

**HLB**  
HOOPER, LUNDY & BOOKMAN, P.C.  
 HEALTH CARE LAWYERS

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**NEW HEALTH CARE MODELS:  
 NEW COMPLIANCE ISSUES**

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HEALTH CARE COMPLIANCE  
 ASSOCIATION  
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**Changes to Healthcare Delivery – Changes to Compliance**

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*How Changing Healthcare Delivery Systems are  
 Changing Compliance*

- Creating Integrated Delivery Systems: Get it Right the First Time
- New Compensation Arrangements: New Perils
- New Risk Areas; New Rules: What You Don't Know Can Hurt You
- Compliance Tips & Practical Takeaways

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**Creating Integrated Delivery Systems – Examples**

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- Physician Practice Acquisitions
- Hospital/Physician Joint Ventures
- Clinically Integrated Networks

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**Creating Integrated Delivery Systems**

Physician Practice Acquisitions/Legal Issues

- Anti-Kickback Statutes
- Physician Self-Referral (Stark & PORA)
- Tax-Exemption Issues
- Antitrust
- Corporate Practice of Medicine

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**Creating Integrated Delivery Systems**

Physician Practice Acquisition/Structural Issues

- Who is acquiring what?
  - > What kind of practice?
  - > Hard assets or goodwill?
- Hospital as acquiror
- Foundation as acquiror
- “Affiliated PC” as acquiror

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**Creating Integrated Delivery Systems**

Physician Practice Acquisitions/Keys to Compliance : Motives

- What is the reason for the acquisition?
- Who initiated discussions and why?
- Does it fit your mission?
- What are the likely consequences of the acquisition?
  - > What will hospital do with the practice?
  - > What will physicians do post-acquisition?
  - > Will referral patterns shift?
  - > Will the hospital lose money on professional medical services post-acquisition?

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**Creating Integrated Delivery Systems**

Physician Practice Acquisitions/Keys to Compliance : Valuation

- When was the valuation done?
- Who engaged the valuator(s)?
- What is being valued (acquisition & ongoing agreement)?
- What valuation method is being used?
- Do the pieces fit together?
- Are the assumptions reasonable?
- Beware of Bradford & Toumey

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**Creating Integrated Delivery Systems**

Hospital/Physician Joint Ventures

- Many of the same issues (structural, legal, motivational, valuation)
- Additional issues
  - > What services will the joint venture provide?
  - > Governance issues
  - > Fiduciary duties
  - > Scope of noncompetes
  - > Exit strategy

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**Creating Integrated Delivery Systems**

*Role of Compliance*

- > Planning
- > Structuring
- > Due Diligence
- > Corrective Action
- > Mitigation
- > Monitoring

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**New Compensation Arrangements - Examples**

- Pay for Quality Performance (P4P)
- Nurse Navigators/Patient Outreach
- Gainsharing/Cost Containment
- Readmission Rates/Hospitalists
- ACO Agreements
- Bundled Payment Arrangements

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**New Compensation Arrangements**

Paying for Quality Performance (P4P)

- What's being paid for?
- How is it measured?
- How much is being paid?
- How is it valued?
- How were physicians selected?

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**New Compensation Arrangements**

Nurse Navigators/Patient Outreach

- Who is being benefited (hospital, patient, physician)?
- Is there a "steering" issue?
- Are the services reimbursable?

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**New Compensation Arrangements**

Gainsharing/Cost Containment

- Civil Monetary Penalty (CMP) prohibition on payments to reduce or limit medically necessary services
- New pressures to contain cost
  - > ACOs
  - > Bundled Payments
  - > Readmission Rates
- Can you pay to reduce length of stay (LOS)?
- Can you pay to lower readmissions?
- Is a Fraud and Abuse “Waiver” available?

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**Fraud and Abuse Waivers**

- Pioneer ACO Waiver
- Bundled Payments for Care Improvements (BPCI) Waiver
- Health Care Innovation Awards (HCIA) Round Two
- Comprehensive ESRD Care (CEC) Model
- Comprehensive Care for Joint Replacement (CJR) Model
- Next Generation ACO Model
- Oncology Care Model
- Part D Enhanced Medication Therapy Management (MTM) Model
- Medicare Shared Savings Program

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**Fraud and Abuse Waivers**

- Apply to the federal anti-kickback statute and federal physician self-referral law (Stark), and sometimes to the beneficiary inducement law
- Each one contains its own particular requirements
- These are not “blank checks” or “get out of jail free” cards
- They can be used only for narrowly tailored activities in furtherance of that payment model
- Don't apply to outside activities
- Don't waive state anti-kickback or self-referral laws

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**Other Developments in Fraud and Abuse**

- New Regulations: Leniency under the Stark Law
  - Flexibility on “written agreement”
  - Flexibility on holdover terms
  - Other new exceptions
- New Regulations: Leniency on Anti-Kickback Statute
  - Patient transportation
  - Protection for certain cost-sharing waivers, for pharmacy, emergency transport, etc.

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**Other Developments in Fraud and Abuse (Cont'd)**

- Leniency on Beneficiary Inducement Prohibition:
  - Permits any remuneration that “promotes access to care” or “improves a particular beneficiary’s ability to obtain medically necessary health care items and services” and “poses a low risk of harm” to patients and programs
  
  - *This may be the missing link to population health, improved quality and lower cost ... the patient!*

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**New Compensation Arrangements**

*Role of Compliance*

- Structuring
- Mitigation
- Monitoring
- Corrective Action

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**New Risk Areas/New Rules**

- Quality Issues
- Bundled Payments/ACOs
- Medical Group Issues
- Clinically Integrated Network (CIN) Issues

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**New Risk Areas/New Rules**

Quality Issues

- Reporting on quality
- Ties to reimbursement (ACOs, readmissions, HAC, VBP, etc.)
- Documentation issues
- “Smart” software/data mining
- Poor quality care/unnecessary care
- Credentialing/peer review

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**New Risk Areas/New Rules**

Bundled Payments

- Waiver of Anti-kickback, Stark and Civil Money Penalty statute
- How will this work?
- What about antitrust, tax-exemption and corporate practice?

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**New Risk Areas/New Rules**

ACOs

- Waiver of Anti-kickback, Stark and CMP statute
- Guidance for tax-exempt organizations
- Antitrust guidance
- Compliance with ACO requirements
- Private payor ACOs?
- State laws?

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**New Risk Areas/New Rules**

Medical Group Issues

- Billing for physician services
- Definition of “group practice” for Stark law
- In-office ancillaries
- Knox-Keene issues?

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**Clinically Integrated Networks**

- What are Clinically Integrated Networks?
- Antitrust Agency Definition of Clinical Integration
  - “An active and ongoing program to evaluate and modify practice patterns by the network’s physician participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality.”
- Antitrust Requirements for Clinical Integration
  - Clinical integration arrangements should include the following:
    - ◆ Mechanisms to monitor and control utilization, control costs or improve quality of care;
    - ◆ Significant investment in human and other capital for infrastructure to achieve efficiencies;
    - ◆ Clinical protocols for most of the services provided by participating physicians;
    - ◆ Establishment of efficiency goals for physician members and the organization

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**Clinically Integrated Networks**

- Antitrust Requirements for Clinical Integration
  - Selective inclusion of physicians who are likely to further efficiency goals;
  - Methods to monitor physician compliance with protocols;
  - Mechanisms to correct and improve performance of participating physicians; and
  - Expulsion or other negative consequences for physicians who will not or cannot comply with protocols
- Licensing Issues at CIN Level
- Licensing Issues at Provider Level
- Formation and Governance Issues
- Fraud and Abuse Concerns

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**Compliance Tips & Practical Takeaways**

*Get involved early in new transactions/arrangements*

- Planning Counts! (What types of arrangements, services, transactions are involved?)
- Business Purpose/Rationale (who, what, where, why) Is it necessary or just desired? Alternatives?
- Anticipate Consequences!
- The Power of Words (they can help or hurt)
- Fair Market Value (Without Regard to Referrals) & Commercial Reasonableness

*Beware of new risk areas/new rules*

- Bundled payments
- ACO's
- Readmission rates; HAC
- Medical groups; HMOs
- Quality; cost control

*How are these changes affecting your role?*

- Substantive issues
- Reporting responsibility

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*Questions  
and  
Answers*

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