

# Dialysis facility joint ventures-current structures and issues

JAMES B. RILEY, JR., ESQ. • ROBERT PRISTAVE, ESQ.

*Mr. Riley and Mr. Pristave are partners in the Health Care Department of the Chicago office of McGuireWoods LLP. Both serve as co-editors for NN&I's Legal Angle column.*

*With the ongoing consolidation of the health care industry, including renal care, providers and physicians alike are using joint ventures as a means to partner on business transactions. This article discusses the expanding use of joint ventures in health care, including the dialysis industry, and looks at the types of structures being utilized and key legal concerns relating to such structures and issues.*



James B. Riley, Jr., Esq.



Robert Pristave, Esq.

## Joint ventures in the health care industry

Over the past few years, there has been a significant increase in the number of joint ventures in health care. This includes substantial growth with respect to dialysis facility joint ventures, ambulatory surgery center joint ventures, and to a lesser extent, growth of imaging facility joint ventures, cardiac catheterization facilities, and hospitals (principally specialty hospitals).

Joint venture dialysis facilities have experienced significant growth. This is due, in part, to the fact that composite rate dialysis services are not subject to the federal prohibitions on physician self-referral. Ambulatory surgery centers (ASCs) have many of the same characteristics and the same motivations for joint venturing as dialysis facilities.

Imaging facilities are also experiencing significant growth. But joint venturing imaging facilities is much more complex than joint venturing dialysis facilities. This is partly because imaging facilities, except for positron emission tomography ("PET") centers,<sup>1</sup> are subject to Stark Act prohibitions. This means that physicians and hospitals cannot joint venture the actual provider of imaging services, unless they are in rural areas or joint venturing with radiologists, or radiation oncologists with regard to radiation therapy. Thus, the parties must resort to other methods of trying to develop efforts aimed at jointly serving imaging needs. These can include, for example, time block, equipment leases, and management models.

## Advantages, disadvantages of joint venturing

From a business perspective, there are several advantages to joint venturing. First, the parties have the ability to share business risk with a joint venture partner. Second, a joint venture involving a large provider of dialysis services may provide access to professional management that handles development and day-to-day operations. Third, a joint venture partner may provide access to favorable supplier/payer contracts. Finally, a joint venture provides a mechanism to increase access and competition in the marketplace.

There are other considerations when selecting a joint venture partner. Large provider partners have many advantages, such as a deeper infrastructure in terms of development, bill-

ing and collection, etc., as well as access to clinical initiatives and recruiting assistance. Alternatively, small provider partners can provide greater flexibility in terms of ownership percentages, and greater flexibility in terms of influencing operational issues.

On the other hand, disadvantages exist to joint venturing as well. For example, in many cases, joint venturing will result in loss of control over operational and strategic decisions. Typically, in most joint ventures, the professional manager essentially runs the business, subject to those decisions which the parties agree must be consented to by all parties. A further disadvantage of a joint venture is the resulting sharing of profits, which occurs by the very nature of a joint venture. Thus, the party holding the larger ownership percentage receives the larger share of the profits, in addition to any other fees that the parties receive for services rendered. Finally, there are certain additional regulatory issues that are raised by a joint venture that are not present in a physician-owned facility.

In the dialysis industry, there are many providers of dialysis services involved in joint venturing with physicians, including the large public companies such as DaVita and Renal Care Group. Many other providers use the joint venture model, among them American Renal Associates, Innovative Dialysis, Satellite Healthcare, and National Renal Alliance, which has a niche in rural initiatives. It should be noted, however, that in connection with its recent settlement with the government, Gambro AB has sought to terminate its involvement in joint ventures with physicians.

## Structure of joint ventures

There are several principal structures utilized for joint ventures. These models are subject to different legal risks and have various applicability, depending on whether a service is a "Stark" or "non-Stark" service. The typical model for dialysis facility joint ventures is a true, or traditional, joint venture.

- **True joint venture.** A true or traditional joint venture is a jointly-owned entity. The entity has its own provider number, license, and generally owns the assets that comprise the joint venture operations. The profits in the joint venture are split

1. Positron emission tomography is a nuclear medicine procedure. Nuclear medicine procedures were exempted from the original Stark Act and that exemption was reaffirmed in the final regulations. To read the passages relevant to nuclear medicine see *Federal Register*, Vol. 69, No. 56, pp. 16102-04.

by ownership. This is the predominant model of joint venture for dialysis facilities and ASCs. The division of ownership in these types of ventures depends greatly upon such issues as the regulatory constraints, the relative bargaining positions of the parties, and whether the venture is a start-up venture or an existing venture. The division of ownership also depends on the extent of capital available to the physician partners in the venture. Typically, these joint ventures are structured as limited liability companies (subject to certain tax concerns in certain states), and a board of managers is often elected in proportion to the ownership to manage the entity. The ventures generally have a management contract with the non-physician investor to oversee management.

With respect to dialysis facilities, there are several models:

- **Start-up facility joint ventures.** Under a new facility joint venture model, parties with no prior relationship could establish an entity to develop and operate a new dialysis facility.
- **Satellite joint ventures.** In a satellite joint venture model, an existing provider and physician would build dialysis facilities outside the areas covered by the physicians' restrictive covenant. While this model may result in patients transferring from an existing facility, it is generally directed at serving a new geographic area and providing greater access to patients.
- **Existing facility joint ventures.** In an existing facility joint venture model, parties would establish a new entity to acquire and operate the existing facility in which the physicians provide services.

Under most joint venture models, the physician owner will serve as medical director pursuant to a medical director agreement. These agreements would be structured to meet as many elements of the applicable anti-kickback statute safe harbor as possible and all the elements of the applicable Stark Act exception.

## Key legal issues

There are several key legal issues involved in structuring joint ventures between physicians and other investors. They include:

- issues raised under the Stark Act.
- issues raised under the federal Anti-Kickback Statute.
- issues raised under state self-referral and anti-kickback statutes.
- issues raised with respect to a provider's Internal Revenue Code Section 501(c)(3) status, where applicable, and the operation and organization of the joint venture.

- issues raised under certificate of need laws.
- issues raised under federal and state antitrust laws.
- issues with respect to the affiliated service group rules and the impact on pension plans where physicians and other providers jointly own and operate facilities.
- issues raised under the securities laws, with respect to the sale and issuance of ownership in facilities.

Here, in more detail, are the legal concerns with joint ventures.

- **The Stark Act.** The Stark Act specifically restricts the ownership and operation of certain types of providers by physicians. With respect to joint ventures, it is a critical statute because it essentially outlaws joint ventures where a service is a designated health service.<sup>2</sup> With respect to the types of joint ventures stated above, ambulatory surgery centers and dialysis facilities, i.e., composite rate services, typically, are not providing designated health services. However, physician joint ventures with hospitals or with dialysis providers which have labs will have Stark issues that have to be addressed and resolved. Thus, they can be established as a true joint venture. In contrast, imaging services, except for PET services and nuclear services, are considered Stark services.<sup>3</sup> This means there are substantially greater restrictions on the ability to joint venture imaging services.
- **The Anti-Kickback Statute.** Joint ventures raise many issues under the Anti-Kickback Statute. The OIG promulgated safe harbor regulations for certain arrangements that do not pose a risk of fraud and abuse.<sup>4</sup> Included is a safe harbor for ambulatory surgery center joint ventures.<sup>5</sup> There is also a safe harbor, for example, for investments in smaller investment entities.<sup>6</sup> There is not a specific safe harbor for dialysis facility joint venture, although the group practice safe harbor may apply in cases of dialysis facilities wholly owned by a physician group practice.

The relevant safe harbor for a nephrologists' ownership of interest in a joint venture is the small investment interest safe harbor. The elements of this safe harbor are as follows: 1) no more than 40% of the value of the investment interests may be held by investors who are in a position to make referrals to, provide items or services to, or otherwise generate business for the entity; 2) the terms of the offering of investment interests to any "passive" referring investors, if any, are no different than terms offered to other investors; 3) the terms of the offering of investment interests to referring investors must be unrelated to the previous or projected volume of referrals,

2. The Federal Ethics in Patient Referrals Act, 42 U.S.C. § 1395nn, as amended and 42 C.F.R. § 411.350 et seq. (the "Stark Act") prohibits, with certain exceptions, a physician who has a financial relationship (either ownership, compensation or investment) with an entity from referring patients to that entity for the provision of "designated health services" (DHS) if payment for those services may be made under Medicare or Medicaid. There are 11 DHS to which the prohibition applies. These include clinical laboratory services; physical therapy services, including speech-language pathology services; occupational therapy services; radiology and certain other imaging services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients; equipment and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services.

3. Nuclear medicine has been excluded from the list of designated health services. However, CMS has commented that although PET scans and nuclear medicine procedures are not Stark services, arrangements involving nuclear medicine may violate the anti-kickback statute depending on the circumstances. To read the passages relevant to nuclear medicine see the *Federal Register*, Vol. 69, No. 56, pp. 16102-04.

4. 42 C.F.R. § 1001.952(a) - (u). Under the regulations, arrangements which satisfy all of the requirements of the safe harbor are immune from both criminal prosecution and administrative enforcement by the OIG.

5. 42 C.F.R. § 1001.952(r).

6. 42 C.F.R. § 1001.952(c), (d), and (a).

items or services furnished, or business otherwise generated; 4) there is no requirement that a “passive” referring investor, if any, make referrals, provide items or services, or otherwise generate business as a condition for remaining an investor; 5) the entity must not market or furnish services differently to “passive investors” and non-investors; 6) no more than 40% of the gross revenue of the entity may come from investors in a position to make referrals, to provide items or services to, or generate business for, the entity; 7) neither the entity nor any other investor may loan funds to or guarantee a loan for a referring investor to enable him, her, or it to make a capital contribution; and 8) the returns to investors must be directly proportional to their capital contributions.

While all of the elements of the safe harbor are important, the “60/40” requirements have generated controversy because they impose arbitrary numerical standards and are very narrow in their potential applicability to health care ventures. In fact, it is generally recognized that a large number of ventures will be unable to meet the “60/40” standards and it is almost impossible for a dialysis facility joint venture to meet these standards.

With respect to joint ventures that will not meet a safe harbor, one must intend that the return on ownership in the joint venture is not prohibited remuneration or that any compensation received is not in exchange for referrals. Then, one must implement a number of steps to help clarify that the parties are not receiving any sort of a special compensation or remuneration as a result of being owners in the joint venture. For example, it must be clear that a party is not required to make referrals, a party is not able to buy shares below fair market value, and a party is not receiving a special or unnecessary compensation.

- **State self-referral and anti-kickback statute.** Many state self-referral and anti-kickback statute laws mirror those of the Stark Act and/or the Anti-Kickback Statute. With respect to completing a joint venture in a specific state, it is critical that a party fully examine the laws of that state and its impact on the potential joint venture.<sup>7</sup>
- **Tax-exempt entity involvement.** There are two core issues with respect to the inclusion of a tax-exempt partner in a joint venture. First, the exempt party typically desires to treat the income of the joint venture as exempt from taxation (i.e., not subject to tax as “unrelated business income”). Second, the tax-exempt entity desires to ensure that its involvement in the joint venture, even if the income is taxed, will not have a negative impact on the tax-exempt status as a whole. To this end, the joint venture in which the tax-entity invests must be organized and operated in a manner that allows the joint

venture to serve the community and charitable purposes of the tax-exempt partner.<sup>8</sup> Internal Revenue Service guidance can help determine whether facts and circumstances show that a joint venture furthers the charitable purposes of the exempt nonprofit partner, and whether the arrangement permits the exempt partner to act exclusively in furtherance of its exempt purposes, and only incidentally for the benefit of the for-profit partner. The revenue rulings consider whether or not the exempt partner has been able to maintain sufficient control over its activities for it to be able to establish that it will be operated exclusively for exempt purposes. It is not a narrow look at control.<sup>9</sup>

The core challenge with respect to tax-exempt issues is balancing the needs of a tax-exempt entity to have comfort that the joint venture will not negatively impact the tax-exempt status with the need of physicians to have input into the joint venture in which they are investing.

- **Certificate of need.** In many states, to develop a new health service, a party is required to obtain a Certificate of Need (CON). Less than 15 states have a CON requirement applicable to dialysis facilities. In contrast, in more than 25 states there remains a CON requirement for surgery centers. In CON states, the parties must determine whether there is an exemption for the CON law or whether they can obtain a CON.
- **Affiliated service group issues.** Generally, parties desire to avoid a situation where their own practice is deemed affiliated for pension purposes or those of the joint venture. There are a number of rules that impact this type of analysis.
- **Securities law issues.** In developing a joint venture, depending upon the number of potential participants and whether the parties are forming a joint venture together or whether one party is selling interests to another, an issue may be raised as to whether one party is selling securities to others. Where a party is selling securities, it is important to assure that one meets an exemption for the sale of securities under each state and federal law perspective.

## Conclusion

Joint ventures continue to be a viable alternative to ownership of certain types of services in today’s health care industry. Such ownership, however, does not come without some degree of uncertainty in the business and regulatory environment in which today’s health care providers exist. Proper guidance in the structuring of a joint venture is essential in that environment. ♦

7. See e.g., CAL. BUS. & PROF. CODE § 650.01 (West 2005); COLO. REV. STAT. § 26-4-410.5 (West 2005).

8. I.R.C. § 501(c)(3). To qualify as a tax-exempt organization, an entity must be organized and operated exclusively for one or more charitable purposes. Moreover, a 501(c)(3) entity must furnish a public benefit through its activities and there cannot be more an incidental private benefit and inurement.

9. *Continuing Professional Education (“CPE”) Text for Fiscal Year 2002, Part I, Exempt Organizations Technical Topics*, p. 13. Revenue Ruling 98-15, which is cited in the CPE text, provided guidance on the tax treatment of exempt hospitals participating in whole hospital joint ventures with for-profit entities. The Internal Revenue Service analyzed two fact patterns, one of which was permissible and one of which resulted in revocation of tax-exempt status. The general concepts coming out of the permissible fact pattern involved the tax-exempt partner having significant board and operational control. In addition, the governing documents required the venture to serve community needs.