

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

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

Butte, Montana

October 2-4, 2005

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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.) “*21st Century Health Information Act*” May 11th, 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 16th
- \$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 30th
- 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 30th,
- 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 6th, 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 21st 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 13th, 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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