

LESSONS LEARNED: CONDUCTING A COMPLIANCE REVIEW OF HOSPITAL-PHYSICIAN FINANCIAL ARRANGEMENTS

presented by

Dennis S. Diaz, Esq.
Davis Wright Tremaine LLP

Shannon G. Dwyer, Esq.
Senior Vice President and
General Counsel
St. Joseph Health System

Anchorage
Bellevue
Los Angeles

New York
Portland
San Francisco

Seattle
Shanghai
Washington, D.C.



Why Conduct a Compliance Review?

- A. CMS Has a Duty to Determine whether Hospitals Are Complying with Stark. See 42 CFR 411.361
- B. CMS Has the Authority to Require Hospitals to Provide Information concerning Stark Compliance. See Deficit Reduction Act (DRA) of 2005, Section 1877(f) of the Social Security Act; 42 CFR 411.361
- C. CMS's DFRR Surveys



Why Conduct a Compliance Review? *(cont'd.)*

1. CMS's proposed rule dated April 30, 2008
2. Disclose Physician Ownership, Investment and Compensation Arrangements
 - a. Joint ventures
 - b. Office and equipment rentals
 - c. Leases
 - d. Personal services arrangements
 - e. Medical director agreements
 - f. On-call stipends
 - g. Physician recruitment



Why Conduct a Compliance Review? *(cont'd.)*

- D. Entities and Individuals May Be Liable for Reports to the Government that Falsely State a Hospital's Physician Arrangements Are Compliant with Stark



Why Conduct a Compliance Review? *(cont'd.)*

1. The proposed DFRR certification provides: “I hereby certify that the attached responses to the Section 1877(f) Disclosure of Financial Relationships Report, filed on behalf of (insert Medicare provider name) _____ (insert Medicare provider number) _____ ***are true and correct to the best of my knowledge.***”

Must be signed by CEO, CFO, or comparable officer of the hospital



Why Conduct a Compliance Review? *(cont'd.)*

2. The Medicare cost report certification provides:

“CERTIFICATION BY OFFICER OR ADMINISTRATOR OF PROVIDER(S)
I HEREBY CERTIFY that I have read the above statement and that I have examined the accompanying electronically filed or manually submitted cost report and the Balance Sheet and Statement of Revenue and Expenses prepared by _____ (Provider Names(s) and Number(s)) for the cost reporting period beginning _____ and ending _____ and ***that to the best of my knowledge and belief, it is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.*** (Emphasis added.)

(Signed) _____

Officer or Administrator of Provider(s)

Title

Date



Why Conduct a Compliance Review? *(cont'd.)*

[MISREPRESENTATION OR FALSIFICATION OF ANY INFORMATION CONTAINED IN THIS COST REPORT MAY BE PUNISHABLE BY CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINE AND/OR IMPRISONMENT UNDER FEDERAL LAW. FURTHERMORE, IF SERVICES IDENTIFIED IN THIS REPORT WERE PROVIDED OR PROCURED THROUGH THE PAYMENT DIRECTLY OR INDIRECTLY OF A KICKBACK OR WHERE OTHERWISE ILLEGAL, CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINES AND/OR IMPRISONMENT MAY RESULT.]



Why Conduct a Compliance Review? *(cont'd.)*

3. Liability under the False Claims Act (FCA)
 - a. The government can and has sued individuals, in addition to the organizations that employ them, under the FCA
 - b. An entity that furnishes designated health services (DHS) pursuant to a referral that is prohibited under Stark “may not present or cause to be presented a claim or bill ...for the DHS performed pursuant to a prohibited referral.”

42 CFR 411.353



Why Conduct a Compliance Review? *(cont'd.)*

- c. Who at the hospital is responsible for presenting or causing to be presented the bill or claim?
 1. Job description
 2. Multiple persons potentially responsible for claim preparation and submission

- d. Was the claim or bill submitted with the requisite level of knowledge required under Stark and the FCA?



Why Conduct a Compliance Review? *(cont'd.)*

- d. “Reason to suspect” standard intended by CMS to mirror the FCA standard of knowledge including reckless disregard and deliberate ignorance. Stark II, Phase II, 69 Fed. Reg. 16062 (March 26, 2004)
- f. FCA standard:
 - i. Knowing,
 - ii. Reckless disregard
 - iii. Deliberate ignorance
- g. SB 386, The Fraud Enforcement and Recovery Act of 2009 (FERA), broadens FCA liability in several respects, including liability for the retention of overpayments



Why Conduct a Compliance Review? *(cont'd.)*

4. DOJ Lawsuit Against Tenet General Counsel (September, 2007)

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

CASE NO. **07-61329**
CIV-MARRA

UNITED STATES OF AMERICA,
Plaintiff,
vs.
CHRISTI R. SULZBACH,
Defendant.

MAJESTIC RULES
10/10/06

FILED BY *[Signature]*
SEP 18 2007

COMPLAINT

For its Complaint, the United States of America alleges as follows:

I. NATURE OF ACTION

1. The United States brings this action to recover statutory damages and civil penalties under the False Claims Act, 31 U.S.C. §§ 3729-35.

102. The United States was injured and suffered damages because of Defendant Sulzbach's submission of false certifications, her failure to stop Tenet from violating the Stark Statute, and her failure to report Tenet's violations to the Government, because (1) her actions permitted Tenet to receive payments that it was not entitled to receive, and (2) her actions obstructed the Government's efforts to discover and recover past improper payments.

Press release and Complaint at
www.usdoj.gov/usao/fls/PressReleases/070918-05.html

LLP

5. Sample Activity and Historic Settlements

Stark and Anti-Kickback Statute settlements have cost organizations tens of millions of dollars.

The Baltimore Sun

Restructuring Team Brought in to St. Joseph Medical Center Amid Federal Investigation

by Stephanie Desmon and Robert Little

March 14, 2009

TOWSON, Maryland — St. Joseph Medical Center, where three top executives went on leave two weeks ago amid a federal investigation, has brought in an outside “restructuring team” to manage the hospital and ensure that it is not violating federal health laws, according to a memo circulated among employees.

Officials at the hospital, a 354-bed facility in Towson that is among the region’s largest employers, did not elaborate yesterday on the restructuring team’s role. But Beth O’Brien, who is leading the team, said in a memo that “the overarching goal is to create a compliance program at St. Joseph that parallels the same high standards as our clinical quality.

According to documents from the U.S. Department of Health and Human Services, such programs are put in place primarily to avoid fraudulent payment claims to Medicare and Medicaid. Violating these laws can lead to substantial penalties, ranging from fines to exclusion from Medicare, which would effectively shut down a hospital by cutting off a major source of income.

“Hospitals are highly regulated environments; investigations of this nature are becoming more commonplace.”

Historic Settlements

- Condell Medical Center, Libertyville, IL - \$36 million.
- Lester E. Cox Medical Centers, Springfield, MO - \$60 million.
- HealthSouth Corporation, Birmingham, AL - \$15 million.
- Memorial Health University Medical Center, Savannah, GA - \$5 million.
- Alvarado Hospital, San Diego, California – \$21 million.
- University Hospitals Health System, Cleveland, Ohio – \$14 million.

Why Conduct a Compliance Review? *(cont'd.)*

6. Boards of directors and board compliance committees increasingly are interested in whether their hospitals are in compliance with Stark and related laws



When Your Board Chair Asks. . .



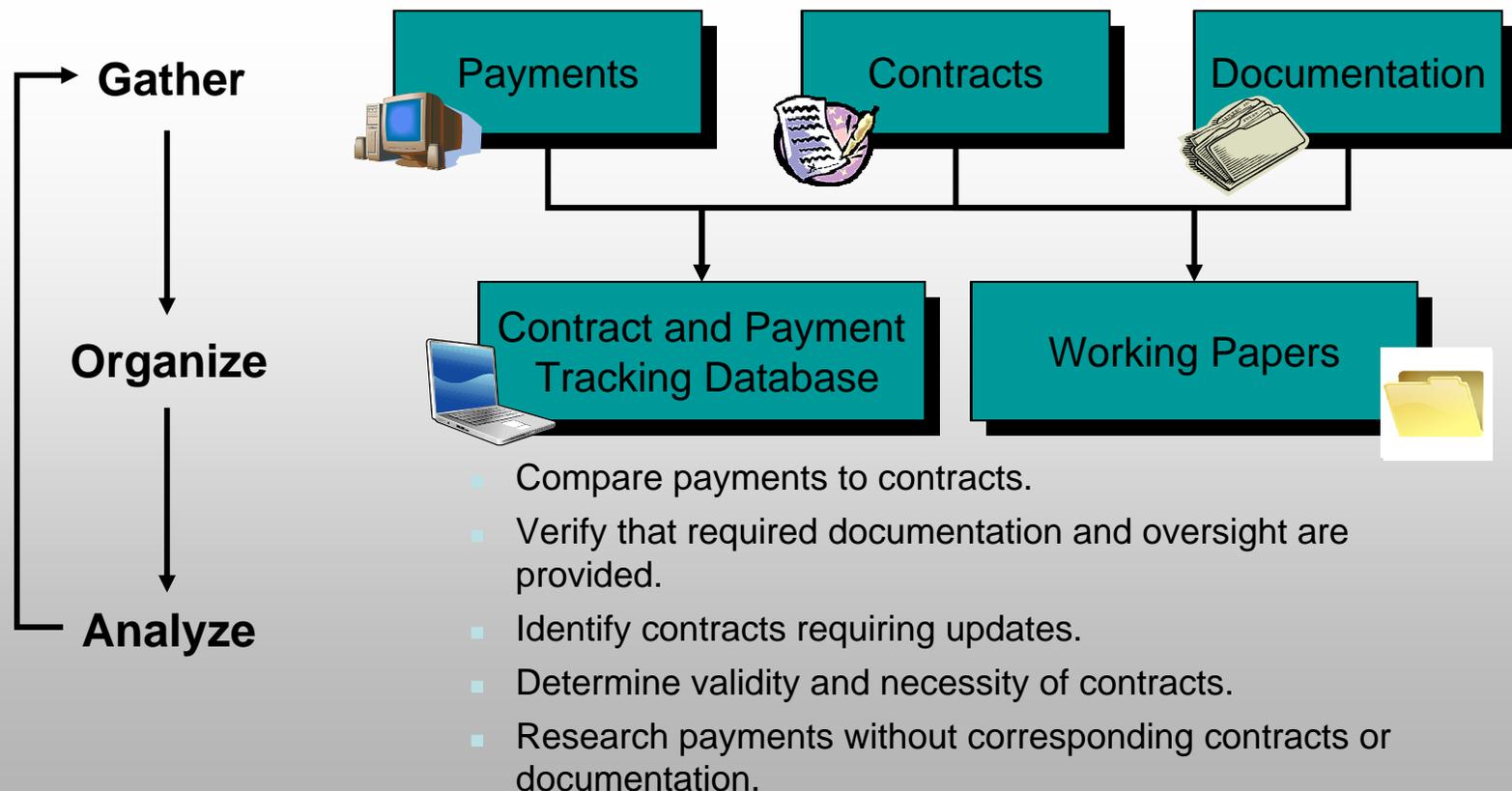
**Are we complying
with Stark?**

How Do You Answer?

HOW TO CONDUCT A COMPLIANCE REVIEW

Understanding the Methodology

The approach involves an iterative process whereby all payments made to physicians are identified, documented, categorized, and justified.



HOW TO CONDUCT A COMPLIANCE REVIEW

Gathering Payment Data

The depth of a review of payments depends on the hospital's goal for the project.

Auditing Known Payments

- Pull all physician services payments from the check registry.
- Pull additional payments for other known contracts (e.g., rental payments).
- Eliminate unrelated payments.

Managing All Payments

- Pull all physician services payments from the check registry.
- Pull additional payments for other known contracts (e.g., rental payments).
- **Review all other payments that match certain queries (e.g., partial names of every physician and physician group in the area).**
- Eliminate unrelated payments.

Seeking Hidden Payments

- Pull all physician services payments from the check registry.
- Pull additional payments for other known contracts (e.g., rental payments).
- Review all other payments that match certain queries (e.g., partial names of every physician and physician group in the area).
- Eliminate unrelated payments.
- **Search for suspect payments and audit sample**



HOW TO CONDUCT A COMPLIANCE REVIEW

Examples of Reported Facts

Facts About Arrangements	Facts About Payments
<ul style="list-style-type: none">▪ Contract is expired or not signed.▪ New agreement was entered into beyond the Stark 6-month holdover time period.▪ No evidence of legal counsel or board approval.▪ No community need assessment.▪ No FMV materials.▪ FMV materials are inappropriate for the contract.▪ Time sheet or invoicing documentation is missing.	<ul style="list-style-type: none">▪ Payment made with no contract.▪ Payments do not match the contract terms.▪ Payment does not match time sheet or invoice.▪ Payment exceeds monthly maximum.▪ Compensation exceeds benchmark.



HOW TO CONDUCT A COMPLIANCE REVIEW

Delivering Work Products

The content and format of deliverables should be agreed upon early in the process to ensure the appropriate level of detail.

- Database of all financial relationships, contract terms, legal elements, supporting documentation, and payment history.
- Electronic working papers for each contract, including:
 - Completed checklist
 - Contract
 - Contract documentation (e.g., FMV, community need)
 - Payment history
 - Payment documentation (e.g., time sheets, coverage logs)
- Reports by type of physician arrangement and by physician that include a summary of each contract



LEGAL AND PRACTICAL ISSUES IN CONDUCTING THE COMPLIANCE REVIEW

- A. Purpose and scope of review
 - 1. Issues reviewed for compliance:
 - a. Stark
 - b. Anti-kickback
 - c. Tax exemption and bonds
 - d. Fair market value determination
 - e. Community needs assessment
 - f. Compliance with hospital policies and procedures, e.g., compliance plan, contract approval protocols, physician compensation policies, joint venture policies, conflict of interest policies



LEGAL AND PRACTICAL ISSUES... (*cont'd.*)

2. Issues not reviewed
 3. Physician arrangements; other referral sources?
- B. Roles of outside counsel, in-house counsel, compliance officer and consultants; attorney-client privilege
1. Outside counsel
 - a. Provides legal review and advice on documents and information collected pursuant to data request; coordinates legal review and renders advice on information collected; discusses next steps with in-house counsel



LEGAL AND PRACTICAL ISSUES... *(cont'd.)*

- b. Use of outside counsel enhances protections under attorney-client privilege. Business and operational communications by in-house lawyers will not be protected
 - c. Boards of Directors often prefer outside counsel review and involvement
2. In-house counsel and compliance officer – work directly with each other and with hospital personnel in data request and collection and with outside counsel on legal issues



LEGAL AND PRACTICAL ISSUES... *(cont'd.)*

3. Consultants

- a. Develop goals and scope of overall project; work with in-house counsel to collect documents and information; match payments to contracts; coordinate review
- b. Engaged by outside counsel to enhance protections under attorney-client privilege
- c. No legal or operational conclusions in reports to counsel or hospital



LEGAL AND PRACTICAL ISSUES... *(cont'd.)*

4. SJHS Approach
 - a. Outside counsel engaged to perform legal analysis and provide oversight of consultants
 - b. Consultants with expertise selected
 - c. Weekly conference calls with team
 - d. Communications plan developed and coordinated by in-house counsel
 - e. Findings reviewed throughout the process



LEGAL AND PRACTICAL ISSUES... *(cont'd.)*

- C. Data gathering – documents and information requested for production by hospital
 - 1. Contracts and data requested
 - a. All written contracts and supporting written documentation between hospital and physicians, e.g.:
 - i. Medical director
 - ii. Coverage



LEGAL AND PRACTICAL ISSUES... *(cont'd.)*

- iii. on call
- iv. recruitment
- v. facility and equipment lease
- vi. consultant and development
- vii. joint venture
- viii. loan, including promissory note and security agreement
- ix. management services



LEGAL AND PRACTICAL ISSUES... *(cont'd.)*

- b. Writings including emails concerning hospital financial arrangements (whether written agreement or not) with physicians
- c. Community need assessments
- d. Fair market value opinions and analyses
- e. Accounts paid, payable, and receivable for physicians
- f. UPIN's/NPI's, name of physicians with whom hospital have financial arrangements
- g. All tools used to track payments and services to and from physicians
- h. Physician contracting policies and procedures, including contract approval procedures



LEGAL AND PRACTICAL ISSUES... *(cont'd.)*

2. Physician contract database
 - a. Work product from review used to populate database
 - i. Contracts
 - ii. Amendments
 - iii. Community needs assessments
 - iv. FMV analysis
 - b. IT interface to allow easy transfer of documentation
 - c. Revision and strengthening of policies and procedures



LEGAL AND PRACTICAL ISSUES... *(cont'd.)*

3. Temporal scope of review – review of documents and data in effect:
 - a. only at time data collected
 - b. for current calendar year
 - c. for current hospital fiscal year
 - d. to track applicable statute of limitations – generally five to ten years, depending on whether criminal or FCA
 - e. Proposed DFRR



LEGAL AND PRACTICAL ISSUES... *(cont'd.)*

D. Written contract review checklist

1. Elicits facts from face of written contracts pertaining to compliance with elements of Stark exceptions, e.g., services, signatures, compensation, term, termination, fair market value assessment, etc., anti-kickback safe harbors, and tax-exemption guidelines



LEGAL AND PRACTICAL ISSUES... *(cont'd.)*

2. Written contract review checklist does not include:
 - a. Information not identifiable from face of written contract, e.g., whether contract covers all services to be furnished by the physician to the hospital, whether aggregate services contracted for do not exceed those reasonable and necessary for legitimate business purposes of arrangement, whether remuneration is determined based on the volume or value of actual or anticipated physician referrals, or
 - b. Information concerning compliance with hospital policies and procedures concerning physician contracting, including whether contracts were approved in accordance with hospital policies



DEVELOPING AND COMPLETING CHECKLISTS

Checklists should be prepared for every type of arrangement and completed consistently for every contract.

#	Recruitment or Retention Agreement Checklist	True	False	Instructions/Comments
1	The agreement is signed by all parties.			List the parties to the agreement.
2	The agreement specifies the benefits to be provided by the hospital, the terms under which benefits are to be provided, and the obligations of the parties.			List the services to be performed.
3	The agreement contains a statement that the parties' arrangement was negotiated at arm's length.			List the intervals, length, and charge per interval.
4	The agreement indicates that the hospital's service area is a federally designated health profession shortage area or that a community need assessment indicates a documented need for the physician's specialty.			
5	The agreement indicates that the recruited physician has been practicing medicine for less than 1 year and is opening a practice in the hospital's service area.			
6	The agreement indicates that the recruited physician is relocating his/her practice by at least 25 miles or that the physician's new practice will derive at least 75% of its revenues from professional services to patients not seen or treated by the physician in the prior 3 years.			
7	The agreement indicates that the physician was not on the medical staff of the hospital prior to recruitment, including temporary staff privileges or other seemingly inactive privileges.			Indicate the term of the agreement, including the effective date.
8	The agreement indicates that a fair market value (FMV) analysis was performed by an independent third party.			
9	The recruitment benefits provided under the agreement do not exceed the range identified in the FMV assessment.			Briefly describe the termination provisions.

COMMON MISTAKES

Contracting Mistakes	Documentation Mistakes	Compensation Mistakes
<ul style="list-style-type: none">▪ Expired contract▪ Conflicting contracts▪ Elements of state exception not met▪ Lack of signatures	<ul style="list-style-type: none">▪ No evidence of legal counsel or board approval▪ No community need assessment▪ No fair market value (FMV) materials▪ Inappropriate FMV materials for the contract▪ Missing time sheet or invoicing documentation	<ul style="list-style-type: none">▪ Payment made with no contract▪ Payments do not match the contract terms▪ Payment for services inconsistent with the contract▪ Payment exceeds the monthly maximum▪ At risk compensation is inappropriately applied or inaccurately calculated

CORRECTIVE ACTION

1. Enhanced policies and procedures with additional approval requirements (including CEO, GC and CCO)
2. Internal control – payment certification requirement that must be signed by CFO or COO
3. Widespread education on revised policies and procedures , payment certification, etc.
4. Quarterly auditing of arrangements by compliance officer with dashboard reporting to the corporate board
5. Selection and partial implementation of centralized database for these arrangements at corporate office



CORRECTIVE ACTION

	Issue	Corrective Action	Pending Action
1	Documentation Deficiencies	Engage third party to provide missing data (community need; FMV)	
2	Inconsistent contracting practices resulting in failure to consistently follow policies and procedures	Identify a member of management to have oversight responsibilities for all physician compensation arrangements	
3	Lease of space agreements inconsistent with the terms of the written agreement	Case by case review to determine if arrangement is within FMV; standardize/centralize property management function	
4	Payments made/received inconsistent with the terms of the written agreement	Repayment to hospital by physician for over-payment OR refund by hospital to physician for underpayment	
5	Arrangement does not appear to fit within a Stark exception	Conduct further due diligence in an effort to identify writings (email, meeting minutes, etc.) or their absence to make a definitive determination regarding whether the arrangement fits within a Stark exception	Option 1: Repayment of any amounts collected in violation of Stark to Fiscal Intermediary
			Option 2: Voluntarily self-disclosure to OIG
			Option 3: Take no further action related to retrospective issues if no legal duty to do so, then take prospective improvement actions
			Option 4: Combination of any of the above

