

Stark & Anti-Kickback Impact on EHR Adoption

HIMSS Advocacy Day

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Existing Physician Self-Referral Law (Stark II)

- Prohibits physicians from making certain referrals to an entity for designated health services if physician (or an immediate family member) has a financial relationship (i.e., ownership interest in or receives compensation from) with the entity; and
- Prohibits entities from billing for any services resulting from such referrals, **unless** an exception applies

Stark (cont'd)

- Impedes adoption of HIT by discouraging providers from supplying physicians with hardware, software or other resources
- Subsequent referrals by physician may be viewed as Stark violation
- Violations may result in:
 - Return of payments
 - Exclusion from participation in federal health care programs
 - Civil penalties

Existing Federal Anti-Kickback Law

- Prohibits an individual or entity from knowingly and willfully offering or accepting remuneration of any kind to induce a patient referral or purchase of an item or service covered by any federal health care program
- Discourages physicians from accepting IT resources from providers, since it may be construed as unlawful remuneration

Anti-Kickback Law (cont'd)

- Violations may result in:
 - Civil or criminal fines, penalties & imprisonment
 - Exclusion from participation in federal health care programs
- State self-referral and anti-kickback laws present similar concerns for providers and typically have fewer or more limited exceptions

Legal Issues – Fraud & Abuse

- Various statutory and regulatory exceptions to both Stark & Anti-Kickback law -- complex/ambiguous
- Existing Stark exceptions – of limited usefulness in forming a RHIO
 - Non Monetary Compensation up to \$300
 - Medical Staff Incidental Benefits
 - Payments at Fair Market Value
 - Commercially Reasonable Equipment Rental

Proposed New Rules for E-Prescribing & EHR

- Medicare Prescription Drug Act of 2003 required HHS to establish additional exceptions to promote E-prescribing
- Published on 10/11/05 in Federal Register by HHS Office of Inspector General (“OIG”) and Administrator of Centers for Medicare and Medicaid Services (“CMS”)
- Intended to permit hospitals, group practices, prescription drug plan sponsors & Medicare Advantage organizations to provide physicians with technology for e-prescribing and interoperable electronic health records (“EHR”) without violating Federal Anti-Kickback statute or Stark II

e-Rx Limitations

- Limited to specified “Donors” (hospitals, PDPs, MA plans & medical groups)
- For Anti-Kickback, “Recipients” limited to hospital medical staff, prescribers & pharmacies & medical group members
- For Stark, “Recipients” limited to physicians & their staff
- Permissible technology includes computer hardware, software, training & Internet access
- Technology must be used “only” (or “substantially”) for e-prescribing
- Technology must be something that the Recipient does not already have

Electronic Health Records

- CMS and OIG took different approaches
- CMS proposed two Stark exceptions, based upon when donation of items & services occurs
 - Prior to future HHS adoption of certification standards (pre- interoperability EHR exception)
 - After certification standards are adopted (post- interoperability EHR exception)
- OIG only outlined proposed “pre-interoperability” safe harbor with similar elements to CMS’ exceptions

EHR (cont'd)

- Certification Commission for Healthcare Information Technology (CCHIT) Conference Call on March 9, 2006
- Released Pilot Test Results and Plans for Commercial Certification
- First round of certification results due July 2006
- Public Comment period ended March 31, 2006
- For final proposed Ambulatory EHR criteria & inspection process, pilot test results and new Inpatient EHR focus areas – see: <http://www.cchit.org/publiccomment4.htm>

EHR (cont'd)

- Stark exceptions comparable to e-Rx requirements
 - Limited to software & direct training services, but *not* billing, scheduling or general office management functions
 - Prohibits donation of hardware or equipment
- Additional requirements for post-interoperability EHR exception:
 - Prohibits office staffing services; items/services unrelated to medical practice
 - All donated technology must be certified per HHS criteria
 - Donor may consider certain economic criteria

Problems with Proposed Regs

- Proposed regulations are still far too restrictive to permit widespread expansion of EHRs & RHIOs
 - Hospitals cannot donate to non-medical staff physicians
 - Group practices cannot donate to non-group member physicians
 - Donations do not permit costs of implementation and support/maintenance to be included
 - Post-acute care providers (nursing homes, home health agencies) omitted entirely

Conclusions

- Work within available exceptions, if possible
- Establish independent third party funding source (e.g., private foundation, community-based entity)
- Seek advisory opinion from HHS
- Be inclusive rather than exclusive
- Await further clarifications of existing rules & regulations

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