Financial Arrangements Between Anesthesiologists, Ambulatory Surgery Centers and Gastroenterologists

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Ambulatory surgery centers ("ASCs"), particularly those whose physicians specialize in gastroenterology and endoscopy ("GI"), have been placing increasing pressure on anesthesiologists to enter into various financial arrangements that would allow the ASC or its owners to share in the income received by the anesthesiologists who provide anesthesiology services at the ASC. These arrangements take a variety of forms; however, they all have one element in common: the ASC and/or the surgeons who own the ASC, who are in a position to refer business to the anesthesiologists, are seeking to share in the revenue generated by the anesthesiologists, who are the beneficiaries of such referrals. Therefore, any arrangement must be analyzed in the context of the general prohibitions in both New York and federal law against kickbacks and fee-splitting, sometimes referred to herein as the "anti-kickback laws," particularly given the severe consequences of violating these laws.

I. Summary of Anti-Kickback Laws

A. Federal Anti-Kickback Statute

The federal anti-kickback statute provides, in pertinent part:

(1) whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind — (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a federal health care program ...

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

In addition to the criminal penalties described above, violation of the federal anti-kickback statute can result in civil penalties and exclusion from participation in Medicare and Medicaid.²

B. Third-Party Payor Agreements

Furthermore, many private third-party payor contracts contain provisions that allow the third-party payor to deny payment for any service rendered at a time when the provider was not in compliance with all applicable laws. Thus, violation of the federal anti-kickback law can result in significant loss of reimbursement, or claims for recovery of reimbursements previously paid, not only with respect to Medicare and Medicaid but also with respect to private third-party payors.

C. New York Anti-Kickback and Fee-Splitting Laws

In addition to the federal prohibitions and penalties described above, New York state law prohibits (i) "Directly or indirectly offering, giving, soliciting, or receiving or agreeing to receive, any fee or other consideration to or from a third party for the referral of a patient or in connection with the performance of professional services," and fee-splitting other than with a partner, employee, associate or subcontractor.

The fee-splitting prohibition specifically includes arrangements for furnishing space, facilities, equipment or personnel services where the payment is based on a percentage of income or receipts.⁴

D. Federal Safe Harbor Regulations

Applicable regulations of the Department of Health and Human Services include a series of "safe harbors," which describe certain financial arrangements that will not be treated as a criminal offense or serve as the basis for exclusion from Medicare and Medicaid. In general, arrangements that satisfy a safe harbor will also be acceptable under the New York laws cited above. Although arrangements that do not satisfy a safe harbor do not automatically constitute a violation of the anti-kickback laws, such arrangements will be subject to scrutiny by the Office of Inspector General ("OIG") and other regulatory authorities to determine whether, in fact, at least one purpose of the arrangement was to provide remuneration to induce referrals.

In light of the significant criminal and civil penalties that may be assessed for violation of the anti-kickback laws, every effort should be made to structure an arrangement to satisfy the requirements of a safe harbor. If the safe harbor cannot be satisfied, each arrangement must be carefully analyzed on a case-by-case basis to assess the risk that the arrangement will be found to violate the anti-kickback laws.

E. OIG Special Advisory Bulletin on Contractual Joint Ventures

The OIG issued a Special Advisory Bulletin in April 2003 concerning Contractual Joint Ventures (the "Advisory Bulletin"), in which the OIG identifies suspect features of contractual joint ventures that would lead it to view them as violating the anti-kickback law. For purposes of the Advisory Bulletin, "joint ventures" are defined very broadly to include "any common enterprise with mutual economic benefit." The Advisory Bulletin also cautions that even where particular contractual arrangements meet the technical requirements of a safe harbor, the overall joint venture may still violate the anti-kickback law. Given this broad definition, any analysis of any of the business arrangements discussed in this article must take the OIG's joint venture analysis into account.

Among the characteristics that could indicate a prohibited arrangement, as described in the Advisory Bulletin, are the following:

- New Line of Business. One party is seeking to expand into a new line of business that can be provided to the first party's existing patient base.
- <u>Captive Referral Base</u>. The new venture is serving the owner's existing patient base, rather than expanding into an area that would allow it to serve an additional patient base.
- <u>Little or No Bona Fide Business Risk</u>. The main contribution of the owner of the joint venture is referrals. The owner is not taking on significant financial risk in exchange for the income it will receive.
- Remuneration for Referrals. The practical effect of the arrangement, viewed in its entirety, is to allow one party (the GI physician or ASC) to bill for services that were previously being provided and billed by another party (the anesthesiologists) and to be compensated in a manner that takes into account the volume and value of business generated between the parties.

The principals enunciated in the Advisory Bulletin were reiterated by the OIG in the "OIG Supplemental Compliance Program for Hospitals" (the "SCP").

With this backdrop, we will now look at a few business models that have been considered, bearing in mind that each of these models is susceptible to numerous variations in details.

II. Business Models

While there are an infinite variety of arrangements that can be created, the possible structures can be divided into five basic types, each of which entails risks and benefits. This article attempts to highlight some of the relative risks and benefits of each type of arrangement. However, it is merely an introductory article for purposes of drawing attention to the issues involved and does not constitute an endorsement or condemnation of any particular transaction.

A. Service Agreement Model

Under the "Service Agreement Model," an ASC will enter into an agreement with an anesthesiologist or anesthesiology group whereby the ASC will provide office space, equipment, and/or administrative support services to the anesthesiology group in exchange for a fee. As noted above, to satisfy New York law, the fee paid to the ASC cannot be determined as a percentage of revenues. This model implicates three safe harbor rules: space rental, ⁷ equipment rental, ⁸ and personal services and management contracts. ⁹ The primary requirements common to each of these safe harbor regulations are:

- 1. The agreement must be in writing.
- 2. The written agreement must cover all of the space, equipment, and/or services involved.
- 3. If the arrangement is less than full time, the intervals of use or periods of service must be specified in advance in the agreement.
- 4. The term of the agreement must be at least one year.
- 5. The aggregate compensation must be set in advance, be consistent with fair market value in an arms-length transaction, and not be determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.
- 6. The aggregate services, space or equipment contracted for do not exceed what is reasonably necessary to accomplish the commercially reasonable business purpose of the contracting party.

While it is possible to satisfy all of the above safe harbor requirements in the context of the Service Agreement Model, GI practitioners and ASCs have become dissatisfied with this model because of the relatively low amount of compensation that the anesthesiologists can pay if all of the above conditions are to be strictly adhered to.

B. Endoscopy Suite Model

The Endoscopy Suite Model builds upon the basic contractual structure of the Service Agreement Model but attempts to increase the profitability of the enterprise by replacing the ambulatory surgery center with an office-based surgical practice (an "OBS"). The GI physicians lease the space, obtain the necessary accreditation for the facility, ¹⁰ hire all the necessary support staff, and purchase all of the endoscopy equipment. The OBS then subleases space to the anesthesiologists (either directly or through their professional entity), and provides all services to the anesthesiologists, including administrative and billing services. The contractual elements — a real estate lease, an equipment lease, and a personal services contract — are the same elements present in the Service Agreement Model and are subject to the same analysis in determining whether each element satisfies an applicable safe harbor.

The advantage of the Endoscopy Suite Model is that, if it is done properly, it can reduce overall overhead while increasing the services and facilities available to be provided and paid for by the anesthesiologists, without taking on significant additional risk with respect to the anti-kickback laws.

However, the other business models considered herein assume that there is an existing ASC that is seeking to restructure its relationship with its anesthesiologists. Assuming that to be the case, the obvious downside to the Endoscopy Suite Model is that it requires a more comprehensive overhaul of the entire practice structure and the creation of a new OBS facility, with its attendant time and expense.

C. Company Model

A model commonly referred to as the "Company Model" is described in a June 16, 2010, letter from the American Society of Anesthesiologists to the Office of Inspector General of the United States Department of Health and Human Services (the "ASA Letter"). Under this model, a separate group or company is formed, which is owned by some or all of the same individuals who own the ASC (the "Anesthesiology Company"). The Anesthesiology Company contracts to provide anesthesiology services to the ASC, and the Anesthesiology Company hires the anesthesiologists as employees or independent contractors. Income received by the Anesthesiology Company in excess of the compensation paid to the anesthesiologists is distributed to the GI physician owners of the Anesthesiology Company.

It should be noted at the outset that, in order to satisfy the corporate practice of medicine requirements under New York law, all of the owners of the Anesthesiology Company must be physicians. Assuming this requirement is satisfied, New York, as noted above, permits the sharing of fees between a practice and its employees or independent contractors.

Under the safe harbor regulations, payments by the Anesthesiology Company to the anesthesiologists, whether as employees or independent contractors, can be structured to fall within the bona fide employee safe harbor or the personal services safe harbor described above. However, the payments from the Anesthesiology Company to its owners would not satisfy any applicable safe harbor. Since the owners of the Anesthesiology Company do not provide services to it, payments to the owners constitute a return on investment in the Anesthesiology Company. Therefore, the payments to the owners would have to qualify either under the safe harbor for investment interests or for investments in group practices. 14

The investment safe harbor requires, among other things, that no more than 40 percent of the equity interests in the entity be held by investors who are in a position to make referrals. Under the Company Model, all of the investment interests in the Anesthesiology Company are held by physicians who are in a position to make referrals to the Anesthesiology Company.

The group practice safe harbor includes a requirement that "the equity interests in the practice or group must be held by licensed health care professionals who practice in the practice or group." However, as described in the ASA Letter, this requirement would not be satisfied because the Anesthesiology Company only provides anesthesiology services, while its owners are GI physicians who practice through other practice entities.

Since the model would not comply with a safe harbor, it would be subject to scrutiny. Furthermore, there are several factors that appear to fall squarely within those factors specifically outlined in the Advisory Bulletin and the SCP. All the owners of the Anesthesiology Company are in a position to make referrals, and the owners who make the referrals have a more favorable investment interest than the anesthesiologists, who have no investment interest. Therefore, any attempt to structure an arrangement in accordance with the Company Model must be subjected to careful risk analysis with respect to potential anti-kickback violations.

Some of these concerns might be ameliorated by allowing the anesthesiologists to acquire equity interests in the Anesthesiology Company. However, the basic problem of having GI physicians share in the profits of a group practice through which they do not practice would remain.

D. Employer/Employee Model

In the Employer/Employee Model, the GI practice entity hires the anesthesiologists as direct employees. This differs from the Company Model by having the anesthesiology services and the GI services performed and billed through the same entity. As with the Company Model, the employment agreement between the practice entity and the anesthesiologist(s) can be structured so as to comply with the bona fide employee safe harbor regulations, as well as the New York law permitting "fee-splitting" with employees. It also has the ability, not present in the Company Model, to be structured to comply with the requirements of the group practice investment safe harbor. As noted above, in order for profits distributed to owners to be covered by that safe harbor, the owners must practice through the group practice entity.

However, there are several legal and practical concerns raised by this structure that would need to be addressed in order for it to succeed in any given situation.

First, the business motive for entering into an arrangement is to permit the members of the ASC to benefit from the income generated by the anesthesiologists. Unless all of the members of the ASC are also members of the same GI group practice, having one GI group practice employ the anesthesiologists would not permit all of the members of the ASC to benefit from the arrangement.

Second, anesthesiologists are often out-of-network providers, while the GI physicians are in-network providers. Having both services provided through the same group practice could therefore create problems with third-party payors. Either the anesthesiologists would have to become in-network providers, thus reducing their reimbursement rates, or they would have to bill for their services under a separate billing number, which could result in their not being considered to be practicing in the same group for purposes of the safe harbor rules. As noted above, if the GI physicians are not practicing through the same group as the anesthesiologists, the safe harbor for investment interests in a group practice is no longer available. The same concerns would apply if the anesthesiologists were made equity owners or independent contractors of the GI practice.

E. Independent Contractor Agreement Model

A variation on the Employer/Employee Model is the Independent Contractor Model, in which a GI practice retains the services of anesthesiologists, either directly or through their separate professional entity, to provide anesthesiology services to the GI physician patients. As with the Employer/Employee Model, it does not violate the New York prohibition against fee-splitting. It also has the advantage of keeping the anesthesiology practice independent and allowing its anesthesiologists, directly or through their entity, to contract with more than one GI practice entity. However, it does not address concerns raised by in-network vs. out-of-network participation status. It also creates additional hurdles to compliance with an anti-kickback safe harbor.

The agreement would have to comply with the safe harbor for personal services and management contracts. In particular, the agreement would have to specify the aggregate compensation paid to the anesthesiologists over the term of the agreement. Any arrangement that compensated the anesthesiologists on a per-case basis (without specifying the number of cases to be performed) or based on a percentage of revenue collected for anesthesiology services would not satisfy this requirement. Furthermore, if the agreement was for less than full-time services, the agreement must specify "exactly

the schedule of such intervals, their precise length and the exact charge for such intervals." Given these constraints, it is not likely that such an arrangement could be structured so as to comply with a safe harbor.

III. Conclusion

All of the models described above share one feature in common: They each seek to allow physicians who are in a position to make referrals (i.e., GI physicians) to share in the income generated by the providers to whom the referrals are made (i.e., the anesthesiologists). However, any of these arrangements is subject to being considered a "joint venture" under the Advisory Bulletin and will therefore be subject to close scrutiny. Furthermore, each model poses significant hurdles (in varying degrees) to satisfying a safe harbor; and even where a particular arrangement appears to satisfy a safe harbor, there may be aspects of the arrangement that the safe harbor does not cover. (For example, an employment contract that satisfies the safe harbor for bona fide employment relationships protects the payments made by the employer to the employee, but does not address the payments made by the practice entity to its owners.) Given the difficulty of meeting safe harbor requirements and the potentially devastating consequences, both civil and criminal, of violating state and federal anti-kickback laws, it is imperative that any proposed arrangement be closely and carefully analyzed in light of all the facts and circumstances before being acted upon.

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