HCCA Regional Conference
Physician Contracting Issues

Overview of Anti-Kickback Statute & Stark Law and Downstream Revenue

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AGENDA

- Government Emphasis on Fraud
- Overview of AKS & Stark
- Recent Cases
  - *U.S. v. Anderson*
  - *U.S. v. Bradford*
  - *U.S. ex rel. Drakeford v. Tuomey*
  - *U.S. ex rel. Baklid-Kunz v. Halifax*
- Takeaways

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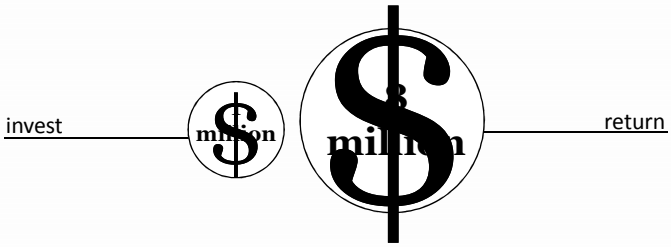
GOVERNMENT EMPHASIS ON FRAUD

Prosecuting 'fraud' is good business



In 2012, an OIG report stated that for every $1 invested in OIG, DOJ and FBI investigations related to health care fraud, $7.90 is returned

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GOVERNMENT EMPHASIS ON FRAUD

Health Care Reform
provides the OIG with:

- expanded **law enforcement** authorities
- opportunities for **greater coordination** with other federal agencies
- **enhanced funding** for the Health Care Fraud and Abuse Control (HFAC) program

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ANTI-KICKBACK STATUTE

Anti-Kickback Statute

42 U.S.C. § 1320a-7b

It is a criminal offense for a hospital to:

knowingly and willfully **1**

solicit, receive, offer or pay **2**

remuneration, directly or indirectly, overtly or covertly, in cash or in kind **3**

for referring or arranging Medicare or Medicaid services **4**

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ANTI-KICKBACK STATUTE

"Knowingly" and "Willfully"

As part of healthcare reform, the new section on AKS now states:

> "...with respect to violations of this section, a person **need not have actual knowledge** of this section **or specific intent** to commit a violation of this section."
>
> 31 USC § 1320a-7b(h)

This potentially lessens the burden on government to demonstrate a violation of AKS and clarifies some of the disagreement within the circuits

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ANTI-KICKBACK STATUTE

Personal Services Safe Harbor Elements

The Agreement must

- Be set out in **writing** and **signed** by the parties
- Cover and **specify all** of the services to be provided
- **Specify the interval** schedule of the services (if periodic or part-time)
- Be for a term of **at least one year**

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ANTI-KICKBACK STATUTE

Personal Services Safe Harbor Elements (cont.)

The Agreement must

- Set the **aggregate compensation in advance**, be consistent with fair market value and **not** be determined **in a manner that takes into account** the **volume or value** of any referrals or other business generated between the parties
- **Not involve promotion** of a business arrangement that violates the law
- Be **commercially reasonable**

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STARK LAW

When a **physician** (or physician's **immediate family member**) has a **financial relationship** with an entity (unless an exception applies*) the federal Stark Law provides that:

- Physician **may not make referrals** to the entity for "designated health services"
- Entity **may not present a claim or bill** to the government, patient, or any other party for designated health services furnished pursuant to a prohibited referral

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STARK LAW

* If Stark applies, an exception must be found. Stark is a strict liability law.

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STARK LAW

Personal Services Exception Elements

The Agreement must

- Be set out in **writing**, be **signed** by the parties and **specify** the services
- **Cover all of the services** to be provided
- Provide aggregate services which are **reasonable and necessary** for the legitimate business purposes of the arrangement(s)

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STARK LAW

Personal Services Exception Elements (cont.)

The Agreement must

- Be for a term of at least **one year**
- **Set the compensation in advance**
- Not exceed **fair market value**
- Not be determined **in a manner that takes into account** the **volume or value** of any referrals or other business generated between the parties (except in the case of a physician incentive plan)

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RECENT CASES

NEWS

April 2013

Intermountain Healthcare
Settlement of **$25.5 Million**
Resulting from Stark Law Violations
Revealed during
Voluntary Disclosures

NEWS

April 2012

Tenet Healthcare Agreed to
$42.75 Million Settlement
to Resolve Allegations it Overbilled
Medicare

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RECENT CASES

"Our five-year integrity agreement with GlaxoSmithKline requires individual accountability of its board and executives."

2012

Daniel Levinson,
Inspector General of the U.S.
Department of Health and
Human Services

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RECENT CASES

Recent cases help us to understand what types of arrangements the Government is **currently targeting**

Even though the infraction may seem small (or even non-existent), the **penalties** imposed in each of these cases is large

Thus, it is important to
ensure compliance at all times

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RECENT CASES

- The complexity of hospital financial relationships with physicians, along with the ambiguity of the Stark law, have increased the frequency of prosecution and harsh consequences as a result of Stark violations
- The *Anderson, Bradford, Tuomey* and *Halifax* cases illustrate the types of arrangements that may draw the government's attention and result in steep financial penalties for hospitals, physicians and their legal counsel

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U.S. v. ANDERSON

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U.S. v. ANDERSON

Facts

Two attorneys were **indicted** as co-conspirators (other attorneys were identified as unindicted co-conspirators)

Two physicians (the LaHues) sought compensation from hospitals for their referrals of nursing home patients

The LaHues entered into several arrangements with Baptist Medical Center, including a consulting arrangement for which minimal services were provided and an uncompensated management arrangement

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U.S. V. ANDERSON

Allegation

Conspiring
with hospital client
to create
sham agreements
designed to cover up
a payment-for-referrals scheme

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U.S. V. ANDERSON

Allegations

Why did the government target the attorneys?

One attorney told the other that the consulting agreement was a **"clean-up deal"** and that the LaHue's motive was to sell referrals

One attorney wrote a **letter describing services that could be used to justify** the LaHues compensation

Baptist's counsel wrote a letter to its executives stating:
"it is absolutely essential that there be **no documentation of any intent to refer patients for services or items** for which Medicare or Medicaid might pay"

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U.S. V. ANDERSON

Allegations

The government argued that the attorneys were on notice of the allegedly illegal intent, and any further documentation constituted **acts in furtherance of a conspiracy to violate the AKS**

Communications regarding the LaHues were made through attorneys **to conceal information** under attorney/client privilege

The government construed the guidance on the requirements of the law as **instructions on how to hide illegal activity**

The attorneys prepared documents **designed to fraudulently conceal** the alleged kickbacks

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U.S. V. ANDERSON

Acquittal

"The problem here is that a very simple concept, 'payment for patients is illegal,' became far from simple as Congress, the Executive Branch, and the Courts got more deeply involved. 'Remuneration to induce' language invites judicial interpretation as to what these words mean. Indeed, the government in this case adamantly maintains that the words require definition as part of jury instructions. Judicial catch phrases like 'one purpose rule' or 'primary purpose rule,' the reversals of field by the Office of Inspector General, the checkered history of the *Hanlester* case and the reservation by Congress of a safe harbor provision in the Act, the promulgation of regulations concerning which were delayed for a considerable time**,** all **invite lawyers to attempt to devise legal ways for parties to have a relationship which has as a component hoped-for and anticipated referrals**. That's what defendants Lehr and Thompson did under the evidence presented in this case."

– 55 F.Supp.2d 1163, 1171 (D. Kan. 1999)

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U.S.

v.

BRADFORD

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U.S. v. BRADFORD

Background

- **The *Qui Tam* Relators:** Four physicians practicing in the community.
- **The Defendants:** Bradford Regional Medical Center, a Pennsylvania nonprofit corporation and two internists who jointly owned a physician group LLC.
- The Physicians had privileges at the Hospital.
- Referrals from their Group equaled over 40% of the Hospital's nuclear imaging revenues.
- The Group purchased a GE nuclear imaging camera for its office.
- **Hospital alleged Physicians violated internal policy against conflicting financial interests; threatened to revoke privileges.**

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U.S. v. BRADFORD

Background

- Resolution:
  - Hospital subleased GE camera from the Group.
  - Parties agreed to continue discussion regarding potential "under arrangements" deal.
  - The Group then entered into a lease for a new camera, which included a "buy out" obligation for amounts Group owed on the original GE lease.
  - Hospital guaranteed the Group's "buy out" obligation.
  - This subsequent arrangement was never documented in a formal written lease or agreement.

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U.S. v. BRADFORD

Fair Market Value

- Hospital requested an accountant prepare a fair market value assessment of the sublease.
- Accountant concluded:
  - Amounts to be paid were reasonable based on:
    - *Hospital revenues expected with sublease vs. Hospital revenues expected without sublease*
  - Revenue projections assume Physicians will refer imaging.
  - Hospital board approved sublease arrangement.

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U.S. v. Bradford

Deposition of George Leonhardt
Bradford Regional Medical Center
CEO

Q:
It's fair to say
that the purpose of the non
compete agreement was to protect
that revenue stream [referrals
from Dr. Saleh and
Dr. Vaccaro]?

A:
The purpose of the non
compete, from my point of view,
was to make sure that Drs. Vaccaro
and Saleh didn't have a financial
incentive to refer away from the
hospital.

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U.S. v. Bradford

Q:
Because if they didn't
have a financial incentive
to refer away, they would
refer it to you?

A:
We could hope that
they would,
yes.

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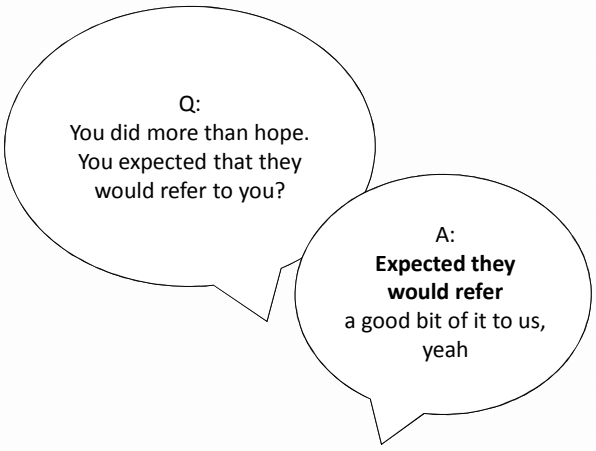
U.S. v. Bradford



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U.S. v. Bradford

Opinion

- **As a matter of law, the agreements violated the Stark Law.**
- *However*, there exist genuine issues of material fact as to whether the Hospital violated the Anti-Kickback Statute or the False Claims Act ("FCA").
  - *Both require showing of intent, which is left to a jury;* but
  - *"The record evidence is <u>not</u> strongly in favor of Defendant," regarding the FCA.*

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U.S. ex rel. DRAKEFORD

v.

TUOMEY

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U.S. ex rel. DRAKEFORD v. TUOMEY

Facts

Tuomey located in a MUA – rural community of 42,000

301 hospital beds at Tuomey – 150 members of medical staff

The closest hospital is a 56-bed hospital 20 miles away

Nearby air force base hospital closure created need to ensure specialty physician services available

Physicians Compensation:
- base salary
- % of collections
- up to 7% productivity bonus

10 year term

Negotiated contracts with specialists from specialty physician groups currently on staff

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U.S. ex rel. DRAKEFORD v. TUOMEY

Facts

Physicians were employed on a part-time basis with a non-competition clause and a use requirement

Physicians were employed at a loss to the hospital

Some physicians' compensation exceeded collections

A competing ASC being developed with ownership offered to physicians

Board Comments - in general:

- Discussed the loss that would be suffered by the hospital if the physicians went to the new ASC
- Discussed the gain in revenues that the hospital would receive by retaining the physicians
- Hospital calculated expected loss from physician practices

Expert's Fair Market Value report was used against the hospital at trial

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U.S. ex rel. DRAKEFORD v. TUOMEY

"[The Valuation Firm] recognizes that this is an aggressive compensation plan that should be reviewed by a third party periodically to ensure that the terms continue to provide total compensation that is within fair market value."

Excerpt from Valuation Opinion prepared for Tuomey Regional Medical Center

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U.S. ex rel. DRAKEFORD v. TUOMEY

Allegation

By entering into contracts that **varied with** and **took into account the volume or value** of referrals, the arrangement:

1. Created an indirect compensation arrangement – causing Stark to apply
2. Violated Stark

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U.S. ex rel. DRAKEFORD v. TUOMEY

First Trial

1. **Agreements created an indirect compensation arrangement**
2. **Agreements violated the Stark law**
3. **Agreement did NOT violate the False Claims Act**

Tuomey ordered to repay the government
$45+/- million plus interest

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U.S. ex rel. DRAKEFORD v. TUOMEY

Outcome

APPEAL:

The Fourth Circuit
vacated the decision and remanded for retrial

FOURTH CIRCUIT SAID:

"We agree with the *Villafane* court that intent alone does not create a violation. However, that does not aid Tuomey if the jury determines that the contracts took into account the volume or value of anticipated referrals."

"On remand, **a jury must determine**, in light of our holding, whether the aggregate compensation received by the physicians under the contracts varied with, or took into account, the volume or value of the facility component referrals."

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U.S. ex rel. DRAKEFORD v. TUOMEY

Second Trial

1. **Agreements created an indirect compensation arrangement**
2. **Agreements violated the Stark law**
3. **Agreement violated the False Claims Act**

The Stark violations totaled $39.3 Million

With penalties and FCA trebling,
the Judgment was approximately $237.5 Million

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U.S. ex rel. DRAKEFORD v. TUOMEY

Discussion of Referrals

Theme:
Cannot use volume "sales pitch" to physicians
to get them to sign

Clear discussion of referrals, **that were recorded**!

Many hours of recorded
physician-hospital meetings

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U.S. ex rel. DRAKEFORD v. TUOMEY

Compensation to Physicians

Government Argued :

Government > FMV

1. compensation > private practice
2. compensation > collections
3. compensation > loss to Tuomey
4. "not CR" > 75% + 90%

Government FMV expert

1. not greater than 75%
2. not CR if compensation > collections

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U.S. ex rel. DRAKEFORD v. TUOMEY

Calculation of Value of Referrals

Government argued

Tuomey "took into account" referrals

Hospital would lose $96 M over 13 years if gastro redirect endoscopies to ASC

Also, calculate potential revenue to hospital

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U.S. ex rel. DRAKEFORD v. TUOMEY

Calculation of Value of Referrals

Government argued **three** key elements:

1	2	3
Substantial talk by hospitals about referrals	Aggressive compensation	Financial analysis of "volume and value" – the value of the downstream

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U.S. ex rel. DRAKEFORD v. TUOMEY

Jury Deliberations

Jury Instructions – the jury instructions were 16 pages long and gave explanations regarding the burden of proof, evidence, witness testimony, the Stark law and its pertinent definitions, Stark law exceptions, the False Claims Act and its pertinent definitions, and affirmative defenses

Verdict Form – form was very simple (no specific findings to support the decision)

Fact Findings – no specific findings of fact

Stark Violation – the jury found that Tuomey violated the Stark law

False Claims Act Violation – the jury found that Tuomey violated the FCA

False Claims Submitted – the jury found that Tuomey submitted 21,730 false claims with a value of $39,313,065

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U.S. ex rel. DRAKEFORD v. TUOMEY

Takeaways

Bread crumbs or context– analysis of the downstream; chatter about referrals and value of downstream

Do not consider required ***or*** anticipated referrals when setting compensation – or, if you must consider, maintain clear separation between data on referrals and compensation – do not use downstream to set compensation

Valuation reports and outside opinions do not always provide sufficient protection from violations

Burden of proof for Stark compliance falls to Defendant

Calculation of referrals that appears to have affected the physician's compensation creates risk – it is a question for jury.

Calculation of lost opportunity – valuing a non-compete creates risk

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U.S. ex rel. BAKLID-KUNZ

v.

HALIFAX

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U.S. ex rel. BAKLID-KUNZ v. HALIFAX

Allegations

Qui Tam Relator = Director of Physician Services

Government alleges Stark violations based on compensation that:

1. Was not fair market value
2. Was not commercially reasonable, and/or
3. Took into account the volume or value of referrals or other business generated by the referring physician

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U.S. ex rel. BAKLID-KUNZ v. HALIFAX

Facts

The complaint supports the allegations with the following facts:

- The employed **physicians referred patients** to the hospital for care
- Physicians were **not employed by the hospital**, but by an entity owned by the hospital
- Some employment **agreements were not signed** at all and some were signed late
- Physician compensation was **not set in advance** (agreements allowed for each oncologist to receive an "equitable portion" of a bonus pool)
- The physicians were some of the **most profitable physicians** for the hospital

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U.S. ex rel. BAKLID-KUNZ v. HALIFAX

Facts (cont.)

- Total physician **compensation exceeded cash collections**
- Some of the physician compensation was **above the 90th percentile**
- Some bonuses were based on professional services performed by nurses and/or physician assistants
- Hospital tracked physician referrals (the CFO questioned why one physician generated a low dollar value of referral services when he saw more patients than the other oncologists)
- In 2008, two neurosurgeons were compensated over $1.5 million each
- Bonuses were computed in different manners over the years, based on: employer discretion, cash collections, Medicare payment amounts, bonus pool, and **15 percent of the operating margin** of Medical Oncology department, including revenue from services not "personally performed"

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U.S. ex rel. BAKLID-KUNZ v. HALIFAX

"Halifax tracked the referrals generated by each medical oncologist. In February 2010, [The Chief Financial Officer] of Halifax Hospital, questioned why Dr. Sorathia generated a comparatively low dollar value of referral services when he saw more patients than any of the other medical oncologists."

U.S. ex rel. Baklid-Kunz v. Halifax,
United States' Complaint in Intervention

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U.S. ex rel. BAKLID-KUNZ v. HALIFAX

Facts (cont.)

"[T]he Government points out that the pool from which the Incentive Bonus was drawn is equal to **15 percent of the operating margin** of the Medical Oncology program, and the program's revenue **included fees for designated health services such as outpatient prescription drugs and outpatient services not personally performed** by the Medical Oncologists. Thus, revenue from referrals made by the Medical Oncologists would flow into the Incentive Bonus pool, and additional referrals would be expected to increase the size of the pool. All other things being equal, this would in turn increase the size of the Incentive Bonus received by the referring Medical Oncologist."

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U.S. ex rel. BAKLID-KUNZ v. HALIFAX

Facts (cont.)

"The Incentive Bonus was not a 'bonus ***based on*** services personally performed' by the Medical Oncologists, as the exception requires. 42 USC 1395(e)(2). Rather, as described by the Defendants themselves, this was a bonus that ***divided up*** based on services personally performed by the Medical Oncologists. The bonus itself was based on factors in addition to personally performed services – including revenue from referrals made by the Medical Oncologists for DHS.

The fact that each oncologist could increase his or her share of the bonus pool by personally performing more services cannot alter the fact that the size of the pool (and thus the size of each oncologist's bonus) could be increased by making more referrals."

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U.S. ex rel. BAKLID-KUNZ v. HALIFAX

Summary Judgment

- In Fall 2013, the United States District Court denied Halifax summary judgment and granted summary judgment to U.S. on Stark claim
- Legal Standard: A party is entitled to summary judgment when the party can show that there is no genuine issues as to any material fact
- The Court agrees with the Government that there is dispute in regards to genuine issues of material facts, including physician compensation and whether it was consistent with FMV
- The Court concluded that the amount of damages is for a jury to decide

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CONCLUSION

Triumvirate of Questionable Deals

1. Hospitals providing physicians with items or services for free or less than fair market value
2. Hospitals relieve physicians of financial obligations they would otherwise incur
3. Hospitals inflate compensation paid to physicians for items and services

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CONCLUSION

Examination of Downstream Data

• Stark generally prohibits taking DHS referrals into account when establishing the economics of hospital-physician deals

• If a health system chooses to accept the higher legal risk associated with examining future referrals, then the utilization of this information will affect the level of risk

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CONCLUSION

In order to mitigate the risk, as many of the following steps as possible should be taken:

– Separate physician negotiations and financial arrangements from projections data;

– Attempt to use aggregated, broader data than physician-specific data;

– Limit the use of downstream data examined and the number of individuals involved;

– Use an independent valuation entity to determine fair market value and commercial reasonableness; and

– Explicitly state that the remuneration does not "take into account" referrals or other business generated by the physician(s)

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CONCLUSION

For every arrangement:

Legitimate Business Purpose	Commercially Reasonable	Fair Market Value

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CONCLUSION

The government is **increasing its focus and scrutiny of potential fraud** in the health care industry

Health care reform has increased the strength of law enforcement and the resources available to the government for the identification and prosecution of fraud

Legal counsel and consultants may also become a target of government investigations if the government believes that the attorneys played a role in the fraud

Attorneys and health care administration should not assume that a court will construe the law the way they think it should be interpreted or is commonly construed by the Health Care Bar

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CONCLUSION

Be careful with communications

"We have worked with the ____ group in the past in an attempt to partner with them and to acquire their referrals for MRI."

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Questions

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