

Health Law and Policy
The “Fraud and Abuse”
Rules

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Overview

- The economics of enforcement
- Selected laws
- The burden of keeping pace
- Some unknowns



Economics: Health Care Reform Will be Costly

- \$122.6 Billion a year?
- \$136 Billion?
- \$150 Billion?
- \$298 Billion?
- \$1-\$2 Trillion over ten years?

Uwe Reinhardt

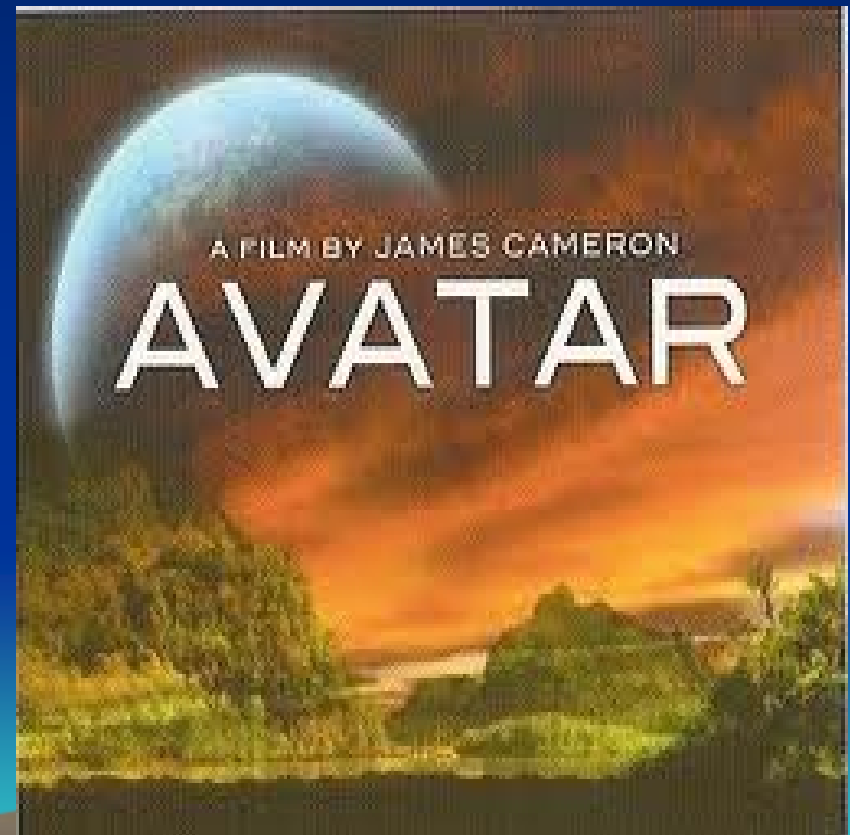
Economix, June 12, 2009.



An Estimate of the Cost of Fraud and Abuse

- \$60 billion annually
- 33 times the gross of the biggest box office movie of all time.

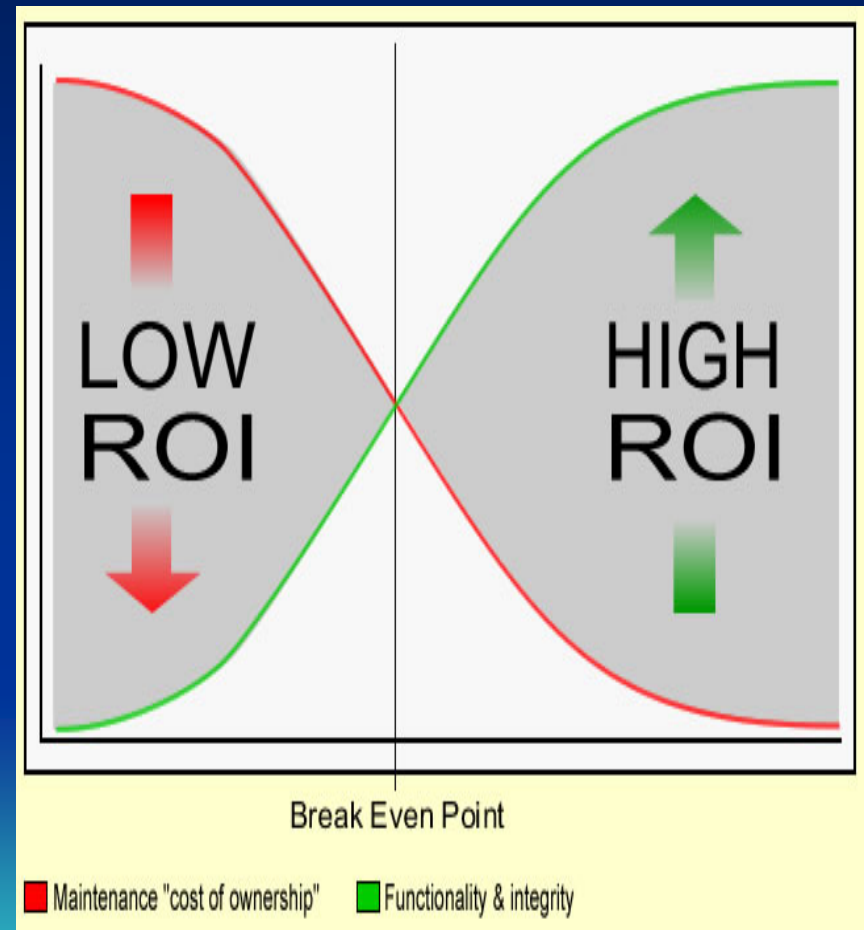
Eric Holder, www.mainjustice.com
(Jan. 28, 2010)



ROI on F&A Enforcement

Estimates of the ROI from enforcement activities range from

- \$6.8:1 per Sec. Sibelius
- \$15:1 per Taxpayers against Fraud
- \$16.7:1 2012 DHHS OIG Report



Enforcement Drivers

- If
 - Health care reform will be costly,
 - Fraud and abuse costs billions and
 - Money invested in enforcement activities yields a handsome return,
- Then
 - The smart move is to invest heavily in fraud and abuse enforcement.



Funding Reform with Enforcement

- “...the cost of medical fraud in the United States ... might actually exceed the price tag for health care reform.” – NPR (2009)
- “Cracking down on health care fraud ... is one way the health care reform bill plans to pay for its \$940 billion price tag.” – CS Monitor (2010)
- “About half of the cost of the health reform bill is paid for by targeting waste, fraud and inefficiency in Medicare and Medicaid.” – House of Representatives (2010)



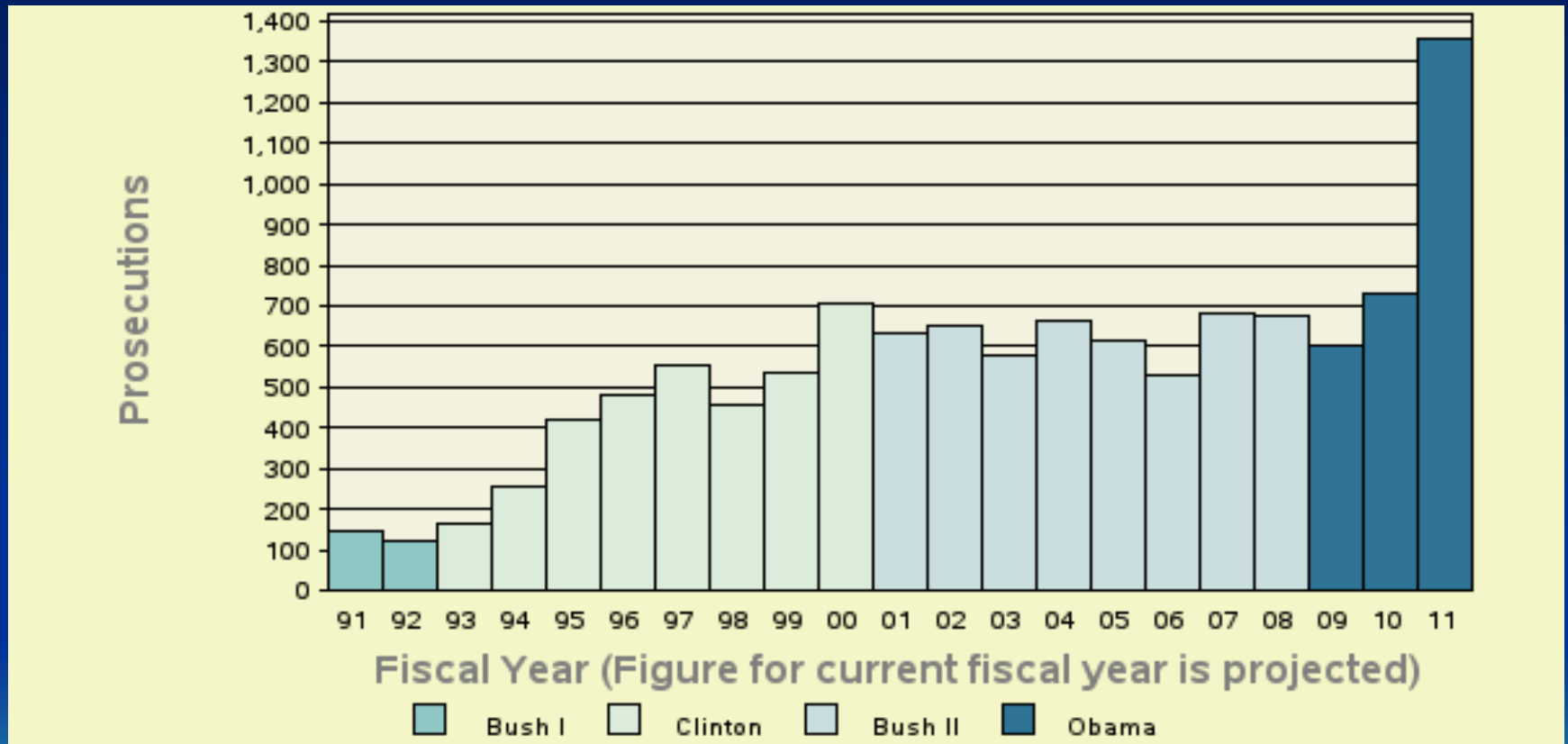
The F&A Enforcement Business is Booming.

- “Data Analysis Finds Health Care Fraud Investigations up 85% in 2011.” (over 2010)
- Prosecutions up 157% from five years ago and 822% from twenty years ago.
- “Health care fraud” was the most frequently recorded lead charge in federal actions.

Transactional Records Access Clearinghouse, August 17, 2011



Business is Booming



Transactional Records Access Clearing House, August 17, 2011

Words Matter

- What is fraud?
- What is abuse?
- What is “fraud and abuse?”



Terminology: Fraud

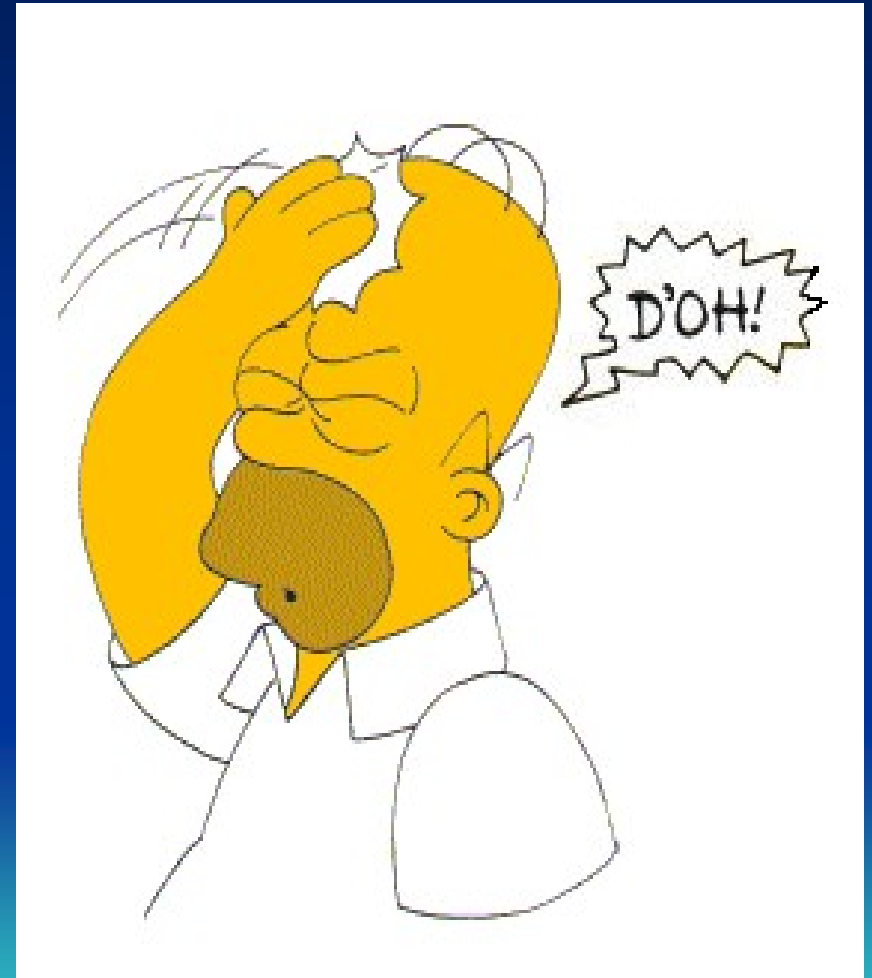
“Fraud is an intentional deception or misrepresentation....”



BCBS of South Dakota

Terminology: Abuse


Per CMS, abuse means "payment for items or services that are billed by *mistake....*"





Terminology: Abuse

Per Medicaid regulations, “abuse” includes provider practices that:

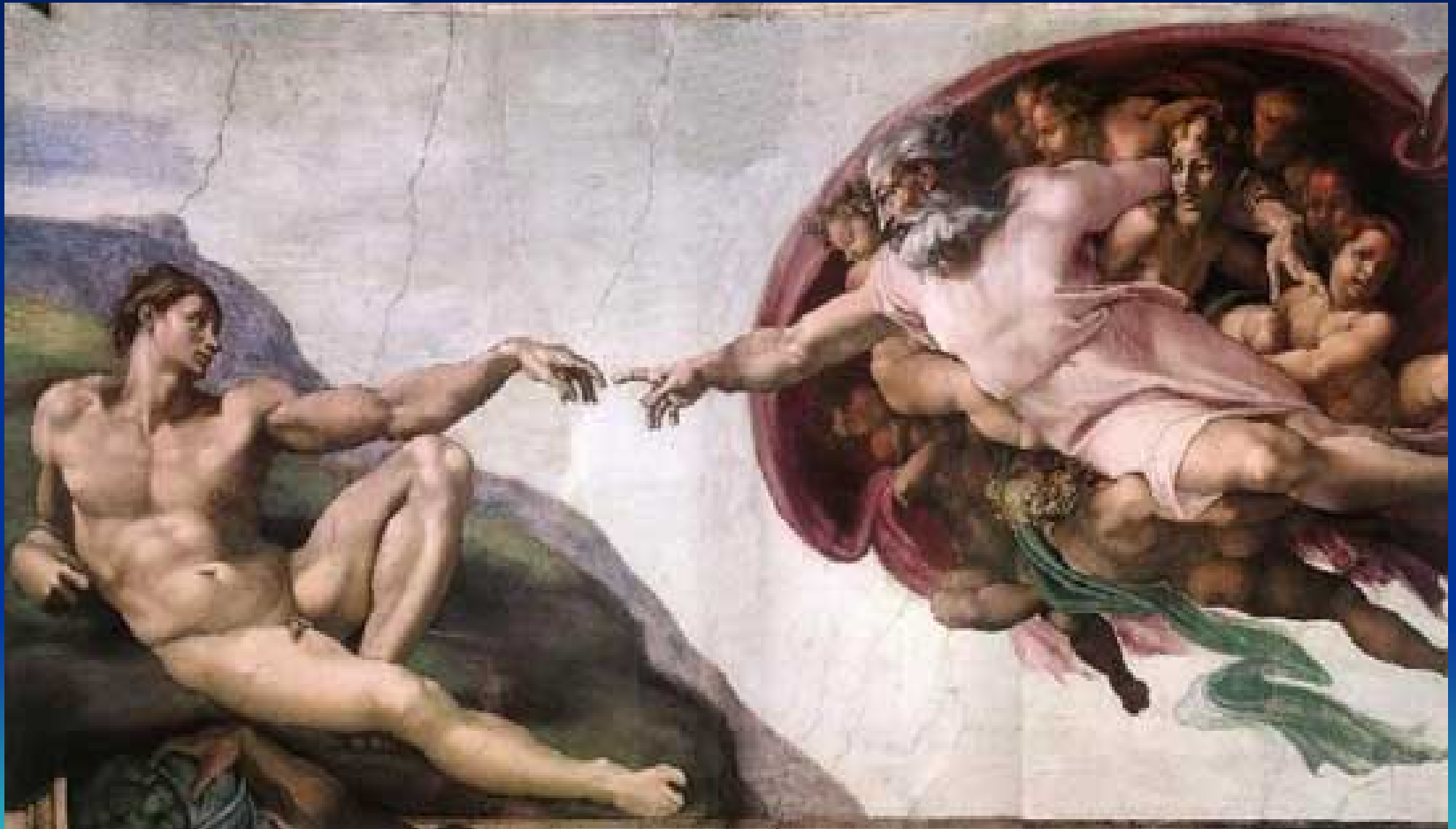
- Are inconsistent with sound fiscal, business, or medical practices;
 - Result in reimbursement for services that are not medically necessary; or
 - Result in unnecessary cost to the Medicaid program.
- 

Selected Fraud and Abuse Laws

- The False Claims Act
 - Civil
 - Criminal
- The Anti-Kickback Act
- The Stark Amendments
- The Civil Monetary Penalties Statute



Fraud and Abuse Enforcement In the beginning...



Civil False Claims Act

General False Claim Prohibition:

- “knowingly” presenting
- to the federal gov’t
- a “false” or “fraudulent” claim
- for payment or approval



When is a Claim False? Some Obvious Examples

- Billing for imaginary wheelchairs provided to nonexistent patients;
- Billing for professional services not rendered; and
- Upcoding, e.g., performing a \$100 service and billing for a \$200 service.



When is a Claim False? Not so Obvious

- Medical necessity
- Documentation deficiencies
- Failure to comply with highly technical billing rules
- Quality of care



Medical Necessity



“Of course, I’ll want to run a few tests on you, just to cover my ass.”

Liability for “Unartful” Documentation?

The Criminal FCA prohibits submission of claims that were not provided as described in the claim.

- “The standard of care imposed by this requirement is an exacting one, and an “unartful” description of medical services in a Medicare claim is a description of services that were not provided as claimed.” *Anesthesiologists Affiliated v Sullivan*



FCA Liability for Failure to Comply with Billing Rules

Centers for Medicare and Medicaid Services:

- Legislation
- Regulations
- Manuals
- Transmittals
- Quarterly Provider Updates
- [More...](#)

<https://www.cms.gov/>



FCA and Quality of Care

United States v Chester Care Center

“The Government’s complaint charges that the defendants caused the submission of false or fraudulent claims to the United States for payment for care that was not adequately rendered to frail and vulnerable elderly residing at Chester Care Center...”



FCA and Quality of Care

“Law enforcement’s role will become the policing of deliberate denial or limitation of necessary services, and *the provision of poor quality services.*”

James G. Sheehan, then-AUSA,
Philadelphia, PA



Civil FCA Penalties

- Monetary penalties of \$5,500 to \$11,000 per claim;
- Treble damages, i.e., three times the amount of the overpayment;
- Exclusion from government healthcare programs;
- Collateral damage
 - Medical staff privileges;
 - Medical board action, discipline, etc.;
 - Legal fees. (No physician has ever “won” an FCA case.)

\$11,000.00 Per Claim



\$11,000 *Per Claim*

United States vs Lorenzo:

- \$130,719.10 in claims @ \$5,000 per claim

=

- An \$18,415,000 judgment



United States v Krizek

- The government claimed overcharges totaling \$245,392 during a six year period.
- Trebling the amount of overcharges and adding the maximum statutory penalty yielded a damage claim of \$80,750,000.



United States v Krizek

“The system cannot be so arbitrary, so perverse, as to subject a doctor whose annual income during the relevant period averaged between \$100,000 and \$120,000, to potential liability in excess of 80 million dollars because telephone calls were made in one room rather than another.”



Amendment VIII

Excessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted.



FCA Qui Tam Provisions

- 31 USC 3730(b) allows private individuals to bring suit on behalf of the government under the FCA.
- DOJ has sixty days plus extensions to decide whether to intervene.
- If DOJ intervenes, the qui tam relator may be awarded 15-25% of the proceeds.
- If DOJ does not intervene, relator may pursue but DOJ retains certain rights



Qui Tam Relators

The Google logo is displayed in its characteristic multi-colored font (blue, red, yellow, blue, green, red) on a white rectangular background.

- A November 11, 2012 search for “health care qui tam law firms”
- Yields “about 520,000 results.”

Potential relators

- Patients
- Disgruntled current and former employees
- Disgruntled former shareholders
- Former spouses and soon to be former spouses

Criminal False Claims Act

Whoever ... knowingly and willfully makes or causes to be made any false statement ... in any application for any benefit or payment under a Federal health care program ... shall ... be guilty of a felony and upon conviction thereof fined not more than \$25,000 or imprisoned for not more than five years or both....”

18 U.S.C. 287



The Anti-Kickback Act

Enacted in 1972, the Act prohibits:

- “knowingly and willfully”
- offering, soliciting, paying or receiving “remuneration”
- as an inducement
- for referring, purchasing, leasing, ordering any item or service paid for by a federal health care program



Anti-Kickback Act

A very broad prohibition.

- “Remuneration” means anything of value.
- Judicial Interpretation: The Act is violated if “one purpose” of the remuneration was for a referral of to induce further referrals.
 - A below fmv lease from a hospital to a physician?
 - Basketball tickets?



Anti-Kickback Act

Penalties:

- \$25,000 in fines, imprisonment or both
- Civil money penalties
 - Treble damages
 - \$50,000 per violation
- Exclusion from government programs
- False Claims Act liability



Congressman Stark Strikes Back

Frustration with

- The scienter requirement under the Anti-Kickback Act,
- Evidence that financial relationships influence referral and utilization practices, and
- A desire for a “bright line” to determine compliance

led to the passage of the Ethics in Patient Referrals Act (“Stark Law”).



Stark Law: Bright Lines?

Prohibits:

- Physicians
- from making referrals
- of Medicare/Medicaid patients
- to an Entity
- with which the physician or family member
- has a financial relationship
- for certain “designated health services”
- unless an exception applies



Designated Health Services

- (1) Lab services
- (2) Therapy services;
- (3) Imaging services;
- (4) Radiation therapy;
- (5) Durable medical equipment;
- (6) Parenteral and enteral nutrients, etc.:
- (7) Prosthetics and orthotics;
- (8) Home health services;
- (9) Outpatient prescription drugs; and
- (10) Inpatient and outpatient hospital services.

A Bright Line?

YES

NO

“PHYSICIAN”?

“REFERRAL”?

“A GOVERNMENT PAYOR”?

“ENTITY”?

“FINANCIAL RELATIONSHIP”?

“DESIGNATED HEALTH SERVICES”?

APPLICABLE EXCEPTION?



Bright Line?

- If a hospital leases space to a physician and the physician refers Medicare patients to the hospital,
- The referral violates the Stark Law, unless
- An exception applies.



Congressman Stark and the Red Queen Hypothesis



Some exceptions are reasonably simple...

Space Lease Exception (key elements)

- A signed agreement for
- Specified premises, a
- Term of one year or more, and
- Fair market value lease amount, unrelated to volume or value of referrals.



... as long as the agreements
are signed...

- A Chicago hospital paid more than \$1.5 MM in FCA case arising out of Stark violations.
- Settlement based on leasing arrangements between the Hospital and referring physicians.
- Some of the physicians had not signed the lease.



... and the payments are fmv.

FMV for doctors:

- \$500.00 per hour.

FMV for Attorneys:

- \$895.00 per hour, plus
- \$250,000 @ month in expenses, totaling
- \$52,000,000.00 in fees in eighteen months.

Zimmer Orthopedics
Deferred Prosecution
Agreement

The Star Ledger, Nov.
2007

Other Exceptions Have Become Hellishly Complex

In-Office Ancillary Services Exception

- Pages and pages of definitions, requirements and CMS commentary.

For example,

- A referral that is legal if the radiologist reads the image on-site may be illegal if the read is off-site; and
- A referral that is legal if there are five physicians in a division becomes illegal if one of those physicians retires.



Consequences of Non-Compliance

- Civil money penalties of up to \$15,000 for each prohibited referral
 - One physician group with an unsigned lease X thousands of referrals = \$Millions
- Denial or recoupment of payment for services
- Exclusion from government programs
- False Claims Act liability



Concerns about the Stark Law

- The law is very complex;
- Partial compliance with an exception is no defense;
- Ignorance is no excuse: physicians can be and have been sanctioned for innocent violations;
- The Stark penalties are potentially devastating, and
- A Stark violation can lead to FCA liability.



Stark's Regret

- The idea was suggested by an M.D./J.D. staffer ("The worse kind of staffer," according to Stark) who pushed for a bright-line rule.
- The result, Stark concedes, is "a whole cottage industry of entrepreneurs and Stark law firms that create and sign off on convoluted legal arrangements between doctors and their vendors. "



Civil Monetary Penalties Statute

The OIG may seek CMPs for many things, including violations of the:

- False Claims Act;
- Anti-Kickback Act; and
- Stark Law



Civil Monetary Penalties Statute

- OIG may impose exclusion from participation in Medicare, Medicaid, etc., in addition to CMPs.

“In most cases for which the OIG may seek CMPs, the OIG may also seek exclusion from participation in all Federal health care programs.”

– <http://oig.hhs.gov/fraud/enforcement/cmp/index.asp>



Civil Monetary Penalties Statute

- Penalties:
 - For false or fraudulent claims, up to \$10,000 for each item or service improperly claimed, and an assessment of up to three times the amount improperly claimed.
 - For kickbacks, up to \$50,000 for each improper act and damages of up to three times the amount of remuneration at issue (regardless of whether some of the remuneration was for a lawful purpose).



The False Claims Act, Revisited

- Under recent amendments to the False Claims Act, if, e.g.
 - A hospital realizes that it billed for services per referrals from Dr. X, and
 - Dr. X forgot to sign his office lease, and
 - The hospital does not return the payments for those referrals,
 - The hospital can be subject to FCA liability.
- The hospital also could be subject to criminal liability.



Piling On?

- So an unknowing violation of the Stark Law can lead to
 - Stark penalties,
 - An FCA violation and penalties,
 - Civil Monetary Penalties,
 - Exclusion from Medicare and
 - Criminal charges

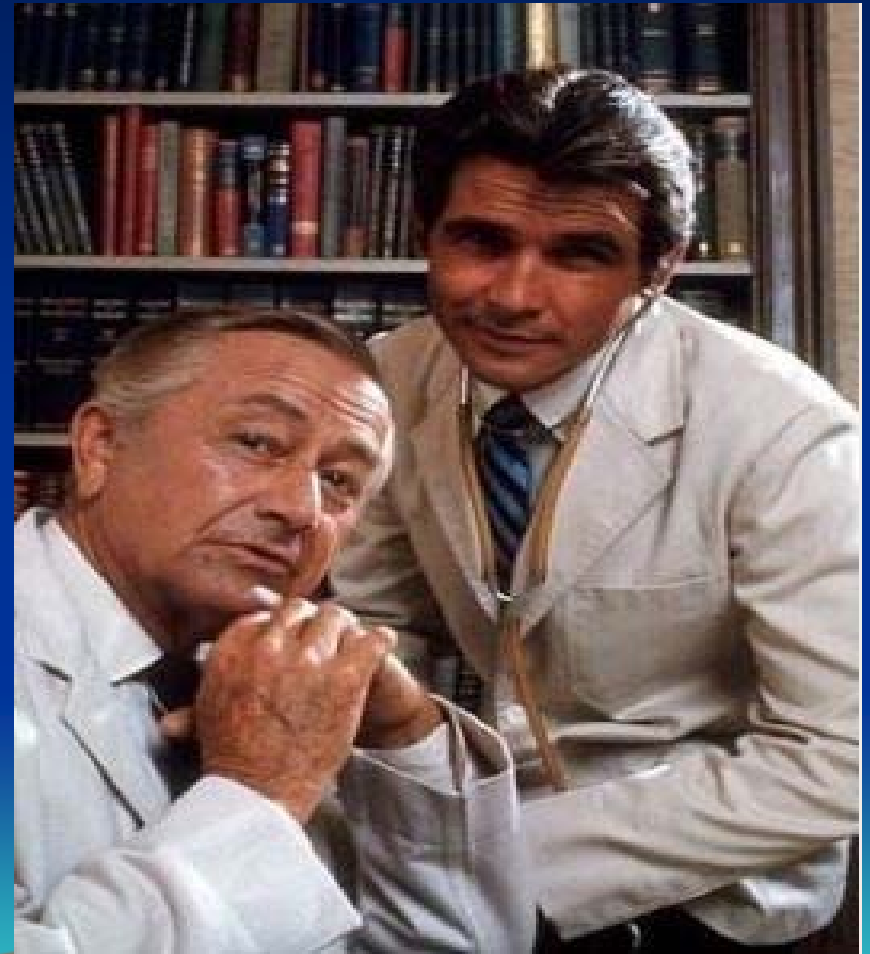


The Regulatory Environment

Twenty-five years ago there were few if any regulations governing physician practices.

An attorney who represented physicians was a:

Tax lawyer,
Malpractice lawyer or
Divorce Lawyer.



Keeping Pace with the Regulatory Environment

“HIPAA-Health Insurance Portability and Accountability Act, CMS-Centers for Medicare and Medicaid Services, OSHA Occupational Safety and Health Administration, PQR-Physician Quality Reporting Initiative, CCHIT-Certification Commission for Healthcare Information Technology, HEDIS-Healthcare Effectiveness Data and Information Set, COBRA-Consolidated Omnibus Budget Reconciliation Act, ICD10- International Classification of Diseases, CLIA-Clinical Laboratory Improvement Amendments, OIG- Office of Inspector General, RBRVS-Resource Based Relative Value Scale, CON-Certificate of Need, CHAMPUS-Civilian Health and Medical Program of the Uniformed Services, HMO-Health Maintenance Organization, PPO-Preferred Provider Organization, EHR- Electronic Health Record, PHR- Personal Health Record, PCMH-Patient Centered Medical Home, RVS- Relative Value Scale, MLR-Medical Loss Ratio, FFS- Fee for Service, DME-Durable Medical Equipment, STARK-Stark Laws on Physician Self Referral, DRG-Diagnosis Related Groups, EMTALA-Emergency Medical Treatment and Labor Act, ERISA- Employee Retirement Income Security Act, EOB-Explanation of Benefits, HL7-Health Level 7, NCQA-National Committee for Quality Assurance, JCAHO - Joint Commission on the Accreditation of Health Care Organizations, NPD- National Practitioners Data Bank, PPP- Pay for Performance, RAC-Recovery Audit Contractor program, RAF-Risk Adjustment Factor, ARRA-American Recovery and Reinvestment Act, SCHIP-State Children’s Health Insurance Fund, HHS- Health and Human Services, NHIN-National Health Information Network HITECH-Health Information Technology for Economic and Clinical Health Act”

Keeping Pace with the Regulatory Environment

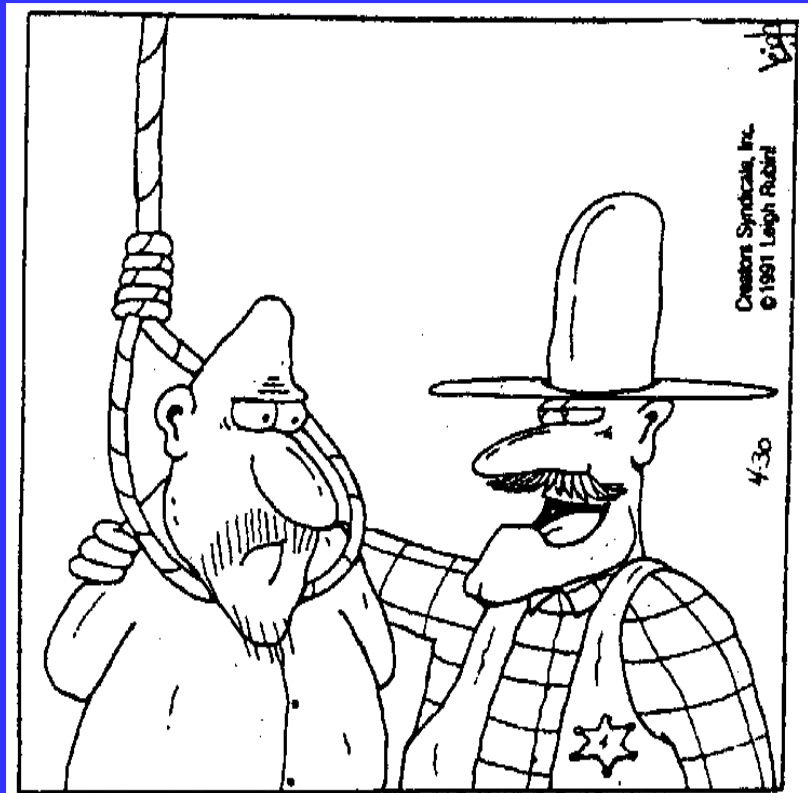


“Would everyone check to see if they have an attorney? I seem to have ended up with two.”

The Regulatory Environment Today

A thicket of rules, the cost of reform, the fraud and abuse ROI and sloppy terminology

- Make hospitals and physicians politically attractive targets,
- And generate a lack of respect for the rules.



"Of course I realize that society is partially to blame for the crime y'all committed. Unfortunately, I only have enough rope for you."

Does this Regulatory Scheme Address a Legitimate Problem?



“By all means, dear-buy it if you want it.
We’ll find the money for it somehow.”

A Legitimate Problem?

- A physician recommends a test or treatment,
- The patient accepts the recommendation, and
- The payor/insurer pays for it.

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Unknowns

- Will enforcement agencies use the fraud and abuse rules to finance health care delivery?
- Is that a proper regulatory purpose?
- Does that purpose foster clear and fair rules, and reasonable enforcement?
- Does that purpose conflict with other goals of regulation?



Unknowns

Is fee service medicine becoming obsolete? New payment mechanisms result in increased profit for providers who do less (while achieving favorable outcomes):

- Pay for performance
- Never events
- Gain sharing
- Risk sharing
- Shared savings plans

If so, what types of laws will be appropriate to guard against mischief?



CMP for Payments to Reduce Care

42 U.S.C. 1320a-7a(b) provides civil monetary penalties for

- Hospitals that knowingly make payments to physicians to induce a reduction in services, and
- Physicians who knowingly accept those payments.



Questions?

