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](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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