Watch Your Step! Treading Carefully with Compliance in Affiliation Arrangements (and in Practice Generally)

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Agenda

- The Who, What, Where, When, Why of Compliance
- Compliance in Affiliation Arrangements:
  - Negotiation
  - Due Diligence
  - Documentation
- Lessons Learned from Recent Cases
- 2016 Compliance Forecast

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Who?

- Physicians
- Hospitals/Providers
- Pharmaceutical Companies
- Marketing/Management/Billing Companies

Note: Government payments implicate Stark II, AKBS, FCA

BUT: State laws can have broader impact than government payments

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What?

Morass of federal and state regulations governing healthcare programs focused on all aspects of the healthcare industry including:

- Billing
- Coding
- Referrals
- Compensation
- Information Privacy
- Relationships
- Corporate Governance

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Why?

- It is required by law
- It is the right thing to do – lead by example:
  - Help maintain a commitment to being an honest and responsible provider by identifying and preventing illegal and unethical conduct
  - Improve the quality and consistency of patient care
  - Create a structure for employees to report potential problems
  - Develop procedures for prompt and thorough investigation of potential misconduct

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Why?

- Less expensive on the front-end than the back-end
- Bad things can happen:
  - Suspended from/Kicked out of Medicare program
  - Fined – treble damages
  - Costs of defense
  - Reputational damage
  - Go to Jail

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Where? Everywhere!

- Billing/Coding
- Ownership interests/referrals
- Relationships with hospitals and other healthcare providers – acquisition, employment, professional services, medical director, joint ventures
- Rental of Property; Lease of Equipment
- Contracting with Vendors
- Consulting with pharmaceutical companies; relationships with drug rep
- GPO Arrangements
- Discounted arrangements
- Information Privacy

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When? All the time!

- Important to establish an environment of compliance from the outset with all employees and physicians
- Not enough just to have a compliance program – need to live by it, review it, audit yourselves
- Not just "the other guy's" problem

Compliance in Affiliation Arrangements

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A. Negotiation – Key Areas

- Structure of arrangement – employment, professional services, medical director, other
- Provider-based
- Personnel employment
- EMR
- Pharmacy/clinical research included
- Asset Acquisitions – FF&E, workforce, medical records, drugs/supplies/inventory; intangibles
- Valuation Considerations: FMV; commercially reasonable; not based on volume or value of referrals; cannot account for what specific buyer brings to the table; adjustments permitted to historical financial statements
- Provider compensation – Salary; Productivity; Bonus; Hourly
- Billing/Collection going forward

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B. Due Diligence – Key Areas:

- Independent Third Party Valuation Critical
- Understand the Practice – provider mix; payor mix; coding and site of service; types of procedures
- Contract Compliance – lease/equipment/vendors/banking
- Financial/Corporate Governance
- Permits/Licenses/Accreditations/Certifications
- Billing/Coding Practices – previous investigations; buyer audit
- Employment/Independent Contractor Arrangements
- Relationships with Outside Parties – vendors/pharmaceutical companies/other providers
- Compliance Program

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C. Documentation – Key Areas

- Transaction Documents
  - Address regulatory compliance with reps/warranties
  - May include holdbacks or escrows
  - Address indemnification
    - Standard vs. Fundamental
    - Caps and Baskets
- Vendor/Lessor assignments
- Implementation of Policies/Procedures
- Licensure/CHOW Notifications
- Ongoing Monitoring

Lessons Learned from Recent Cases

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U.S. ex rel. Drakeford v. Tuomey Healthcare System, Inc.

Case No. 3:05-cv-02858-MBS (D. S.C. 2013) ; Settled October 2015

- Court found payments to physicians were unlawful under Stark and the False Claims Act ("FCA"). FCA judgment of $237 million. The United States Court of Appeals for the Fourth Circuit affirmed the judgment in July 2015.
- Relator alleged that Tuomey entered into part-time employment contracts with specialty physicians, which led to several issues including:
  - Compensation packages above Fair Market Value with compensation set at 31% above total net collections as independent contractors.
  - Contract required physicians to perform all outpatient procedures at Tuomey Hospital or facilities owned/operated by Tuomey.
  - Tuomey was solely responsible for billing/collections and physicians reassigned to Tuomey all benefits payable to the physician by third parties, including Medicare and Medicaid.
  - Physicians' annual base salaries fluctuated based on net collections of outpatient procedures and physicians were eligible for productivity bonuses of 80% of net collections.

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Tuomey Continued…

- In October 2015, Tuomey entered into a settlement agreement with the United States to resolve its initial $237 million dollar judgment.
- Under the settlement agreement Tuomey agreed to pay $72.4 million.
- The settlement agreement was conditioned on the sale of Tuomey to Palmetto Health, a multi-hospital healthcare system based in Columbia, South Carolina. The sale of Tuomey to Palmetto Health was finalized in December 2015.
- Tuomey agreed to enter into a Corporate Integrity Agreement, which is effective for five (5) years.

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U.S. ex rel. Baklid-Kunz v. Halifax Hospital Medical Center

Case No. 6:09-cv-1002-Orl-31TBS (M.D. Fla. 2014); Settled March 2014

- Halifax agreed to pay $85 million to settle claims that it violated the False Claims Act by submitting claims to Medicare that violated the Stark Law.
- Government alleged that Halifax executed contracts with six (6) medical oncologists that provided incentive bonuses that included the value of prescription drugs and tests.
- The government also alleged that Halifax entered into three (3) contracts with neurosurgeons at more than Fair Market Value.
- Halifax agreed to enter into a Corporate Integrity Agreement, which is effective for five (5) years.

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Memorial Hospital n/k/a ProMedica Memorial Hospital

- Memorial Hospital agreed to pay $8.5 million in March 2014 to settle claims that it violated the False Claims Act, the Anti-Kickback Statute, and Stark.
- Memorial self-disclosed that its financial relationships with two physicians violated the above-referenced statutes.
- The relationships at issue involved:
  - A joint venture with a pain management physician through which improper remuneration was paid; and
  - An arrangement with an ophthalmologist in which the ophthalmologist purchased intraocular lenses and then resold them to Memorial at inflated prices.
- Memorial voluntarily dissolved the joint venture at issue.

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West Penn Allegheny Health System

- West Penn Allegheny Health System ("WPAHS") agreed to pay $1.5 million in March 2014 to settle claims that it violated the False Claims Act, the Anti-Kickback Statute, and Stark.
- WPAHS self-disclosed the potential violations to the United States Attorney's Office after discovering the issues during a self-audit.
- Based on WPAHS' self-disclosure, the government alleged that WPAHS entered into lease arrangements with physicians at below Fair Market Value to induce referrals, resulting in improper claims being submitted to the federal healthcare programs.

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Community Health Systems, Inc.

- Community Health Systems ("CHS") agreed to pay $98.15 million to settle eight lawsuits filed in five states (IL, IN, NC, TN, and TX) in August 2014.
- Government alleged that CHS knowingly billed Medicare, Medicaid, and TriCare for inpatient services that should have been billed as observation or outpatient services. CHS agreed to pay $89.15 million to settle these allegations.
- The government also alleged that CHS billed Medicare for services referred to one of its affiliated hospitals, Laredo Medical Center, by a physician who was offered a medical directorship at the hospital, in violation of Stark. CHS agreed to pay $9 million to settle these allegations.
- CHS agreed to enter into a Corporate Integrity Agreement, which is effective for five (5) years.

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U.S. ex rel. Barker v. Columbus Regional Medical Center, et al.

Case No. 4:12-cv-108 (M.D. Ga. 2012) and 4:14-cv-304 (M.D. Ga 2014) ("Barker I" and "Barker II", respectively); Settled September 2015

- Columbus Regional Healthcare System ("CRHS") agreed to pay $25 million, plus an additional contingent $10 million, to settle allegations that it violated the False Claims Act by submitting claims in violation of the Stark Law.
- A medical oncologist employed by CRHS, who served as the medical director of The Medical Center d/b/a John B. Amos Cancer Center ("JBACC"), agreed to pay $425,000 to settle allegations that he received improper salary and medical directorship payments from CRHS.
- The government alleged that from 2003 to 2013, CRHS paid excessive salary and medical directorship payments to an employed oncologist.
- The government also alleged that CRHS submitted claims for E&M services at higher levels than supported by documentation and submitted claims for radiation therapy at higher levels than the therapy that was actually provided.
- CHS agreed to enter into a Corporate Integrity Agreement, which is effective for five (5) years.

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U.S. ex rel. Reilly v. North Broward Hospital District, et al.

Case No. 10-60590 (S.D. Fla. 2010); Settled September 2015

- North Broward Hospital District ("NBHD") agreed to pay $69.5 million to settle allegations that it violated the False Claims Act by submitting claims to Medicare that violated the Stark Law.
- Government alleged that NBHD paid compensation to nine (9) employed physicians in excess of Fair Market Value.
- NBHD also allegedly maintained "Contribution Margin Reports" that detailed the volume and value of referrals and revenue generated by each employed physician.
- Also alleged that employed physician practices were being operated at a loss. Arrangements were not "commercially reasonable." Indication that physician referrals were being considered.
- NBHD agreed to enter into a Corporate Integrity Agreement, which is effective for five (5) years.

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Adventist Health System

U.S. ex rel. Payne, et al. v. Adventist Health System/Sunbelt, Inc., et al., No 12-856 (W.D. N.C. 2012); U.S. ex rel. Dorsey v. Adventist Health System Sunbelt Healthcare Corp., et al., No. 13-217 (W.D. N.C. 2013); Settled September 2015

- Adventist Health System agreed to pay $115 million to the federal government to settle allegations that it violated the False Claims Act by submitting claims to Medicare that violated the Stark Law.
- Compensation for employed physicians and mid-level practitioners (NPs and PAs) was allegedly paid in excess of Fair Market Value, as evidenced by Adventist's substantial and consistent losses on its physician practices.
- Adventist also allegedly paid employed physicians bonuses based on a formula that took into account the value of the physicians' referrals (including the number of tests and procedures they ordered).
- The government also alleged that Adventist submitted bills to Medicare for professional services performed by employed physicians using improper coding modifiers resulting in higher reimbursement amounts than Adventist was entitled to.

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Lessons Learned

- **Carefully review any compensation arrangements between physicians and hospitals**.
  - Medical directors should document time performing medical director services and be paid a reasonable amount for services performed.
  - High physician compensation coupled with significant operating losses at the physician practice level can be used as evidence that physician referrals to the hospital are being considered.
  - Bonus formulas should not take into account the volume or value of services provided.
  - Be careful when hospitals direct referrals – employment vs. professional services
- **Leases should be at fair market value**. A lease below Fair Market Value or above Fair Market Value can be used as evidence of kickbacks.
- **Self-audit.** While self-disclosed violations may result in hefty fines, such fines are generally lower than those that would be imposed if the case were brought by the government or a relator.
- **Code appropriately**. Upcoding can lead to significant overpayment liability; understand changing coding requirements for different arrangement structures.

2016 Compliance Forecast – Key Issues for Investigation

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False Claim Recovery Amounts

Government Investigations and Recoveries are BIG BUSINESS:

2015 - $1.9B

2014 – $3.3B

2013 – $4.3B

2012 – $4.2B

Rationale for decrease: Targeting to prevent fraud before it happens

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FCA based on Stark Law violations

- Several LARGE Settlements lately
- Concerns: despite cases, few bright lines; application is inconsistent across circuits; analysis are very fact-specific; whistleblower haven
- 2016 Medicare Physician Fee Schedule Stark Changes:
  - New Exceptions (recruitment assistance for non-physician practitioners; time share arrangements)
  - Modifications to Existing Exceptions (written arrangements; 1-year requirement; signature requirement; indefinite holdover)

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Individual Enforcement

- August 2015 Yates Memo – emphasis on pursuing individuals
- Result: May not be as much criminal prosecution because individuals have greater incentive to litigate
- Result: May make it difficult for companies to conduct internal investigations

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Medicare 60-Day Rule

- Rule: overpayments must be returned by the later of (i) 60 days after the overpayment was “identified” or (ii) the date the cost report is due.
- "Identify" requires use of reasonable diligence investigating – both proactive and reactive investigations
- Failure to report and return the overpayment is an obligation for the purpose of the False Claims Act (31 U.S.C. § 3729(a)(1)(G)).
- Look-back period is 6 years (not 10); effective March 14, 2016

Maintain an Effective Compliance Program

- Have one
- Use it
- Monitor compliance with it
- Act when issues arise
- NOTE: DOJ recently hired compliance counsel expert

Implied Certification

- Supreme Court case pending – Universal Health Servs., Inc. v. United States
- Does FCA just apply to conditions of payment or also conditions of participation?
- Subject to current circuit court split (First Circuit yes; 5th and 7th – no)

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Other Issues

- Use of Statistical Sampling – quantitative techniques that determine the characteristics of a large data set (e.g., all Medicare claims submitted by a defendant in a period of time) using the observed characteristics of a sample (e.g., a random selection of claims from that period).
- Pharma/Physician relationships – kickbacks in the form of speaking fees, trips with stipends and offers to fund research in exchange for increased drug prescriptions and off-label prescribing
- Hospital/Physician Relationships post-Tuomey

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Any Questions?

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