Health Care Compliance Adviser: OIG to Scrutinize “Suspect Contractual Joint Ventures”

Earlier this year, in a Special Advisory Bulletin (the “Bulletin”), the HHS Office of Inspector General (“OIG”) gave notice of its intent to investigate so-called “contractual joint ventures,” the term coined by the OIG to describe relationships where a provider expands into a new line of business by contracting with an entity that is already in that business. Asserting that “contractual joint venture arrangements are proliferating,” the OIG identified common features of “suspect” contractual joint venture arrangements and warned that such arrangements may violate the Anti-Kickback Statute. While OIG scrutiny of joint venture arrangements is not new, the latest Bulletin goes beyond previous guidance and calls into question commonplace contractual arrangements that do not involve referrals by investors. It even suggests that arrangements that fit within a regulatory safe harbor are not necessarily safe.

**Contractual Joint Venture Arrangements**

The Bulletin defines so-called contractual joint venture arrangements as arrangements where a health care provider in one line of business (the “Owner”) expands into a new line of business by contracting with an existing provider of a related item or service (the “Supplier”) to provide the new item or service to the Owner’s existing patient population (which includes federal health care program patients). Three examples are provided:

- A hospital expands into the durable medical equipment (“DME”) field by forming a new subsidiary that contracts with an existing DME company to operate the business and provide DME inventory. The existing DME company operates the business, the hospital subsidiary pays the DME company a management fee, and the hospital subsidiary bills insurers and patients and collects the money.
- A DME company forms a mail order pharmacy to sell certain nebulizer drugs reimbursable by federal health care programs. The DME company enters into a management agreement with an existing mail order pharmacy to run the DME company’s new business. The existing mail order pharmacy also sells all the drugs required by the new pharmacy.
- A nephrology group practice creates a wholly owned company to provide dialysis supplies to its patients. An existing supplier enters into a management agreement to operate the new company and to provide all goods and services required by the new company.

These arrangements are not “joint ventures” in any traditional sense (i.e., investment ventures where ownership is locked together in a single entity), but instead are contractual arrangements that more resemble outsourcing agreements. Obviously, outsourcing arrangements are extremely common in the health care and other industries. The Bulletin, however, focuses on those contractual arrangements with

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certain “suspect” features. According to the OIG, “suspect” contractual joint venture arrangements, i.e., arrangements that potentially violate the federal Anti-Kickback Statute, share the following common elements:

- **New Line of Business With Captive Referral Base.** Does the Owner’s new line of business depend on referrals from, or other business generated by, the Owner’s existing business? Does the Owner expect the business line to service new patients or at least to make a *bona fide* effort to generate new patient business?

- **Lack of Risk.** Does the Owner operate the new business? Does the Owner commit substantial financial, capital, or human resources to the venture? Is the Owner’s chief contribution its own referrals?

- **Supplier Provides Key Services.** Does the Supplier provide important services to the Owner such as management, billing, personnel, space, and inventory?

- **Supplier Is Competitor.** Is the Supplier a potential competitor of the Owner’s new line of business?

- **Remuneration Varies with the Volume or Value of Services Generated.** Do the Owner’s payments to the Supplier for goods and services vary based on the number of goods and services provided to federal health care program patients? Do the Owner’s profits for the new business vary based on the referrals generated by the Owner?

- **Exclusivity.** Does the parties’ agreement include a noncompete clause? Such a clause could either prohibit the Owner from providing services to patients other than patients referred by the Owner to the new business and/or could prohibit the Supplier independently from providing services to the Owner’s patients.

The Bulletin states that the presence or absence of one element is not determinative, but does not address the legality of an arrangement with some, but not all, of the above characteristics.

### Anti-Kickback Concerns

In its analysis of how suspect contractual joint ventures may violate the Anti-Kickback Statute, the OIG raises a number of troubling issues.

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3 For example, under these facts, the arrangement involves a new line of business to serve an existing patient population, the supplier of expert services is a potential competitor of the hospital, and the supplier provides many key services, such as management and training.
purchased services billed to Medicare, it has done so expressly. For example, a specific provision of the Medicare statute bars physicians from marking up the cost of purchased clinical laboratory services on claims submitted to Medicare.  

**No Arms-Length Transaction.** The Bulletin notes that while some arrangements involving the sale of discounted goods or services can qualify for the “discount” safe harbor; this safe harbor applies only to arms-length transactions. According to the OIG, an arms-length transaction cannot occur between two parties to a joint venture and thus the discount safe harbor cannot apply to contractual joint ventures. This proposition is troubling and illogical. Why should one assume that an agreement between an Owner and a Supplier not be an arms-length transaction when, for instance, there is no common ownership or control?

**Safe Arrangements Are Not Really Safe, According to the OIG.** Most troubling of all, the Bulletin asserts that even if a contractual joint venture satisfies a safe harbor; the safe harbor would only protect the remuneration from the Owner to the Supplier. It allegedly would not protect the remuneration that the OIG believes flows from the Supplier to the Owner in the form of the Owner’s “opportunity to generate a fee and a profit.” In other words, according to the OIG, an arrangement that otherwise fits into a safe harbor is not in fact “safe.” This unsupported assertion contradicts the very purpose of the safe harbor protections. The safe harbors were intended to assure providers that conforming arrangements would be deemed lawful under the Anti-Kickback Statute. The Bulletin’s dismissive approach to safe harbors seems dubious, and certainly runs contrary to settled understandings of the safe harbor regulations.

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4 See 42 U.S.C. § 1395u(n).  
5 42 C.F.R. § 1001.952(h).  
6 The OIG bases its position not on the text of the discount safe harbor regulation itself, but on language in the preamble to the final safe harbor regulations:  

> Another problem exists where an entity, which is both a provider and supplier of items or services and joint venture partner with referring physicians, makes discounts to the joint venture as a way to share its profits with the physician partners. Very often this entity furnishes items or services to the joint venture, and also acts as the joint venture’s general partner or provides management services to the joint venture. . . . These arrangements are not arms length transactions where the joint venture shops around for the best price on a good or service. Rather it has entered into a collusive arrangement with a particular provider or supplier of items or services that seeks to share its profits with referring physician partners. [W]e do . . . not intend to protect these types of transactions which are sometimes made to appear as ‘discounts.’  

7 See 42 U.S.C. § 1320a-7b(b) (3); 42 C.F.R. § 1001.952.  
8 See 56 Fed. Reg. at 35954 (July 29, 1991) (“If a person participates in an arrangement that fully complies with a given provision, he or she will be assured of not being prosecuted criminally or civilly for the arrangement that is the subject of that provision.”).
Of course, each transaction is different and must be considered on its own facts. In light of the OIG’s expressed skepticism regarding so-called contractual joint venture arrangements, however, hospitals should consult with counsel prior to entering into relationships potentially implicated by the Bulletin.

**Further Information**

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