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*Presenting a live 90-minute webinar with interactive Q&A*

# Physician-Vendor Relationships Under Heightened Scrutiny

Avoiding or Minimizing Liability Under False Claims, Stark and Anti-Kickback Laws

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WEDNESDAY, JANUARY 4, 2012

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

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Today's faculty features:

R. Michael Barry, Partner, Arnall Golden Gregory, Atlanta

Jennifer Downs Burgar, Of Counsel, Arnall Golden Gregory, Atlanta

Arianne N. Callender, Of Counsel, Morgan Lewis & Bockius, Washington, D.C.

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Morgan Lewis

together  
**Physician-Vendor Relationships Under  
Heightened Scrutiny**

Strafford Live Webinar  
January 4, 2012

Arianne Callender  
Of Counsel

Morgan, Lewis & Bockius

202.739.5280

[acallender@morganlewis.com](mailto:acallender@morganlewis.com)

[www.morganlewis.com](http://www.morganlewis.com)

# FAIR MARKET VALUE

## What is the right rate?



- Varies based on transaction
- Must not consider volume or value of referrals

***Items ordinarily considered in determining the fair market value may be expressly barred by the anti-kickback statute's prohibition against payments for referrals.***

D. McCarty Thorton, Asst. General Counsel, OIG, Letter to IRS, December 22, 1992

# FAIR MARKET VALUE

## Perspectives from Litigation



- Klaczak v. Consolidated Medical Transport
  - Not Credible
    - *Review of single firm's prices to determine FMV*
  - Credible
    - *Comparison of rates of all participants in marketplace*
    - *Competitive bidding/RFP process*

# FAIR MARKET VALUE

## Perspectives from Litigation



- Advanced Neuromodulation Systems OIG Settlement

- Red Flags

- OIG Allegations*

- *No FMV analysis performed to assign value for physician's services*
      - *\$5,000 fee paid for physicians' "data collection" of information company never used*

# FAIR MARKET VALUE OIG Guidance



- Compliance Program Guidance
  - Process and documentation
  - Reasonable, consistent, and objective determinations of FMV

# FAIR MARKET VALUE

## Clues from Government Mandated Compliance



- United Shockwave Services CIA
  - Written review and approval for arrangements with hospitals to which physician investors refer
  - Arrangements database
  - Legal review
  - Documentation of FMV determination
  - Annual arrangements review by independent entity
- Exactech DPA
  - FMV analysis conducted by qualified independent organization

# FAIR MARKET VALUE

## Compliance Practice Pointers



- Consult legal counsel
- Establish policies and provide training
- Require written approval of FMV
- Document basis for FMV during transaction and retain records afterwards
- Centralized tracking
- Use Template Contracts
- Sales force firewall
- Seek expert analysis when appropriate
- Regularly review arrangements

# DOCUMENTATION PROTOCOLS

## A Critical Safeguard



- Evidence of legitimate business arrangement
- Notice to vendors of compliance standards and duties
- Facilitates internal monitoring and auditing

# DOCUMENTATION PROTOCOLS Come Together!



- Keep compliance, legal, and operations in the loop
- Require physician vendors to document work and retain records
- Make documentation as easy as possible
  - Workflows
  - Checklists
  - Templates
  - IT systems

# DOCUMENTATION PROTOCOLS

## Clues from Subpoenas & Government-Mandated Compliance



### ARRANGEMENTS

- Activity Logs
- Work Product
  - Presentation slides
  - White papers
  - Minutes of product teams
- Sales staff certifications
- FMV analysis prior to execution
- Needs assessment
- Selection criteria for investors/consultants
- Executed contracts and prior drafts

# DOCUMENTATION PROTOCOLS

## Clues from Subpoenas & Government-Mandated Compliance



### **SALES AND MARKETING**

- Communications/Emails
- Sales data
- Marketing expenditures
- Discussions of Medicare/Medicaid coverage
- Personnel evaluations and incentives

# DOCUMENTATION PROTOCOLS

## Clues from Subpoenas & Government-Mandated Compliance



### COMPLIANCE

- Board minutes
- HCP contracting policies
- Internal audit data
- Training materials

# DOCUMENTATION PROTOCOLS

## Compliance Practice Pointers



- Harmonize documentation/tracking systems
- Engage internal and external players
- Develop tools to facilitate compliance
- Prioritize high-risk arrangements

# VOLUNTARY DISCLOSURE



- PPACA 6402 requirement to return identified overpayment in 60 days
- Whistleblower concerns
- Component of successful compliance program

# VOLUNTARY DISCLOSURE Considerations



- False Claims Act liability for retention of overpayment
- Concessions for voluntary disclosure
- Multi-million dollar payouts even for companies that self disclose
- Government agencies publicize self disclosure settlements

# VOLUNTARY DISCLOSURES

## Where to disclose?



- Agency authorities to offer releases vary
- Agencies may refer cases to each other
- Formality and transparency varies



# VOLUNTARY DISCLOSURE

## Compliance Practice Pointers



- Consult legal counsel
- Consider ongoing relationship with regulatory agencies
- Balance cooperation with advocacy
- Follow up with agency to speed up resolution

# RESPONDING TO A SUBPOENA



- Documents and testimony
- OIG subpoenas for DOJ investigations
- Grand jury
- DOJ civil investigative demands



# RESPONDING TO A SUBPOENA Strategies



- Protect privilege
- Assess costs/burdens of production
- Negotiate with government on scope, time period, sequence & extensions
- Keep government in loop on progress
- Follow up to get information on status of investigation

# QUESTIONS



# our team



## Arianne Callender

1111 Pennsylvania Ave. NW  
Washington, DC 20004  
acallender@morganlewis.com  
tel. 202.739.5280  
fax. 202.739.3001

- **Arianne N. Callender is of counsel in Morgan Lewis's FDA and Healthcare Practice.** Ms. Callender represents companies and individuals in health industry government enforcement and compliance matters. She previously served as a Senior Counsel in the Office of Inspector General (OIG) to the U.S. Department of Health and Human Services, U.S. Department of Justice Special Trial Attorney, and Deputy Oversight Counsel to the House Committee on Homeland Security. Ms. Callender is a recipient of the Hubert H. Humphrey Group Award for Service to America, Office of Inspector General Achievement Awards, and is a co-author of the joint OIG-Association of Health Lawyers of America publication, *Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors*.



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