Legal Issues: Fraud and Abuse
Navigating Stark and Kickback

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The Counterintuitive Industry

- Business arrangements that make perfect sense in other industries can violate a host of health care laws and regulations.
- One of the most heavily regulated industries.
- A legitimate business purpose is not a defense.
The Need for Health Care IT

- Few argue that the health care industry desperately needs to develop a more sophisticated and interoperable IT infrastructure.
  - In 2001, the Institute of Medicine cited IT as one of the principal ways to improve the quality of health care in America.
  - President Bush’s call for adoption of electronic health records (EHRs) in the next 10 years.
  - Establishment of the Office of the National Coordinator for Health Information Technology (ONCHIT)
  - March 3, 2005: HHS Secretary Mike Leavitt touts EHRs to House appropriations committee.
  - President Bush’s 2006 budget proposal includes $125 million for HIT.
The Main Barrier -- Cost

- The pace of adoption of HCIT by physicians has been slow and uneven.
  - 2000 Harris survey indicated that only 17% of physicians in office-based practice used electronic medical records (EMRs).
  - 2003 survey: the median physician practice spends only 2% of its operating budget on IT.
The Cost of EMRs

• Partners Healthcare in Boston – cost of an EMR system may exceed $25K per provider, attributable to:
  ■ Hardware costs
  ■ Software licensing
  ■ Training
  ■ Losses in productivity associated with conversion
The Cost of EMRs

- Given the narrow profit margins of most physician practices, physicians are unlikely to make the large investments necessary to implement a fully interoperable HCIT system using EMRs.

- Health plans, hospitals and pharmaceutical companies must be the driver’s of HCIT change.
  - “That’s where the money is” (Willie Sutton)
Accelerating HCIT Adoption by Physicians

- Many barriers to Physician Adoption
  - Legal
  - Generational
  - Lack of Interoperability
  - Cost
Accelerating HCIT Adoption by Physician

- Many hospitals/IDNs want to wire their staff and non-staff physicians by providing them with:
  - Office Systems
  - Handheld Devices
- Fraud & abuse laws must be carefully evaluated
Principal Health Care Fraud & Abuse Statutes

- The Stark Law
- Anti-Kickback Law
- State Fraud and Abuse Laws
The Stark Law
The Basic Prohibition

- Prohibits a physician from referring patients to an entity for the “furnishing” at least one of 11 “designated health services” if the physician (or immediate family) has a “financial relationship” with the entity, unless the relationship falls within an exception.
Stark Law Prohibitions

Two Basic Prohibitions

First, if a “physician” (or “immediate family member”) has a “financial relationship” with an “entity,” then the physician may not “refer” Medicare patients “to” the entity for the furnishing of “designated health services,” unless an exception applies.

Second, an entity may not bill Medicare (or any other individual or entity) for services furnished pursuant to a prohibited referral.
Stark Law - Penalties

● Sanctions
  ■ Civil: refunds, $15,000 CMP per claim, $100,000 for “scheme” to circumvent, permissive exclusion
  ■ Collateral: potential FCA liability ($11,000 per claim, treble damages, private whistleblowers)
The Anti-Kickback Law
The Basic Prohibition

- It is illegal for any individual or entity “knowingly and willfully” to offer or pay “remuneration” -- directly or indirectly, overtly or covertly, in cash or in kind – to “induce” another individual or entity to:

  - “refer” an individual to a person for the furnishing of any item or service for which payment may be made under a federal health care program;

  - “purchase,” “lease” or “order” any covered item or service; or

  - “arrange for or recommend” the purchase or order of any covered item or service.
AKL- Elements

- **Step One** - Remuneration
  - Does proposed arrangement provide for “remuneration” of any kind to flow from the hospital to the physician?

- **Step Two** – Inducement
  - Unlawful to give or to accept remuneration in exchange for:
    - referring program patients
    - purchasing or ordering covered items
    - arranging for others to make such referrals/purchases/orders
    - recommending that others make such referrals/purchases/orders
AKL - Penalties and Sanctions

- **Sanctions**
  - **Criminal**: five years, $25,000 fine, mandatory exclusion
  - **Civil**: $50,000 CMP, three times total amount of “remuneration,” permissive exclusion
  - **Collateral**: potential FCA liability ($11,000 per claim, treble damages, private whistleblowers)
Stark Law v. Anti-Kickback Law

- Differences
  - AKL is criminal; Stark Law is civil
  - AKL has a “state of mind” requirement; Stark Law is “strict liability”
  - AKL applies to arrangements between providers, suppliers, and physicians; Stark Law is limited to physician arrangements
  - AKL applies to all federal health care programs (other than FEHBP); Stark Law (effectively) applies only to Medicare
Some Threshold Questions

- Does the provision of HCIT by a hospital to a physician = remuneration?
- If yes, does such remuneration act as an “inducement” to the physician to refer federal health care program patients to the hospital?
- Does provision of access or technology for EMRs give rise to a financial relationship between the hospital and the physician, per the Stark law?
Potential Exceptions and Safe Harbors

- **Stark Law**
  - Non-monetary compensation up to $300
  - Medical staff incidental benefits
  - Payments at fair market value
  - Community wide health information system
- **Anti-Kickback Law**
  - Personal services
  - Equipment rental
Stark Law

Exceptions
Non-Monetary Compensation Up to $300

- Items or services (not including cash or cash equivalents) that do not exceed, on aggregate, $300 per year;
- Compensation is not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician;
- The compensation may not be solicited by the physician or his or her practice; and
- The compensation arrangement does not violate the AKL.
Medical Staff Incidental Benefits

- Universal availability of the benefit to members of the medical staff, without regard to the volume or value of referrals or other business generated between the parties;
- The benefits must be offered only during periods when the medical staff members are making rounds or are engaged in other services or activities that benefit the facility or its patients – CMS acknowledgement that dedicated electronic or Internet items or services, dedicated pagers or two-way radios may meet the requirements of this exception;
Medical Staff (cont.)

- The benefits must be provided by the facility and used by the medical staff members only on the facility’s campus - CMS acknowledges that this requirement may be met if communication devices are used exclusively to access hospital medical records, patient information or patients or personnel located on campus;

- The benefits must be reasonably related to the provision of, or designed to facilitate directly or indirectly the delivery of, medical services at the facility;
Medical Staff (cont.)

- The benefits must be of low value (i.e., less than $25, now indexed for inflation by reference to the CPI) with respect to each occurrence;
- The benefits must not be determined in any manner that takes into account the volume or value of referrals or other business generated between the parties; and
- The compensation arrangement does not violate the federal health care program anti-kickback law.
Payments at FMV

- Useful where physicians must pay a fee to access the network
- Fee must be at FMV, without regard to volume or value of DHS referrals between the entities
Community Wide Health Information System

- Added in new Stark Phase II regulations, effective July 26, 2004
- Creates Stark exception for hospitals to provide HCIT to physicians in a community
Community Wide HIS - Requirements

- Items or services principally used by physician as part of the community-wide HIS;
- Items or services must be provided to physicians in a manner that do not take into account the volume or value of referrals;
- The HIS must be “community wide,” i.e., available to all providers, practitioners and residents of the community;
- The arrangement does not violate the AKL.
Community Wide HIS

- **Multiple Issues:**
  - How do you define “community?”
  - How do you make technology available to all, while ensuring security and proper use of system?
  - How do you finance such a system?
  - Difficulty in ensuring compliance with AKL.
Anti-Kickback Law

Safe Harbors
AKL – Personal Services & Equipment Safe Harbors

- Arrangement is in writing
- The written agreement covers all the services/items the EMR network will provide
- If the arrangement is for part-time or sporadic use (as opposed to full-time), the agreement specifies the exact schedule of use
- The aggregate compensation over the term of the agreement is set in advance, consistent with FMV, and not determined in a manner that takes into account existing or expected referrals of federal health care program business between the parties
Assessing Risk

- If arrangement does not fit within an AKL safe harbor, what are the risk factors?
  - To what extent are AKL policy objectives implicated?
  - Has OIG issued any guidance (fraud alerts, advisory opinions, etc.)?
  - What is current enforcement environment?
  - What is organization’s risk tolerance level?
Removing the Fraud and Abuse Barriers to HCIT

- GAO Report finds F&A laws are barrier to HCIT dissemination
- Revisions to Stark regulations or possible new safer harbor under the AKL
- Promotion of interoperability and open-source software may minimize the need for a sponsor to fund a network
- Use of RHIOs with multiple funding sources, greater availability and access
Some Examples and Case Studies
Hospital Clinical Lab

Pharmacy

Medical Staff Member Physicians

Unaffiliated Physicians

EXAMPLE 1

Remuneration

DHS Referrals
Hand-held Devices

- A hospital’s provision of PDAs and other hand-held devices to physicians would constitute “remuneration” under the anti-kickback law.
- Are the PDAs used to order prescriptions and other services paid for by Medicare or Medi-Cal? Most likely.
- Analysis will always be highly fact-specific.
Computers and Connectivity

- Hospital provides computers and Internet connectivity to medical staff physicians.
  - Serves a legitimate purpose – aiding clinical communications.
  - Computers and connectivity constitute “remuneration.”
    - Are the computers dedicated to the function or can they be used for general business operations of the physician practice?
OIG Advisory Opinion 99-14

- OIG considered a telemedicine network funded by a health system.
  - Health system funded transmission line charges, equipment maintenance and purchase of new equipment by rural physicians.
  - OIG chose not to impose sanctions, finding that community benefits outweighed potential for abuse.
  - No guarantee that same conclusion would be reached in a non-rural setting or for other technologies.
Independent Regional Health Information Organization

- Hospital
- Physicians
- Clinical Labs
- Nursing Home

EXAMPLE 2

- Technology
- Remuneration
- Funds
- Funds
- Funds
- Technology
- Technology

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Breaking the Link Between Funding and Referral Sources

- RHIOs offer the possibility of providing HCIT solutions to physicians through a vehicle that is not directly linked to a referral source.

- RHIO organizational models:
  - Tax-exempt 501(c)(3) organization.
  - Non-profit mutual benefit organization.
  - For-profit corporation or LLC capitalized by multiple parties (perhaps with minority hospital interest).
Breaking the Link Between Funding and Referral Sources

- The Office of Inspector General (OIG) has issued advisory opinions indicating that an intermediary charitable organization can “break the link” between funding source and referrals:
  - Patient assistance program funded by operators of dialysis facilities.
  - Program offering financial assistance for medical expenses funded by drug manufacturers.