Smooth Sailing Into Joint Venture Compliance

Best Practices for Providers, Payers and Vendors

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Objectives

- Overview of Different JV Models
- OIG Guidance Documents
- Compliance Program— Development, Implementation, and Maintenance in JVs
- Compliance Program Challenges & Best Practices

Focus on Compliance in Joint Ventures

Best Practices for Compliance Programs Within an Existing Joint Venture

- Identify Standards
- Examine Challenges
- Propose Solutions

Governance, regulatory and legal issues are addressed only as background and as they impact Compliance Program development, implementation and maintenance.

Overview of Different JV Models

Joint Ventures – Why?

Best align diverse partners:

- Leveraged resources
- Balance individual strengths & weaknesses
- Share financial risks
- Vertical Integration

And purposes:

- Clinical efficiency & standardized practices
- Manage business threats
- Speed to market
- Market dominance

Joint Ventures – Who?

Complementary Partners

-**Service Lines**

-**Industry**

-**Geography**

-**Access to Capital**

-**Specific Expertise**

Common Elements of JV Agreements

- Contribution Agreement
- Governance Agreement
- Management Agreement

JV Models

- Purchased assets
  - Seller JV (Hospital seeks Investors)
  - Buyer JV (Investors seek Clinical Entity)
- New Enterprises ("Shelf" JV)
- Contractual Joint Ventures

Ownership Models

- Equity ownership models
  - Contributions
  - Valuation
- REIT partnerships
- Contractual Joint Ventures
- Management Services Agreements

OIG Guidance Documents

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OIG Guidance Documents

1. OIG Special Fraud Alert (August 1989, reprinted December 1994)
(https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html)

2. OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the AntiKickback Statute (Nov 1999)
https://oig.hhs.gov/fraud/docs/safeharborregulations/getdoc1.pdf

3. OIG Special Advisory Bulletin – Contractual Joint Ventures (April 2003)
(https://oig.hhs.gov/fraud/docs/alertsandbulletins/042303SABJointVentures.pdf)
    - Remuneration for Referrals
    - Improper Incentives
    - Reduced competition

4. OIG Special Fraud Alert – Physician Owned Distributorships (March 2013)
https://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD_Special_Fraud_Alert.pdf

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Questionable Features of Suspect Joint Ventures (OIG 1994)

Investors

• Investors chosen because they can make referrals.

• Greater investment opportunity offered to physicians who can make a larger number of referrals.

• Physician investors encouraged to make referrals to the JV, or to divest their interest if they don't.

• The JV tracks its sources of referrals, and distributes this information to the investors.

• Investors required to divest their interest if they cease to practice in the service area.

• Investment interests may be nontransferable.

Financing and Profit Distribution

• Disproportionately small investment and large returns compared to a typical new business.

• Physician investors may invest only a nominal amount, such as $500 to $1500.

• Physician investors may ``borrow'' the amount of the ``investment'' from the entity, and pay it back through deductions from profit distributions.

• Investors may be paid extraordinary returns on the investment in comparison with the risk involved, often well over 50 to 100 percent per year.

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Examples of Questionable Joint Ventures Business Structure (OIG 1994)

- A shell reference laboratory that:

-- conducts very little testing on the premises.

-- does most of the testing at its central processing laboratory

-- has the local ``shell'' laboratory bill Medicare directly for these tests.

- A shell DME joint venture that:

-- owns very little of the DME or other capital equipment; rather the ongoing entity owns them.

--The ongoing entity is responsible for all day-to-day operations of the joint venture, such as delivery of the DME and billing.

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Safe Harbor Guidelines (OIG, 1999)

• No more than 40% of the total value of the investment interests in the venture may be held by investors who are in a position to make or influence referrals to the entity, furnish items or services to the entity, or otherwise generate business for the entity.

• No more than 40% of the entity's gross revenue from health care items and services may come from investor referrals or business otherwise generated by investors.

• The terms on which an investment interest is offered to investors who are in a position to generate business for the entity may not be different from the terms offered to other investors.

• The terms on which an investment interest is offered to an investor may not be related to the previous or expected volume of referrals or business generated from that investor.

Safe Harbor Guidelines (cont'd)

• An investor who is in a position to refer patients to the entity may not purchase the investment interest with funds borrowed from the entity or with a loan guaranteed by the entity.

• The entity may not market or furnish the entity's services to investors and non-investors differently.

• The entity may not require investors to make referrals to the entity.

• The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the investor's capital investment.

- OIG, 1999

Five Risk Indicators for Contractual JVs (OIG 04/2003)

Owner expands into a related line of business, which is dependent on referrals from, or other business generated by, the Owner's existing business.

Owner neither operates the new business itself nor commits substantial financial, capital, or human resources to the venture. Instead, it contracts out substantially all the operations of the new business.

Manager/Supplier is an established provider of the same services as the Owner's new line of business. In other words, absent the contractual arrangement, the Manager/Supplier would be a competitor of the new line of business.

Owner and the Manager/Supplier share in the economic benefit of the Owner's new business.

Aggregate payments to the Manager/Supplier typically vary with the value or volume of business generated for the new business by the Owner. - **OIG 04/2003**

SUSPECT CONTRACTUAL JV

- New Line of Business
- Captive Referral Base
- Little or No Bona Fide Business Risk
- Status of the Manager/Supplier
- Scope of Services Provided by the Manager or Supplier
- Remuneration
- Exclusivity

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Examples of Suspect Arrangements (OIG 04/2003)

A hospital establishes a subsidiary to provide DME. The new subsidiary enters into a contract with an existing DME company to operate the new subsidiary and to provide the new subsidiary with DME inventory. The existing DME company already provides DME services comparable to those provided by the new hospital DME subsidiary and bills insurers and patients for them.

A DME company sells nebulizers to federal health care beneficiaries. A mail order pharmacy suggests that the DME company form its own mail order pharmacy to provide nebulizer drugs. Through a management agreement, the mail order pharmacy runs the DME company's pharmacy, providing personnel, equipment, and space. The existing mail order pharmacy also sells all nebulizer drugs to the DME company's pharmacy for its inventory.

A group of nephrologists establishes a wholly-owned company to provide home dialysis supplies to their dialysis patients. The new company contracts with an existing supplier of home dialysis supplies to operate the new company and provide all goods and services to the new company.

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Discounted Goods/Services

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.

-OIG 04/2003

Non-payment for services (debt forgiveness, capital calls, in-kind contributions of goods/services)

Due Diligence

- Deficit Reduction Act certification
- Policy & Procedure review
- Documentation of Compliance Program
- Public Domain (Exclusion lists, Open Payments, OCR breach filings)

Compliance Program Development, Implementation, and Maintenance in JVs

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Decision Making and Joint Governance

- Managing diverse interests for partners buy-in
- Voting Rights
  - Ownership Stake
  - Reserved powers
  - Odd-number of Director(s)
  - Outside Director(s)

- Delineating Compliance Program responsibility
- Defining a Code of Conduct
- Policy Convergence
- Conditions of Default

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Standard Compliance Program Requirements

1. Compliance Officer & Committee
2. Policies & Procedures
3. Lines of Communication
4. Training & Education
5. Auditing & Monitoring
6. Disciplinary Standards
7. Remediation & Response
8. Accountability – reporting and assessment

Appoint Compliance Officer

- Independence
- Authority
- Resources
- Access

NY OMIG Guidance

NY OMIG Guidance on Compliance Officers

"vested with the day-to-day operation"

- "Wholly-owned" (holding company):
  - -Can be employed by either/both
- Partially owned or Joint Venture:
  - Must be an Employee of the JV entity
  - Can also be employed by JV participant

"no unity of ownership and control"

http://www.omig.ny.gov/images/stories/compliance_alerts/20150330_Compliance_Guidance_2015-02_final.pdf

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Reporting Responsibilities

Reporting to:

- Legal
- CEO
- Compliance Committee
- Board

Managing reporting relationships with multiple entities requires significant coordination

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Compliance Committee

May be:

- Sub Committee of Board
- Full Board
- Management Company
- Coordination with parent entities

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Policies and Procedures

- Adopt and/or Adapt?
  - Review parent entities' policies
  - Assess differences
    - Operational
    - Cultural
  - Gap analysis
  - Communication
  - Approval & Implementation

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Policies and Procedures Must Meet…

Legal Requirements (examples):

- FMV / Related Party
- Breach response
- Lines of Communication

Ethical Standards (examples):

- Gifts policy
- Professional Courtesy
- Charity Care

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Lines of Communication

- External vs. Internal HelpLine
- Defined lines of communication with entities
- Employee reporting of concerns

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Training and Education

- Will reflect Policy Analysis Adoption
  - -New training
  - -Single Entity training
  - - Hybrid (modular) training
- Board & Staff
- Management Services Providers

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Risk Assessment / Work Plan

Billing:

- Charge capture
- Coding
- Documentation

Regulatory:

- Contract performance (MSA)
- Stark provisions/protections (FMV)
- HIPAA/HITECH

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Month Day, Year

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Auditing & Monitoring

- Leveraging Participant Resources
- Defining scope
- Maintaining separation of interests
- Clarifying contractual definitions
  - -Clinical Quality Management
  - -Productivity Benchmarks
  - -Substantial participation

Remediation and Response

- Identification of potential problem
  - Work Plan findings
  - Internal/external reports
- Referral to Legal Counsel
  - Communication (to Board, Agencies)
- Investigation
  - Applicable regulations
  - Determination of facts
- Implement response/remediation

Potential Pitfalls

- Split decisions (50-50 governance)
- Risk tolerance
- Off-contract arrangements
- Conflicts of Interest/Business Associates
- Maintaining confidentiality

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Questions?

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