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8.05: Taking Advantage of the Anti-Kickback and Stark Law Exceptions for EHR Donations

National HIT Summit March 28-30, 2007, Washington DC

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AKS Background

- **Anti-kickback statute (AKS) and safe harbors**

    - **Knowing or willful offers, payments, solicitation to induce or reward the referral of business reimbursable by a federal health law program – an intent-based statute**

    - **Safe harbors describe arrangements that will not been deemed to violate the AKS, regardless of intent**

Stark Law Background

- **Stark law and exceptions**

  - **Stark law prohibits physicians from making referrals to an entity for certain designed health services (DHS) covered by the Medicare program if the physician has a financial relationship with the entity**

  - **Stark law exceptions describe financial relationships with entities to which physicians make referrals that will not violate the Stark law**

Overview of the Regulations

- **Permitted technology**
- **Minimum technology standards**
- **Permitted donors**
- **Permitted recipients**
- **Payment obligations**
- **Technology not duplicative**
- **Documentation**
- **No condition of future business between donor and recipient**

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Permitted Technology

- **Software necessary and used predominantly to create, maintain, transmit, or receive electronic health records**

- **EHR software MUST include e-prescribing component**

- **EHR donation cannot include hardware**

- **E-prescribing donation can include hardware**

"Create, Maintain, Transmit or Receive" EHRs

- **Interface and translation software**
- **IP related to EHR software**
- **Connectivity services (e.g., broadband and wireless internet services)**
- **Clinical support and information services related to patient care**
- **Maintenance services**
- **Secure messaging**
- **Training and support services**

"Necessary"

- **Necessary and used predominantly to create, maintain, transmit or receive electronic health records**

- **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,**

- **Provision of staff support is never "necessary"**

"Used Predominantly"

- **The core functionality of the technology must be the creation, maintenance, transmission, or receipt of individual patients' electronic health records**

- **Software packages can 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 can be included**

Standards with which Donated Technology Must Comply

- **Electronic health records software that is interoperable**

- **Certified software may be deemed interoperable under certain circumstances**

- **Electronic prescribing capability must comply with final standards for electronic prescribing adopted by the Secretary**

Interoperability

- "The software is interoperable at the time it is provided to the recipient. For purposes of this subparagraph, software is deemed to be interoperable if a certifying body recognized by the Secretary has certified the software within no more than 12 months prior to the date it is provided to the recipient."

Technology is evolving

- **The software should be as interoperable as feasible given the prevailing state of technology at the time the items or services are provided to the recipient**
- **How do we know what's feasible?**
  - **what's in the market**
  - **what vendors say they can do**
  - **what products actually can do**

Interoperability Concerns

- **No certification standards yet for specialty EHRs – "certification ready?"**

- **When does a donation occur? -- time lag between product selection and implementation**

- **Home grown systems**

- **Open source software**

- **Certified within the last 12 months**

- **Who can set the standard – it's a moving target**

Donors

- **Safe Harbors - 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 Exceptions - Entities that furnish designated health services (DHS) to any physician**

Selection of Recipients

- **Donors may not select recipients using any method that takes into account directly the volume or value of referrals from the recipient or other business generated between the parties**

Cost of Protected Technology

- **Recipients of e-prescribing technology do not have a co-payment obligation**

- **Recipients of EHR technology must pay at least 15% of the donor's cost for the donated technology**

- **The donor (or any affiliate) must not finance the recipient's payment or loan funds to the recipient for use by the recipient to pay for the technology**

Documentation

- **Prior to donation, must document donated technology and its cost to the donor, as well as the recipient's contributions**

- **Documentation is to take the form of an agreement to which the donor and the recipient are parties**

- **Documentation on of cost by vendors is not a required portion of the documentation, but it "may be a prudent business practice"**

- **A tax-exempt donor needs to satisfy itself that a particular donations is consistent with limitations on private benefit**

- **Donated technology may be taxable income to physicians in certain circumstances**

Things to Remember

- **AKS safe harbors and Stark exceptions do not pre-empt state law**
- **EHR rules expire December 31, 2013**

Things to do now

- **Establish a legal compliance plan**
- **Ensure future compatibility with existing systems – make certain existing and new licenses provide flexibility for EHR**
- **Determine and track costs for purposes of physician contributions**
- **Streamline and systematize documentation**
- **Communication**
  - **physicians and physician organizations**
  - **governance structure**
  - **philanthropic community**

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