

<p>HLB HOOPER, LUNDY & BOOKMAN, P.C. HEALTH CARE LAWYERS</p>
<p>NEW HEALTH CARE MODELS: NEW COMPLIANCE ISSUES</p>
<p>Charles B. Oppenheim Hooper, Lundy & Bookman, P.C.</p> <p>HEALTH CARE COMPLIANCE ASSOCIATION Orange County Regional Conference Friday, June 16, 2017</p>
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<p>Changes to Healthcare Delivery – Changes to Compliance</p>
<p><i>How Changing Healthcare Delivery Systems are Changing Compliance</i></p>
<ul style="list-style-type: none">● 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 <u>Can</u> Hurt You● Compliance Tips & Practical Takeaways
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Creating Integrated Delivery Systems – Examples

- 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*