

***“Legal, Regulatory, and Policy Issues  
Facing the Implementation of Health  
Information Technologies for Rural  
Communities”***

***Connecting Rural Health Communities Through  
Information Technology***

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# What Everyone is Going Thru:

## Some Planning Considerations

- Governance
- Principles & Key Objectives
- Stakeholder Perspectives
- Establishing a Business Case
- Needs Assessment
- Legal & Regulatory Challenges
- Defining Interoperable Architectures
- Evaluation Methodologies

# Some Additional Rural & Practice Challenges

- Small Rurals may have no IT support let alone an IT Department
- Hard to find M.D. or Adm leaders / change agents
- Other business priorities i.e. “surviving”
- No business case for connectivity / linkages to other institutions (stand-alone EHRs ?)
- No aggregate buying power (hence pooled vendor selection processes)
- Need to address critical referral pattern issues, disruptions, patient flows etc.
- Rural Healthcare Organizations will need special legislative consideration

Put Positively...

*“There are no problems....just insurmountable opportunities”*

# **Focusing Attention On Rural Communities**

**“Efforts to develop local and national health information technology infrastructures should focus specific attention on rural communities”**

**Further, the benefits of HIT "may be even more substantial in rural communities"** ("Quality Through Collaboration: The Future of Rural Health Care", Institute of Medicine, November 2004).

# Policy Considerations

- **Reimbursement & Capital Costs**
  - **Aligning Financial Incentives**
  - **Driving Cost-Effectiveness (i.e. Chronic Care & Disease Mgmt)**
  - **Start-up Costs Capital Investment**
- **Standards (Clinical & Communications)**
  - **Quality & Safety**
- **Infrastructure Issues**
  - **Network Infrastructure / Access / Interoperability**
- **Human Dimension Issues**
  - **Practitioner and Patient Acceptance**
  - **Licensure, Accreditation, Certification**
  - **Legal (Stark Law, Liability, FDA, HIPAA)**

# Reimbursement & Capital Costs

- Financial Incentives targeted toward physicians and providers
- Reimbursement for implementation of EHRs and other incremental applications
- Access to capital for EHR purchases
- Matching grants, clinical IT purchasing contracts
- EHRs as a Tax Credit rather than Business Expense
- Reduce liability insurance premiums for HIT users
  - » (Markle Foundation, Legal and Organizational Approaches)

# Standards

- **Needed: Standards for information (data) collection and exchange; classifications and coding; terminology and vocabularies; and education**
- **Standards for an EHR and for Network Interchange**
- **Various Classification Systems (ICD-9; ICD-10), Terminology Systems (SNOMED); Claims (UB-04; CMS 1500);**
- **Need mappings for vertical and horizontal data integration (AHIMA)**
- **Need guidelines to ensure standardization and interoperability (AHIMA)**

# Infrastructure Issues

- **\$400 B Needed to Build NHIN Over 5 Years**  
(Commonwealth Fund Study)
- **Rural Broadband Access Continue to Lag Behind**  
(California HealthCare Foundation)
- **Yet deployment of fiber and wireless in Rural areas has accelerated sharply in the past year.** (Verizon Foundation)
- **Infrastructure support, limited technical investment, ongoing support - Top Listed Barrier in Surveys** (First Consulting)

# Human Dimension Issues

- Acceptance
  - Referral Patterns, Job Characteristics; Process Change; Training; User Readiness
- Licensure, Accreditation
  - State License Laws; Interstate RN Compact
- Stark Law & Anti Kickback
  - Stark Self-Referrals; CMS OIG Enforces
  - Anti-Kickback – criminal intent, nothing of “value”
  - Safe Harbors Needed For Both

# Human Dimension Issues (con't)

- Liability
  - Need to Address Risks Posed; dilution of property rights in data and systems; liability for misuse of info and security breaches given new vulnerabilities; business interruption potential; lost data.
- FDA
  - FDA is Revising Software Regulation Policies; Current policy – agency regulates only if output directly results in software-directed treatment or diagnosis of patient (AdvaMed)
  - EHR is NOT a medical device, so FDA intervention is unwarranted

# Human Dimension Issues (cont.)

- HIPAA
  - Physical Security, Technical and Administrative Measures, Media Controls, Workstation Use
  - Data at Rest and Data in Motion
  - Technical Security: Access & Audit Controls; Data Authentication; Entity Authentication Encryption;
  - Administrative Procedures
  - Privacy Requirements; Use & Disclosure Rules

# Numerous Players

- Federal Government
  - Congress
  - Agencies (DHHS, DoC, Ag, DoD, VA, IHS, NASA)
- States
  - Statewide Initiatives (Governors, Legislatures, Regional Networks)
- Private Sector
  - Coalitions / Consortia (ATA, HIMSS, eHI, AHIMA, AMIA, NAHIT, CCHIT) Capitol Hill Steering Committee on Telehealth and Healthcare Informatics )
  - Standards Groups
  - Foundations (Markle, RWJ, Commonwealth, eHI Fndt)

# Complementary Private Sector Efforts

## Working to address the Issues:

- **eHealth Initiative “Connecting Communities for Better Health” \$6.9 M**
- **Robert Wood Johnson “Health e-Technologies Initiative” \$10.3 M**
- **Markle Foundation “Connecting for Health “ 100 partners**
- **Commonwealth Fund**

# Federal Legislative Mechanisms

- Budgets
  - Reconciliation (Medicare & Medicaid Policy)
- Appropriations (DHHS, DoD, DoC, DoA, VA)
- Authorization Measures
  - Health Reform
  - SCHIP
  - Health Professions
  - Telecom Legislation?

# 2006 Budget

- **\$125 Million for HIT**
  - **\$75 Million ONCHIT**
  - **\$50 Million New AHRQ THQIT Grants**
  - \$ 10 Million AHRQ Clin. Message Stds.**
  - \$ 4 Million OAT Same as 2005**
  - \$ 25 Million RUS DLT (\$37.5 M in 2005)**
  - \$ 79 Million CDC Biosurveillance (Same as 05)**
  - \$ 68 Million CDC Public Health Informatics**
  - \$ 45.2 M. Medicare R&D (\$65 M. less than 05)**

# Major HIT Funding Efforts

- AHRQ THQIT \$139 M DHHS effort, over 100 Grants to Communities, Hospitals, Providers, Systems for planning, implementation, RHIOs
- eHealth Initiative - “Connecting Communities for Better Health” \$6.9 M
- RWJ - “Health e-Technologies Initiative” \$10.3 M
- Markle - “Connecting For Health” collaboration of 100 partners

# Pending Legislation

- Rep. Murphy (R-PA) & Kennedy (D-R.I.) “*21<sup>st</sup> Century Health Information Act*” May 11<sup>th</sup>, 2005, \$2.5 billion for RHIOs
  - 20 three year grants for M.D. IT adoption
  - Ten year loans available to RHIOs
  - Exceptions to Stark and anti-kickback laws
  - M.D.s in RHIOs to get bump-up in Medicare
  - Federal funds for “certified” IT
  - Minimum design requirements RHIOs
  - Networks to meet PH & quality reporting needs
  - Compliance with HIPAA

# Pending Legislation

- Sens. Stabenow & Snowe, “*Health Information Technology Act*”, June 13th
- \$4.05 B grants over 5 years
- Grants of up to \$15,000 to physicians, and tax deductions for health care providers to purchase and install EHRs and other HIT devices.
- Adjustments to the Medicare physician payments when an identifiable medical service is provided using HIT to manage chronic patients
- Priority to providers serving mostly Medicare, Medicaid, and S-chip, or in designated shortage areas.
- Adopt uniform IT standards within two years

# Pending Legislation

- Sen. Dodd, “*Information Technology for Healthcare Quality Act*”, June 13th, S. 1223
- \$250 M grants & \$250 M loans over 5 years to support development of NHIN
- Authorize adoption of standards w/in two years
- Create Office of Health Information Technology

# Pending Legislation

- Sens. Frist & Clinton “*Health Technology to Enhance Quality Act of 2005*”, June 16<sup>th</sup>
- \$125 million in federal IT funding for each of the next five years.
- Furthers development of IT interoperability stnds
- Authorizes Medicare pay-for-performance pilot project.
- Establish safe harbors for providers engaged in the development of IT systems

# Pending Legislation

- Enzi, Kennedy, Grassley, Baucus & 17 Senators, S. 1355, “*Better Healthcare Through Information Technology Act*”, June 30<sup>th</sup>
- Matching grants to states to create loan programs
- Entity to recommend data standards
- National policies to promote information exchange
- Demonstration to integrate IT into clinical education
- Exception to anti-kickback and stark laws

# Pending Legislation

- Grassley & Baucus, “*Medicare Value Purchasing Act*”, June 30<sup>th</sup>,
- Establishes Medicare Pay for Performance System
- Reward providers first for reporting quality data and later for both quality improvement and attaining certain quality thresholds
- “Value-based purchasing” systems for providers.
- National HIT network pilot program to facilitate exchange of clinical, claims, and outcomes for beneficiaries

# Agency Activities

## Health IT Strategic Framework

### “ONCHIT”

- Inform Clinical Practice – Incentivize EHRs; Reduce EHR investment risks; Promote EHR in Rural and Underserved Areas
- Interconnect Clinicians – Regional collaborations; develop an NHII; Coordinate federal systems
- Personalize Care – Encourage PHRs; Enhance consumer choice; Promote Telehealth
- Improve Population Health- PH Surveillance Architectures; streamline status monitoring; accelerate research and dissemination of evidence

# Agency Activities

## ONCHIT RFI Response

### A Unified Voice

- January, 2005 - Groups started speaking with one voice – AHIMA, AMIA, ANSI, CITL, eHI, HIMSS, HL7, NAHIT
- Build on internet; leverage existing and upcoming open, non-proprietary standards; est. National Common Framework; of essential standards and technology policies; data is decentralized; record locator services; incremental buildout; multi-stakeholder

# Agency Activities - Grants

- **AHRQ “Transforming Healthcare Quality through Information Technology (THQIT)”**
- 3 Grant Solicitations (\$139 million announced so far; more than 100 grants)
- National Resource Center for Health IT (NORC Contract \$18.5 M over 3 years)
- State and Regional HIT Demonstrations
- CMS – AHRQ Collaboration
- Indian Health Service Project
- Privacy and Legal Framework

# Agency Activities – Grants

## Wisconsin Project Example

- **Wisconsin AHRQ THQIT Planning**
  - 19 Institutions (12 Rural & 7 Urban)
  - Drive patient safety, increase access, improve patient-provider relationships, increase cost-effectiveness
  - Build baseline capacity among member organizations
  - Help hospitals build their local EHRs
  - Interconnect facilities and clinicians through a common framework, standards-based, federated approach
  - Move toward a RHIO down the road
  - Establish an Evaluation Framework
  - Establish and effective communications strategy
  - An likely early project: A web-based approach to secure messaging for individual providers

# Agency Activities - Programs

- **DHHS Medicare Demonstrations – Support for Health IT**
- Medicare Modernization Act (Sec. 649) Improve quality and coordination of care for chronically ill and promote use of IT by M.D. practices including EHRs; Registries, Reminders, Decision Support.
- Bonuses for M.D.s who adopt HIT; achieve quality benchmarks for chronic patients – diabetes, heart failure, CAD. (Pay for Performance)

# Agency Activities – Programs

- DHHS 800 projects engaged in DOQ-IT in four states: AK, CA, MA, UT. Doctors Office Quality-IT Project.
- CMS wants to “hardwire” quality into delivery system; integrate HIT into clinical practice
- Broad waiver authority for eligible physician groups
- Payment models: Shared savings; Capitation; Per member monthly fee; restructure fee-for-service; regional global budget.

# Agency Activities –Rules

- DHHS to publish proposed rules allowing outside organizations to help physicians adopt electronic prescribing technology for use in conjunction with the Medicare drug Benefit.
- Exceptions to self-referral prohibitions (Stark Law). Then, rules to create “safe-harbors” – allowing provision of nonmonetary remuneration – in the form of hardware, software, services without fear of violating anti-kickback provisions in law.

# Agency Activities - Rules

## **Some Other expected DHHS rules:**

- National Health Plan Identifier (November, 2005)
- Final action on HIPAA enforcement provisions (August, 2006)
- Final rule on submission of electronic Medicare claims (December, 2006)
- Modifications to HIPAA transactions and code set rules (February, 2006)

# Agency Activities - \$ Contracts \$

- DHHS ONCHIT RFPs – June 6<sup>th</sup>, 2005
- Public-private collaboration “American Health Info. Community” toward common standards and interoperability, 17 members, 5 years
- Four RFPs up to \$86.5 M in 2005, \$125 M in 2006 (all efforts). 30 days to respond.
- Plans to Address Privacy and Security
- Processes for Harmonizing Data Standards
- NHIN Architectures for Internet-based Exchange
- Prototypes Evaluate Conformance Certification Process

# Agency Activities

- Its Not Just DHHS !
- VHA – across the VISNs “My health-e Vet”
- DoD – TRICARE on-line, CHCS II
- NASA, HIS, DoC, RUS
- Medpac

# Agency Activities

**Med PAC Recognition of IT.** The Medicare Payment Advisory Commission (MedPAC) recommended in their March, 2005 report that Congress adopt pay-for-performance programs for physicians, hospitals and home health agencies.

# Coordination Efforts

- House 21<sup>st</sup> Century Healthcare Caucus
- Senate Health IT Caucus in the Works
- Capitol Hill Steering Committee on Telehealth and Healthcare Informatics
- Joint Working Group on Telehealth
- Industry Standards Group
- Efforts of eHI, AHIMA, NAHIT, AMIA, AdvaMed, ATA, others

# Some Reports

- ***“Achieving Electronic Connectivity in Healthcare”***, Markle Foundation, July, 2004
- ***“HHS’s efforts to Promote Health Information Technology and Legal Barriers to Its Adoption”***, General Accounting Office, August, 2004
- ***“Health Information Technology: Promoting Electronic Connectivity in Healthcare”***, CRS, Library of Congress, April 13<sup>th</sup>, 2005
- ***“At A Tipping Point: Transforming Medicine with Health Information Technology, A Guide for Consumers”***, MedStar e-Health Initiative, Verizon Foundation, April 2005
- ***“Health Information Technology: Improving Safety and Quality of Care”***, AdvaMed, June 2005



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