

Disclaimer

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Objectives

- Overview of Different JV Models
- Decision-Making and Joint Governance
- Auditing, Monitoring and Reporting
- Compliance Program Challenges & Best Practices

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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.

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Overview of Different JV Models

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Joint Ventures - Why?

Best align diverse partners and purposes

- Leverage resources
- Balance individual strengths &weaknesses
- Speed to market
- Market dominance



Joint Ventures – Why?

- Vertical integration
- Clinical Efficiency & standardization
- Manage business threats
- Share financial risks



Joint Ventures - Who?

Complementary Partners

- -Service Lines
- -Industry
- -Geography
- -Access to Capital
- -Specific Expertise



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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

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Ownership Models

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

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JV Compliance Risks

- OIG Special Fraud Alert (August 1989, reprinted December 1994)
 (https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html)
- Key Concerns
 - Investors
 - Business Structure
 - Financing and Distribution
- OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the AntiKickback Statute (Nov 1999)
- $\ \underline{https://oig.hhs.gov/fraud/docs/safeharborregulations/getdoc1.pdf}$
- OIG Special Advisory Bulletin (April 2003)
- (https://oig.hhs.gov/fraud/docs/alertsandbulletins/042303SABJointVentures.pdf)
 - Remuneration for Referrals
 - Improper Incentives
 - Reduced competition

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Five Risk Indicators (O

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

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"Suspect" Contractual Joint Ventures (OIG, 2014)

- •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

- OIG, 04/2003

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Example

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.

- OIG 04/200

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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.

- OIE 04/2003

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Example

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.

OIG 04/2003

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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)

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.

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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

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Due Diligence

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

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Decision Making and	
Decision-Making and Joint Governance	
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Decision Making and Joint Governance	
Managing diverse interests for partners buy-in	
Voting RightsOwnership Stake	
- Reserved powers	
Odd-number of Director(s)Outside Director(s)	
- Outside Director(3)	
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Decision Making and Joint Governance	
Delineating Compliance Program responsibility	
Defining a Code of Conduct	
Policy Convergence Conditions of Default	
Conditions of Default	

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Compliance Program Development, Implementation, and Maintenance in JVs	
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Standard Compliance Program Requirements

- •Compliance Officer & Committee
- Policies & Procedures
- •Lines of Communication
- •Training & Education
- Auditing & Monitoring
- •Disciplinary Standards
- •Remediation & Response
- compliance ventualizations the organizations of the confidence of •Accountability – reporting and assessment



Appoint Compliance Officer

- Independence
- Authority
- Resources
- Access

Appoint Compliance Officer

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"

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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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Training

- 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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Auditing & Monitoring

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

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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

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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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