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Managing the Legal Risks Associated with Collaborating on Quality: How Can We Do The Right Thing and Remain Compliant?

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Jennifer W. Payton, J.D., CHC
Compliance Auditor
Baptist Health, Little Rock, AR

Lawrence W. Vernaglia, J.D., M.P.H.
Chair, Payments, Fraud & Abuse and Compliance Group and Partner
Foley & Lardner, LLP, Boston, MA

Goals for today

- Orientation for non-lawyers to the key compliance concerns in the core physician integration models
- Learn how to issue spot for transactions with greater risk
- Discuss compliance controls and safeguards that can reduce regulatory risk while maintaining quality and other integration goals
- Not a comprehensive legal discussion
- What compliance officers need to think about

An Ambitious Agenda!

I. Background on collaborating around quality
II. Compliance issue spotting
III. Questions Compliance officers should be asking
IV. Thoughts on the proposed Stark exception for shared savings programs
V. Auditing referral source contracts

(We won't cover all these slides – some are for future reference)

Quality Revolution

- 1999 Institute of Medicine Report: *To Err is Human: Building a Safer Health Care System*
- OIG/AHLA White papers: *Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors.*

Three Prong Approach

1. Payment Reform
2. Public Reporting/ Transparency
3. Government Enforcement

Value Based Purchasing

- Premier Hospital Quality Incentive Demonstration
- CMS Value Based Purchasing Projects (Deficit Reduction Act of 2005)
- Never Events Payment Restrictions

Transparency

- Hospital Quality Initiative
- Physician Quality Reporting Initiative
- Performance Measurement and Reporting System ("PMRS")
- Program for Evaluation Payment Patterns Electronic Report ("PEPPER")
- Comprehensive Error Rate Testing ("CERT")
- Payment Error Rate Measurement ("PERM")
- Recovery Audit Contractors ("RAC")

What Does "Collaborating On Quality" Mean?

- Probably many ways to slice it
- We might define "it" as:
  - *Forming new relationships, through contract or ownership, through which physician leadership and expertise is leveraged to improve quality and outcomes for an institutional provider.*
  - Not discussing P4P strictly, though that is how a payor might "collaborate for quality."

What Kinds Of Collaborations Are We Discussing?

1. Administrative management
2. Clinical co-management
3. P4P/P4Q contracting between provider/physician
4. Gainsharing
5. Hybrids (combinations of above

Motherhood and Apple Pie?

- So what are the compliance problems?
  - Stark;
  - Anti-kickback;
  - Gainsharing prohibitions (CMP);
  - Antitrust;
  - Tax and tax-exemption limitations;
  - Peer review;
  - State law issues;
  - HIPAA security law issues
  - Others

Compliance Issue Spotting

- You don't have to solve all these problems – but you have to be able to:
  1. Spot the issues;
  2. Ask the right questions;
  3. Be prepared to audit for compliance; and
  4. Education.

Compliance Issue Spotting

- Stark:
  - If the collaboration shares revenue or just pays the MDs – a financial relationship by compensation
  - If it creates a JV – ownership
    - If the JV provides a service, new Stark IV risk
  - The MDs inevitably refer DHS
  - Therefore, must meet Stark "exceptions"

Compliance Issue Spotting

- Anti-Kickback:
  - Similar to Stark in terms of triggers
  - Applies in all settings, regardless of DHS referrals
  - "Safe Harbors" available and advantageous, but rarely will squarely met in most of these collaborations
    - So maybe don't be dogmatic on Safe Harbors, but be sure management/board/compliance committee understands

Compliance Issue Spotting

- Gainsharing:
  - Hospitals can't make payment to induce a physician to reduce or limit services to Medicare or Medicaid beneficiaries under the physician's direct care.
  - OIG has interpreted as prohibiting payment to induce MD to reduce medically *unnecessary* services
  - Where cost containment is a goal, "gainsharing" prohibitions implicated.

Compliance Issue Spotting

- Antitrust:
  - If arrangement calls for joint contracting with payors to achieve quality goals, and share bonus, is that a conspiracy to fix prices?
  - Must have sufficient *clinical* or *financial* integration.
  - Within single legal entity, minimal risk here.
  - When outside physicians contracting, risk increases . . . but is solvable.

Compliance Issue Spotting

- Tax/Tax-Exemption issues:
  - Is the revenue NP hospital revenue or FP jv revenue?
  - Is there UBI to the hospital?
  - Does physician ownership threaten tax exemption?
  - Private benefit
  - Bond financed property requirements

Compliance Issue Spotting

- Other Issues
  - Licensure (joint ventures)
  - State Law: self-Referral and fee-splitting laws
  - Certificate of Need process in state
  - State Law: Corporate practice of medicine
  - Physician pension plan issues (affiliate service group)
  - Provider-based service issues

A Few Words On FMV . . .

- COs should dig in to fair market value
- For most purposes, compensation must not only be "consistent with FMV," it must also be "commercially reasonable."
  - A transaction can be "FMV," but not commercially reasonable, and vice versa.
  - Eg's of FMV not commercially reasonable:
    - Leasing (at prevailing rents) more space than needed
    - Buying (at market hourly rates) reports or other services not needed

A Few Words On FMV . . .

- Important to understand how FMV calculated – reliance on one of the compensation surveys (without context) is not necessarily FMV
  - Comp surveys do not address new collaboration models
- COs should dig in to fair market value
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A Few Words On FMV . . .

- Larger question: does the Hospital need the services of the MDs in the quality project? Or is it just a way to put cash in the hands of MDs?
  - Even if comp/fees are FMV, still a compliance risk – and may violate AKS and Stark.
  - Good role for CO to probe *behind the documents*.
- FMV for administrative services is different from FMV value of Clinical Services
- Documentation of methodology of the FMV is very important.

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Questions Compliance Officers Should be Asking . . .

Administrative Management Services

- Do the MDs have the skills/resources?
- Does this service require a specialist?
- Does it duplicate management hospital already has in place and available?
- FMV?
- Why?

Audit ideas:

- ❑ Time sheets
- ❑ Payment per the contract
- ❑ Renewal date
- ❑ FMV studies

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Questions Compliance Officers Should be Asking . . .

Clinical Co-management

- Physician/hospital ventures to manage hospital service lines (cardio, oncology, ortho, etc.)
- Incentives for hitting quality/performance targets

Questions Compliance Officers Should be Asking . . .

Clinical Co-management (cont.)

- Pay for performance models seem to have broad support (including with regulators).
  - May be structured to include partial incentives for quality measures and higher payments for meeting higher quality measures
- Similar to any management K (skills, resources, duplication . . .)

Audit ideas:

- ❑ Quality study done?
- ❑ Quality study measureable

Questions Compliance Officers Should be Asking . . .

Clinical Co-management (cont.)

- What protections for Hospital's TJC/CoPs duties?
- Provider-based risks if all services "under arrangements" and off-campus "management contracts"
- How are incentives calculated? Are targets so easy the bonus is guaranteed?
- Do MDs have to add real value to earn the comp?
- Protections for quality "slippage"
- Monitor acuity of patients to avoid "cherry picking".

Questions Compliance Officers Should be Asking . . .

P4P/P4Q contracting models

- Are MDs sufficiently integrated for joint contracting
  - Financial Risk
  - Clinical Integration
- How is MD's share calculated

Audit ideas:

- ❑ Is share calculated accurately?
- ❑ Financial integration on old paper (old contracts)
- ❑ Quality measures must be clearly and separately identifiable. May need a to establish the baseline for documentation purposes.

Questions Compliance Officers Should be Asking . . .

P4P/P4Q contracting models

- OIG AO No. 08-16 provides 1 possible roadmap:
  1. Only MDs on active medical staff for at least 1 year;
  2. MD-owners receive distributions on *per capita* basis;
  3. No payments to induce patient referrals to the hospital
  4. Payments by hospital to MD entity capped on historical activity of the payor(s)
  5. Hospital written disclosure of arrangement to patients.
  6. Hospital monitor quality of care *and* the volume and case mix
  7. Quality targets limited to those listed by CMS and TJC in the *Specifications Manual for National Hospital Quality Measures.*

Questions Compliance Officers Should be Asking . . .

Gainsharing

- Who is involved? New physicians?
- Product availability
- Patient disclosures
- Length of project
- Measureable quality studies

Questions Compliance Officers Should be Asking . . .

Gainsharing (cont.)

- Duration and scope clearly outlined
- Cost savings clearly determined

Audit ideas:

- ❑ Physician choice
- ❑ Product selection
- ❑ Were cost savings realized
- ❑ Patient disclosures
- ❑ Term (for tax exemption/bond financing)

Proposed Stark Exception For Incentive Payment and Shared Savings Programs

- Aimed at permitting appropriate quality improvement and cost savings programs while guarding against:
  - Stinting
  - Steering
  - Cherry-picking
  - Gaming
  - Paying for referrals/volume increase
  - Quicker-sicker discharges

Proposed Stark Exception For Incentive Payment and Shared Savings Programs

- 16 detailed standards
- Positive development, but limited utility?
- Continued reliance on other exceptions?
  - Fair Market Value Compensation
  - Personal Service Arrangements
  - Indirect Compensation Arrangements
- Insight into CMS thinking about Anti-Kickback Statute and Civil Monetary Penalty Law implications

The New Proposed Exception

- Remuneration from a documented "incentive payment" or "shared savings" program to:
  - Improve quality; or
  - Reduce costs (with no adverse impact on quality)
- The program uses performance measures that:
  - Are objective, verifiable, supported by medical evidence, and individually tracked
  - Relate to the hospital's (or comparable hospitals') practices and patients

The New Proposed Exception (cont'd)

- Are listed in CMS' Specification Manual for National Hospital Quality Measures (for patient care quality measures); and

  [Website link: http://www.qualitynet.org/dcs/ContentServer?cid=1141662756099&pagename=QnetPublic%2FPage%2FQnetTier2&c=Page]

  [Question: Is this too narrow?]
- Are monitored to prevent inappropriate reductions or limitations on patient care

The New Proposed Exception (cont'd)

- The Program establishes:
  - Baseline levels for performance measures using the hospital's historical and clinical data
    [Question: What if the service is new, or data is limited?]
  - Target levels for performance measures developed by comparing the hospital's historical data to national or regional data for comparable hospitals; and
  - Thresholds above or below which no payments are earned

The New Proposed Exception (cont'd)

- At least five physicians must participate in each performance measure, and they must be on the medical staff from the start; may not be selected based on referrals or business generated between the parties; a hospital may include only physicians in a particular department or specialty, if the opportunity is offered to all physicians in the department or specialty; only individual physicians and "physician organizations" where all physicians who participate can qualify
  [Questions: What about new physicians? What if there aren't 5 physicians? Why can't special purpose entities be formed?

The New Proposed Exception (cont'd)

- Independent medical review of the program's impact on patient care quality is required, and corrective action if indicated in that review; the independent medical review must be completed before the program starts (as to the potential impact on quality), and at least annually thereafter
  [Question: Is this necessary?]

The New Proposed Exception (cont'd)

- Under the Program:
  - Physicians must have "access" to the same selection of items, supplies or devices as available before, and must not be restricted in their ability to make medically appropriate decisions, including as to tests, treatments, procedures, services, supplies or discharge
    [Note: It's ok not to pay if physicians use non-preferred items, but you can't prohibit it.]

The New Proposed Exception (cont'd)

  - Payments may not be made for using an item, supply or device if the physician or physician organization has a financial relationship with the manufacturer, distributor or GPO that sells the item, supply or device; and
  - The hospital may not limit access to new technology that (i) is linked to improved outcomes and is clinically appropriate for a particular patient; and (ii) meets the same Federal regulatory standards as technology under the program

The New Proposed Exception (cont'd)

- The hospital provides written notice to patients that: identifies the participating physician; (ii) discloses that they receive payments for meeting performance measures; and (iii) describes the performance measures
  [Note: CMS asks if patients should have "opt out" rights.]

The New Proposed Exception (cont'd)

- Payments must take into account prior performance payments to ensure that no payments are made for measures that were achieved during a prior period; no payment may be made for cost savings that diminish quality of care
  [Question: If you can't pay, will there be backsliding?]
- Payments must be limited in duration and amount. Cost savings must be measured by comparing the actual acquisition costs to the baseline costs for the same items, supplies or services during the one year period immediately preceding the program's start

The New Proposed Exception (cont'd)

- The arrangement is set out in writing, signed by the parties, specifies the remuneration to be paid and the specifics of the program, the applicable baseline measures, and the targets for performance; each specific performance measure and the resulting payment must be clearly and separately identified
- The performance measures may not involve the counseling or promotion of any unlawful arrangement or activity, and must (in the aggregate) be "reasonable and necessary" for the legitimate business purposes of the arrangement

  [Question: How is "reasonable and necessary" determined?]

The New Proposed Exception (cont'd)

- The term of the program must be for at least one year, and be no more than three years
- The remuneration paid over the term of the program (or the formula for the remuneration) is:
  - Set in advance, without regard to the volume or value of referrals or other business generated between the parties

    [Question: Will percentage compensation work under "set in advance" requirement?]

The New Proposed Exception (cont'd)

- Not based on a reduction in the length of stay for a particular patient or the whole hospital; and
- Distributed to the participating physicians on a per capita basis for each performance measure.

[Note: Fair market value is not required.]

- Remuneration cannot take into account any increase in volume of Federal health care patient procedures or services compared to the prior period

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The New Proposed Exception (cont'd)

- The hospital maintains at least the following documentation and makes it available to the Secretary upon request:
  - The written agreement between the parties
  - The basis for selecting the performance measures
  - The selection and qualifications of the independent medical reviewer
  - The written findings of the independent medical reviewer
  - Corrective actions taken based on the independent medical review

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The New Proposed Exception (cont'd)

- The amount and calculation of payments made, including projected and actual acquisition costs, as relevant
- The re-basing of performance measures; and
- The written notification provided to hospital patients

- The Program does not violate the Anti-Kickback Statute or any Federal or State law or regulation governing billing or claims submission

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Baptist Health System

- Largest system in Arkansas
- 3 acute care hospitals
- 1 inpatient rehabilitation hospital
- 2 critical access hospitals
- Multiple outpatient services
- Physician practices
- Diploma nursing school

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BH Compliance Department

- Corporate Compliance & Privacy Officer
  - Clinical Therapist background
  - Weekly meetings with the President of BH
- Compliance Auditor
  - Coding background
- Compliance Auditor
  - Legal / Management background
- RAC Coordinator
  - HIM/Admissions background
- Office Manager
  - Information Systems background

Active Compliance Committee

- Corporate Compliance & Privacy Officer
- VP of Clinical Services (Radiology, Laboratory, Respiratory Therapy)
- VP, Clinic System & Employed Physicians
- VP of Patient Care
- VP of Financial Services
- VP, Human Resources
- Director of Home Health
- Director of Perioperative Services
- Director of Patient Accounts
- Director of Nursing (CAH-4)
- Director of Admissions (CAH-3)
- Director of Health Information Management (Urban Acute Hospital-1)
- Director of Health Information Management (Urban Acute Hospital–2)
- Director of Health Information Management (Rural Acute Care Hospital-5)
- Director of Emergency Services
- Director of Public Relations

Baptist Health Annual Compliance Implementation Plan

- Input
  - Senior leadership, OIG Work Plan, Corporate Compliance Committee, legal counsel, fiscal intermediary, QIO "hot topics"
- Approval
  - Diversification & Compliance Committee/ Executive Committee of Board of Trustees
- Reporting
  - Quarterly to the Board

Annual Audit Plan

- Audit for high risk areas
- Review documentation to support payments
- Self audit process by departments

Contract Control Process for Referral Source Contracts

- Contract policies and procedures
- Board committee review of referral sources contracts.
- Legal review of high risk contracts
- High level signatures required (SVP/President level on high risk)
- Contract management system
  - Tracking & auditing

Compliance Involvement in System Committees

- Quality Review Committee
  - Membership
  - Monthly reporting
  - Focus of reviews-medical necessity, utilization review, risk management, patient safety, infection control, etc.
  - Financial/performance outcomes
  - Quality agenda
    - Safety
    - Timeliness and efficiency
    - Effectiveness
    - Customer centered

Compliance Involvement in System Committees (con't)

- Information resources
  - Internal chart audits and customized reports
  - External reports from QIO and Hospital Compare
  - Clinical Quality Value Analysis Committee– Consultant Role
- Joint Commission Committee (Urban Acute Hospital)
  - Formulates many patient care policies for the system
- Department Director meetings – provides education monthly/bimonthly
- Finance & Audit Committee

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Questions?

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