

THE TENTH NATIONAL HIPPA SUMMIT

ELECTRONIC HEALTH RECORDS NATIONAL HEALTH INFORMATION INFRASTRUCTURE LEGAL ISSUES

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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
 - ONCHIT 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

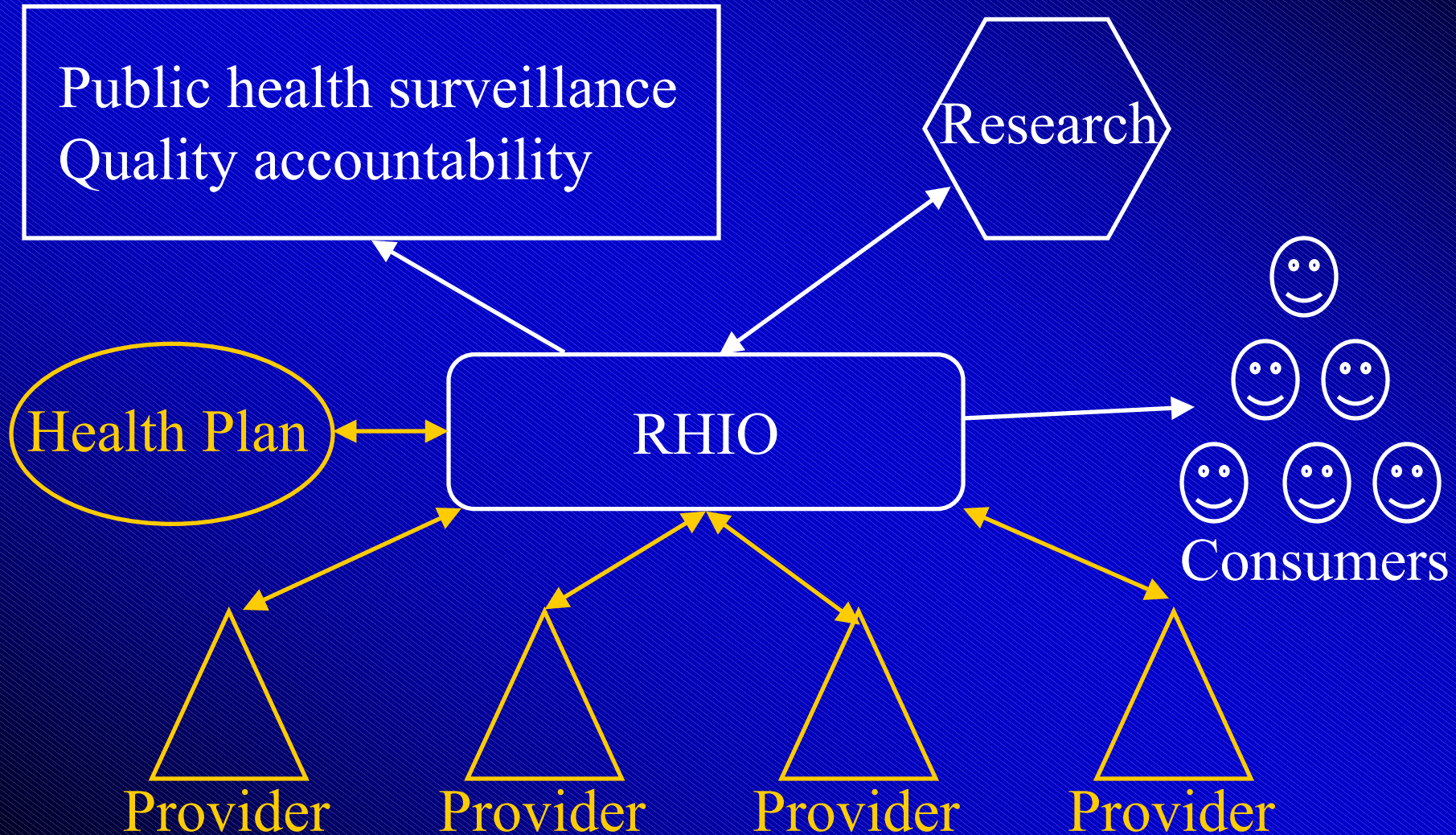
❖ Incentives

- 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

Regional Health Information Organizations

- ❖ State and local health information exchange projects
- ❖ Seed funding through
 - HHS Agency for Health Care Policy and Research (AHCPR)
 - Foundation for eHealth Initiative's Connecting Communities for Better Health program

Regional Health Information Organization



Consumer Control

- ❖ NHII—

- “Consumer-centric”

- Includes a personal health record

- Has a strong theme of consumer “ownership”

- ❖ Consumer consent not required for inclusion in RHIO by provider, as long as there are

- Appropriate safeguards

- Restrictions on use and disclosure

Consumer Control

- ❖ Many advocate an “opt-in” model
- ❖ What rights should the consumer have to—
 - Control data going into the NHII?
 - Control access to that data?
 - HIPAA does not differentiate
- ❖ What are the implications for providers?

What is the privacy rule?

Covered by HIPAA:

- ❖ Health care providers
- ❖ Health plans

Not Covered:

- ❖ Public health authorities
- ❖ Health care regulatory authorities
- ❖ Researchers
- ❖ The RHIO itself

Does the NHII need a uniform privacy standard?

Policing the RHIO

- ❖ Not directly regulated
- ❖ Covered entities disclosing health information are required to obtain & enforce contractual assurances that the RHIO will--
 - Safeguard the data (security)
 - Restrict uses and disclosures to those permitted to the covered entity (privacy)
 - Return or destroy the data on termination, if feasible

Policing the RHIO

- ❖ A covered entity is liable for breaches by business associate if the covered entity--
 - Learns of a pattern or practice of violations, and
 - Fails to take reasonable and appropriate remedial measures
- ❖ Weak standard

Regulating Secondary Uses

- ❖ Health care oversight and regulatory agencies
 - As permitted by state or federal law
- ❖ Law enforcement
 - As permitted by state or federal law
 - HIPAA allows administrative requests
- ❖ Researchers
 - Non-identifying information, or
 - Identifying information with individual authorization
 - Authorization can be “waived” by IRC or privacy committee

Security in a RHIO

Covered entities must maintain *reasonable and appropriate* administrative, technical and physical safeguards—

- ❖ To ensure confidentiality and integrity of information
- ❖ To protect against reasonably anticipated--
 - threats to security or integrity
 - unauthorized uses or disclosures

Security in a RHIO

- ❖ Basic requirements with implementation features
- ❖ Technology neutral, flexible and scalable
- ❖ To be implemented in a manner that best suits the entity's needs, circumstances and resources, taking into account
 - Size, complexity and capabilities
 - Technical infrastructure and capabilities
 - Cost of security measures
 - Potential risks to health information

Security in a RHIO

- ❖ Standards with implementation features:
 - Standard: access control
 - Implementation feature: Unique user identification (password, PIN, biometric)

Security in a RHIO

Implementation features are either—

- ❖ Required—must be implemented
 - e.g., unique user identification
- ❖ Addressable
 - Must be implemented if reasonable and appropriate; otherwise alternative measure must be implemented
 - e.g., encryption

Security in a RHIO

What is missing?

- ❖ Clearly defined, uniform security requirements
- ❖ Access restrictions
 - Authentication with non-repudiation
- ❖ Technical restrictions on use
- ❖ Audit trails
- ❖ Enforcement

E-Prescribing – MMA of 2003

- ❖ Federally mandated standards for electronic prescriptions for Medicare enrollees
- ❖ Would preempt state law
- ❖ Implementation Schedule:
 - Proposed standards issued February 4, 2005
 - Compliance date January 1, 2006
 - Additional standards by April 1, 2008

E-Prescribing – MMA of 2003

E-Prescribing will—

- ❖ Improve quality by reducing errors resulting from
 - Bad handwriting
 - Drug interactions and allergies
- ❖ Provide current drug information to inform choices
- ❖ Promote the use of lower-cost alternatives

E-Prescribing – MMA of 2003

- ❖ Electronic transmittal between prescriber and dispensing pharmacist of information on –
 - The prescription
 - Eligibility and benefits
 - Formulary information, including lower-cost alternatives

E-Prescribing – MMA of 2003

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

Email

- ❖ It's here
 - AMA supports use
 - Some payers reimburse email consultations
- ❖ Security issues
 - Lack of encryption
 - Impersonation & other problems
- ❖ Appropriate use
- ❖ Integration into the health record