

HEALTH INFORMATION TECHNOLOGY SUMMIT
OCTOBER 23, 2004

**COMMUNITY-BASED COLLABORATIONS:
LEGAL ISSUES:
STARK, FRAUD & ABUSE**

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Restrictions on Referrals

- ❖ Federal law prohibits referrals among providers that have tainted financial relationships
- ❖ Any arrangement that confers an economic benefit may trigger these prohibitions, including providing information technology
- ❖ A legitimate business purpose is not a defense

Restrictions on Referrals

- ❖ A provider that receives a prohibited referral and obtains payment for services may be subject to:
 - Recoupment
 - Civil money penalties
 - Treble damages under the False Claims Act
 - A vacation at government expense

Restrictions on Referrals

- ❖ The prohibitions extend to all referrals between providers who have a tainted relationship (or all referrals for certain services, e.g., hospital services)
- ❖ Violations are vigorously prosecuted by the HHS OIG, the DOJ, and private whistleblowers

Restrictions on Referrals

- ❖ The prohibitions include:
 - Federal and state anti-kickback statutes
 - The federal “Stark Law” and state equivalents
 - The federal False Claims Act
 - Covers not just false claims, but also claims tainted by the first two
- ❖ These are notoriously difficult laws

Exceptions

- ❖ Fair market value
 - This would not permit hospitals or pharmaceutical companies to subsidize HIT for physicians
- ❖ Some other specific exception

Community-Wide Health Networks

- ❖ Stark has an exception for IT provided to a physician to participate in a community-wide health network, if the technology--
 - Is needed by the physician to participate
 - Is used principally for participation in the network
 - Is available to all willing providers and residents, without regard to referrals
 - Is not intended to induce referrals

Community-Wide Health Networks

- ❖ A community-wide health network allows access to and sharing of electronic health records and related drug information systems
- ❖ May also have related and general health information, medical alerts, etc.
- ❖ Must be to enhance the community's overall health

Other Stark Exceptions

- ❖ Medical staff incidental benefits
 - Can be used only to access hospital systems
 - Must be of small value (\$25 per occurrence)
- ❖ Non-monetary compensation
 - Items or services not exceeding \$300 annually

E-Prescribing – MMA of 2003

- ❖ Anti-kickback safe harbor and Stark exception for providing information technology to physicians for e-prescribing by
 - Hospitals for their medical staffs
 - Group practices for their members
 - PDP sponsors and Medical Advantage organizations for participating pharmacists and prescribers

E-Prescribing – MMA of 2003

- ❖ Federally mandated standards for electronic prescriptions for Medicare enrollees
- ❖ Would preempt state law
- ❖ Implementation Schedule:
 - Proposed standards by September 1, 2005
 - Pilot projects during 2006
 - Final standards by April 1, 2008

E-Prescribing – MMA of 2003

- ❖ Electronic transmittal between prescriber and dispensing pharmacist of information on –
 - The prescription
 - Eligibility and benefits, including formulary
 - Drug information (interactions, warnings)
 - Lower-cost alternatives
 - In time, related medical history

National Health Information Infrastructure

- ❖ One of the incentives that the NHII will provide for adoption of EHRs is to explore additional safe harbors and exceptions that will allow provision of in-kind technology and support without creating inappropriate conflicts of interest or potential for abuse