Medicare's IT Paradigm: How Real, How Soon? The Medical Device Regulatory and Compliance Congress

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The Mission of eHealth Initiative and its Foundation

- Independent, non-profit, multi-stakeholder consortium whose mission is to improve the quality, safety, and efficiency of healthcare through information and information technology
  - Focus on states, regions and communities as the center of implementation: aligning national standards with local solutions
  - Develop and drive adoption of sustainable model for healthcare transformation through quality-based incentives
  - Advocate for continued favorable national policies

Our Diverse Membership

- Consumer and patient groups
- Employers, healthcare purchasers, and payers
- Health care information technology suppliers
  - Including device manufacturers
- Hospitals and other providers
- Pharmaceutical and medical device manufacturers
- Pharmacies, laboratories and other ancillary providers
- Practicing clinicians and clinician groups
- Public health agencies
- Quality improvement organizations
- Research and academic institutions
- State, regional and community-based health information organizations

Local Markets

- **Supporting State, Regional and Community-Based Collaborative Efforts Who Are Improving Healthcare through Health Information Exchange.**

  While eHI places significant focus on driving change at the national level, we also recognize the importance of aligning national policy with efforts on the ground—in markets across the United States.

Medicare's HIT Paradigm

- Physicians and EHRs
- Health Information Exchange
- Pay for Performance (P4P) Experience
- HHS and other Federal Agencies
- Status of Legislation
- Action Steps for Device Manufacturers

Healthcare Challenges

- Fractured healthcare system
  - Medicare beneficiaries see 1.3 – 13.8 unique providers annually,
  - On average 6.4 different providers/yr
  - 1 in 10 tests were ordered on the same patient by more than one physician
  - Patient's multiple healthcare records do not interoperate
- An 'unwired' healthcare system
  - 90% of the >30B healthcare transactions in the US every year are conducted via mail, fax, or phone

Physicians and EHRs

- The Electronic Health Record (EHR) is a longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting. Included are patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports.
- 5% to 9% of American physicians overall use electronic health records (ACP March 2004 discussion paper, “The Paperless Medical Office”)
- 17% of primary care physicians and fewer than 5% of all physicians have electronic record systems. (American Medical News 2005)

How Do EHRs Improve Clinical Outcomes?

- Streamline, structure order process
- Ensure completeness, correctness
- Perform drug interaction checks
- Supply patient data
- Calculate and adjust doses based upon age, weight, renal function
- Improve patient communication and service

EHRs, Clinical Outcomes and Device Technologies

- Evaluate clinical effectiveness of device technologies and long term cost savings
- Track medical device use to aid in coverage decisions
- Track device-related adverse events
- Develop clinical and economic evidence necessary to support breakthrough research on life-saving technologies
- Empower patients through use of remote monitoring devices and related technologies

Health Information Exchange

What is Health Information Exchange?

- Health information exchange (HIE) is the mobilization of healthcare information electronically across organizations and disparate information systems within a region or community
- Goal of HIE is to facilitate access to and retrieval of clinical data to provide safer, more timely, efficient, effective, equitable, patient-centered care

What is an HIE Initiative?

- Formal organizations are now emerging to provide both form and function for HIE efforts.

- These organizations are geographically-defined entities (sometimes called RHIO's) which develop and manage a set of contractual conventions and terms, arrange for the means of electronic exchange of information, and develop and maintain HIE standards.

- Although HIE initiatives differ in many ways, those that experience the most success share common characteristics.

Key Functionalities

- Developing consensus on shared goals and principles for health information exchange
- Facilitating the actual exchange of clinical data (technical and policy aspects)
- Supporting usage of the data (help desk, implementation guides, physician practice adoption)
- Supporting other functions such as performance reporting or coordination of financial incentives

Health Information Exchange Value

- Standardized, encoded, electronic HIE would save $78B/yr:
  - Net Benefits to Stakeholders
    - Providers - $34B
    - Payers - $22B
    - Labs - $13B
    - Radiology Centers - $8B
    - Pharmacies = $1B
  - Reduces administrative burden of manual exchange
  - Decreases unnecessary duplicative tests

  Center for Information Technology Leadership 2004

Survey of Over 100 State, Regional and Community-Based Initiatives

- 109 respondents from 45 states and the District of Columbia surveyed June 2005
- Covered aspects related to goals, functionality, organization and governance models, information sharing policies, technical aspects, funding and sustainability
- Health information exchange is clearly on the rise….more of them…and demonstrating greater levels of maturity
  - http://www.ehealthinitiative.org/pressrelease825main.mspx

Stage of Health Information Exchange Programs

Stage 1	Stage 2	Stage 3	Stage 4	Stage 5	Stage 6
▪ 12%	▪ 15%	▪ 14%	▪ 36%	▪ 12%	▪ 10%
▪ Recognition of the need for HIE among multiple stakeholders in your state, region, or community	▪ Getting organized ▪ Defining shared vision, goals, & objectives ▪ Identifying funding sources ▪ Setting up legal & governance structures	▪ Transferring vision, goals, & objectives to tactics and business plan ▪ Defining needs and requirements ▪ Securing funding	▪ Well under-way with implementation – technical, financial, and legal	▪ Fully operational health information organization ▪ Transmitting data that is being used by healthcare stakeholders ▪ Sustainable business model	▪ Demonstration of expansion of organization to encompass a broader coalition of stakeholders than present in the initial operational model

eHI Support of Communities

- Nearly **2,000 stakeholders involved in approximately 200 states**, regions and communities engaged in health information exchange - 500 “eHealth Initiative Connecting Communities Members”
- **Sporting health information technology policy and planning initiatives in seven states,** including AZ, CA, KS, LA, MN, NY, OH, and WI supporting public and private sector leaders who are building multi-stakeholder consensus on the principles, policies, and plans for supporting local innovation and building health information exchange network capabilities. Five additional states will be added to the portfolio in 2006
- **DHHS** contract to assist health information exchange development among the Gulf states – AL, FL, LA, MS and TX

eHI Tool-kit for Health Information Exchange

- Comprehensive on-line, interactive resource that walks the community through the six critical components of success:
  - Getting started: Assessing environment, engaging stakeholders, developing shared vision and goals
  - Organization and governance, legal issues
  - Value creation, financing and sustainability
  - Policies for information sharing
  - Practice transformation and quality improvement
  - Technical implementation
    - http://toolkit.ehealthinitiative.org/

Pay for Performance (P4P)

Increasing Interest in Pay for Performance and Quality

- Medicare Value Based Purchasing legislation introduced in both House and Senate n 2005 and included in Senate Budget Reconciliation
- Health plans including, BCBSA, and RWJ grants
- National Quality Forum getting consensus on ambulatory care measures
- Large private sector purchasers and CMS increasing interest in quality within ambulatory care… *Bridges to Excellence* a key player

MedPac

- March 2005 report focused on strategies to improve care through pay for performance and information technology. Recommended that Medicare:
  - change system incentives by basing a portion of provider payment on performance
  - link a portion of payment to quality as an incentive for hospitals, home health agencies, and physicians to improve care

Bridges to Excellence

- Multi-state, multi-employer coalition developed by employers, physicians, healthcare services researchers and other industry experts. A grantee of the Robert Wood Johnson's Rewarding Results grant program
- Mission: Improve quality of care through rewards and incentives that
  - (1) encourage providers to deliver optimal care, and
  - (2) encourage patients to seek evidence-based care and self-manage their own conditions
- Focus:
  - Reengineer office practices by adopting better systems of care
  - Demonstrate excellence in outcomes for patients with chronic conditions, starting with diabetes and cardio-vascular diseases – Bridges to Excellence

Bridges to Excellence Designed to encourage adoption and use of better systems

- 3 PCP Practice with 1000 patients covered by the program:
  - 3.5% are diabetic patients
  - 2.5% are cardiac patients
- Practice receives total of $54,800:
  - $40 * 1000 = $40,000 for meeting PPC measures
  - $80 * 60 + $10 * 1000 = $14,800 for meeting DPRP & HSRP measures
- Purchaser saves a total of $55,000 less program costs ($6 pmpy) –Bridges to Excellence

P4P, Devices and IT

- P4P systems include clinical as well as administrative components
- System design should help providers capture clinical data in compliance with P4P administrative requirements
- Design of systems for monitoring hemoglobin A1c levels in diabetic patients, for example, might capture clinical data while feeding back overall provider performance
- Systems that help providers meet P4P administrative requirements (as well as clinical goals) will add value for providers.
- Device manufacturers should engage with P4P program architects and sponsors to identify areas of mutual opportunity

Understanding the National Agenda – Administration and Congress

- Enormous momentum around HIT and health information exchange both within Administration *and* Congress
- Key themes
  - Role of government, role of private sector
  - Need for standards and interoperability: technical AND privacy and security
  - Need for alignment of incentives with BOTH quality and efficiency goals and the HIT infrastructure to support them

Centers for Medicare & Medicaid Services Linking Quality and HIT

- Section 649 – Pay for Performance Demonstration Programs – link payment to better outcomes and use of HIT – launched in early 2005
- Quality Improvement Organizations playing a critical role…. Doctors Office Quality – Information Technology Program (DOQ-IT) – technical assistance for HIT in small physician practices included in eighth scope of work
- Chronic Care Demonstration Program (Medicare Support) linking payment to better outcomes – IT a critical component
- Section 646 “area-wide” demonstration announced in September 2005
- Physician Voluntary Program Reporting Program regarding quality of care began January 2006

U.S. Agency for Healthcare Research and Quality HIT Programs

- Over $150 million in grants and contracts for HIT
- Over 100 grants to support HIT – 38 states with special focus on small and rural hospitals and communities – Over $100 million over three years
- Five-year contracts to six states to help develop statewide networks – CO, DE, IN, RI, TN, UT - $30 million over five years
- National HIT Resource Center: collaboration led by NORC and including eHealth Initiative, CITL, Regenstrief Institute/Indiana University, Vanderbilt and CSC

Strong Momentum for HIT and Health Information Exchange: Activities in Administration

- President George W. Bush creates new sub-cabinet level position – April 2004
- Secretary Tommy Thompson appoints David J. Brailer, MD, PhD National Coordinator for HIT- April 2004
- Strategic Framework released in July 2004

Strong Momentum for HIT and Health Information Exchange: Activities in Administration

- AHIC public-private "community" formed to provide input to Sec. Leavitt re how to make health records digital and *interoperable* and assure that privacy and security are protected
- Reviewed "break-through" areas that will create realizable benefits to consumers in two to three years and established workgroups
  - Consumer empowerment
  - Electronic heath records
  - Chronic disease
  - Biosurveillance

HIT and Health Information Exchange: Activities in Administration

- Four awards emerged from DHHS:
  - Standards harmonization process – awarded by ONC to ANSI in Oct 2005
  - Compliance certification process for EHRs – awarded by ONC to Certification Commission for HIT in Oct 2005
  - Variations in organization-level business policies and state laws that affect privacy and security practices (including HIPAA) – awarded by AHRQ to RTI International in Oct 2005
  - Nationwide health information network prototypes – ONC awarded four projects in November covering 12 communities

Legislation and Congressional Leadership

Common Themes of Legislation

- The need for standards —creation of a public-private sector body designed to achieve consensus on and drive adoption of interoperability standards
- Grant and loan programs, for providers and regional health information technology networks – most link to use of standards and adoption of "quality measurement systems"
- Value-based purchasing programs – measures related to reporting of data, process measures including HIT, and eventually outcomes
- Role of government – catalyst, driver of change

Signs of Momentum for HIT and Health Info Exchange: Activities in Congress

- 13 bills introduced in 2005, 3 in 2006
- Most bi-partisan
- Unprecedented collaboration between the Republicans and Democrats on the importance of leveraging HIT and the mobilization of information to address healthcare challenges

Legislation

HIT Bills Pending Action

- S 1418 (Wired for Health Care Act) passed Senate in 2005
- HR 4157 – Ways & Means (Johnson R-CT) HIT bill
- HR 4642 – Same as S 1418 (introduced in House, Issa R-CA)
- HR 4641 - Assisting Doctors to Obtain Proficient and Transmissible Health Information Technology (Gingrey R-GA) tax credits
- Federal Employee Personal Health Records Act (Carper D-DE) - draft
- Federal Family Health 4 Information Technology Act (Porter R-NV) - draft

Legislation

- “Medicare Home Health Telehealth Access Act of 2005 (H.R. 3588)
- Medicare Telehealth Enhancement Act of 2005 (H.R. 2807)
- The Remote Monitoring Access Act of 2005 (S. 2022)

Outlook

- Strong bi-partisan interest in HIT enabling legislation re standards and infrastructure
- House Energy and Commerce Committee information gathering to supplement W&M legislation
- President proposed $169M to fund ONC, double FY 2006, although limited funds to support seed fund grants
- Election year favors HIT as strategy to address issues of cost and patient safety
- Privacy and Stark/Anti-kickback pose challenges

Action Steps for Device Manufacturers

- Develop examples/stories on how the intersection of device technologies and HIT can save lives and improve the cost-effectiveness of care
- Develop specific provisions in HIT legislation, including focused demonstrations on device technologies
- Join with other stakeholders, nationally, to support HIT legislation that would create a nationwide, interoperable health information technology environment focused on standards
- Join with other stakeholders locally and encourage your customers to participate in HIEs to facilitate access to and retrieval of clinical data to provide safer, more timely, efficient, effective, equitable, patient-centered care