

NINTH NATIONAL HIPAA SUMMIT
SEPTEMBER 13, 2004

**ELECTRONIC HEALTH RECORDS/NATIONAL
HEALTH INFORMATION INFRASTRUCTURE:
LEGAL ISSUES IN HIPAA AND EMERGING
TECHNOLOGIES**

Paul T. Smith, Esq.
Partner, Davis Wright Tremaine LLP
One Embarcadero Center, Suite 600
San Francisco, CA 94111
415.276.6532
paulsmith@dwt.com

HIPAA

- ❖ Health information privacy standards – April, 2003
- ❖ Electronic transaction standards – October, 2003
- ❖ National employer identifiers – July, 2004
- ❖ Electronic health information security standards – April, 2005
- ❖ National provider identifiers – May, 2007
- ❖ National individual identifiers – on hold

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

E-Prescribing – MMA of 2003

- ❖ Anti-kickback safe harbor and Stark exception for providing information technology to physicians for e-prescribing

Stark II, Phase II

- ❖ Stark prohibits referrals for Medicare-covered hospital and other services among providers that have financial relationships
- ❖ Regulations published March 2004 create exception for IT provided for community-wide health information systems providing access to and sharing of EHRs
- ❖ IT must be necessary for participation, and used primarily for participation
- ❖ Participation must be available to any provider, practitioner or individual who wished to participate

Consolidated Health Informatics

- ❖ Part of the President's E-Government Initiative
- ❖ Initiative to establish clinical vocabularies and messaging standards for interoperability among federal agencies sharing health information
- ❖ Applies only to federal agencies, but influential
- ❖ Over 20 participating agencies - chiefly HHS, VA and DOD

Consolidated Health Informatics

- ❖ Adopted 20 standards to date, including--
 - HL7 messaging standards
 - NCPDP drug ordering standards
 - HIPAA electronic transaction standards
 - Clinical terminology - SNOMED-CT and RxNorm
 - Other standards for, e.g. -
 - Digital imaging communication
 - Medical device interfaces
- ❖ Read all about it at www.egov.gov

SNOMED-CT

- ❖ College of American Pathologists' Systematized Nomenclature of Medicine Clinical Terms
- ❖ Most comprehensive medical terminology available
- ❖ HHS has entered into agreement with CAP to make the terminology available to U.S. users without cost
- ❖ Cornerstone of electronic health record

Other Initiatives

- ❖ HL7 Draft Standard for a Functional Model for EHR
- ❖ HHS Agency for Health Care Policy and Research (AHCPR) will fund state-level health information sharing projects
- ❖ Foundation for eHealth Initiative's Connecting Communities for Better Health program, funded by HHS, awarded \$2 million in funding to nine community EHR collaboratives

National Health Information Infrastructure

- ❖ Executive Order 1335, April, 2004—
 - Called for widespread adoption of interoperable EHRs within 10 years
 - Created position of National Coordinator for Health Information Technology
 - National Coordinator issued a Framework for Strategic Action issued July 21, 2004
 - Consists of 4 goals, each with 3 strategies

Goals of the NHII

❖ Informing Clinical Practice

➤ Promoting use of EHRs by

- Incentivizing EHR adoption
- Reducing the risk of EHR investment

Goals of the NHII

- ❖ Interconnecting clinicians by creating interoperability through
 - Regional health information exchanges
 - National health information infrastructure
 - Coordinating federal health information systems

Goals of the NHII

❖ Personalizing care

- Promotion of personal health records
- Enhancing consumer choice by providing information about institutions and clinicians
- Promoting tele-health in rural and underserved areas

Goals of the NHII

- ❖ Improving population health
 - Unifying public health surveillance
 - Streamlining quality of care monitoring
 - Accelerating research and dissemination of evidence

National Health Information Infrastructure

- ❖ NHII will consist of standards and technology for--
 - EHR interoperability
 - Mobile authentication
 - Web services architecture
 - Security technologies
- ❖ Based on standards developed by privately financed consortiums facilitated by HHS

National Health Information Infrastructure

❖ Incentives

- Regional grants and contracts for EHR collaboratives
- Improving access to low-interest loans
- Updating anti-kickback and Stark restrictions
- Medicare reimbursement for use of EHRs
- Medicare pay-for-performance

Health Information Privacy & Security

- ❖ Three phases of implementation
 - Foster development of market institutions
 - Organizations for certification, group purchasing, implementation support
 - Investment in infrastructure
 - Transition to quality and performance accountability

National Health Information Infrastructure

❖ Key planned actions:

- Establish Health Information Technology Leadership Panel to recommend priorities for federal action
- Foster private sector certification of HIT for functionality, interoperability and security
- Funding community health information exchange demonstration projects
- Establish a private sector consortium to plan, develop and operate a health information network
- Establish a Medicare beneficiary Internet portal

Implications

- ❖ Technology
- ❖ Funding
- ❖ Public health
- ❖ Research
- ❖ Providers
- ❖ Consumers

Health Information Privacy & Security

- ❖ Much depends on the model
 - Consumer controlled
 - Central database
 - Napster model

Health Information Privacy & Security

❖ Uniformity of privacy laws

- HIPAA does not pre-empt more stringent state laws, i.e., state laws that provide:
 - Greater privacy protection
 - Stronger consumer rights
- Does the NHII require a truly national standard?

Health Information Privacy & Security

- ❖ Access to health information by providers
 - Unrestricted under HIPAA
 - Promotes quality
 - Reduces the individual's control over health information

Health Information Privacy & Security

- ❖ Access to health information by payers
 - Restricted to minimum necessary under HIPAA
 - Expedites claims adjudication and payment
 - Potentially affects insurability

Health Information Privacy & Security

- ❖ Access to health information by consumers
- ❖ Unrestricted under HIPAA
- ❖ NHII contemplates a personal health record
 - Assists health care management
 - Promotes informed health care choices
 - Can sometimes be harmful

Health Information Privacy & Security

❖ Ownership of EHR

- Provider and payer-owned today; individuals have limited rights
- NHII—
 - Anticipates a personal health record
 - Has a strong theme of consumer ownership
- What rights should the consumer have to—
 - Control data in the NHII?
 - Control access to that data?

Health Information Privacy & Security

❖ Secondary uses of health information

- NHII will benefit public health and research
- Secondary users are not covered under HIPAA
- Who should be the gate-keeper?
- Should there be a comprehensive privacy and security rule for the NHII?

Health Information Privacy & Security

- ❖ Secondary uses of health information
 - What secondary uses should be permitted?
 - Public health surveillance
 - Quality monitoring
 - Research
 - What level of de-identification/aggregation is appropriate for these uses?
 - Who should decide what uses are permitted?
 - Should this information be made available to consumers?

Health Information Privacy & Security

❖ Information Security

- Consumer confidence is an issue
- Standards will likely need to be more prescriptive than HIPAA standards

Health Information Privacy & Security

❖ Access restrictions

- Clearly defined
- Authentication with non-repudiation
- Technical restrictions on use
- Audit trails
- Enforcement

Health Information Privacy & Security

- ❖ Accurate identification of consumers
 - National identifier vs voluntary, consumer-controlled, identifier