

Legal Issues in Electronic Health Records Acquisition, Implementation and Monitoring

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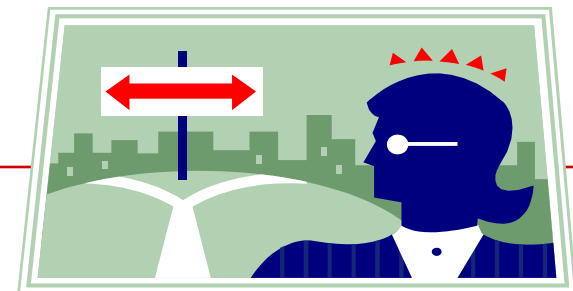
Introduction – What's Driving EHRs?

- ◆ National initiative toward interoperable health records (by 2014)
- ◆ Quality of care and the push to reduce medical errors
- ◆ Transparency
- ◆ Electronic billing
- ◆ E-prescribing
- ◆ Homeland Security – dealing with disasters



Key Decisions with Legal Impacts

- ◆ Nature of network: Centralized or peer-to-peer; record locator or central record repository; types of services – e.g. ASP, closed or internet based
- ◆ Stand alone or integration with hospital or community; involvement of participating providers in governance and operations
- ◆ Plan for expansion; integration with RHIOs and the NHIN; who will decide who participates in network – labs, pharmacies, public health agencies
- ◆ Acquisition and payment for necessary equipment and software to run the network, purchased by or given to physician participants; scope of training and support; ongoing fees and charges



The Stark Law

- ◆ Prohibits paying remuneration for referrals of Designated Health Services by physicians to entities with whom the physician has a financial relationship, unless an exception applies
- ◆ Financial relationship includes direct and indirect compensation arrangements even if the compensation is unrelated to a Designated Health Service
- ◆ Free or discounted hardware, software and other access to EHRs could qualify as remuneration creating an indirect compensation arrangement
- ◆ Argument: No financial relationship
 - ❖ Historic relationship of information sharing between a hospital and its medical staff
 - ❖ Caveat: other valuable remuneration may be at issue (e.g., hardware or software used for other purposes; network fees paid by hospital)
- ◆ If remuneration, find an exception



The Stark Law: Electronic Health Records Items and Services Exception

- ◆ **IT items or services provided to a physician “necessary and used predominantly” to create, maintain, or share EHRs are not remuneration if all requirements of the exception are met.**
- ◆ **Donor requirements**
 - ❖ Any entity that provides designated health services
 - ❖ Donor does not take any action to limit or restrict use, compatibility, or interoperability of EHR items or services
 - ❖ Donor does not know that recipient has obtained equivalent items/services – No reckless disregard
- ◆ **Recipient requirements**
 - ❖ Recipient may be any physician
 - ❖ Recipient physician does not make items/services a condition of doing business
- ◆ **Selection of recipients/determination of nature of donation**
 - ❖ Not provided in a manner that takes into account the volume or value of referrals
- ◆ **Donation**
 - ❖ Hardware, software, information technology and training
- ◆ **Technology requirements**
 - ❖ Interoperable software
 - “Able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings” and so purpose and meaning of data are reserved
 - At the time it is provided
 - Certification by certifying body recognized by the Secretary within 12 months of date provided
 - No current standards
 - ❖ Usable for all patients and payors
 - ❖ Contains e-prescribing capabilities



The Stark Law: EHR Exception

◆ Payment for Technology

- ❖ Donors may not pay more than 85% of the cost of the donated technology
- ❖ Recipient must pay at least 15% of the donor's cost
- ❖ Cost sharing also applies to related services, e.g. training, help desk
- ❖ Recipient pays its share before receipt of items/services – No donor financing

◆ Arrangement is

- ❖ Written and signed by the parties
- ❖ Specifies the items and services, donor's cost and recipient's contribution
- ❖ Covers all EHR items/services by donor
- ❖ Does not include physicians office staffing
- ❖ Items and services are not used primarily for personal business

◆ The arrangement does not violate the Anti-kickback or other laws related to claims submission

◆ Sunset: December 31, 2013



The Stark Law: EHR Exception

- ◆ Not Considered Volume or Value: The determination is based on:
 - ❖ Total number of prescriptions written (but not volume or value of Rx dispensed or paid by donor or billed to the Medicare program)
 - ❖ Size of medical practice (e.g., total patients, total patient encounters, total RVUs)
 - ❖ Number of hours the physician practices medicine
 - ❖ Overall use of automated technology in medical practice
 - ❖ Whether physician is a medical staff member
 - ❖ Other reasonable and verifiable manner that does not directly take into account the volume or value of referrals or business generated between parties



The Stark Law: Other Exceptions

- ◆ **Medical staff incidental benefit**
 - ❖ Offered only on the hospital campus
 - ❖ Related to facilitating hospital services
 - ❖ Low value (less than \$25/occurrence)
- ◆ **Equipment lease**
- ◆ **Payments by a physician at FMV**
- ◆ **Non-monetary compensation up to \$300**
- ◆ **E-Prescribing**
 - ❖ Necessary and used solely for e-prescribing
 - ❖ Compliant with Part D standards, including interoperability
 - ❖ Donor-recipients: hospitals-medical staffs; physician practices-physician members; prescription drug plan sponsors and Medicare Advantage organizations-prescribing physicians
 - ❖ No recipient cost sharing



Anti-Kickback Law

- ◆ Prohibits payment, solicitation, offer or acceptance of remuneration in exchange for a referral
- ◆ 2004 GAO Report: Physicians may be reluctant to accept . . . resources from a hospital . . . knowing that the resources may be viewed as remuneration and a violation of the Anti-kickback laws



Anti-Kickback Law: Safe Harbors

- ◆ Electronic health records items and services (More or less equivalent to Stark exception)
 - ❖ Very different approach for OIG
- ◆ E-prescribing (also similar to Stark exception)
- ◆ Rental
- ◆ Personal services
- ◆ Otherwise rely on other considerations to negate intent that one purpose was to encourage referrals
 - ❖ FMV
 - ❖ No requirements to refer



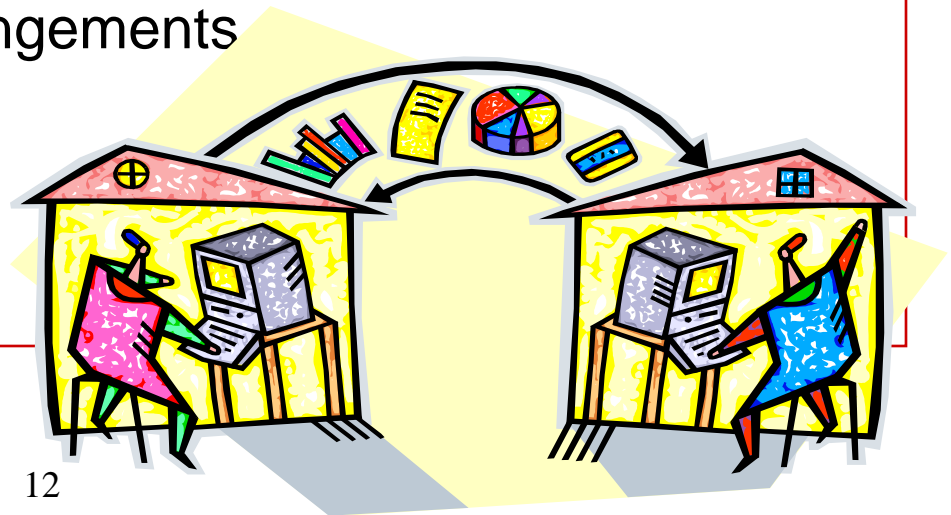
Tax-Exempt Status [501(c)(3)]

- ◆ Charitable purposes
 - ❖ Operated exclusively for charitable, scientific, educational and religious purposes
 - ❖ Includes community benefits consistent with purposes
 - ❖ Avoids more than incidental benefits Private inurement
- ◆ Private inurement
 - ❖ No part of net earnings inures to the benefit of an “insider”
 - ❖ Could include key members of the medical staff
- ◆ Private benefit
 - ❖ Prohibition on conferring more than incidental benefits on private parties (quantitative v. qualitative)
- ◆ RHIOs as tax-exempt organizations
 - ❖ IRS plans to release its “hold” this fall on PLRs
 - ❖ Fact-specific analysis including no competition with for-profits and examination of funding sources



Privacy: Use and Disclosure

- ◆ Compliance with HIPAA and State laws related to privacy of health information
- ◆ Uses and disclosures generally permitted for:
 - ❖ Treatment, payment and (at least limited) health care operations
 - ❖ With authorization from patient or personal representative
 - ❖ Business associate
 - ❖ Organized Health Care Arrangements



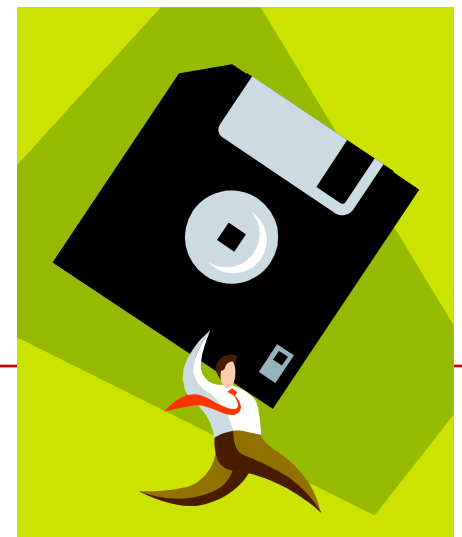
Privacy: Individual Rights

- ◆ General issues
 - ❖ Determine responsibilities
 - ❖ Centralized v. de-centralized
 - ❖ Allocation of risk
- ◆ Access
- ◆ Amendment
- ◆ Accounting of Disclosures
- ◆ Requests for additional privacy protections
- ◆ Alternate communications
- ◆ Notice of privacy practices



Security

- ◆ HIPAA security standards apply to protected health information (PHI) that is either stored or transmitted electronically
- ◆ Security is only as good as the weakest link in the network
- ◆ Need to consider administrative, physical and technical safeguards related to storage and transmission of electronic data
- ◆ Authentication of users who access records
- ◆ Protection from alteration or destruction
- ◆ Monitoring where it goes – who protects the audit trail



Antitrust

- ◆ Antitrust laws prohibit anti-competitive behavior
 - ❖ Price-Fixing
 - ❖ Exclusionary, anti-competitive practices
 - ❖ Tying arrangements
- ◆ Permissible forms of clinical integration as compared with unlawful horizontal integration
 - ❖ IPAs
 - ❖ Financially and operationally integrated medical groups



Coordination of Agreements

- ◆ Acquisition of hardware
- ◆ Software licenses
- ◆ User agreements
 - ❖ Sanctions
- ◆ Service agreements
 - ❖ Connectivity
 - ❖ Business associate contracts
- ◆ Network policies and procedures



Liability

- ◆ Breaches of privacy/security
- ◆ Breach of user agreement and licenses
- ◆ Malpractices issues
- ◆ Exit strategy
 - ❖ Ownership of records
 - ❖ Determine if/how to separate
 - ❖ Porting data to new platform
 - ❖ Records retention



Questions

