirming the OIG's position.

Some legal commentary has questioned the OIG comments in Advisory Opinion 12-06 regarding the inapplicability of the safe harbor for ASC investments as a means to protect profits derived from anesthesia services. They point to the fact that ASCs can contract for anesthesia services and bill for them under a reassignment of benefits, and that the ASC is eligible for safe harbor protection.

To be clear, ASA does not request changes in the safe harbor for ASC investments other than clarification that the safe harbor does not protect distribution of profits from the provision of anesthesia services. This change is necessary to avoid referring physicians from profiting on their referrals for anesthesia services.

c. ***Safe harbor for employees***. ASA requests that you modify the existing safe harbor for employees (42 C.F.R. § 1001.952(i)) to provide that safe harbor protection is not available for employment arrangements in which referring physicians, directly or through a group or other entity they own, employ physicians in other medical specialties to whom they make referrals and pay the employed physicians less than the employed physicians would otherwise receive if they billed directly for their services. Exceptions eligible for safe harbor protection could include (i) tax-exempt multispecialty groups and (ii) multispecialty groups involving ownership by specialists in multiple specialties (for example, in more than five specialties), provided that those specialists do not make referrals for services to the employed physicians. Hospital-owned medical groups and faculty practice plans, which generally are not owned by referring physicians, would continue to qualify for safe harbor protection.

An alternative, but less preferable, approach would be to introduce some of the concepts from the safe harbor for personal services and management contracts (42 C.F.R. § 1001.952(d)), in particular the requirements of commercial reasonableness and of compensation not varying with the volume or value of referrals from the employing referring physicians who practice in a separate specialty from the employed physicians. These concepts would serve to limit safe harbor protection for suspect employment arrangements that are designed to enable the referring physician employers to profit from their referrals to their employed physicians for professional services in a separate medical specialty. This approach is less preferable, in that there is little guidance on commercial reasonableness and abusive arrangements might still qualify for protection.

In summary, our three proposals are aimed at eliminating possible safe harbor protection for reconfigured company model arrangements that reward referring physicians for their referrals. Unless you move to narrow existing safe harbor protections so they do not protect employment arrangements that enable referring physicians to "capture the anesthesia revenue stream" from their referrals for anesthesia services, you will not protect Federal health care program beneficiaries from the corruption of medical judgment or preserve the integrity of Federal health care programs. ASA stands ready to discuss these proposed modifications to existing safe harbors with the goal of narrowing existing safe harbors to protect only legitimate arrangements.

D. Additional Information Responsive to OIG Requests for Specific Information

You already have recognized that company model arrangements implicate the Anti-Kickback Statute by allowing referring physicians to profit from their referrals. As discussed in Section A, above, and this Section D, company model arrangements adversely affect Federal health care programs and patients in many of the ways the OIG considers when assessing proposals for Special Fraud Alerts and modification of safe harbor protection, including the following:

- Decreasing access to health care services;
- Decreasing the quality of health care services;
- Limiting patient freedom of choice among health care providers;
- Decreasing competition among health care providers;
- Increasing the cost to Federal health care programs;
- Increasing the potential overutilization of the health care services, and
- Increasing the financial benefit to health care professionals or providers that may take into account their decisions whether to
  a) Order a health care item or service or
  b) Arrange for a referral of health care items or services to a particular practitioner or provider.

Our comments address each of these factors, along with supporting data of the volume and frequency of the conduct in question, to demonstrate the grave nature of the company model in its various forms.

Decreasing Access to Health Care Services

In company model arrangements, referring physicians make the choice of anesthesia provider based upon which anesthesia providers are willing to turn over their professional fees as a condition of providing anesthesia services. Since the referring physicians retain any profit over expenses, they often seek the lowest cost anesthesia providers in order to maximize the anesthesia profit. These choices can and do result in selection of anesthesia providers based upon profit, not quality, considerations. If the referring physicians choose to provide only nonphysician anesthetists rather than anesthesiologists or a care team model that involves both anesthesiologists and nonphysician anesthetists, company model arrangements can result in decreased access to physician services.

Company model arrangements further disrupt the market and decrease access to anesthesia services, as company model employment agreements typically contain noncompetition agreements. As a result, anesthesiologists who leave company model arrangements may be foreclosed from practicing in their communities for several years post-termination.

Decreasing the Quality of Health Care Services

As recognized leaders in patient safety, anesthesiologists pride themselves on providing the highest level of quality and safe patient care. ASA develops, modifies and updates evidence-based guidelines, statements and practice parameters to assist our members in keeping current with the latest science and best practices with respect to anesthesia care. As further evidence of our commitment to quality, ASA launched a separate organization, the Anesthesia Quality Institute (AQI), with the primary mission of establishing a national anesthesia outcomes registry. AQI began collecting data in January 2010 with the intent that researchers, ASA and other interested parties will use the data to further enhance the science and practice of anesthesia.

a. Creating pressure on employed anesthesiologists to provide services against their clinical judgment. Company model arrangements create incentives and pressures that represent the complete antithesis of these strides in quality care that ASA and anesthesiologists have achieved. Because the referring physician has a direct stake in the fees generated by anesthesia services, and because the referring physicians are not anesthesiologists and do not appreciate the risks of anesthesia, they can exert pressure on anesthesia providers to administer anesthesia services against their better clinical judgment. The issues may arise with patients whom the anesthesiologists consider too sick to be treated in an ASC, rather than in a hospital, or "production" pressure to rush through preanesthetic assessments without taking adequate time to assess patients. We have heard reports of referring physicians who, after implementing a company model arrangement, have scrimped on staff to increase their profits, creating a situation in which an anesthesiologist who is personally performing a case is expected to abandon his/her patient in order to attend to a second patient in another room, if a problem arises in that other room. Such a model violates basic patient care standards, but increases profits to the referring physicians. More commonly, adequate staff are retained so an anesthesiologist who is personally performing a case is not interrupted and can care for her or her patient without being requested to attend to patients in other rooms.

ASA has received anecdotal reports of these circumstances having occurred. Faced with such pressure, an anesthesia provider can be placed in a predicament – refuse to administer anesthesia and lose his/her job, or administer anesthesia. Although one would hope that all anesthesia providers would elect the former; the reality is that the referring physicians can exert pressure on some providers to compromise their clinical judgment in order to secure gainful employment.

As such scenarios play out and less qualified providers are hired or retained by referring physicians, quality of patient care will suffer dramatically. In an environment in which ASCs are only beginning to submit quality data to CMS, the quality of care could greatly diminish and no one would know until a catastrophic event occurred.

b. *Forcing employed anesthesia personnel to provide anesthesia services for the referring physician's gain, not for reasons of medical necessity*. Company model arrangements adversely affect the quality of health care services in yet another way, by creating a direct financial incentive for referring physicians to require that patients receive anesthesia services, even if they do not need them. This point is particularly applicable in the case of anesthesia for certain gastrointestinal procedures, such as endoscopies and colonoscopies. Company model arrangements can create unnecessary risks for patients by exposing them to anesthetic risk in circumstances in which is it not always necessary.

c. *Creating a second layer of profit that incentivizes performance of medically unnecessary procedures*. To the extent that company models give referring physicians a second profit stream, referring physicians have double the incentive to perform medically unnecessary procedures, as they capture two professional fees for their services – their own fee and that of the anesthesiologist.

d. *The corruption of medical judgment threatens delivery of quality health care services*. In all of these ways, company model arrangements result in a corruption of medical judgment, decreased quality of health care services, and increased risk to patients.

Limiting Patient Freedom of Choice Among Health Care Providers

To the extent that referring physicians select anesthesia providers in company model arrangements based upon financial rather than quality considerations, company model arrangements necessarily limit patient freedom of choice. This point is further exacerbated by the role of consultants that operate the "anesthesia end" of a company model arrangement. The result can be nonphysicians making the decision of which anesthesia provider to hire or engage, based solely on price considerations. Anesthesia providers are not interchangeable; there are quality differences among them, just as there are with other professionals. Company model arrangements can and do limit the ability of patients to select their anesthesia provider, with the referring physicians' selection based entirely on profit, not quality or assurance of coverage.

Decreasing Competition Among Health Care Providers

Company model arrangements reduce competition among health care providers in at least two ways. First, as referring physicians implement company model arrangements, anesthesiologists who are unwilling to share their professional fee are shut out from more and more opportunities. ASA has heard anecdotal reports of anesthesiologists who had provided anesthesia services for referring physicians for more than twenty years, whose contracts were terminated when the referring physicians implemented a company model arrangement in which the referring physicians billed for and retained the anesthesia professional fee, sharing only a fraction with the new replacement anesthesiologists.

Second, as some anesthesia management companies develop which are willing to take risk and to enter into these arrangements in multiple locations nationwide, local competitors are foreclosed and competition decreases. ASA has heard reports of at least one ASC management company

creating its own anesthesia company to provide services at its ASCs, which could result in further market consolidation.

As reported by ASA in 2012, an ASA survey on company model arrangements conducted from December 2010-January 2011 demonstrated that 125 of 308 (41%) responding anesthesia practices from across the country had been requested by an ASC and/or referring physician practice to participate in a company model arrangement. Those 125 practices, representing 21 states, also reported multiple requests from multiple ASCs (n=332). Of the 332 requests reported in the survey, anesthesia practices lost a contract in at least 159 (48%) of those instances. These numbers were surprising and troubling to the ASA, and further underscore the need for issuance of a Special Fraud Alert and modification of existing safe harbors.

As company model arrangements continue to increase in frequency, the eventual outcome is that those who reject contracts they believe to be illegal will be forced out of the competitive marketplace. Only those who concede to these illegal models will remain, and competition thus will be decreased.

Further, according to the U.S. Government Accountability Office (GAO),[5] Medicare pays anesthesiologists approximately 33% of their average commercial payment for the same anesthesia services. The rest of medicine receives from Medicare approximately 80-85% of their average commercial payments. There is no question that Medicare payment rates are not sustainable for anesthesia practices, particularly if the commercial payor mix declines over time. Given this economic reality, and with continuing implementation of company model arrangements, anesthesia practices cannot sustain themselves by also providing 40% or higher shares of anesthesia profits to referring physicians.

Increasing the Cost to Federal Health Care Programs

Since the purpose of company model arrangements is to enable referring physicians to profit from their referrals, such arrangements can be expected to, and do, result in increased cost to Federal health care programs. *First*, the referring physicians have every incentive to perform medically unnecessary services when they stand to capture two revenue streams – their own professional fee and the anesthesia fee. *Second*, when the referring physicians employ the anesthesiologists, as is common in company model arrangements, referring physicians stifle the anesthesiologists' exercise of independent medical judgment with the insistence that cases be performed with anesthesia, without regard to medical necessity for the anesthesia.

To the extent that patients are receiving services they do not need, health care costs increase.

Third, and less obvious, is the overall upward pressure on the health care system when referring physicians syphon off the little profit available in the performance of anesthesiology services. For most anesthesia practices, any profits they can realize on the performance of anesthesia

[5] GAO, *Medicare Physician Payments: Medicare and Private Payment Differences for Anesthesia Services*, GAO-07-463 (July 2007), available at http://www.gao.gov/new.items/d07463.pdf.

services in the ASC setting (where company model arrangements most frequently occur) are used to offset the very significant costs of providing anesthesia for underinsured and uninsured patients. Over the past ten or so years, industry surveys have shown that some two-thirds to three-quarters of anesthesiology practices nationwide receive compensation from the hospitals at which they provide services. Such compensation usually pays for losses associated with coverage for service lines such as obstetrics, cardiovascular, trauma, and transplant services, which are not self-supporting in many hospitals. As referring physicians in company model arrangements retain anesthesia revenue, anesthesiology practices have fewer opportunities to cross-subsidize their losses, which creates further pressure on hospitals, which provide care to all comers.

This syphoning off of anesthesia profits and the resulting increased pressure on the health care system to pay for anesthesia services will have long-term deleterious effects on the health care system and on health care costs.

Notably, MedPAC estimates that Medicare payments and beneficiary spending on ASCs in 2010 was $3.4 billion, which represents an increase of 2.6 percent from 2009.[6] These payments do not include CMS professional fee payments to surgeons/proceduralists or anesthesia providers. Data also show that 27-30% of procedures performed in ASCs are performed by gastroenterologists.[7] The ASA survey conducted in December 2010-January 2011 demonstrated that the vast majority (66%) of specialties requesting company model arrangements were gastroenterologists, though there have since been increasing reports of orthopedists, ophthalmologists, and others implementing company model arrangements. Given the level of Federal health care payments and the volume of services provided to Medicare beneficiaries potentially under this economic model, there is significant opportunity to escalate the costs to Federal health care programs by the increased utilization of anesthesia services driven by referring physicians who profit from their ownership stake in the anesthesia revenue. Additional information appears in the following section.

Increasing the Potential Overutilization of Health Care Services

Anesthesiologists play a critical role in the perioperative process by performing pre-anesthesia evaluations to assess whether the patient is appropriate for the procedure and whether the proposed location for the procedure is appropriate (*e.g.*, ASC, outpatient facility, inpatient admission, etc.).

Company model arrangements compromise this critical phase in the patient's perioperative care. The referring physician's direct financial interest in the anesthesia company creates the strong incentive to increase the utilization of anesthesia services and the depth of sedation to maximize anesthesia profits. Though there is no current registry or analysis being performed to determine with scientific precision whether ASCs that implement company model arrangements increase

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[6] MedPAC, *Report to the Congress: Medicare Payment Policy*, at 115 (March 2012), available at http://medpac.gov/documents/Mar12_EntireReport.pdf.
[7] *Id*. at 126.

utilization of anesthesia services, ASA has heard from multiple sources that such ASCs have in fact increased from 45-60% utilization rates to nearly 100% once referring physicians are capturing the anesthesia revenue stream.

CMS data shows huge disparities in different parts of the United States among the use of anesthesia for two of the procedures most frequently performed by gastroenterologists, endoscopies (CPT™ code 00740) and colonoscopies (CPT™ code 00810) (the GI procedures). We are discussing these data, as these two codes account for fourteen percent (14%) of the total amount paid by Medicare for anesthesia services in 2011, and because ASA data indicate that requests to participate in company model arrangements occur most frequently with gastroenterologists.

We are enclosing two maps that summarize the incidence of anesthesia cases for GI procedures in 2011. In some states, the incidence of anesthesia cases for these GI procedures occurs as little as 1.6 to 8 percent of the time. In contrast, in some locations, the incidence of these cases occurs an astounding 64-81.73 percent of the time for CPT™ code 00740, and up to 95.49 percent of the time in the case of CPT™ code 00810. In states in which anecdotal evidence of company model arrangements is high, such as Florida, Tennessee, Georgia, Pennsylvania, New Jersey. New York, and Connecticut, anesthesia utilization for GI procedures occurs from 48 to 95.49 percent of the time, a much higher rate than in states such as Utah and Montana, in which the incidence of anesthesia utilization for GI procedures is less than eight percent. Those two states are not ones in which company model arrangements are common.

While these data do not conclusively demonstrate that company model arrangements cause overutilization of anesthesia services, they do serve as a compelling reflection of the high incidence of anesthesia services in some states, which happen to coincide with states in which there are frequent reports of company model arrangements, and the far lower rate of anesthesia services in states in which company model arrangements have not been reported.

Increasing the Financial Benefit to Health Care Professionals or Providers That May Take Into Account Their Decisions Whether to Order a Health Care Item or Service

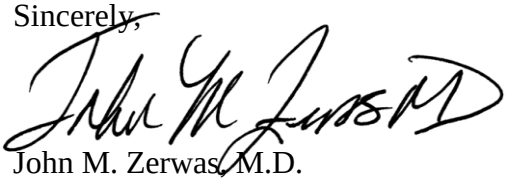
For all of the reasons outlined in this letter, ASA believes that company model arrangements directly motivate referring physicians to consider financial incentives and how much money they will receive when they decide whether to order anesthesia services for a procedure. Again, anesthesia for GI procedures is a compelling example, as anesthesia is not always used for these procedures (see discussion in the preceding section). In the past, referring physicians received only the professional fees for their own professional services, and facility fees for any facilities, such as ASCs, in which they held an ownership interest. *With implementation of a company model arrangement, referring physicians are able to receive hundreds of thousands, if not millions, of dollars each year in anesthesia professional fees*. It simply is not possible to reach any conclusion other than that the direct linkage between ordering anesthesia services and pocketing enormous sums of money for those services absolutely affects referring physicians' decisions to order anesthesia services.

E. Summary

We appreciate the enormous burden and workload of the OIG and applaud your ongoing efforts to identify fraudulent activity within our Federal health care programs. ASA believes that company model arrangements involve illegal kickback arrangements that threaten the quality of care that Federal health care program patients receive, corrupt medical decision making, and threaten the integrity of Federal health care programs by enabling referring physicians to realize enormous profits from their referrals. **We hope that you agree and take action to minimize the ability of referring physicians to profit from their referrals for anesthesia services.**

As always, we welcome a conversation to discuss this issue further if you would find it helpful. Please feel free to contact Grant Couch, Federal Affairs Associate, or Sharon Merrick, M.S., CCS-P, Director of Payment and Practice Management, in our Washington office via e-mail (g.couch@asawash.org or s.merrick@asawash.org) or phone (202-289-2222), with any questions or for additional information.

Sincerely,



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President
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Enclosures