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Legal Issues in Health Information Technology Acquisition, Implementation and Cooperation

Wednesday October 20,2005

The Health Information Technology Summit

Keith M. Korenchuk

McGuireWoods LLP

100 North Tryon Street, Suite 2900

Charlotte, NC 28202-4011

Direct Dial: 704.373.8860   Fax: 704.373.8935

email: kkorenchuk@mcguirewoods.com

www.mcguirewoods.com

GAO Report on HHS Efforts to Promote HIT and Barriers to Adoption

Scope and Methodology of GAO Report

- HHS identified its major activities in this area, reviewed agency documents, and interviewed relevant HHS officials

- Focused on health IT used in clinical health care delivery (electronic health records (EHR))

- Work from May 2004 through August 2004

Benefits of Health IT

- In a previous study, GAO found examples of reported cost savings or other benefits in 20 health IT initiatives across the United States
- There are still significant barriers to its adoption

Financial, Technical, and Cultural Barriers to the Adoption of Health IT

- Financial Barriers
  - Inability to access high-quality IT services at affordable prices
  - Need for greater access to capital
  - Inability to provide evidence of return on investment
- Technical Barriers
  - Complex and lengthy implementation processes
  - Lack of uniform standards for data submission and reporting
  - Inability to sufficiently integrate and incorporate changes to business processes

Financial, Technical, and Cultural Barriers to the Adoption of Health IT
(continued)

- ## Cultural Barriers
  - Need for a better understanding of best practices for IT adoption
  - Lack of leadership support from the public and private sectors
  - Resistance by health care providers

Overview of HHS's Major Health IT Initiatives

- HHS reported 19 major health IT initiatives in operating divisions across the department.

- The majority of initiatives, and most of the funding, are for programmatic activities and grant programs. These initiatives range from support for standards development to demonstrations of interoperable health information systems.

Various Laws Present Barriers to Adoption of Health IT

- These laws involve:
  - Fraud and abuse
  - Antitrust
  - Federal income tax
  - Intellectual property
  - Liability/malpractice
  - State licensing

Various Laws Present Barriers to Adoption of Health IT (continued)

- These laws frequently do not address health IT arrangements directly. Health care providers are reluctant to take action and make significant investments in health IT.

Physician Self-Referral (Stark) Law

- The law presents a barrier by impeding the establishment of arrangements that promote the adoption of health IT. Specifically, because many physicians find health IT cost-prohibitive, hospitals or other providers are sometimes willing to provide physicians with hardware, software, or other resources. Parties have been reluctant to establish such arrangements, however, out of concern that if the physician subsequently makes a referral to that provider, they may be viewed as having violated the law.

Anti-Kickback Law

- Like the self-referral law, it presents a barrier by impeding the establishment of certain arrangements that promote the adoption of health IT. Physicians may be reluctant to accept IT resources from a hospital or other provider, knowing that the resources may be viewed as remuneration and that any referrals the physician subsequently makes to the provider may be viewed as having been made in return for such resources in violation of the law.

Antitrust

- Some experts are concerned that certain arrangements that may promote the adoption of health IT may be viewed as anticompetitive and thereby violate antitrust laws.

- The Department of Justice states that to the extent that the benefits of such arrangements can be shown to outweigh any anticompetitive impact, they are not likely to violate federal antitrust laws.

Antitrust (continued)

- Given the uncertainty about the impact of health IT arrangements on competition and what constitutes a violation, antitrust laws still present a barrier to the adoption of health IT.

Federal Income Tax

- Private Inurement/Benefit
  - Tax-exempt organizations that provide financial or other benefits to private individuals may jeopardize their tax-exempt status. Some experts are concerned that the provision of IT resources by tax-exempt hospitals to physicians may be viewed as providing just such benefits to private individuals.

Federal Income Tax (continued)

- Unrelated Business Income
  - Tax-exempt organizations that generate income from business activities not substantially related to the role that qualified them for tax-exempt status must pay income tax on that income. Some experts are concerned that any charges tax-exempt hospitals impose on others for using IT resources that the hospitals have financed and developed may be taxable.

Intellectual Property

- Copyright Protection
  - Hospitals and other entities that are investing (or considering investing) significant financial resources in the development of health IT systems are concerned that copyright protections applicable to such systems may be inadequate to prevent unauthorized use and they will be unable, as a result, to recoup their investments.

Liability/Malpractice

- Some physicians are concerned that the more information they have access to through health IT, the more information they will be held responsible for knowing and that this will increase their risk of being held liable for malpractice.

- Physicians are generally responsible, however, for obtaining relevant information from patients to provide proper treatment, and the adoption of health IT may make it easier for physicians to obtain all relevant information and provide better care, which may reduce the risk of malpractice.

　
State Licensing

- Physicians generally must be licensed to practice medicine in any state in which they practice, and state licensing requirements vary from state to state. If physicians provide medical advice electronically or engage in telemedicine across state boundaries, there is concern that they may be viewed as practicing medicine in a state where they are not licensed to do so.

Stark Exception: Community-Wide Health Information Systems

- Exception for items or services of information technology provided by an entity to a physician that allow access to, and sharing of, electronic health care records and any complementary drug information systems, general health information, medical alerts, and related information for patients served by community providers and practitioners, in order to enhance the community's overall health, provided that:

Stark Exception: Community-Wide Health Information Systems (continued)

1. The items or services are available as necessary to enable the physician to participate in a community-wide health information system, are principally used by the physician as part of the community-wide health information system, and are not provided to the physician in any manner that takes into account the volume or value of referrals or other business generated by the physician;

Stark Exception: Community-Wide Health Information Systems (continued)

2. The community-wide health information systems are available to all providers, practitioners, and residents of the community who desire to participate; and

3. The arrangement does not violate the anti-kickback statute, or any Federal or State law or regulation governing billing or claims submission.