

How to Overcome Growing Pains by Maturing your Compliance Program from the Wonder Years to the Golden Years: Physician-Hospital Arrangements

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Objectives

The Wonder Years



- Understand common legal and regulatory compliance pitfalls in new and maturing physician-hospital relationships

Coming of Age



- Learn to successfully implement key operational and compliance success factors and instill a culture of compliance post-transaction to ensure long term success

Gray Zone



- Present best practices in handling complex and subjective government guidance to protect your investment, including critical planning steps and key considerations in contract renewals

The Wonder Years

The Wonder Years



- Identifying potential alignment options
- Numerous legal and regulatory considerations
- Careful planning required
- Coding and compliance considerations
- Financial and operational due diligence
- Valuation documentation

Identifying Potential Alignment Options

| | | | | | |
|--|--|--|---|---|-------------------|
| Independent Physician and Independent Medical Staff Privileges | Cooperation through Professional Services Contract | Direct Employment Employment through Affiliates | Purchase Physician Practice and Employ Physicians | Clinical and Contractual Joint Ventures Ambulatory Surgery Center Imaging Modality PHO Management Services Service Line Co-Management Agreements | CIN PHO ACO |
|--|--|--|---|---|-------------------|

Numerous Regulatory and Legal Issues

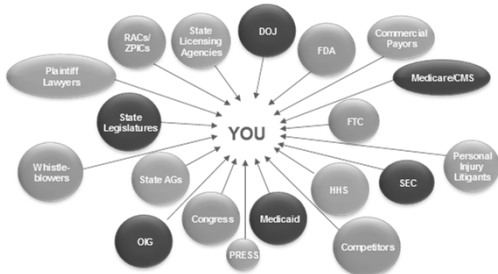
- State and federal fraud and abuse
- Anti-trust
- Provider-based requirements
- Physician/provider credentialing
- Licensure/CLIA/Pharmacy
- Change of ownership documentation/notification
- Group purchasing organization purchasing/340B pricing
- Commercial reasonableness (i.e., need for services, financial viability, etc.)

It's All About the Plan

- Understand the Complex Regulatory Environment
- Understand the Forces Driving Integration
- Be Aware of Recent Compliance Trends
- Know the High Cost of Poor Planning



They're all watching you



The Intricate Compliance Web

- State and Federal Agencies
 - Carrying out
- State and Federal Laws
 - In partnership with
- Private and Public Organizations



State and Federal Laws & Regulations

| Laws | Regulations |
|---|--|
| <ul style="list-style-type: none"> ▪ Affordable Care Act (ACA) ▪ Anti-kickback Statute (AKS) ▪ Stark Law ▪ Civil Monetary Penalties (CMP) ▪ False Claims Act (FCA) ▪ Social Security Act (SSA) ▪ HIPAA & HITECH ▪ State Physician Self-Referral (Baby Stark) ▪ CON ▪ CPOM & Fee Splitting | <ul style="list-style-type: none"> ▪ Conditions of Participation ▪ Enrollment & Recertification ▪ Reimbursement ▪ Licensure ▪ Assignment ▪ Suspension and Exclusion ▪ Antitrust |

The Bad Boys of Healthcare Justice -
Ft. Anti-Kickback Statute (AKS)

- Prohibits the "knowing" and "willful" offer, payment, solicitation, receipt or facilitation of remuneration— i.e., both sides of any kickback
 - Intent Required
- "Remuneration" defined broadly as anything of value including cash, discounts, rebates and even free goods
- Applies to arrangements involving items or services reimbursed in whole OR in part by a Federal Healthcare Program
- Virtually any type of marketing program or marketing relationship with a physician, long term care facility, or other provider can implicate the AKS
- Applies to virtually any financial relationship with any party in a position to refer or recommend business

AKS (cont.)

- Regulated by the Office of Inspector General (OIG) and the Department of Justice (DOJ)
- Criminal + Civil penalties - fines, imprisonment, potential Medicare/Medicaid exclusion, potential "bootstrapped" False Claims Act claims:
 - **5 year prison or \$25K per violation**
 - **Up to 5-year exclusion**
 - **3x remuneration offered + 50K per violation**
- "Safe Harbors" are "voluntary", but if met, immunize the arrangement from prosecution
- "Safe Harbors" are narrowly drawn and there is no "marketing" safe harbor

The Bad Boys of Healthcare Justice –
Ft. Physician Self-Referral Act (Stark)

- "a physician [or their immediate family member] who has a direct or indirect financial relationship with [a DHS] entity, may not make a referral for the furnishing of DHS for which payment otherwise may be made under Medicare."
 - Strict Liability – NO INTENT REQUIRED
- An entity that furnishes DHS pursuant to a prohibited referral may not present or cause to be presented a claim or bill to the Medicare program or to any individual, third party payer, or other entity for the DHS performed pursuant to the prohibited referral

Stark (cont.)

- DHS is a defined term (e.g., DME equipment and supplies, home health, prosthetics)
- Physician is a defined term
- Financial Relationship is...a defined term
- ONLY applies to "Physicians" (and those that the physician deals with) and "Medicare" BUT
- Applies to referrals between any third-party DHS entities AND even the physician's own practice entity
 - UNLESS AN EXCEPTION IS MET

The Bad Boys of Healthcare Justice –
Ft. False Claims Act (FCA)

FCA 101

Treble damages and fines for knowingly:

- ✓ Filing a false claim with the Federal government, or *causing* the filing of a false claim
- ✓ Creating a false record in order to get a claim paid
- ✓ Conspiring to get a false claim paid, or
- ✓ Concealing an obligation to repay monies owed to the Federal government

FCA (cont.)

- **Bootstrapping to AKS Claims**
 - ACA allows the government to "bootstrap" an FCA claim to an AKS claim, arguing, in essence that the kickback relationship made the claim false.
- **Qui Tam Relators**
 - FCA allows individuals to bring suit against companies as qui tam relators.
- **Sixty Day Rule**
 - Failing to return "identified" overpayment within 60 days.
- **Bottom Line**
 - Violating AKS, the Stark Law or failing to return overpayments 60 days after identifying may create FCA liability even with an indirect seller of goods or services.

The Bad Boys of Healthcare Justice –
Ft. HIPAA & HITECH

- The Health Insurance Portability and Accountability Act (HIPAA) and the related Health Information Technology for Economic and Clinical Health (HITECH)
- HIPAA requires Covered Entities and their Business Associates to protect Private Health Information (PHI)
- HITECH has specific security standards for PHI and requires mandatory disclosure when a data breach has occurred

HIPAA & HITECH (cont.)

- Further requirements:
 - Covered Entities must conduct security assessments to identify vulnerabilities
 - Business Associates are also subject to audit & investigation
 - Covered Entities must report Business Associate breaches of unsecured PHI
 - OCR may open a compliance review to investigate any reported breach of unsecured PHI
 - Covered Entities have greater liability if Business Associate is acting as “agent”
 - Unclear how OCR is interpreting this term

Careful Planning Required

- Initiate confidentiality and non-solicitation agreements
- Assemble the “engagement team”
 - Board of Directors, administration (C-suite), legal, compliance, finance, operations, human resources, internal audit
 - Outside counsel
 - Appraisers to conduct business and compensation valuations
- Execute letter of intent (LOI) or term sheet

Careful Planning Required (cont.)

- Identify assets to be acquired
 - Permits/licenses/certifications/government approvals
 - Rights under contracts (vendors, suppliers, software, etc.)
 - All tangible and personal property (FFE)
 - Inventories of supplies, purchased goods, drugs, etc.
 - Intellectual property
 - Rights under leases
 - Prepaids; security deposits
 - Patient records
 - EHR
 - Personnel

Careful Planning Required (cont.)

- Other "up front" considerations
 - Length of agreement
 - Minimum period of time that party cannot terminate "without cause"
 - Compensation structure
 - Minimum guaranteed base salary plus productivity bonus
 - Compensation or collections/wRVU (for PSA)
 - Incorporation of quality component
 - Specific reference to modifier adjusted, personally performed wRVUs
 - Consistent compensation terms, subject to existing practice metrics

Careful Planning Required (cont.)

- Other "up front" considerations (cont.)
 - Inclusion of clause that expects the provider to bill according to government and commercial payer requirements
 - Renegotiating leverage tied to individual performance
 - Compensation at all times must be subject to fair market value and commercial reasonableness requirements
 - Include clause for assessing contract if a specific % shift in coding or wRVU totals occurs from year to year
 - Any obvious unbundled codes to be excluded at true up
 - Noncompetes – duration, scope of services, geographic scope
 - Unwind provisions

Coding and Compliance Considerations

- Detailed analysis of data and assessment of risk
 - Internal
 - External
- Anticipate practice changes

Data Analysis & Risk Assessment: Internal Data

- Benchmark and Review:
 - Evaluation and Management (E/M) services
 - Procedures (high use of at-risk procedures)
 - Use of modifiers
 - wRVUs (productivity)
 - Quality metrics

Data Analysis & Risk Assessment: External Data

- Publically reported data
 - Highest utilizers of codes or modifiers are targets for audits
- OIG, CMS, CERT, RAC audit activity
- Recent CIAs

Data Analysis and Risk Assessment: Tip

- Be careful of exposing issues
 - Once exposed, issues must be addressed
 - Ensure due diligence is only as aggressive as the hospital's ability to react to potential issues

Anticipate Practice Changes

- Practice pattern changes once employed that impact the data:
 - Shift to provider-based,
 - Physician and nonphysician provider (NPP) services/utilization,
 - Shift of ancillary services to the hospital

Due Diligence

- Traditional Purpose: obtain information about what is material to the Seller's business and identify items that may need additional attention and analysis.
- Typical requests include information regarding:
 - Corporate Documents
 - Accounting and Financial Statements
 - Assets and Liens
 - Material Contracts and Payor Agreements
 - Real Property – Owned/Leased
 - Intellectual Property
 - Insurance
 - Legal Issues and Govt. Investigations
 - Licensure and Certifications
 - Compliance Program and Training
 - Privacy and Security
 - Employees / Independent Contractors
 - Medical Staff
 - Environmental

The Due Diligence Balancing Act

- Educate C-Suite on importance of including Compliance ON THE FRONT END of deals
- Have Due Diligence Plan
 - Clearly Define Goals
 - Select tools (interviews, document review, etc.)
 - Stay within parameters
- 60 Day Rule = Due Diligence Balancing Act

Financial and Operational Due Diligence

- Historical compensation and production
- Historical billing and collections activities
- Overhead expenses
 - Staff
 - Rent
 - Malpractice insurance
 - Physician and staff benefits

Financial and Operational Due Diligence (cont.)

- Staffing complement and ratios
- Payer mix
- Credentialing considerations
 - Medicare/Medicaid processing times can be lengthy
- Future billing and collection activities
 - Who will conduct?
- Financial analysis to estimate potential practice losses/gains

Valuation Documentation

- Documenting and validating supporting documentation for physician compensation
 - Physician needs assessment
- Documenting calculation of designated health services
- Be cognizant of any "special" arrangements for physicians (e.g., anything that differentiates one physician's contract from the general provisions of other physician contracts)
- Obtain fair market valuation and commercial reasonableness opinions, as appropriate, to support physician compensation arrangements

Finally...

- Before closing, prepare a post-closing checklist noting action items for issues identified during due diligence. Don't let issues identified during diligence get lost in the shuffle!
- Addressing issues as soon after closing as possible assists in risk reduction.
- Compile a post-integration multi-disciplinary team and assign responsibilities for post-closing projects.
- If possible, schedule post-close plan kickoff call and regular team meetings to discuss the status of post-close projects.

Coming of Age

Coming of Age



- Most parties go into the relationship with the intention of being "in it for the long haul"
- Post-integration process may take longer than the planning/negotiation, due diligence, and transaction closing steps combined
- The length and complexity of the post-integration process will vary depending on the type of transaction entered
- Thorough due diligence on the front end will help ensure a carefree coming of age period

Coming of Age "To Dos"

- Monitor physician behavior changes
- Continually audit, track and communicate
- Create or confirm audit and disciplinary policies are clear and enforceable/enforced

Coming of Age Catastrophes

- *Successor Liability for Overpayments*
 - United States v. Vernon Home Health, Inc., 21 F.3d 693, 5th Cir. 1994 (Nursing home successor liable for predecessor's overpayments in asset purchase b/c federal law preempts state corporate law and provider number was assigned)
- *Antitrust*
 - Federal Trade Commission v. St. Luke's Health System, Ltd., Case No. 1:12-CV-00560-BLW and 1:13-CV-00116-BLW (D. Idaho 2014) (Merger would result in anticompetitive pricing that could not be overcome by efficiencies and ordered divestiture)

Coming of Age Catastrophes

- *Fraud and Abuse/Physician Compensation*
 - U.S. ex rel. Drakeford v. Tuomey Healthcare System, Inc., Case No. 3:05-2858-MBS (D. S.C. 2013) (M.D. contracts based on referrals result in \$237.5M fines & damages)
 - U.S. ex rel. Baklid-Kunz v. Halifax Hospital Medical Center, Case No. 6:09-cv-1002-Orl-31 TBS (M.D. Fla. 2014) (M.D. bonus compensation not based on personally performed services violates Stark)
- *Provider-Based Status*
 - Mission Regional Hospital Medical Center v. Centers for Medicare and Medicaid Services, Dec. No. CR2458 (November 2, 2011) (Hospital acquired in asset purchase deal could not be added as inpatient remote location and had to undergo full survey before it could bill Medicare for services)

Coming of Age Catastrophes

- *Fraud and Abuse/Physician Compensation and Leasing Issues*
 - Intermountain Health Care, Inc., Settlement Agreement (2013)
 - U.S. ex rel. Osheroff v. Tenet Healthcare, Case No. 09-22253-CIV-HUCK/O'SULLIVAN (S.D. Fla 2013)
 - U.S. ex rel. Schubert v. All Children's Health System, Inc., Case No. 8:11-cv-1687-T-27-EAJ (M.D. Fla 2013)
 - U.S. ex rel. Hector Luque v. Adventist Health, Case No. 2:08-01272 (E.D. Cal. 2013)
- *60 Day Rule*
 - Kane v. Healthfirst Inc. et al. and U.S. v. Continuum Health Partners Inc. et al., Case No. 1:11-cv-02325, (S.D.N.Y. 2015)

Triggers for Physician Behavior Changes

- Compensation based on wRVUs
- Provider education
- Changes in what drives the physician's compensation

Common Behavior Changes – Compensation based on wRVUs

- Upcoding E/M services
- Use of NPPs/Residents for increased volume
- Unbundling E/M services
 - Minor vs. major global periods
- Unbundling surgeries
- Tip:
 - If billing departments are not monitoring for correct coding the claim can be submitted with more codes than are paid or correct
 - If compliance departments are not monitoring for correct coding compared to documentation, there is increased risk for overpayment

Commonly Audited Modifiers

- **25** - Separate E/M on the same day as a Minor Procedure
- **57** - Separate E/M on the same day or day before as a Major Procedure
- **58** - Staged or Related Procedure During a Global
- **59** - Distinct Procedural Service
- **78** - Unplanned Return to the OR/Related Procedure
- **79** - Unrelated Procedure During the Global Period

Modifier 25

Modifier 25: Significant, Separately Identifiable E/M Service by the Same Physician on the Same Day of the Procedure or Other Service.

- If a procedure has a global period of 000 or 010 days, it is defined as a minor surgical procedure
- The decision to perform a minor surgical procedure is included in the payment for the minor procedure and should NOT be reported separately
- If a significant and separately identifiable E/M service is performed, and it is unrelated to the decision to perform the procedure, then it can be separately reported

Time: Risk

- Using time as a work-around to documenting
- Combining E/M time with the time spent performing other procedures/services
 - Psychiatric codes
- Not documenting time
 - Assuming time captured in EHR
 - Too difficult to keep up with

Tip

- Billing and compliance staff should be educated on:
 - Place of service requirements,
 - Modifiers to identify provider-based,
 - If a practice is provider-based or just a specific location is,
 - How to bill for NPPs in order to identify personally performed services vs NPP services and correct billing to Medicare and Medicaid

**Common Behavior Changes:
Provider Education**

- Education and close monitoring can correct physician coding to be more accurate which can increase or decrease wRVUs
 - limited prospective reviews
 - shadowing
 - and lots of education initially
 - limit exposure on new providers
- Lack of education and monitoring can lead to physician manipulation of the system

**Common Behavior Changes:
Changes in What Drives Physician Compensation**

- Change in practice patterns due to NPPs not being included in the calculation
 - Shift in work flow
 - Tip: Confirm omission of NPP services
- Ancillary services no longer directly related
 - Orders may decrease
 - Do not forget to include supervision for services physicians can no longer directly bill for (e.g., infusion supervision)

Continually Audit, Monitor, and Track

- Conduct regular billing and coding audits
 - Annual with follow-up, quarterly
- Conduct periodic operational assessments to ensure best practices are in place
- Provide feedback to physicians routinely
 - Production
 - Quality metrics
 - Financial performance

Gray Zone



- Timing of contract renewals
- Commit to fair market value and commercial reasonableness compliance reviews
- Special considerations

In the Gray Zone

- Conduct thorough review of contracts to identify the contracts to keep and which contracts to terminate or renegotiate
- Many contracts require 30 to 90 days to terminate without cause
- Plan accordingly especially if anticipate significant changes to agreement terms, arrangement structures, defined quality metrics, etc.

Commit to FMV and CR Reviews

- Even if agreement is for multiple years, may still need to evaluate for compliance with fair market value and commercial reasonableness
 - Valuation period may be for only 1 year or 2 years when agreement is for 3 years
 - Survey benchmarks and reimbursement changes annually
 - Quality metrics re-evaluation to ensure robustness
 - Impacts of behavior changes

Special Considerations

- Administration of contract
 - Appropriate calculation of wRVUs
 - Modifier adjusted and personally performed
 - Bonus calculated based on correct threshold
 - Achievement of quality metrics appropriately tracked and recorded
 - Medical director time sheets completed

Special Considerations (cont.)

- Contract mitigation based on audit results
 - Compliance rate impact on bonus
 - Deduction of overpayments to bonus
- Need for self-disclosure?
- Evolving payment models
- "Volume to value"



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