

Katten

Katten Muchin Rosenman LLP

Huron

CONSULTING GROUP

Health Care Compliance Association: 2011 Compliance Institute

Physician and Vendor Relationships: Operationalizing Compliance with the Stark and Anti-kickback Laws

Leah Guidry, Managing Director, Huron Consulting Group
Lisa Ohrin, Esq., Partner, Katten Muchin Rosenman

Experience. **Redefined.**TM

Agenda

Agenda

- Basics of—and reminders about—Stark Law and Anti-kickback Statute compliance with respect to physician and vendor relationships
- Operational Perspective
 - Legal documents are in place, what do you do now? Physician/Vendor relationship compliance goes far beyond the General Counsel's office.
 - Policies and Procedures, Education, Effective Use of Databases and Tickler Systems, Auditing and Monitoring
- IRO Perspective
 - What can the CIAs and IROs in this area teach us about compliance?
 - Who are the whistleblowers?

A Few Reminders BEFORE You Operationalize the Stark and Anti-kickback Laws

Limitations on Physician-Hospital Arrangements

- Stark Law
 - Prohibits physicians from making referrals to a health care entity for designated health services (includes most hospital services) if the physician has an ownership interest in or compensation arrangement with the entity and that relationship does not satisfy the requirements of an exception to the law. The health care entity may not bill Medicare for improperly referred services. This is a payment rule.
- Anti-kickback Statute
 - Prohibits offering, soliciting, paying or receiving remuneration in exchange for referring or arranging for services payable by a Federal health program. This is a criminal statute.
- CMP Statute
 - Prohibits a hospital from paying a physician (and a physician from accepting payment from a hospital) to limit or reduce services to a Medicare beneficiary or Medicaid recipient. This statute carries monetary penalties of \$2000 per individual for whom the improper payment relates).

Penalties for Stark Law Noncompliance

- For knowing or unknowing violations:
 - Denial of payment
 - Refund of amounts collected from beneficiary as a result of improper billing
- For knowing violations, potentially:
 - Civil Money Penalties of \$15,000 per item or service plus 2X the amount claimed
 - Civil Money Penalties of \$100,000 for “circumvention schemes”
 - Exclusion
 - Enforced by OIG
- Potential False Claims Act Liability for knowing violation

Recruitment

- No requirement for FMV
- No requirement for identifiable services
- Community need is an IRS issue for non-profits, not a Stark Law requirement
- Repayment obligation (*i.e.*, commitment to remain in the community) is an IRS issue or business decision, not a Stark Law requirement
- Implicates the anti-kickback statute

Recruitment

- Things for which a hospital may pay or reimburse a group practice through the recruitment payment (*i.e.*, actual incremental expenses of the group practice) IF INCURRED PRIOR TO THE PHYSICIAN JOINING THE GROUP PRACTICE
 - Recruiting dinners (with spouses if intended to introduce the recruited physician and his/her spouse to the hospital, group and community)
 - Headhunter fees
 - Travel expenses associated with the recruited physician's (and his or her spouse's) visits to the relevant geographic area
 - Moving expenses (can also be reimbursed directly to the physician)
 - Tail malpractice insurance covering the recruited physician's prior practice
- Things for which a hospital may pay or reimburse a group practice (or individual physician) when the target physician does not accept the recruitment offer (whether to join the group practice or establish a solo practice)
 - Recruiting dinners (with spouses if intended to introduce the recruited physician and his/her spouse to the hospital, group and community)
 - May or may not be considered "remuneration" (*i.e.*, may not need a written agreement)
 - Time spent by group practice physicians or other personnel recruiting the physician
 - MUST meet the requirements of an applicable exception (*i.e.*, will need a written agreement)

Employment Arrangements

- Need not be in writing (but always a good idea)
- Total compensation (including bonus payments) must be FMV
- Cannot bonus on referrals for ancillary services or in a way that takes into account the volume or value of referrals by the employed physician
- Can create a bonus pool funded by ancillary revenue
 - May only distribute based on personally performed services
 - Should be at the sole discretion of the hospital as to whether to fund the pool or distribute bonuses
- Shared savings payments may be available to employed physicians

Personal Service Arrangements

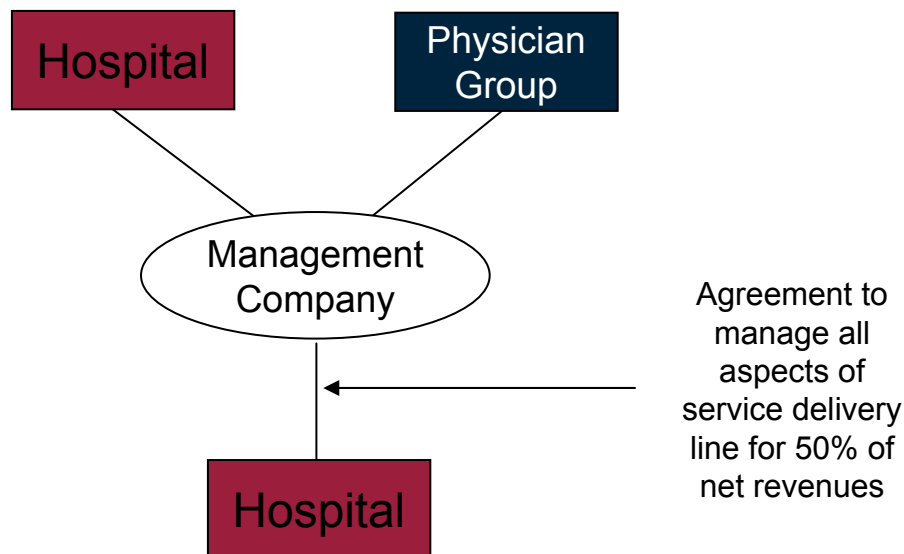
- Must be in writing, identify actual and specific services, and reference other agreements between the parties (or a master list of agreements)
- Must be commercially reasonable, FMV and not take into account the volume or value of referrals or business between the parties
- Compensation must be set in advance and not changed during the term of the agreement unless the amended compensation terms remain in effect for a full year (and the arrangement meets all of the requirements of the exception at the time it is amended)
- When contracting with a group practice, must identify physician owners of the group practice, as these physicians “stand in the shoes” of the group practice
- Not as flexible as employment arrangements

Purchasing Physician Practices

- Generally falls under the Isolated Transactions exception to the Stark Law
- Valuation is critical...and difficult
 - Must be FMV, commercially reasonable
 - Cannot determine purchase price in a manner that takes into account the volume or value of referrals or business between the parties
- May purchase medical records
- Intangibles, such as a fully-trained administrative and billing staff, may be included in purchase price

Service Line Co-management Arrangements

- Although permissible under the Stark Law when structured properly, these carry inherent risk
- Could rise to the level of a circumvention scheme if structured improperly
 - Cannot include space or equipment
- Key is identifiable services and FMV



Tips on Structuring Arrangements

- Consider employing (or contracting with) physicians through a sister entity (e.g., a physician practice management company or services organization) to avoid direct compensation arrangements with the hospital
- Leave room to adjust compensation of employed physician if additional duties are added
- Incorporate flexibility to accommodate changing payer and government rules and regulations
 - Existing rules must be modified to accommodate shared savings within ACOs
 - Waiver of existing laws only allowed in demonstration projects

Tips on Structuring Arrangements

- For recruitment arrangements—
 - Plan ahead for contingencies
 - Consider a provision that allows the group practice (if a party to the recruitment) to find an alternative physician—at its own cost— if the recruited physician leaves the practice and geographic service area
 - Require the group practice to indemnify the hospital in the event the recruited physician does not repay obligations
 - Frequently update the least number of contiguous zip codes that comprise the geographic area served by the hospital to maximize options for where a recruited physician may open a practice

Tips on Structuring Arrangements

- For purchased group practices—
 - Will you continue to run the practice as if it is independent of the hospital?
 - Using the in-office ancillary services exceptions permits group practice physicians to receive ancillary income distributions
 - Physicians remain employees of the group practice
 - Will you employ the physicians directly and move the ancillary services (if any) into hospital-based departments?
 - Consider revenue implications
 - Physicians can no longer be bonused based on referrals for ancillary services (in accordance with the Stark Law rules for group practices)
 - Physician services subject to the site-of-service differential, further reducing physician income
 - Do you have compliance expertise to run a group practice that complies with the detailed requirements of the group practice definition and in-office ancillary services exception?

Operational Issues

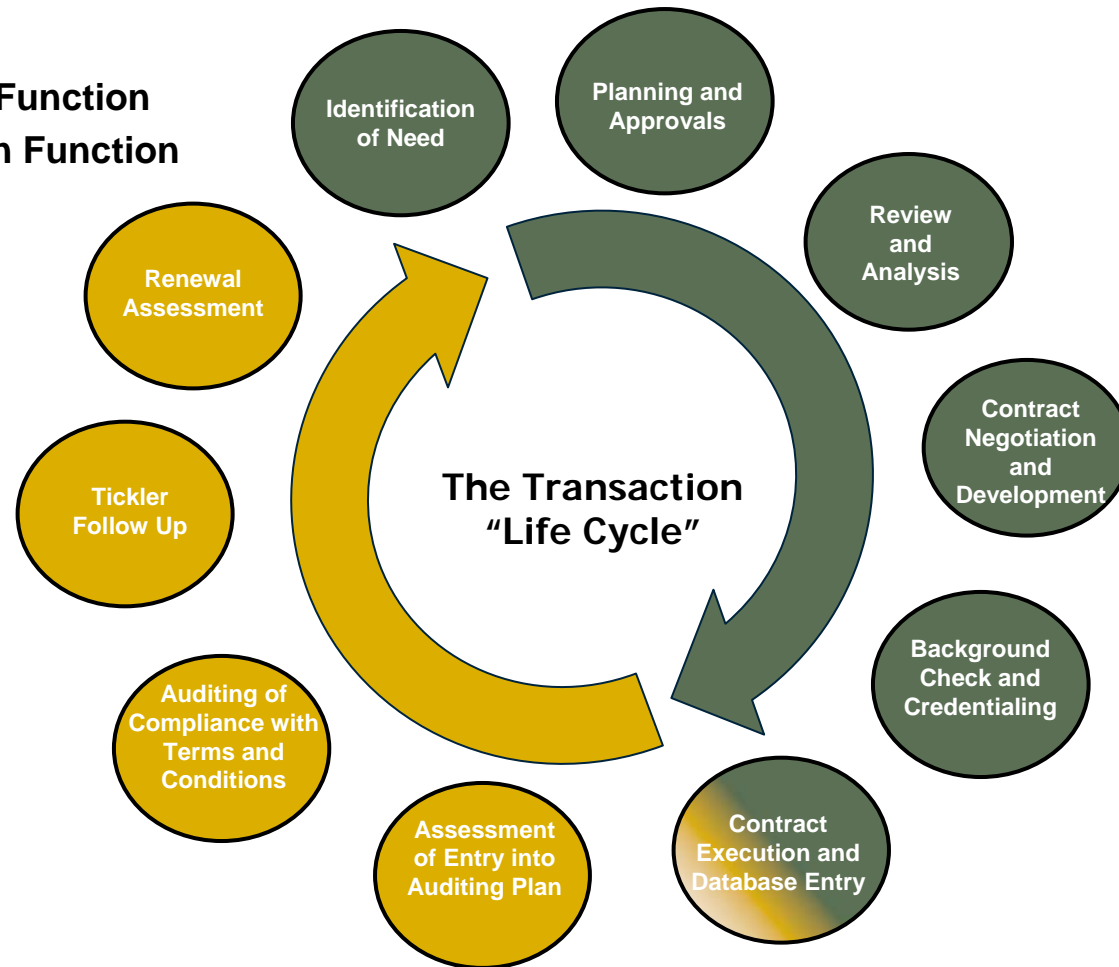
Physician and Vendor Compliance

T-1 and T+1

- T-1 are all of the pre-contracting issues that need to be addressed to facilitate a compliant arrangement
- T+1 are all of the post-contracting issues that need to be addressed to facilitate a compliant arrangement
- T-1 is the area in which most institutions have considerable experience and thus are more compliant
- T+1, conversely, is where most of the risk and trouble lies; therefore, requires the greatest amount of infrastructure development

Transaction Life Cycle

- (T-1) Pre Transaction Function
- (T+1) Post Transaction Function



Transaction Life Cycle



Identification
of Need

- Need identification should trigger a coordinated set of procedures
 - Some industries have strict guidelines around conducting needs analyses before contracting with physicians.
 - The higher the potential for a sham arrangement the greater the need for a more formal needs assessment.
 - Manufacturing (medical device and drug) tend to have these processes in place. For some areas in the provider industry this is a process worth borrowing.
- Sign off procedures or meetings to review the identified need might be warranted
 - Such procedures could be determined by the type of service required (e.g., professional services agreements but not lease space arrangements)

Transaction Life Cycle

Planning
and
Approvals

- Identify and assess various points related to the identified need:
 - Timing
 - Type of arrangement (Medical Director, equipment lease, etc.)
- Determine the correct processes and people involved in the differing types of arrangements
- Who should approve the initiation of these arrangements?
 - Is the approval different for differing types of arrangements?

Transaction Life Cycle

Review
and
Analysis

- Assess the type of review and analysis what the transaction needs
- Who is qualified to conduct the review?
 - In-house versus outside counsel
 - Use of templates and guides
 - Where used, take care to ensure that the scope and terms are applicable to the arrangement and are timely (e.g., updated since last regulatory change, guidance document, etc.)

Transaction Life Cycle

Contract
Negotiation
and
Development

- Similar to prior step, assess the type of arrangement/transaction to determine who is best qualified to draft, negotiate and finalize the contract.

Transaction Life Cycle

Background
Checks and
Credentialing

- Generally handled by the Medical Affairs Office, but could be handled by GC or HR – depending on the type of transaction
- Needs to be coordinated with the contract negotiation to ensure ‘out’ clause if issues arise in background check (e.g., GAO, OIG, malpractice)

Transaction Life Cycle

- Pre Transaction Function
- Post Transaction Function

Contract
Execution &
Database
Entry

- Ensure proper and complete execution of agreement.
- Simple to address but if improperly handled can be source of technical non-compliance as most exceptions and safe harbors require *in writing, signed by the parties*.
- Input transaction data into the database.
- Ensure that the database has the appropriate parameters to properly manage the ongoing arrangement and facilitate compliance.

Transaction Life Cycle

Assessment
of Entry into
Auditing
Plan

- Assess the type of review and analysis what type of monitoring the transaction warrants
- All arrangements should be monitored
 - Database monitoring – double checks for entry accuracy, tickler output, etc.
- Some arrangements should be audited
 - Determined based on assessment of risk, randomization, etc.

Transaction Life Cycle

Monitoring for
Compliance with
Terms and
Conditions

- Result of risk assessment will determine whether the arrangement is put on a monitoring or monitoring and auditing schedule.
- Care should be taken to assess the internal controls and bring a healthy dose of skepticism
- Ensure that qualified individuals perform tasks to which they have been trained and appreciate the critical nature of this function
- Go outside of the database for monitoring and auditing – assess for non-compliant arrangement or payments outside of deal parameters

Transaction Life Cycle

Tickler
Follow
Up

- Ensure effective use of tickler system
 - Guard against over use that compromises value
- Proper personnel should receive notices, but each notice should warrant a reply
- Provide heightened activity with each successive tickler warning – particularly if no response
- Single point of responsibility for an arrangement
- Consolidated responsibility for aggregate tickler – Compliance Officer, General Counsel, etc.

Transaction Life Cycle

Renewal
Assessment

- Assess need for renewal of arrangement
- Similar to needs assessment in pre-transaction function
- May need to overlap with tickler system to avoid 'push through' of arrangement that has fulfilled its function

Checklist of items

- Effective educational program for those impacted and for whom parts of the transaction cycle fall within their job tasks
- Policies and procedures
- Processes and SOPs that assist and guide decision-makers
- Sign off forms – graduated by risk or type of arrangement
- Templates/tools/checklist/guides to assist with specific arrangement compliance as well as providing means of documenting overall compliance activities
- Proper use of FMV expertise

IRO – Lessons Learned

Lessons Learned

- *Qui tam* whistleblowers are not solely personnel within the institutions. More and more of the Stark and anti-kickback whistleblowers are physicians – competitors who believe another group or peer received a more favorable deal.
- Post transaction issues are the most vexing and the areas to focus the most attention.
 - History of non-attention in this area.
 - Significant degree of resources and expertise focused on the pre-transaction part of the life cycle.
 - Time to shore up the post-transaction part of the life cycle.
- Details, details, details
 - Resting on laurels create a heightened degree of risk.
 - Entry into the database is insufficient for active compliance monitoring.
- Coordination between compliance, legal, medical affairs, procurement, A/P
 - Personnel
 - Systems
- Make efficient use of dashboards and have qualified personnel to drill down
 - Photocopying of time entry forms that have been pre-signed, hours and tasks pre-populated with only date changed

Background: Legal Issues and Update

**The Current Enforcement
Environment
and
Recent Changes to Statutes
and Regulations Governing
Fraud and Abuse**

Increased Funding for Government Enforcement Initiatives

- Omnibus Appropriations Act of 2009 provided a one-time additional \$198 million
- 2010 Budget invests \$311 million in 2-year funding (50-percent increase over FY09)
- 2011 Budget seeks \$250 million to expand HEAT
- Affordable Care Act increases Health Care Fraud and Abuse Control (HCFAC) Account for FY 2011 – FY 2020 by \$10 million a year
- Reconciliation Act added an additional \$250 million to the account between 2011 and 2016

Recent Enforcement Action

- Detroit Medical Center
- St. Joseph's Hospital (MD)
- Rush University Medical Center
- Bradford Regional Medical Center
- Tuomey Healthcare System
- UMDNJ
- El Centro Regional Medical Center (among others)
- Christ Hospital
- Covenant Medical Center

The Affordable Care Act (2010)

- Accountable Care Organizations
- Expansion of RAC program
- *Hanlester* overturned
- Mandatory compliance programs
- Mandatory return of overpayments
- Stark Law Issues
 - Stark Self-referral Disclosure Protocol
 - Notice provisions in the in-office ancillary services exception
 - Physician ownership in hospitals

ACA: Mandatory Compliance Programs

- As a condition of enrollment in Medicare, Medicaid and/or CHIP, providers and suppliers must develop and implement a compliance program
- HHS will establish standards and timing through regulations
- Likely different standards for various provider/supplier categories
- Final rule issued January 24, 2011 did NOT finalize rules for mandatory compliance programs
 - CMS to “advance proposals” in a future rulemaking

ACA: Overpayments

- Section 6402 (new §1128J of the Social Security Act) provides that, if an entity has received an overpayment, it is required to report and return the overpayment to the Secretary or the State Medicaid Agency or the appropriate contractor and notify it of the reason for the overpayment
- The overpayment must be reported and returned within 60 days of the date on which the overpayment was determined, or the date any corresponding cost report is due (if applicable), whichever is later
- Any overpayment retained past the deadline is an “obligation” (as defined in, and for purposes of, the reverse false claims provision of the False Claims Act)
 - In 2009 FERA made changes to the reverse false claims provision
 - Whether and under what circumstances FERA imposed a duty to disclose self-discovered overpayments has been the subject of much discussion
- “Overpayment” is defined in section 6402 of the ACA as any funds a person receives or retains under Medicare or Medicaid to which the person, “after applicable reconciliation,” is not entitled

ACA: Stark Law Changes

- In-office ancillary services exception
 - Notice of 5 alternative health care suppliers required for MRI, CT and PET scans furnished by physicians in the group practice (e.g., faculty practice plan) setting
- Physician ownership in hospitals
 - Essentially no new or increased physician ownership in hospitals (without an exception from CMS)
 - More regulations to be issued
- Self-referral Disclosure Protocol established September 23, 2010

SRDP Background and Necessity

- CMS traditionally has had limited (or no) authority to compromise or waive Stark sanctions (or any other claims liability)
 - Under 42 CFR §405.376, claims can be compromised (including compromised to zero) only for certain reasons, which arguably did not encompass Stark violations
 - §405.376 may be amended only with concurrence of DOJ and Treasury
- OIG has broad discretion regarding whether to impose CMP/assessment, the amount of CMP/assessment, and whether to impose exclusion (and length of exclusion)
 - See §1128A(a) of the Social Security Act; 42 CFR Part 1003
- In March 2009, OIG announced it would no longer take Stark-only potential or actual violations into its self-disclosure protocol
- Penalties for Stark Law violations are significant, especially in relation to the “foul” (*i.e.*, failure to obtain a signature of a party or cross-reference a master list of agreements)

Basic Rules for Stark Law Compliance Reviews

Essentials of Stark Law Compliance

- Written agreement (except for employment arrangements)
 - Signed by the parties
- Identifiable services
- FMV compensation
 - Determined in advance of the commencement of the arrangement
 - Does not take into account the volume or value of referrals to or business generated for the hospital
 - Does not change over the course of the arrangement
- Commercially reasonable arrangement

When You Discover Potential Noncompliance with the Stark Law

- First Steps – Current Compliance
 - Bring the arrangement into compliance as quickly as possible
 - Terminate any arrangement that cannot be made compliant
- Consider an investigation to identify other instances of noncompliance
 - Attorney-client privilege issues
 - Design and scope of audit

How to Evaluate Potential Noncompliance with the Stark Law

- Is there remuneration?
- Is there a compensation arrangement?
 - Direct?
 - Indirect?
- Is there a referral for DHS?
- Is the organization furnishing the DHS an “entity” (as defined in the regulations)?
- Is Medicare the payor?

Core Rules for Evaluating Potential Noncompliance with the Stark Law

- Apply the rules that were in effect during the various periods of the arrangement
 - The Stark rules have changed a number of times and the analysis may be different during certain points in the arrangement
- Give proper, but not excessive, weight to preamble language
 - Statutory and regulation text govern
 - **Example:** Is space an “item” or a “service”
 - **Example:** Space and equipment lease exceptions and per-click compensation formulae

Special Stark Law Rules to Consider

- Stand in the Shoes
- Per-click compensation in lease arrangements
- Indirect compensation arrangements
- Definition of “entity” as an organization that “performs” the DHS
- “Grace periods” for signature requirements
- Holdovers

Have you considered...

- Temporary Noncompliance (42 C.F.R. 411.353(f))
- Compensation Unrelated to DHS (42 C.F.R. 411.357(g))
- Payments by a Physician (42 C.F.R. 411.357(h))
- “Grace Periods” (42 C.F.R. 411.353(g))
- Isolated Transactions (42 C.F.R. 411.357(f))

Period of Disallowance

- Determining the beginning and the end of the financial relationship
- Impact of safe harbors
- Practical ability to continue the arrangement
 - Is it likely that the physician will make future referrals to the entity?
 - Is physician still in the geographic area?
- Nature of the previous relationship between the parties and the physician's past referrals

Determining the Overpayment

- With respect to physician-hospital arrangements:
 - Consider all inpatient and outpatient hospital services
 - Is the referring physician the attending or admitting physician?
 - Did furnishing the improperly referred DHS affect the DRG payment?
 - Does this impact the amount of the overpayment?
- With respect to physician organization-hospital arrangements:
 - Is the referring physician an owner of the physician organization?
- Consider the SRDP “look back” period (in contrast to the reopening period for cost reports or Part B claims)

Katten

Katten Muchin Rosenman LLP

Lisa Ohrin

Partner

lisa.ohrin@kattenlaw.com

202.625.3595

Huron

CONSULTING GROUP

Leah Guidry

Managing Director

lguidry@huronconsultinggroup.com

202.250.4679