

Hospital Purchase of EHRs for its Medical Staff: Taking Advantage of the Anti-Kickback Safe Harbor and Stark Law Exception

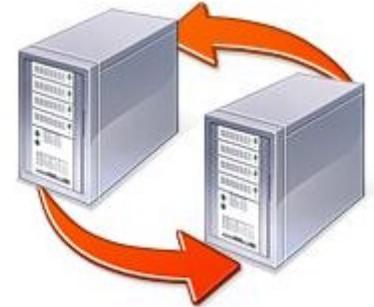
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National EHR Acquisition,
Implementation and
Operations Summit



Window of Opportunity

- Window of opportunity permitting hospitals to subsidize the cost of electronic health record (EHR) implementation for its medical staff
- Regulations adopted in 2006 in response to:
 - Government call for implementation of interoperable health information technology (HIT)
 - Congressional mandate for e-prescribing
 - Recognition that Anti-kickback Statute, Stark Law, and tax-exemption requirements were viewed as obstacles (if not barriers) to EHR adoption assistance
- Departure from regulator's historical stand, e.g., against "free computers" and other technology



Renewed Interest

- Many pursued this opportunity, but not the groundswell some anticipated
- Surveys indicated concerns including:
 - Physician reticence in being interoperable
 - Complexities of compliance
 - Physicians still having to make substantial investment
- Now seeing renewed interest
 - HITECH's carrots and sticks to encourage "Meaningful Use" of interoperable EHRs
 - Hospitals beginning to accept that isolated HIT systems will be a competitive disadvantage (with broad scale deployment across the industry)
 - Consumer awareness of HIT and EHRs
 - Providers recognizing that HIT is inevitable



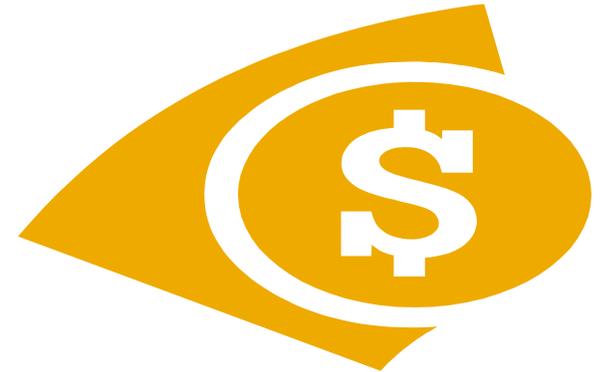
Anti-Kickback Statute (AKS)

- Prohibits
 - Payment, acceptance, solicitation, or offer of any
 - Remuneration in exchange for
 - Referrals or purchase of items or services (e.g., business generated)
- Intent-based
- Facts and circumstance analysis
- Safe harbors
 - Tightly designed
 - Failure to comply does not mean violation



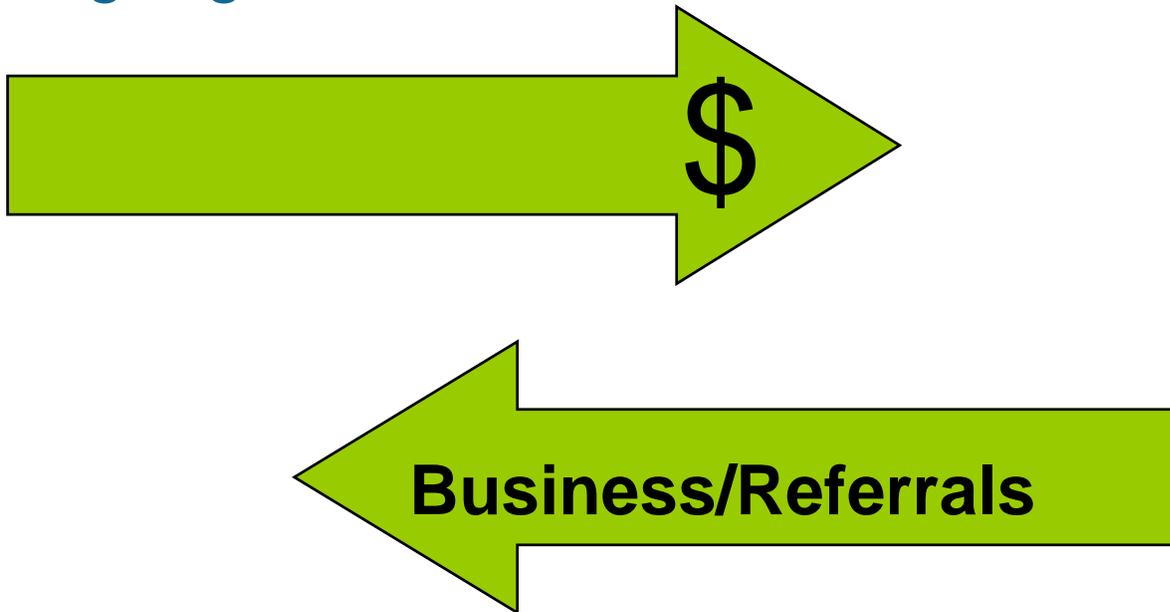
The Stark Law

- Prohibits
 - Physician referrals of
 - Designated Health Services (DHS) to
 - DHS Entities with whom the physician has a
 - Financial relationship
 - Unless an exception applies
- DHS include laboratory, hospital inpatient and outpatient, radiology services, etc.
- Financial relationship includes direct and indirect compensation arrangements – not necessarily tied to DHS
- Strict liability statute: No intent requirement
- If Stark prohibition is triggered, must find an exception



Anti-Kickback Statute and Stark Law

- Warning Sign



Overview of the Safe Harbor/Exception – Very Detailed Requirements

- Technology requirements and standards
- Requirements on donors
- Requirements on recipients
- Payment obligations
- Documentation
- No condition of future business between donor and recipient



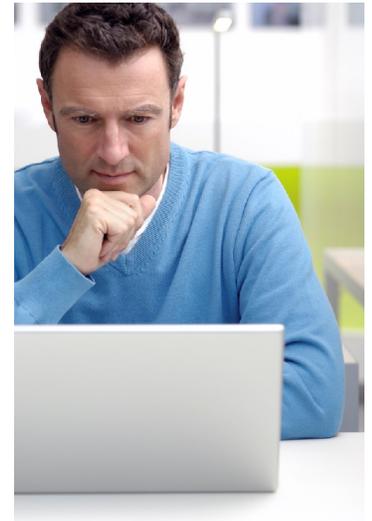
Permitted Technology

- Nonmonetary remuneration
- Software, technology, and training necessary and used predominantly to create, maintain, transmit, or receive electronic health records
- EHR software must include e-prescribing component
- EHR donation may not include hardware (unlike e-prescribing donation)
- No staffing of office (e.g., no staff to perform data migration)



“Necessary” and “Not Duplicative”

- Necessary and used predominantly to create, maintain, transmit, or receive EHR
- No technology used primarily to conduct personal business or business unrelated to the recipient’s clinical practice or clinical operations
- Not duplicative
 - If the recipient already has equivalent technology then equivalent technology confers an inappropriate benefit
 - Reasonable inquiry and documentation of communications
 - Upgrades for standardization, interoperability, user-friendliness acceptable

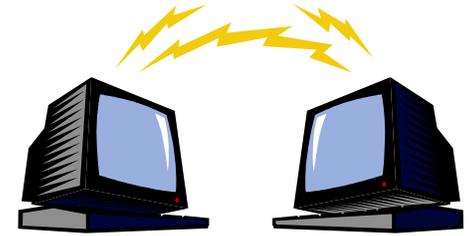


“Used Predominantly”

- Core functionality must be creation, maintenance, transmission, or receipt of EHR, such as:
 - Interface and translation software
 - IP/licenses related to EHR software
 - Connectivity services (e.g., broadband and wireless Internet)
 - Clinical support/information services related to patient care
 - Secure messaging
 - Training and support services (but no on-site personnel)
- Software packages may include other functionality related to the care and treatment of individual patients
 - “Depending on the circumstances,” patient administration, scheduling functions, and billing and clinical support may be included
 - Not Human Resources or payroll



Interoperability



- Ability to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks
- Interoperability determined at the time it is provided to the recipient
- Software is deemed to be interoperable if certified by a certifying body recognized by HHS within 12 months prior to the date it is provided to the recipient
 - Certification Commission for Health Information Technology
 - Drummond Group
- Donor takes no action to limit use, compatibility, or interoperability

Donors

- Safe Harbor – Protected donors are individuals and entities that provide covered services and submit claims or requests for payment, either directly or through reassignment, to any Federal health care program and health plans
- Stark Exception – Entities that furnish DHS services



Selection of Recipients

- Donors may not select recipients using any method that takes into account directly the volume or value of business generated by the recipient
- Acceptable criteria
 - Size of practice (e.g., total patients)
 - Overall use of technology in practice
 - Membership in medical staff
 - Provision of uncompensated care
- Recipients may not condition the arrangement on doing business with the donor



Payment for Technology

- Recipients of EHR technology must pay at least 15% of the donor's cost for the donated technology
- Allocation of costs can be challenging –
 - “Reasonable and verifiable” method
 - Scrutiny to ensure no inappropriate cost shifting
- The donor (or any affiliate) must not finance, or provide loan for, the recipient's share of the payment
- Payment by recipient must be made in advance



Documentation

- Written agreement to which the donor and the recipient are parties
- Prior to donation, must document donated technology and its cost to the donor, as well as the recipient's contributions
- Documentation of cost by vendors is not required but it may be “prudent”



Don't Forget about Tax Consequences

- A tax-exempt donor needs to comply with private benefit and private inurement restrictions
- Private benefit
 - Prohibition on conferring more than incidental benefits on private parties
- Private inurement
 - No part of net earnings inures to the benefit of an “insider”
 - Could include key medical staff members
- Donated technology may be taxable income to physicians in certain circumstances



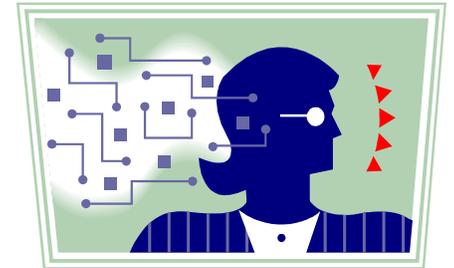
IRS Guidance on EHR Donations

- Field Directive and Q&A
- IRS Safe Harbor — Deemed not to be private inurement or impermissible private benefit if:
 - Benefits are permitted under the EHR rules
 - Continued compliance with EHR rules
 - Hospital has access to medical information on physician's EHR — consistent with privacy laws
 - Hospital makes HIT and related services available to all medical staff physicians — but not necessarily at the same time — or varies by criteria relating to community health needs



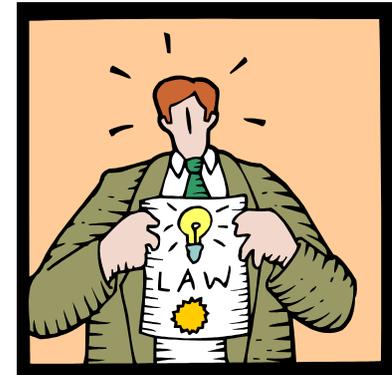
Things to Remember

- EHR rules do not preempt state law
- EHR rules expire December 31, 2013



Things to do to Prepare

- Establish a legal compliance plan
- Ensure future compatibility with existing systems
- Review contracts to verify consistency with EHR rules
 - Check existing and new licenses provide flexibility
 - Verify description/cost allocations
- Determine and track costs for purposes of physician contributions
- Streamline and systematize documentation
- Communicate



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