PHARMACEUTICAL REGULATORY &
COMPLIANCE CONGRESS

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Legal Issues in Health Information Technology Implementation for Pharmaceutical Enterprises

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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
- Adopted 20 standards to date.

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

Commission on Systemic Interoperability

- Members named October, 2004
- Established under MMA to develop a strategy and timeline for implementing health care information technology standards.
- Standards will serve as the foundation for establishing a system of universal health records.
- Report due October 31, 2005

Other Initiatives

- Clinical Data Interchange Standards Consortium (CDISC) standards --
  - Clinical trials data
  - Data submission
- HL7—
  - Draft Standard for a Functional Model for EHR
    - Outreach Committee for Clinical Research
  - Regulated Clinical Research Information Management (RCRIM) committee
    - Cross-organization clinical research information management

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 July, 2004

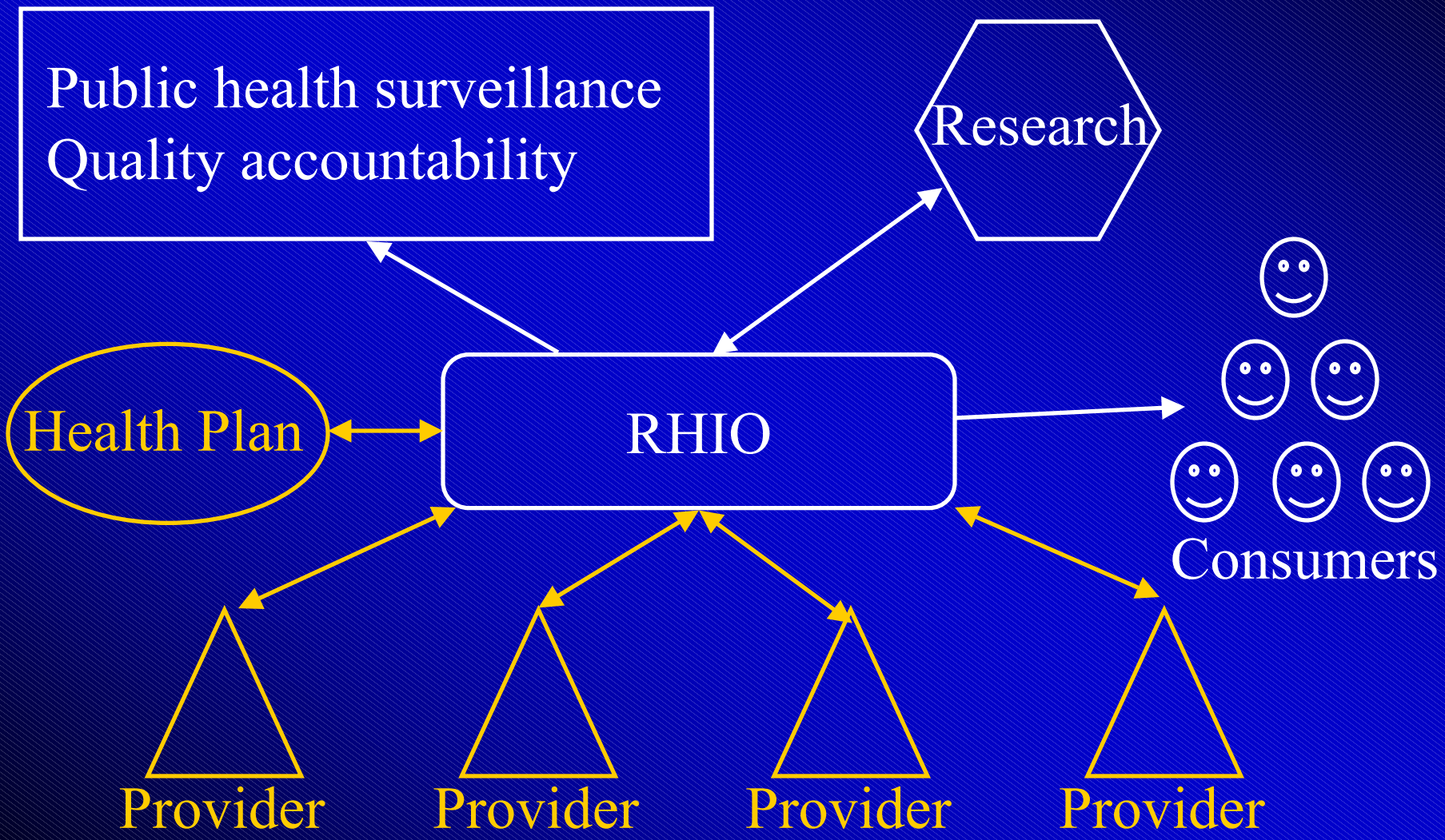
Goals of the NHII

- Promote use of EHRs by clinicians
- Create interoperability through regional and national health information exchanges
- Personalize care through personal health records and providing quality data
- Improve population health through public health surveillance, monitoring quality of care, and accelerating research and dissemination of information.

National Health Information Infrastructure

- 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

Regional Health Information Organization



E-Prescribing – MMA of 2003

- Directive to NCVHS to recommend initial standards – Work Plan "finalized" August 2004; first draft presented to HHS September 2004; testimony to be completed January 2005; full committee meeting to approve final recommendations March 2005

- Standards to include per MMA –
  - The prescription
  - Eligibility and benefits, including formulary, prior authorization
  - Drug information (interactions, warnings, dosage checks—weight, age)
  - Lower-cost alternatives
  - In time, related medical history

E-Prescribing – MMA of 2003

- NCVMS Additional Requirements
  - Not present an undue burden on prescribers or pharmacies
  - Be compatible with other standards
  - Permit electronic exchange of drug labeling and drug listing information
  - Permit patient designation of dispensing pharmacy
  - Provisions for e-signature

E-Prescribing – MMA of 2003

- NCVHS Approach
  - Go beyond recommendations for e-prescribing
  - Identify implementation issues that should be addressed before 2006 pilots
  - Interact regularly with HHS
  - Address certain standards now, propose a foundation to build upon

E-Prescribing – MMA of 2003

- Topics addressed
  - Compatibility with other standards
  - Standards versioning
  - Standard script (NCPDP)
  - Prescription messaging (NCPCP/HL7)
  - Formulary messaging (RxHub)
  - Eligibility and Benefits Messaging (ASC X12N 270/271)
  - Prior authorization (ASC X12N 278)

E-Prescribing – MMA of 2003

- Medication history (to be developed)
- Clinic drug terminology (collaboration required)
- Structured and codified SIGs (encouraged)
- Dispenser identifier (NCPCP – NPI)
- Prescriber identifier (NPI)
- Pilot test objectives (start now)
- HHS support for standards collaboration
- Regulation to eliminate commercial bias, patient choice
- Conformance testing (certification)

E-Prescribing: Implications of anti-fraud/abuse, Stark laws

- 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
- These prohibitions can interfere with the MMA's e-prescribing initiative

E-Prescribing: Implications of anti-fraud/abuse, Stark laws

- The prohibitions include:
  - Federal and state anti-kickback statutes
  - The federal "Stark Law" and state equivalents
  - The federal False Claims Act
- 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

E-Prescribing: Implications of anti-fraud/abuse, Stark laws

- MMA orders the Secretary of HHS to promulgate regulations to eliminate anti-fraud/abuse and Stark exposure
  - for provision of "nonmonetary remuneration" necessary and used solely to receive and transmit electronic prescription information in accordance with the HHS standards
  - Applies to
    - Hospitals for their medical staffs
    - Group practices for their members
    - PDP sponsors and Medical Advantage organizations for participating pharmacists and prescribers (not a problem to begin with; covered by Section 102 of the MMA)

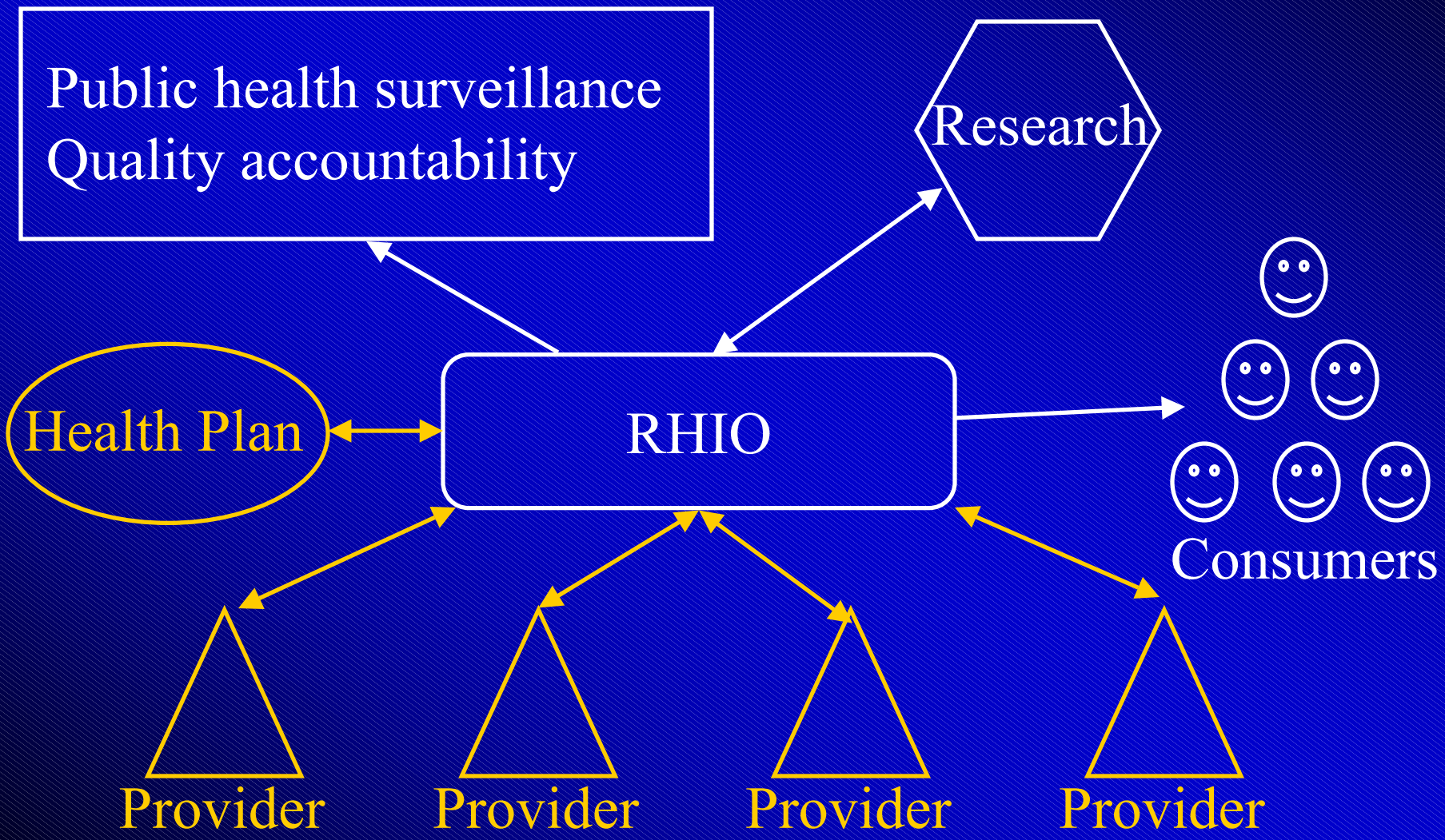
E-Prescribing: Implications of anti-fraud/abuse, Stark laws

- What is missing?
  - Widely reported that the MMA contains the safe harbor
  - Leaves out non-affiliated physicians and prescribers who are not medical staff members (e.g., nurse practitioners)
  - MMA does not address closing the gaps between NHII and e-prescribing – the overlaps for implementation require they be treated the same

E-Prescribing: Implications of anti-fraud/abuse, Stark laws

- What is missing (cont.)
  - Stark exception for community health networks IT to physicians if
    - it 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
  - There is no anti-fraud/abuse safe harbor for community networks

Regional Health Information Organization



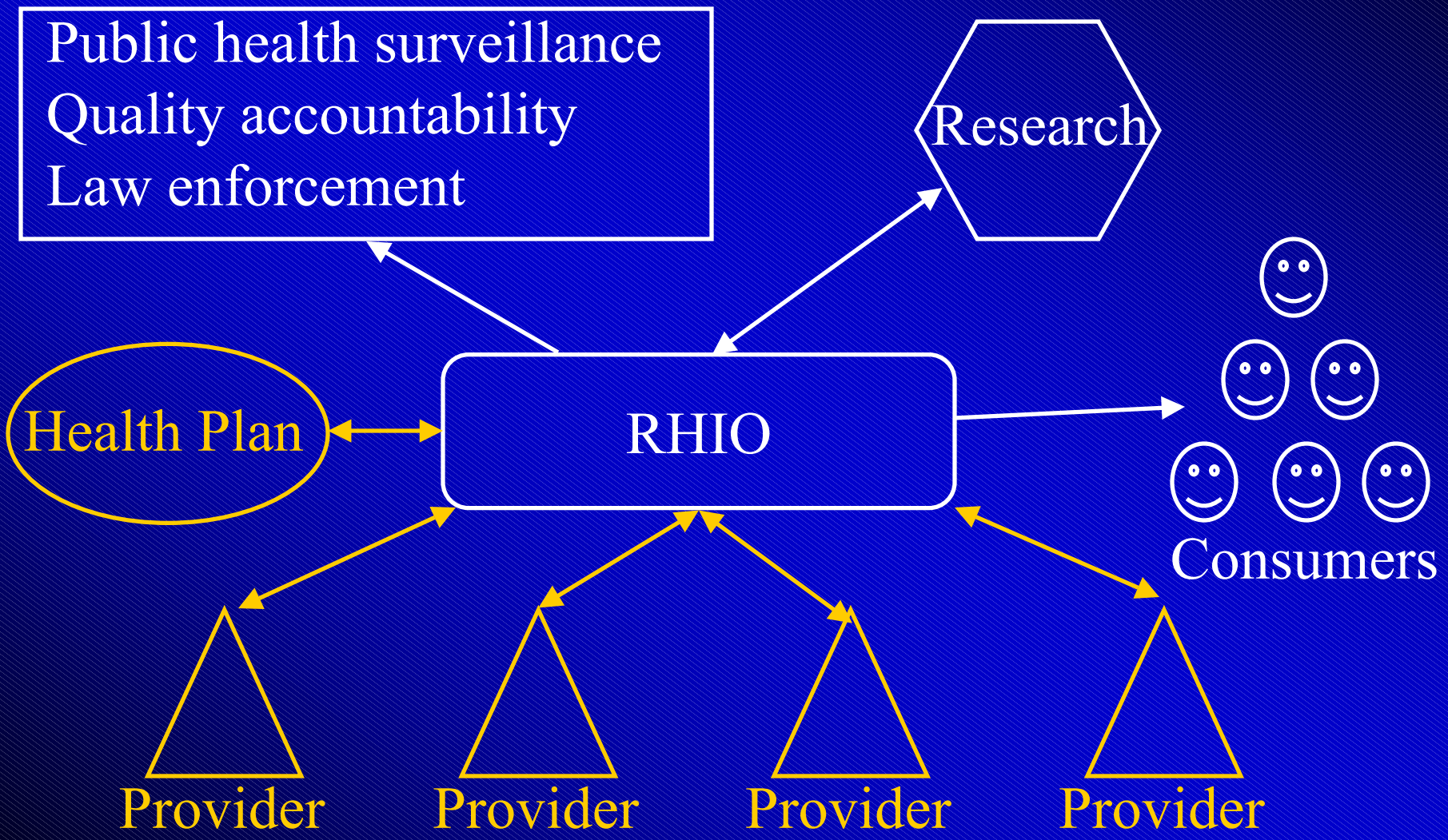
Research under the Privacy Rule

- HIPAA permits access—
  - De-identified data
  - Limited data sets
  - For reviews preparatory to research
  - With patient authorization
  - With IRC or Privacy Board “waiver”

Barriers to Access

- HIPAA is permissive
- Who is the gatekeeper?
  - Providers?
  - The RHIO?
- Consumer confidence

Regional Health Information Organization



Policing the RHIO

- Not directly regulated
- Covered entities have the responsibility of protecting health information and limiting uses through a “business associate contract”
- No obligation to permit use for research

Consumer Confidence

- NHII will likely be optional
- Privacy and security of data in RHIO is weak
  - RHIO not directly regulated
  - No uniform security standard
- Will consumers choose to participate?