

Selecting and Rolling Out an Ambulatory EMR to Community Physicians in the New Regulatory Framework

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Speakers have indicated that they have no relevant financial relationship to disclose

Introduction

Changing landscape for delivery of healthcare services

Industry intensely regulated

Information technology arrangements no exception

- Anti-Kickback Statute (OIG)
- Stark Law (CMS)

The playing field:

- Anti-Kickback Statute Safe Harbors
 - Final regulations issued August 1, 2006
- Stark Law Exceptions
 - Final regulations issued August 1, 2006

New Anti-Kickback Statute Safe Harbors/Stark Law Exceptions

Stark Law (Self Referral Prohibition)

Physician may not refer:

- Medicare or Medicaid patients
- for **designated health services**
- To an **entity** with which the physician or an immediate family member
- Has a **financial relationship**

Unless an **exception** applies

DHS entity prohibited from billing for services provided as a result of prohibited referral

Anti-Kickback Statute

- **Whoever** – anyone – hospital, physician, agent
- **Knowingly and willfully** - “One purpose” test - need not be the sole or primary purpose
- **Offers or pays** – Both sides to the arrangement
- **Any remuneration** (in cash or in kind)
 - Cash, cash equivalents
 - Free equipment
 - Technical support
- **To induce or reward** the **referral** of items or services reimbursed by Federal health care program
- Has committed a **felony**

Overview of New Regulations

Two new safe harbors under Anti-Kickback Statute, and two new exceptions to Stark Law

- E-Rx Safe Exception/Harbor

- Protects arrangements involving donation of hardware and software used solely for electronic prescribing

- EHR Safe Exception/Harbor

- Protect arrangements involving the donation of some IT, software and services to physicians and other designated providers, under certain conditions

- Rules effective October 10, 2006

- Provisions sunset on December 31, 2013

General Requirements for EHR Donation

- Permissible Donors

- Stark Exception

- Designated health services (DHS) entities
 - Non-DHS entities are not covered by Stark Law

- AKS Safe Harbor

- Individuals or entities that provide items or services covered by federal health care program and submit claims, or
 - Health Plans
 - Not IT, Pharma or device vendors

- Permissible Recipients

- Physicians or other health care providers
 - Not IPAs or MSOs

General Requirements for EHR Donation (cont'd)

EHR software, IT and training services:

- Necessary and used predominantly to create, maintain, transmit or receive EHRs
 - "Necessary" – recipient must not already possess equivalent software or services
 - Donor must not have any actual knowledge, or act in reckless disregard or deliberate ignorance of, a recipient's possession of technology that is functionally or technically equivalent to that being donated
- "Electronic Health Record" (EHR) defined:
 - A repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions

General Requirements for EHR Donation (cont'd)

- Items & services donated:
 - Include software and training services (not money or hardware)
 - Software must:
 - Be “interoperable”
 - Contain electronic prescribing capability
- Additional Recipient Requirements
 - Recipient does not make receipt of technology a condition of doing business with donor
 - Recipient pays 15% of donor’s cost of the technology before receiving the technology

General Requirements for EHR Donation (cont'd)

- Additional Donor Requirements
 - Donor does not limit the IT's interoperability or compatibility with other EHR systems
 - Donor does not finance or loan funds to the recipient to pay for technology
 - Donor does not restrict recipient's ability to use technology for any patient without regard to payor status
- The arrangement is set out in a written agreement that meets certain requirements

Permissible “Items and Services”

- Software with core functionality of creating, maintaining, transmitting or receiving EHR
- Software with other functionality directly related to individual patient care and treatment (e.g., registration, scheduling, billing, clinical support software, etc.)
- Interface and translation software
- “Patient portal” software
- Secure messaging
- Upgrades/enhancements to existing technology
 - To enhance functionality
 - To make IT more current or user friendly
- Items and services needed to standardize systems among donors and recipients (if standardization enhances the EHR functionality)

Permissible “Items and Services” (cont’d)

- Connectivity services (including broadband and wireless internet services)
- Clinical support and information services related to patient care
- Maintenance services
- Training and support services
- Data migration services
 - But, not through the provision of staff to the recipients

Permissible “Items and Services” (cont’d)

- Rights, licenses and intellectual property related to EHR software
- Application service provider (ASP) models under which a physician receives access to computer-based EHR services over a network

Non-Donatable “Items and Services”

- Money
- Reimbursement for previously-purchased items and services
- Software with core functionality other than EHR (e.g., HR or payroll software)
- Hardware
 - Equipment
 - Operating Software that makes the hardware function
 - Storage devices
 - Modems, routers or hubs used for connectivity
- Hardware support
- Technology that is “duplicative” of technology currently possessed by recipient

Non-Donatable “Items and Services” (cont’d)

- Support and information services unrelated to EHR or patient care (e.g., research or marketing support services)
- Provision of staff (e.g., to migrate data from paper to electronic records)
- Items and services used primarily to conduct personal business or business unrelated to the physician’s medical practice

Interoperability

EHR technology must be interoperable at the time provided to the recipient

■ “Interoperable” -- Software must be able to:

- Communicate and exchange data accurately, effectively, securely and consistently with different IT systems, software applications, and networks, in various settings, and
- Exchange data such that the clinical and operational purpose and meaning of the data are preserved and unaltered

■ Donor must not take any action to limit or restrict the use, compatibility or interoperability of the items or services with other Rx or EHR systems

Interoperability (cont'd)

Rules acknowledge that technology will evolve

- Standard of interoperability – whether feasible given the prevailing state of technology at the time provided to the physician
- May be “deemed” interoperable if certified by recognized body
 - Software must have an up-to-date certification at the time of donation
 - Must have been certified within 12 months prior to the date of donation
 - HHS has recognized CCHIT as a certification body

Selecting Recipients

- Donors may use any method for selecting recipients, provided that the method does not *directly* take into account the volume or value of referrals or other business between the parties

Selecting Recipients (cont'd)

Acceptable criteria for selection of recipients include (without limitation):

- Total number of Rx's written by physician
- Size of practice
- Total number of hours that physician practices medicine
- Physician's overall use of automated technology in practice
- Medical staff membership

Payment for Technology

- Recipient must pay at least 15% of donor's cost for the items or services
 - Also applies to related services, such as training, help-desk and maintenance
- Payment must be made before receipt of items or services
- Donor may not finance recipient's payment or lend funds to recipient for payment for such items
- Must apply consistently to all recipients

Documentation

- Must document EHR arrangement with written agreement between donor and recipient
- Documentation must be made prior to the donation
- Documentation must:
 - Describe the donated technology (items and/or services)
 - Indicate donor's costs
 - Describe and confirm recipient's contributions

Documentation (cont'd)

Documentation may also contain representations by the parties that:

- Software's interoperability has not been restricted
- Donation is not a condition of doing business
- Donation is not based on volume or value of referrals
- Physician does not possess equivalent software or services
- Physician has not received any loans from donor to finance physician's cost-sharing obligation