

Legal Barriers to the Adoption of Health Information Technology: Fraud and Abuse

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Accelerating HCIT Adoption by Physician

- **Many barriers to Physician Adoption**
 - **Generational**
 - **Changing technology**
 - **Lack of Interoperability**
 - **Cost of hardware, software, connectivity, training (Approx \$20,000/physician).**

Accelerating HCIT Adoption by Physician

- **Many Hospitals/IDNs want to Wire Their Non-Staff Physicians by Providing Them with:**
 - **Office Systems**
 - **Handheld Devices**
- **Fraud & Abuse Laws Stand in the Way**

Fraud & Abuse Fundamentals

- **Anti-Kickback Act**
- **The Stark Law**
- **The False Claims Act**

The Anti-Kickback Act

- 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.

The Stark Law

- Prohibits a physician from referring Medicare 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.

Penalties

- Both the AKA and Stark have major penalties.
- AKA – criminal and civil penalties and exclusion
- Stark – civil penalties and exclusion

Fraud & Abuse Barriers to Health Care IT

- Provision of HCIT by hospital to physicians at less than “fair market value” = remuneration per AKA.
- If physicians refer to the hospital, then remuneration could be “inducement”.
- Also, Stark is violated if physician refers to the hospital since device is a financial relationship.

Fraud & Abuse Barriers to Health Care IT

- Both hospital and physician would be implicated by example under AKA and Stark.
- OIG and CMS concern is that receipt of HCIT by physician from hospital will unduly influence referrals.

New Stark Regs Address HCIT

- Stark Phase II regs published in March, effective July 26, 2004.
- Creates Stark exception for hospitals to provide HCIT to physicians in a “Community-Wide Health Information Systems”.

New Stark Regs Address HCIT

- **Exception requires:**
 - **Community Wide**
 - **Available to all providers, practitioners and residents.**
 - **Afford access to EMRs, and sharing of medical information and alerts.**
 - **Must continue to comply with AKA.**

New Stark Regs Address HCIT

- **New Community Wide HIS exception: a non-starter.**
- **No such community anywhere.**
- **Precludes development.**
- **Lack of an AKA safe harbor makes Stark exception impossible to meet.**
- **GAO Report Finds F&A laws are barrier to HCIT dissemination.**

Removing the F&A Barrier to HCIT

- New Stark Regs may be revised.
- Secretary to issue new eRx regs which may provide new F&A policy.
- Interoperability may make issue go away.
- Defining “fair market value” – market cost or marginal cost?

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