Fraud and Abuse Update

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Medicare and Medicaid Fraud and Abuse Law ("Anti-Kickback Statute")
42 U.S.C. 1320a-7b

• Under the Anti-kickback Statute, it is illegal to knowingly or willfully:
  – offer, pay, solicit, or receive remuneration;
  – directly or indirectly;
  – in cash or in kind;
  – in exchange for:
    ♥ referring an individual; or
    ♥ furnishing or arranging for a good or service; and
  – for which payment may be made under Medicare or Medicaid.
PENALTY

Fined not more than $25,000 or imprisoned for not more than five (5) years or both
THREE NECESSARY ELEMENTS

Intentional Act

Direct or Indirect Payment of Remuneration

To *Induce* the Referral of Patients or Business
What is Remuneration?

• Extremely Broad Scope, whether in cash or in kind, and whether made directly or indirectly, including:
  – Kickbacks;
  – Bribes;
  – Rebates;
  – Gifts;
  – Above or below market rent or lease payments;
  – Discounts;
  – Furnishing of supplies, services or equipment either free, above or below market;
  – Above or below market credit arrangements; and
  – Waivers of payments due.
The Stark II Act prohibits a physician from making a referral to an entity for the furnishing of a designated health service for which payment may be made under Medicare or Medicaid if the physician (or an immediate family member) has a financial relationship with the entity.
Stark II Act

Proof of Intent is *Not* Required
What is a Referral?

- A **referral** is not a DHS personally performed by a physician
- A referral does not include a request by:
  - Pathologists for clinical diagnostic laboratory tests and pathological examination services
  - Radiologists for diagnostic radiology services
  - Radiation Oncologists for Radiation Therapy
- If the request for such additional services results from a consultation initiated by another physician
Designated Health Services

- Designated Health Services include:
  - Clinical laboratory services;
  - Physical therapy and occupational therapy services;
  - Radiology or other diagnostic services (including MRI, CAT scans);
  - Radiation therapy services;
  - Durable medical equipment;
  - Parental and enteral nutrients, equipment and supplies;
  - Prosthetics, orthotics and prosthetic devices;
  - Home health services;
  - Outpatient prescription drugs; and
  - Inpatient and outpatient hospital services (encompassing almost every type of medical procedure).

- Note: Ambulatory Surgery Centers services are not DHS!
What Is a Financial Relationship?

A *Financial Relationship* includes:

- Ownership interests
  - Through equity, debt, compensation or other means; and
- Compensation arrangements
  - Includes virtually any form of direct or indirect *remuneration* (i.e., personal service contracts, medical directorships, lease agreements, consulting arrangements, medical service provider arrangements)
What Is a Financial Relationship?

Remuneration is defined (42 CFR§ 411.351) as “any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind …”
Nature of Exceptions

If *Financial Relationship* exists with an *Entity*, and patients are being *Referred* for *Designated Health Service*, then activity must either comply with an exception or the activity is illegal.
Exceptions

• Permitted Ownership and Compensation Arrangements:
  – Physician Services
  – In-office Ancillary Services
  – Services to Members of Prepaid Health Plans
  – Academic Medical Centers
  – Implants Furnished by ASC
  – Dialysis-related Drugs Furnished by End Stage Renal Disease Facility
  – Preventative Screening Tests, Immunizations and Vaccines
  – Eyeglasses and Contact Lenses Following Cataract Surgery
  – Intra-family Rural Referrals*

*New Phase II (7/26/04 effective date)
Exceptions

• Permitted *Ownership* Interests:
  – Publicly-traded securities
  – Mutual Fund Investment
  – Rural Provider (75% of DHS to Rural Residents)
  – Hospitals in Puerto Rico
  – Hospital Ownership (whole, not department or floor)
Exceptions

• Permitted Compensation Arrangements:
  – Rental of Office Space
  – Rental of Equipment
  – Employment Relationships
  – Personal Service Arrangement
  – Physician Recruitment
  – Isolated Transactions
  – Services Unrelated to Provision of Designated Health Services
  – Hospital-affiliated Group Practice Arrangements
  – Fair Market Value Payments Made by Physicians for Items and Services (i.e., clinical laboratory services)
Exceptions

• Permitted Compensation Arrangements:
  – Charitable Donations by Physician
  – Non-monetary Compensation (Benefits) up to $300 Per Year
  – Fair Market Value Compensation
  – Medical Staff Incidental Benefits
  – Risk-sharing Arrangements (i.e., withholds, bonuses, risk pools)
  – Compliance Training
  – Indirect Compensation Arrangements
  – Referral Services
Exceptions

• Permitted *Compensation* Arrangements:
  – Obstetrical Malpractice Insurance Subsidies
  – Professional Courtesy
  – Retention Payments in Underserved Areas
  – Community-wide Health Information Systems
  – Electronic Prescribing Items and Services
  – Electronic Health Records Items and Services
Recent Stark Changes

Five Recent Major Stark Changes in IPPS
DILBERT

COMPANY LAWYER

CAN YOU TURN A SIMPLE AGREEMENT INTO IMPELENTRABLE GIBBERISH?

ABSOLUTELY. I CAN ALSO LEAVE A SOUR TASTE IN EVERYONE'S MOUTH AND MAKE YOU WANT TO CHOK ME WITH MY SUSPENDERS.

IF YOU EXERCISE AND EAT RIGHT, YOU MIGHT STILL BE ALIVE WHEN I FINISH IT.

GOOD ENOUGH.
Major Stark Change #1

Physicians will be required to “stand in the shoes” of their physician organization only if they have an *ownership* or *investment* interest (not compensation) in the physician organization. Practice plans may be considered to be a “physician organization,” but physicians do not need to “stand in the shoes” of practice plans if meet the AMC exception.

– Physician organization = physician practice or group practice
Direct Compensation Arrangement Created in Phase III with Physicians and their Physician Organizations

- “Stand in the Shoes”
  - 42 CFR 411.354 (c) (ii) - A physician is deemed to have a direct compensation arrangement with an entity furnishing DHS if the only intervening entity between the physician and the entity furnishing DHS is his or her physician organization. In such situations, for purposes of this section, the physician is deemed to stand in the shoes of the physician organization.
Direct Compensation Arrangement Created in Phase III with Physicians and their Physician Organizations

“Stand in the Shoes” continued

Pre-Phase III View

Phase III View

Physician

Group

Hospital

Physician Organization

Hospital

$ Direct

Indirect
Direct Compensation Arrangement Created in Phase III with Physicians and their Physician Organizations

• “Stand in the Shoes” continued
  – Implemented due to CMS’s concern that arrangements between DHS entities and group practices are often viewed as outside the application of the Stark Law
    ♦ For example, an arrangement that did not meet the Stark Law’s definition of a direct compensation arrangement and that also failed to meet one of the prongs of the indirect compensation arrangement definition may allow a physician to make referrals to the entity for the furnishing of DHS without violating the Stark Law’s referral prohibition
  – Phase III definition applies to new arrangements or renewals entered into after September 5, 2007
  – Grandfather provision for arrangements that were “properly structured to comply with the indirect compensation arrangements exception”
Major Stark Change #2
Alternative Method for Compliance with Signature Requirements

• **Effective October 1, 2008**
  – Parties to a compensation arrangement that requires a signed writing may obtain missing signature within:
    ✷ 30 consecutive calendar days after arrangement has commenced if failure was knowing
    ✷ 90 days of failure was inadvertent
  – 42 C.F.R. § 411.353(g)
Captain Integrity™

Becky, if I pay you to be our medical director, will you refer more patients to us?

I'd be glad to be your director, but I don't think it's legal to tie my referrals to this job.

Becky is correct. We cannot pay for referrals.

Contact your compliance officer for a full investigation.
Major Stark Change #3

Percentage-based compensation can be paid for *personally performed services* from revenue generated from physician’s personally performed services. Further, percentage-based compensation can be paid for billing and other administrative services. No percentage-based compensation on leasing arrangements (space and equipment).
Major Stark Change #4

Per-click compensation will not be permitted if the lessor was the source of the patient referral
Per Unit/Percentage-Based Payments

- Effective October 1, 2008, FY 2009 IPPS final rule amends exceptions for:
  - Rental of office space (§ 411.357(a))
  - Rental of equipment (§ 411.357(b))
  - Fair market value compensation arrangements (§ 411.357(l))
  - Indirect compensation arrangements (§ 411.357 (p))
- No grandfathering
Major Stark Change #5

A DHS entity will include the person or entity that *performs* the DHS. Many “under arrangements” may be required to be unwound because of this change.
DHS Entity Defined

• Entity that bills DHS
• Beginning October 1, 2009, an entity that performs DHS
• Under Arrangements are prohibited if entity performs DHS
“Under Arrangements” Services

• Is it an “Under arrangement” if Hospital supplies any of the following?
  – Space
  – Supplies
  – Equipment
  – Staff
Doctor Williams, I believe we can get around the Stark Act by contracting with your wife. Doesn't the Stark Act apply to family members as well?

A physician cannot refer a patient for designated health services to an entity in which they have a financial interest. Under the Stark Act, "physician" includes family members such as Dr. Williams' wife.
Recent Fraud and Abuse Cases
Captain Integrity™

Doctor, we can pay you $500 per hour.

I think so.

I want to be sure. I understand that we could get into trouble if you pay me too much.

That's very generous but, is that fair market value?

That is right! It is important to document that all payments made to physicians are of fair market value.
Memorial Health University Center

• In 2008, Memorial Health negotiated new contracts with Provident Eye Physicians, its affiliate that provides ophthalmologic services to its patients

• The 2003 contracts did not account for the physicians’ teaching and indigent care services

• To correct error, Memorial Health paid Provident Eye Physicians $500,000 per year between 2004 and 2005, and $600,000 per year for 2006
Memorial Health University Center

- The annual payments were not distributed to the physicians performing the teaching and indigent care services
- Instead, the payments were channeled to a small number of high referring physicians in the group
- As a result, the payments constituted an indirect compensation arrangement between the physicians and Medical Center
Memorial Health University Center

- No applicable Stark exception was met. The payments to Provident “varied with the volume or value of referrals or other business generated by the referring Provident physicians” and Memorial acted in reckless disregard of the arrangement.
- Memorial settled with the OIG for $5.08 million.
**United States ex rel. Villafane v. Solinger**

- *Qui tam* case challenging hospital’s application of the Academic Medical Center exception under the Stark Act
- Favorable ruling to hospital, but warns AMCs to carefully tailor their arrangement to fit AMC exception under Stark
United States ex rel. Villafane v. Solinger

• Lessons Learned . . .
  – Document academic and clinical teaching services adequately to qualify for AMC exception
  – Compensation under AMC exception is determined on basis of Fair Market Value
Lessons Learned...

• Appropriately document that majority of medical staff is faculty and that faulty generate a majority of hospital admissions

• Maintain sufficient written documentation of the arrangements between hospital and Medical School
• Court declined to apply the “one purpose” test under the Anti-Kickback Statute to invalidate AMC funding that is clearly permissible under the Stark regulations.
Covenant Medical Center

- Covenant Medical Center paid five employed physicians amounts that the government alleged were above fair market value and commercially unreasonable.
- Compensation formulas were based on personally performed services and, according to the defendant, consistent with fair market value.
- Salaries were among the highest in the nation, according to DOJ ($630,000 to $2.1M).
- Covenant settled the FCA allegations, based on the underlying Stark violations, for $4.5 million.
Lessons Learned

• A fair market value formula to calculate the compensation of employed doctors may not result in fair market value compensation actually received.

• Continued challenges to fair market value and commercial reasonableness are likely.
• **St. John Health System:** $13.2M (12/22/09)
  – OIG self disclosure of Stark & AKS violations; payments to 23 physicians and groups

• **Arlington Memorial Hospital:** $1M (1/4/10)
  – OIG self disclosure of physician financial arrangement for blood gas interpretation – no interpretation needed; payment reallocated for uncompensated care

• **Piedmont Hospital:** $126,000 (12/09)
  – OIG self disclosure (while under CCA): payments to physicians without fully executed contract (as little as 1-day gap); payment rates differing from written amount; services not in writing
• **Cushing Memorial Hospital:** $50,000
  – OIG self disclosure: unsigned medical directorship contract from ‘03 – ’06; all services performed; no rent paid for one year; discovered and corrected
  – OIG reviewed physician’s referral patterns; no increase in referrals

• **Memorial Hospital:** $32,202
  – OIG self disclosure; nonmonetary compensation issues
  – 10 physicians received overpayment of $3,100 through gifts and medical staff leaders at seminar with board; doctors reimbursed hospital; potential $700k in DHS referrals
  – Disgruntled former employee requesting records
Christian Care Health System: $3.3M (3/1/10)

• CCHS has longstanding “evergreen” agreement with neurology group that paid for EEG interpretations at a rate that was “multiples of what Medicare or Medicaid paid CCHS as reimbursement for those services.”

• Competing neurology group desired to contract with CCHS.

• Alleged violation of the False Claims Act and Stark Act.
Anti-Kickback Statute Developments

• No one is safe! New cases pursued under Anti-Kickback theories target more than just corporations!
  – University of Medicine and Dentistry of New Jersey Settlement and subsequent settlements with individual physicians
  – Medtronic Whistleblower Lawsuit targets physicians under Anti-Kickback Statute
  – *U.S. v. Rogan* upholds $64 million fine against hospital manager and financial beneficiary
University of Medicine and Dentistry of New Jersey Settlement

• $8.3 million to settle allegations that the medical school paid for physician referrals in violation of the Anti-Kickback Statute
  – UMDNJ entered into part-time employment deals with local cardiologists to teach classes and deliver lectures at the medical school. In reality, the cardiologists performed little, if any, services under the agreements. In exchange, the cardiologists referred patients to UMDNJ.
University of Medicine and Dentistry of New Jersey Settlement

• Department of Justice also targeted the individual cardiologists that entered into the sham employment agreements with UMDNJ.
  – Several individual cardiologists agreed to settlements, paying back twice the amount of money as received under the sham employment agreements.
Medtronic Whistleblower Lawsuit

• Targeted physicians for improper consulting and royalty agreements in violation of the Anti-Kickback Statute
  – Targeted over 100 orthopedic spine surgeons, neurosurgeons, medical practices and distributors of taking kickbacks from Medtronic for using their products, promoting off-label use of FDA-approved devices, and filing Medicare claims in violation of the False Claims Act
Medtronic Whistleblower Lawsuit

- Allegations that physicians accepted:
  - Consulting fees when no services were performed
  - Consulting fees for more than fair market value of their services
  - Royalties for patents on which they were not true inventor
  - Improper gifts given, including textbooks
  - Excessive travel
  - Consulting compensation based on amount of business they created
Medtronic Whistleblower Lawsuit

• Lawsuit dismissed in March of 2009. Judge stated that the plaintiffs were barred from going forward because plaintiffs in other lawsuits and the news media had aired the lawsuit’s allegations previously.

• Nevertheless, the lawsuit forced all parties, including individual physicians, to spend countless dollars on legal fees.
United States v. Rogan

- 7th Circuit upheld $64 million fine against Peter Rogan, manager and financial beneficiary of Edgewater Medical Center for False Claims Act Violation
  - Anti-Kickback Statute and Stark Act violated through improper payments to physicians
    - Medical director agreements, physician recruiting contracts, teaching contracts, EKG-reading contracts, and physician loan agreements, which provided doctors with compensation that court found was “grossly” above fair market value for services never substantially performed
UMDNJ, Medtronic, and Rogan Lessons

• Physicians and Hospital Administration must take active role in health care compliance or face consequences
• No more hiding behind deep pockets of hospital! More cases targeting individual physicians and administrators
False Claims Act

• The civil False Claims Act, 31 U.S.C. § 3729, *et. seq.*, was amended by Congress in the Fraud Enforcement and Recovery Act of 2009 (“FERA”). The FERA also included:
  – Fraud against health benefit programs, 18 U.S.C. § 1347
  – Criminal penalties for false statements or representations under federal health care programs, 42 U.S.C. § 1320a-7(b)(a)
  – Reporting obligations under government contracts and Federal Acquisition Rules (including new obligation to report if knowledge of significant over payment)
  – State False Claims Acts
False Claims Act Basics

- Providers cannot “knowingly” submit false claims to the government for payment.
- Knowledge includes:
  i) Actual knowledge;
  ii) Deliberate ignorance; and
  iii) Reckless disregard for the law.
False Claims Act

• Severe sanctions include:
  – Treble damages
  – $11,000 penalty per violation
  – Private “qui tam” civil suits can be brought on behalf of the government. The *qui tam* litigant can receive between 15% – 25% of the actual recovery depending upon whether the government intervenes

• Separate statutes exist for civil and criminal enforcement for false claims
False Claims Act

• FERA changes:
  – False Claims Act clearly includes claims submitted for payment to contractors and grantees of the government
  – Strengthened “reverse” false claims on amounts due to the government
  – “Materiality” requirement added
  – “Conspiracy” liability expanded
  – Added a “relating back” authority to help the government beat statute of limitation defenses
  – Enhanced retaliation protection for whistleblowers
  – Broadened government authority to issue investigative demands
  – Eased ability of government to share information with *qui tam* plaintiffs
Change to “Presentment” Requirement and Addition of “Materiality” Element

(a) Liability for Certain Acts.

| Softens “presentment” requirement | (1A) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; |
| Adds “materiality” requirement here | (2B) knowingly makes, uses, or causes to be made or used, a false record or statement material to get a false or fraudulent claim paid or approved by the Government; |
Claim Defined. For purposes of this section, (2) the term “claim” includes:

(A) means any request or demand, whether under a contract or otherwise, for money or property which and whether or not the United States has title to the money or property, that

(i) is presented to an officer, employee, or agent of the United States;

or

(ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government’s behalf or to advance a Government program or interest, and if the United States Government

(I) provides or has provided any portion of the money or property which is requested or demanded; or if the Government

(II) will reimburse such contractor, grantee, or other recipient for any portion of the money of property which is requested or demanded; and

(B) does not include requests or demands for money or property that the Government has paid to an individual as compensation for Federal employment or as an income subsidy with no restrictions on that individual’s use of the money or property.
Claim Does Not Have to be Presented Directly to the United States

• False Claims Act applies to claims made to government contractors and agents
• U.S. ex rel. Totten v. Bombardier was overturned. Totten held that it was not enough for a claim to be presented to Amtrak (government contractor) even though all of the money paid by Amtrak came from the federal government.
• Allison Engine was also overturned as the Supreme Court required proof that the defendant intended that the claim be paid by the U.S. Government itself and was not sufficient that federal funds were used to pay the false claim.
Expanded “Reverse” False Claim Exposure

• (7G) knowingly makes, uses, or causes to be made or used, a false record or statement material to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly or improperly avoids or decreases an obligation to pay or transmit money or property to the Government.

Key Issues:

– Audit results
– Stark Violations
Reverse False Claims

- Reverse false claims is when provider has received money improperly and does not return money to government
Material Defined

• The term “material” means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.
Conspiracy Liability Broadened

(C) Conspires to defraud the Government by getting a false or fraudulent claim allowed or paid commit a violation of subparagraph (A), (B), (D), (E), (F), or (G).
Liability Incurred for Failing to Return All Improperly Received Reimbursement

(D) Has possession, custody, or control of property or money used, or to be used, by the Government and, intending to defraud the Government or willfully to conceal the property, knowingly delivers, or causes to be delivered, less property than the amount for which the person receives a certificate of receipt than all of that money or property.
If Government intervenes, it can bring additional claims that will “relate back” to the filing of the *qui tam* complaint, thereby avoiding the statute of limitations defense.

(c) If the Government elects to intervene and proceed with an action brought under 3730(b), the Government may file its own complaint or amend the complaint of a person who has brought an action under Section 3730(b) to clarify or add detail to the claims in which the Government is intervening and to add any additional claims with respect to which the Government contends it is entitled to relief. For statute of limitations purposes, any such Government pleading shall relate back to the filing date of the complaint of the person who originally brought the action, to the extent that the claim of the Government arises out of the conduct, transactions, or occurrences set forth, or attempted to be set forth, in the prior complaint or that person.
Attorney General can Delegate Authority to Issue Civil Investigative Demands

- The Attorney General may **not** delegate the authority to issue civil investigative demands under this subsection. Whenever a civil investigative demand is an express demand for any product of discovery, the Attorney General, the Deputy Attorney General, or an Assistant Attorney General shall cause to be served, in any manner authorized by this section, a copy of such demand upon the person from whom the discovery was obtained and shall notify the person to whom such demand . . . .
Information Sharing Provisions

(c) Service on State or Local Authorities. With respect to any State or local government that is named as a co-plaintiff with the United States in an action brought under subsection (b), a seal on the action ordered by the court under section 3730(b) shall not preclude the Government or the person bringing the action from serving the complaint, any other pleadings, or the written disclosure of substantially all material evidence and information possessed by the person bringing the action on the law enforcement authorities that are authorized under the law of that State or local government to investigate and prosecute such actions on behalf of such governments, except that such seal applies to the law enforcement authorities so served to the same extent as the seal applies to other parties in the action.
Anti-Retaliation Provisions Revised to Protect Contractors and Agents and Also Internal Whistleblowers, Not Just *Qui Tam* Plaintiffs

(h) Any employee who **Relief from Retaliatory Actions**.

(1) In General. Any employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole, if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment by his or her employer because of lawful acts done by the employee, contractor, or agent on behalf of the employee or contractor, or agent or associated others in furtherance of an action under this section, including investigation for, initiation of, testimony for, or assistance in an action filed or to be filed under this section, shall be entitled to all relief necessary to make the employee whole. Such relief **other efforts to stop 1 or more violations of this subchapter**.
Strengthened Whistleblower Relief

(2) Relief. Relief under paragraph (1) shall include reinstatement with the same seniority status such that employee, contractor, or agent would have had but for the discrimination 2 times the amount of back pay, interest on the back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys’ fees. An employee may bring an action under this subsection may be brought in the appropriate district court of the United States for the relief provided in this subsection.