CONDUCTING A COMPLIANCE REVIEW OF HOSPITAL-PHYSICIAN FINANCIAL ARRANGEMENTS

Dennis S. Diaz, Esq.
Partner
Davis Wright Tremaine LLP
Los Angeles, CA

Shannon G. Dwyer, Esq.
Sr. Vice President
and General Counsel
St. Joseph Health System
Orange, CA

Davis Wright Tremaine LLP

ST. JOSEPH HEALTH SYSTEM

A Ministry of the Sisters of St. Joseph of Orange

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

Why Conduct a Compliance Review?(cont'd)

C. **CMS's DFRR Surveys**

1. **In 2006, CMS sent to:**

   a. **130 specialty hospitals and**

   b. **220 competitor acute care hospitals, a "voluntary" survey requesting information on physician ownership and investment interests in the hospitals**

Why Conduct a Compliance Review?(cont'd)

2. CMS's proposed rule dated April 30, 2008
   a. Increased the scope of its request to include physician compensation arrangements
   b. Made the response mandatory
   c. Request — dubbed the Disclosure of Financial Relationships Report (DFRR) — will be sent to 500 hospitals

Why Conduct a Compliance Review?(cont'd)

d. Hospitals will be *required* to complete the DFRR within 60 days

e. CMS asserts it will take 31 hours per hospital to complete the DFRR

f. Late submissions are subject to fines of up to $10,000 per each day past the deadline in which the report is not submitted

g. 73 Fed. Reg. 23677 (April 30, 2008)

Why Conduct a Compliance Review?(cont'd)

3. Selected Hospitals
    a. Lubbock Heart Hospital: among the 130 specialty hospitals to receive a voluntary survey
    b. Covenant Medical Center: on the list of hospitals that will be required to complete a DFRR

Why Conduct a Compliance Review?(cont'd)

4. 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)

5. Organizational Response
   a. July 1, 2005 – June 30, 2006
   b. Identifying and reviewing all relevant physician arrangements
   c. Process is being coordinated by the legal department
   d. Once the formal letter from CMS is received, the DFRR spreadsheet will be completed

Why Conduct a Compliance Review?(cont'd)

e. If compliance issues are identified with respect to any arrangement, corrective action will be considered and implemented, as appropriate

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?

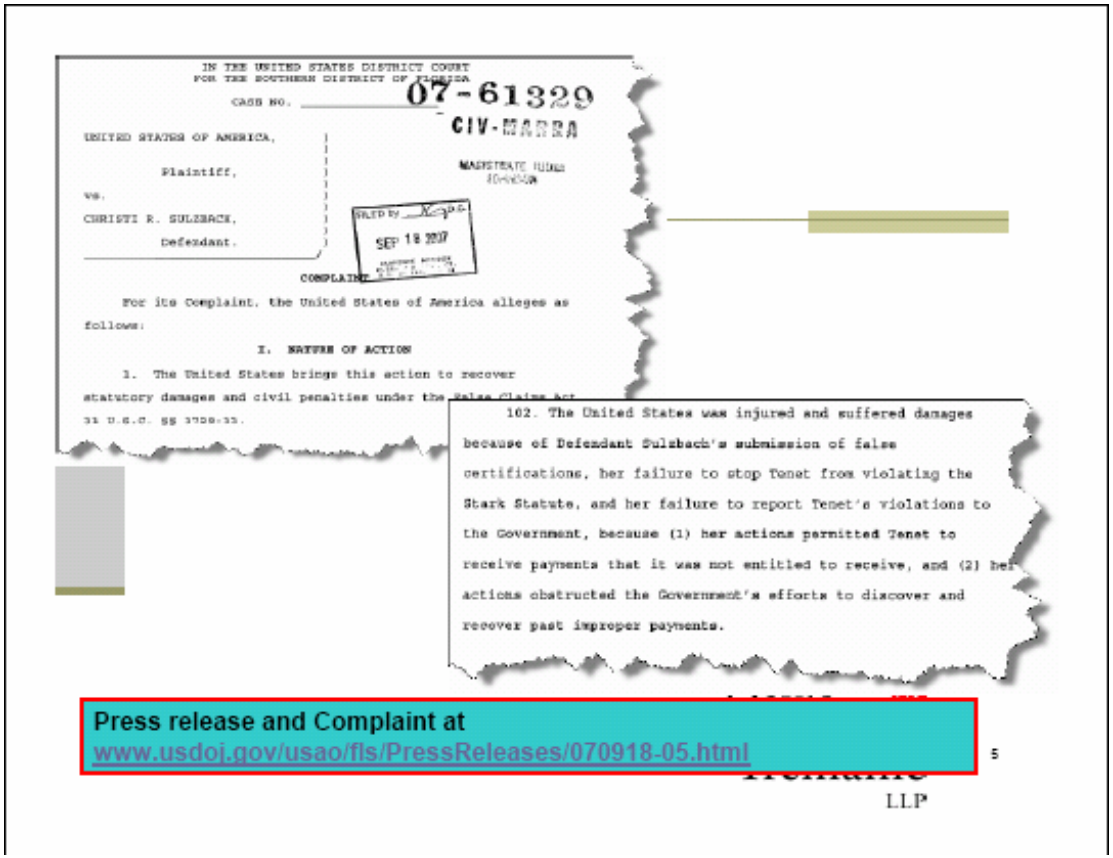
Why Conduct a Compliance Review? (cont'd)

e. "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

Why Conduct a Compliance Review? (cont'd)

4. Sulzbach Lawsuit



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.

FILED by ___ D.C.
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. §§ 3729-33.

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

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Why Conduct a Compliance Review? (cont'd)

a. DOJ alleged that certifications Ms. Sulzbach submitted in 1997 and 1998 to satisfy Tenet's Corporate Integrity Agreement -- that Tenet was in compliance with federal law -- were knowingly false
b. DOJ complaint alleged false certifications to HHS facilitated payment by federal programs on 70,000 claims totaling $18 million

Why Conduct a Compliance Review? (cont'd)

c. After outside counsel allegedly reported that North Ridge Medical Center contracts violated Stark, Ms. Sulzbach certified Tenet's material compliance with ". . . the Corporate Integrity Agreement, as well as . . . other federal program legal requirements . . . ."

Why Conduct a Compliance Review? (cont'd)

d. Following written request for corrective action from Ms. Sulzbach, based on outside counsel's opinion memo, Tenet allegedly continued existing physician contracts and "to bill Medicare illegally for referrals from them . . . ."

Why Conduct a Compliance Review? (cont'd)

5. 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. . .

On What Basis Do You Answer?

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

Legal and Practical Issues in Conducting the Compliance Review

f. Compliance with hospital policies and procedures, e.g., compliance plan, contract approval protocols, physician compensation policies, joint venture policies, conflict of interest policies

2. Issues not reviewed
3. Physician arrangements; other referral sources?

Legal and Practical Issues in Conducting the Compliance Review

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 in Conducting the Compliance Review

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 in Conducting the Compliance Review

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 in Conducting the Compliance Review

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 in Conducting the Compliance Review (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 in Conducting the Compliance Review (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 in Conducting the Compliance Review (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

Legal and Practical Issues in Conducting the Compliance Review (cont'd)

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 in Conducting the Compliance Review (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 in Conducting the Compliance Review (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 – cost reporting period ending 2006

Legal and Practical Issues in Conducting the Compliance Review (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 in Conducting the Compliance Review (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

Legal and Practical Issues in Conducting the Compliance Review (cont'd)

NOW THE FUN STARTS!

1. Reporting to hospital administration and board of directors
2. Renegotiate contracts with physicians?
3. Refund to government?
4. Voluntary disclosure to government?