Dialysis Center Joint Ventures
Evaluating the Opportunity

Renal Physicians Association 2015 Annual Meeting
March 21, 2015, Baltimore, MD

Presented by:

James B. Riley, Jr.
Partner, McGuireWoods LLP
77 W. Wacker Dr., Ste. 4100
Chicago, IL 60601-1818
jriley@mcguirewoods.com
Nothing to Disclose
Dialysis Joint Ventures Generally

- Joint Venture Considerations
  - Regulatory
    - Regulatory concerns in a changing environment
  - Economic
    - Create value
  - Clinical
    - More control as an owner
  - Governance
    - More control as an owner
  - Business
    - Align interests with dialysis provider
  - Compensation
    - Hedge against decrease of practice revenue and MDA compensation
• Essential Elements:
  – Federal and State Laws
  – The Transaction: Parties, Key Agreements and Terms, Analysis of the Deal, etc.
To become one with the universe, you must first become compliant with the universe!
Introduction

Biggest News In Compliance In The Dialysis Industry – DaVita Healthcare Partner’s $389 Million Settlement
The Statutory Analysis

Back to The Basics – What’s Legal And What’s Not
The Statutory Analysis (Cont’d.)

• Anti-Kickback Statute
  42 USC §1320a-7b(b)

• The Stark Act
  42 USC §1395nn(a)(1)

• False Claims Act
  31 USC §3729

• State law (where applicable)
Anti-Kickback Statute

- Social Security Act provisions address fraud and abuse in the Medicare and Medicaid programs

- SSA prohibits the **knowing and willful** solicitation, receipt, offer or payment of “**remuneration**” directly or indirectly, overtly or covertly, in cash or in kind” in return for or to induce the referral, arrangement, or recommendation of Medicare or Medicaid business.

- Violation is a felony, with fine up to $25,000 and/or imprisonment up to 5 years

- Beyond fines and penalties, federal HHS and Office of Inspector General (“OIG”) is empowered to suspend and exclude providers or suppliers from Medicare and/or Medicaid participation that violate the AKS
Anti-Kickback Statute Overview

• **Knowing and willful solicitation** – does not require actual knowledge of, or specific intent to commit a violation of the Anti-Kickback Statute, but must prove **knowledge that the conduct in question was unlawful**
Anti-Kickback Statute Overview (Cont’d.)

- Remuneration- whether in cash or in kind, and whether made directly or indirectly, including:
  - Kickbacks
  - Bribes
  - Gifts
  - Furnishing of supplies, services or equipment either free, above or below market
  - Waivers of payments due
• Remuneration to investing physicians can also be viewed as illegal remuneration, and thus:

  – Investments and risk must be proportionate to ownership and distributions must be proportional to investment
  – Medical director fees must be FMV
  – Management agreement fees must be FMV
  – Lease payments must be FMV
Fair Market Value:
What Does It Mean?
Anti-Kickback Statute Overview (Cont’d.)

• “Fair market value” means the value in **arm’s-length transactions** consistent with the **general market value**

• Fair market value price for assets means the amount paid as a result of a bona fide bargaining between well-informed parties who are not otherwise in a position to generate business for the other party at the time of the agreement

• Fair market value price for compensation may not be determined in any manner that takes into account the value or volume of anticipated or accrual referrals
The following generally accepted valuation approaches can be used for valuing businesses/arrangements:

- Income Approach
- Cost Approach
- Market Approach
Induce Referrals – statute covers any arrangement where only one purpose of the remuneration is to give or receive remuneration for the referral of services or to induce further referrals.

- Greber (3d Cir.) and Kats (9th Cir.) concluded if one purpose of the payment is to induce referrals, even if another purpose is to provide compensation for services rendered (one purpose test), an AKS violation may result.
What Are The Sources Of Guidance By The Government Regarding The Anti-Kickback Statute?
Safe Harbors:

- OIG “safe harbor” regulations under the AKS
- Arrangements that satisfy all requirements of a safe harbor are immune from both criminal prosecution and administrative enforcement by the OIG
- Arrangements outside a safe harbor may still be lawful, particularly those that do not increase program cost, result in over-utilization of services or reduce quality
Small Investment Interest Safe Harbor:

- Relevant to JV company and physician’s ownership interests therein
- Applies to entities other than publicly traded companies
- Entities must meet several standards, including...
  - Investors in position to make referrals or provide services to the JV cannot exceed 40% of the value of the investment interests (dialysis facility JV almost impossible to meet this particular standard
  - No more than 40% of the JV’s gross revenue may come from referrals or business otherwise generated by investors
OIG Guidance:

- OIG Special Fraud Alert
- OIG Special Advisory Bulletins
- OIG Advisory Opinions
OIG Special Fraud Alert:

• Issued in 1989 by the OIG

• Identified “suspect joint ventures”

• Key features of a suspect joint venture:

  (1) selects investors solely on ability to make referrals,
  (2) offer greater investment opportunity for investors more able to make referrals,
  (3) actively encourage investors to make referrals,
  (4) requiring only minimal capital contribution by physician investors,
  (5) investments with disproportionately large returns compared to similar investments with similar risk, and
  (6) Investors may be required to divest their ownership if they cease to practice in the service area.
OIG Advisory Opinions: JV Guidance

• In No. 98-12, the OIG did not sanction physician investors in an ASC, even though the arrangement did not satisfy any of the statutory or regulatory exceptions.

• In No. 07-13, the OIG provided that owners of an ASC could be sanctioned for violations of the AKS if the proposed ownership included (in addition to a hospital and ophthalmologists who would perform surgeries at the ASC) nine non-surgeon optometrists.
Stark Law

- In general, so-called “Stark Law” prohibits a physician who has a financial interest with an entity from referring patients to that entity for the provision of designated health services (“DHS”)

- Outpatient dialysis services are not DHS

- Inpatient hospital services are DHS, but an exception carves out inpatient dialysis services

- Outpatient prescription drugs are DHS unless in a bundle or separately excluded

- Laboratory services are DHS unless in a bundle or separately excluded
False Claims Act Overview

- The federal False Claims Act (FCA), codified at 31 U.S.C Sections 3729-3733, is considered by many to be an important tool for combating fraud against the U.S. government. The FCA is a law of general applicability that is invoked frequently in the health care context. It has been reported that from January 2009 through the end of the 2013 fiscal year, the Justice Department used the False Claims Act to recover more than $12.1 billion in health care fraud cases.
The FCA imposes civil liability on persons who knowingly submit a false or fraudulent claim or engage in various types of misconduct involving federal government money or property. Health care program false claims often arise in terms of billing, including billing for services not rendered, billing for unnecessary medical services, double billing for the same service or equipment, or billing for services at a higher rate than provided (“upcoding”). Penalties under the FCA include a penalty of $5,500 to $11,000 for each false claim filed, plus additional damages.
State Self-Referral and Anti-Kickback

• Many states have self-referral and/or anti-kickback statutes, including California, Florida, Georgia, Illinois, Massachusetts, New Jersey, North Carolina and Texas

• A dialysis JV must consider the state’s law, and determine if the state law applies in the dialysis context
A Case Study: DaVita HealthCare Partners
(History and Allegations)

• Brought against DaVita Healthcare Partners and Total Renal Care (sub) under seal in Denver Federal District Court in 2009 by *qui tam* plaintiff David Barbetta, a former DaVita employee

• Complaint, in part, alleged that DaVita sold equity to physician investors in dialysis facilities for less than fair market value and allowed physicians to sell their equity in dialysis facilities for more than fair market value

• Complaint also alleged that DaVita engaged in other activities directed at benefiting or attracting physicians as referral sources
A Case Study: DaVita HealthCare Partners
(Elements of the Settlement)

• Entered into settlement agreement October 22, 2014 with the DOJ, OIG and the Defense Health Agency

• Entered into a 5-year corporate integrity agreement

• Agreed to pay $350 million in penalties, $39 million civil forfeitures, and agreed, in principal, to an $11.5 million settlement to settle certain Medicaid claims (ultimately settled with 5 Attorneys General to pay $22 million from the original settlement amount)

• Agreed to unwind 11 JVs (covering 26 clinics) created through partial divestitures within 1 year
Some Examples of Allegations
In The United States Complaint
Against DaVita
53. Rather than generating business by simply demonstrating superior quality of clinical services and patient care or providing more convenient care options, DaVita sought out physicians and provided them an economic inducement to ensure that physician/partners would use their considerable influence over their patients to provide referrals, DaVita routinely entered into joint ventures with these physicians, selling them undervalued shares of existing DaVita dialysis centers (“Partial divestitures”), buying over-valued shares of physician-owned dialysis centers (“partial acquisitions”), or engaging in both activities in a “Paired” transaction which was a joint venture formed by both buying and selling partial interests.
78. DaVita’s Deal Depot understood that there was no business integrity to the valuation modeling and that it was only being used as window dressing to hide the real purpose: securing patient referrals from physicians through joint ventures. ..
81. “Partial divestiture” transactions were joint ventures formed by DaVita divesting an ownership interest in one of its existing, wholly-owned dialysis centers to a referring physician. Divesting substantial interests in existing, profitable dialysis centers does not make business sense for a company in the dialysis business that is attempting to grow and capture an even larger share of the market. In many instances the only demonstrable business advantage of divesting to a physician is to ensure patient referrals from the physician.
97. Further, many of DaVita’s joint ventures required physician partners to agree not to induce any patient to go to any other competing dialysis center as follows:

The Members [other than DaVita] further agree that, during the Restricted Period, they will not, directly or indirectly (i) induce any customer of Company or LLC Manager (either individually or in the aggregate) to patronize any competing dialysis facility; (ii) request or advise any patient or customer of Company or LLC Manager to withdraw, curtail or cancel such person’s business with Company or LLC Manager; (iii) enter into any contract (whether for sale of such Member’s medical practice or otherwise), the purpose or result of which would benefit such Member if any customer of Company or LLC Manager were to withdraw, curtail, or cancel such customer’s business with Company or LLC Manager....
104. Another feature of some of DaVita’s joint ventures is that the physician’s interests in the joint ventures were non-transferable. HHS-OIG has noted that one indication that a joint venture may violate the AKS is if the investment interest is non-transferable. OIG Special Fraud Alert, *Joint Venture Arrangements* (1989), republished at 59 Fed. Reg. 65,372 (Dec. 19, 1994). Although DaVita could sell its interest in the joint venture, the physician partner could not. This was a strong indication that the physician’s ability to refer, which was unique to the physician and could not be duplicated by other potential investors, was the real purpose behind the partnership.
A Case Study: DaVita HealthCare Partners
(Elements of the CIA)

The Corporate Integrity Agreement – What Does It Mean?
A Case Study: DaVita HealthCare Partners
(Into The Weeds of the CIA in Search of Clarity)

• In place for 5 years

• Requires procedures to track and ensure compliance between its dialysis business and referral sources

• Retains an independent monitor to, among other things, pre-approve new “Focus Arrangements” (i.e., arrangements with referral sources such as leases, joint ventures, medical director agreements, etc.)
• DaVita must prospectively develop selection criteria for healthcare providers for each type of Focus Arrangement

• DaVita must prospectively develop and consistently apply a valuation methodology for each type of Focus Arrangement

• DaVita will not enforce patient-related non-disparagement or non-solicitation clauses
• DaVita will not enforce investment non-compete provisions contained in JV operating agreements and medical director agreements formed by to be unwound partial divestitures
• DaVita will not enter into any new partial divestiture joint ventures except in limited circumstances
• DaVita is not prohibited from continuing to JV
The Transaction

Typical Dialysis JV Partners:

• Physician Investors
  – Individuals
  – Practices
  – Investment Entities

• Provider Investors
  – Hospitals
  – Dialysis Chain Providers (LDOs and MDOs)
The Transaction (Cont’d.)

Structure of Dialysis JV:

• Choose an entity (LLC or LP generally)
  – What type of entity will the JV and the physician-investor vehicle be, e.g. corporation, LLC, partnership?
  – What will be the jurisdiction of organization?
  – What are the tax implications of the chosen entity type?
  – Are there any accounting or consolidation issues?
Required Agreements:

• Operating Agreement
• Management Agreement
• Medical Director Agreement
• Ancillary Agreements
Key Elements of Operating Agreement:

- Percentage Ownership
- Capitalization
- Governance
  - Board of Managers or Manager or Member Managed
  - Significant decisions
- Sale, major expansion, etc. of the facilities
- Hiring and firing of key personnel
- Significant financings and budgets
- Admission of additional owners
- Agreements with owners or affiliates
- Initiating or settling litigation or investigations
- Covenant Not to Compete – Mutual or Not
- Corporate Opportunities
- Exit Strategy
Key Elements of Operating Agreement:

• Other Issues

  – In larger cities, how will the JV be positioned in relation to company wholly-owned facilities or new unrelated JVs?

  – Staffing issues

  – Compliance

  – JV’s and JV member’s role in new managed care environment
Key Elements of Management Agreement:

• Scope of Services and Authority
• Management Fee and Escalator, if any
• Manager’s Responsibility and Accountability
• Vendor Contracts
• Payor Contracts
• Compliance
Key Elements of Medical Director Agreement Parties:

- Duties and Who May Serve
- Compensation
- Responsibilities of the Dialysis Company
- Term
- Termination and Effect of Termination
- Covenant Not to Compete
- Insurance/Indemnification
- Compliance
- BAA
Ancillary Arrangements Critical to the Deal:

- FMV lease (hospital, physicians, or third party)
- Other Agreements with JV partner (laboratory, supplies, pharmacy, etc.)
The Transaction (Cont’d.)

Analyze the Deal Being Proposed:

• Examine Assumptions Closely
• Examine Proposed Costs, incurred or to be incurred
• Examine Return on Investment (e.g., EBITDA/Revenue)
• Ask for track record of other JVs in your region
The Transaction *(Cont’d.)*

- **Need to Run Proformas**
  - Investment Required
    - Initial Capital
    - Working Capital
  - Bank Financing
    - How much can you borrow – 100% or less – 100% difficult in today’s market
    - Collateral
    - Cost of Borrowing
    - Guarantees
      - Physicians
      - Practice
  - Cash Flow from JV
  - Debt Service
  - Taxes
Next Steps

- Choose a Physician Committee (2-4 Doctors)
- Examine Practice’s Long Term Strategy
- Examine Group’s Financial Status
- Choose Advisors
- Develop a Game Plan
- Develop a Time Line (be generous)
- Begin the Process