Patient Consent Management in a Live RHIO Environment

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The Health Information Technology Summit

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Session Overview

1. **Why is patient consent management an issue?**
2. How did MAeHC approach patient consent?
3. How is MAeHC implementing a solution?

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Why is Patient Consent Management an Issue?

- Regulations
- Consumerism
- Systems and processes
- Ethics

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Life Prior to HIPAA

- Accessibility – the path of least resistance
  - Support and implementation plans focused on what was least disruptive to physicians, nurses, etc.
  - No legally legitimate reasons needed to access private data
- Workstations and paper files equally accessible
  - Patient data remained open on computers to save time and clicks
  - Staff could walk up to the nearest PC and quickly retrieve patient data, regardless of who was logged in
  - Domain administrators didn't build mechanisms to restrict their network or system access

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Regulatory Environment: Federal

- Health Insurance Portability and Accountability Act: 1996
  - Purpose: to give patients the right to access their own information and to set a national standard for medical privacy by making the unauthorized release of medical information a crime
- HIPAA's federal privacy rule first released by HHS: 2000
  - **Required patient consent** for most uses of protected health information, including treatment, payment or "other healthcare operations"
  - Revisions in 2002 (April 2003 compliance deadline) radically changed the rule by authorizing sharing of healthcare information for treatment, payment and other healthcare operations **without patient consent**

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Regulatory Environment: State vs. Federal

- HIPAA allows states to pass or retain their own healthcare privacy laws provided they afford more stringent protections than the federal law
- Most states either had such laws or subsequently passed them, particularly regarding records for mental health, drug and alcohol abuse and HIV/AIDS treatment, and in some cases for genetics

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Regulatory Environment: State vs. Federal…

- In 2006, the unsuccessful H.R. 4157 bill would have allowed HHS to pre-empt state privacy laws when deemed necessary in the interest of information sharing
- Federally, that stalled efforts to create uniformity in privacy regulations
- If change toward uniformity will come, it won’t be in one federal legislative swoop, but in state increments over time

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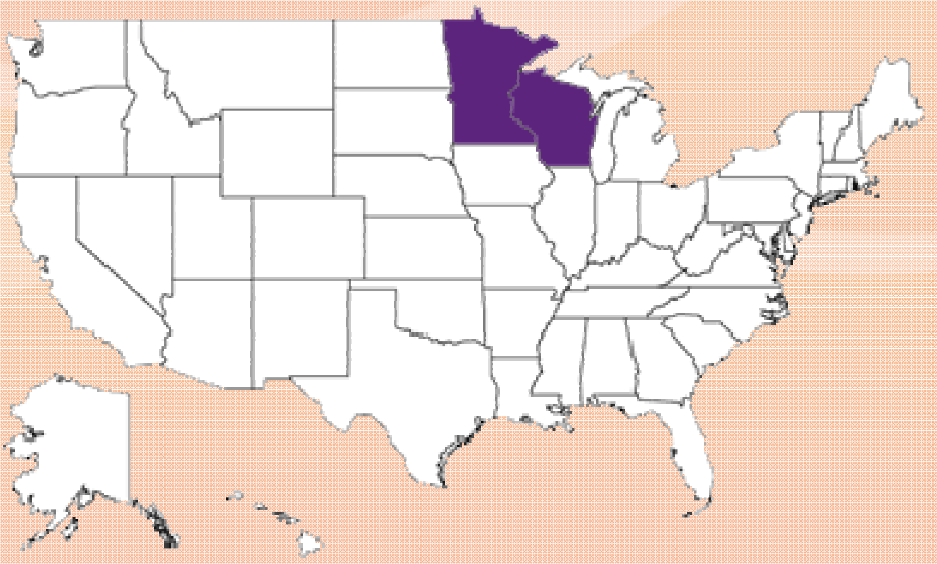
State Regulatory Challenges

- States continue to handle the issue of patient consent for medical information sharing differently



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State Regulatory Challenges …

- Minnesota has some of the nation's toughest privacy protections under its interpretation of HIPAA, while Wisconsin is looking to further relax its already less-stringent rules
- The two are still interested in exchanging electronic health information across each other's borders, but it should prove a challenge given their diverging practices

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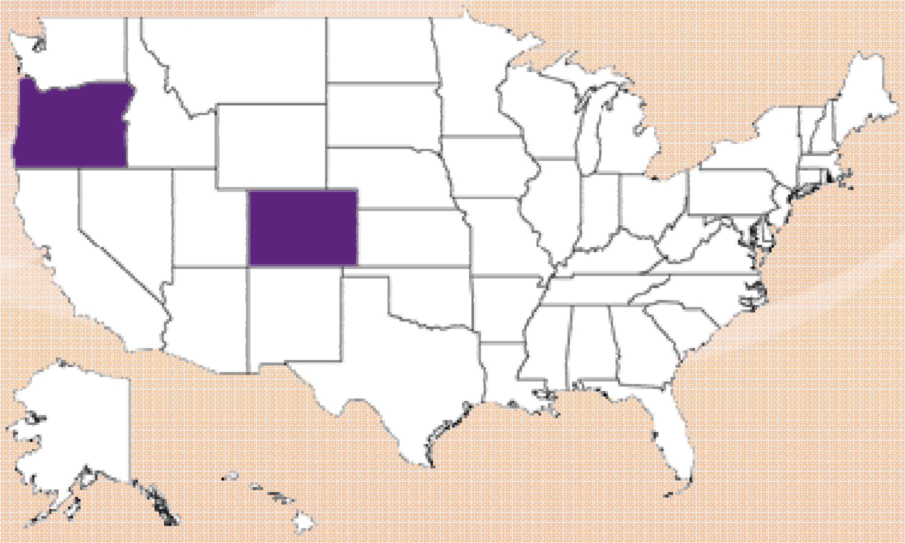
State Regulatory Challenges …

- Other examples:
  - Oregon law requires a patient’s written permission to use genetic information. Problem: law doesn’t define “genetic” – it could be a blood sample; it could be anything
  - Late 2003 in Craig, Colorado: 911 dispatchers wouldn’t disclose the name of a man having a heart attack. EMTs could not find the address, and the man died at home while …



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Lack of Regulatory Clarity

- Bottom line: it has been more than 10 years since HIPAA became law, but many practitioners across the country are still unsure of:
  - What the law requires
  - How its provisions interact with other state and federal privacy laws
  - How to interpret the laws locally

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Advent of Consumerism in Healthcare

- The informed consumer
- The Internet
- Consumer advocacy groups
  - Healthcare for All
  - National Women's Health Network
  - Community Catalyst
  - And others
- 89% want access to their health records, and two-thirds are interested in accessing them online (Nov. 2006 poll of 1000+ Americans)

Source: Markle Foundation, Nov. 2006

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Why are Consumers Concerned?

- Out of 2,237 consumers polled in January, half say patients have lost control over how their medical records are used
- Patients fear discrimination and identity theft
  - Insurance companies, government agencies, family and friends, employers, marketing firms, and more
- Subsequent risk: 21% of consumers say they have withheld information from their health care providers because of worries the information might be disclosed

Source: Harris Interactive, January 2007

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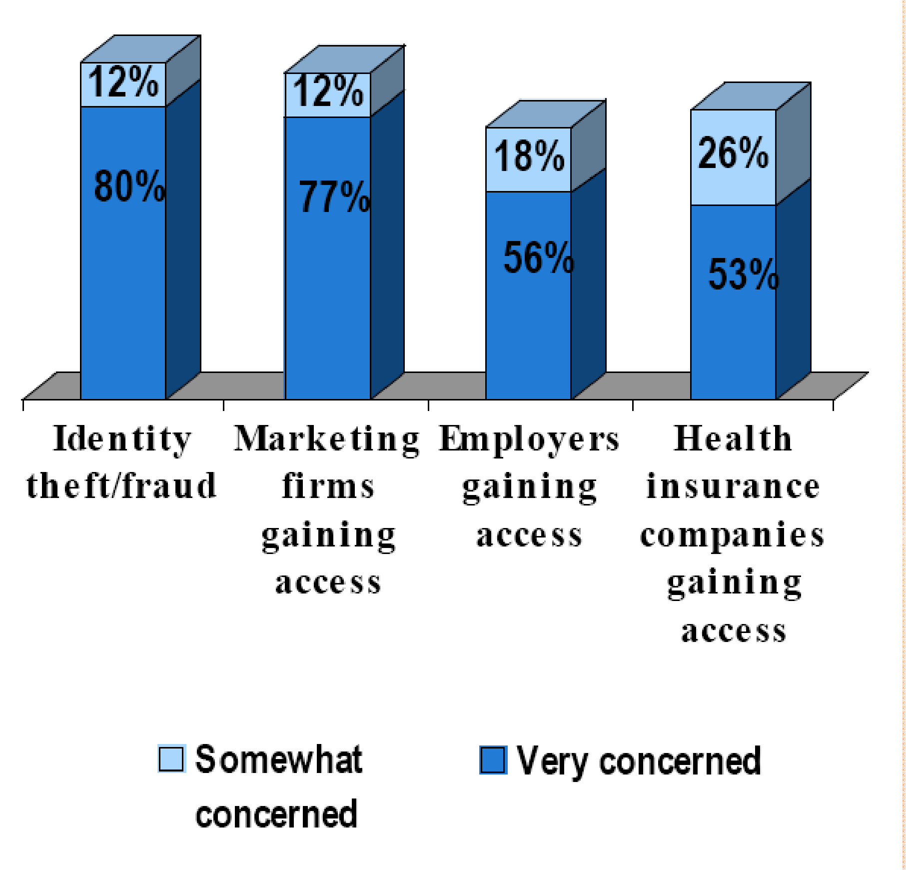
Why are Consumers Concerned? …

- November 2006 poll of 1000+ Americans:
  If your personal health information existed in an online network, how concerned would you be about…



Source: Markle Foundation, Nov. 2006

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The Reality: Compliance

- In 2004, when Bill Clinton had heart surgery at New York's Columbia Presbyterian Medical Center, 17 hospital employees – including a doctor – peeked at the former president's health care records out of curiosity…
- In 2005, in Hawaii, Wilcox Memorial Hospital lost a thumb drive containing personal information on every one of its 120,000 current and former patients…
- In 2006, Boston’s Brigham & Women’s Hospital repeatedly faxed patient admission sheets to a nearby bank by accident. Faxing continued even after bank staff warned the hospital…

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The Reality: Enforcement

- None of the institutions involved in these incidents has been fined under HIPAA
- Since the April 2003 compliance deadline for the privacy rule, the Office for Civil Rights at HHS has received more than 24,000 complaints of privacy violations but has yet to issue a civil fine against a single violator. Only a handful of identity thieves have been prosecuted by the Justice Department under HIPAA criminal provisions.

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The Reality: System Limitations

- Managing consent to share
  - 2 of 6 EHRs in Massachusetts eHealth Collaborative had the ability to manage patient consent
- Limiting access based on relationship - most acute care systems deployed with no such controls
- Complying with state laws - virtually none able to filter beyond consent and “trap” non-shareable information
- In most communities, HIPAA violations are caused daily by simply following routine processes

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The Reality: System Limitations …

The real problem is how to implement disclosure. How do you build **systems** that give patients control, but share liability?

James Golden
Director, Div. of Health Policy
Minnesota Dept. of Health

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The Result

- Too much information
- No information at all
- Either paralysis, or “What, me worry?”

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Patient Consent: The Right Thing to Do

- Our society’s technological advances are growing exponentially
- Need to keep the basic human need for privacy in the equation
- Identity theft and fraud is more rampant than ever
  - TJX Corporation: largest reported security breach ever
  - Therefore, need to do more now than ever to prevent it

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3. How is MAeHC implementing a solution?

Massachusetts eHealth Collaborative (MAeHC) Overview

MAeHC
Massachusetts eHealth Collaborative

- MAeHC formed in 2004 to bring together the state's major health care stakeholders
  - 34 member organizations across the healthcare spectrum
- Selected Wellogic to integrate the first two large communities
- Connecting 3 hospitals, 150+ practices, and reference labs, pharmacies, imaging centers, etc.

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MAeHC - Baseline Consent Assumption

- Consent “as a given”
  - – Enhances clinical decision making and patient safety
  - – Imposes additional burden of review by clinicians
- Consent “as a right to be earned”
  - – Safeguards patient privacy
  - – Potentially keeps vital information from clinicians

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MAeHC - Baseline Consent Assumption …

- MAeHC considers all patients to have opted out until they indicate otherwise
- The exception is initial Master Entity Index construction - a minimal set of carefully chosen patient information is used to create community-wide cross references
- This information is available only to authorized users from the data source organizations

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MAeHC - Sharing Patient Information

- Should all clinical observations at all participating care providing organizations be shared?
- Or a subset? And what is that subset?

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MAeHC - Sharing Patient Information …

- MAeHC chose - like other Wellogic HIEs - to share a subset of clinical observations
- This became each community’s “Shared Patient Information” - SPI
- SPI is the “cost of participation” for each care providing organization

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MAeHC - Considering State Regulations

- Massachusetts requires “instance-by-instance” consent for certain types of clinical observations - HIV/AIDS and Gene Tests
- Massachusetts also mandates no secondary disclosure without additional consent for substance abuse observations
- What about observations that may indicate such problems and conditions?

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MAeHC - Considering State Regulations …

- MAeHC chose to comply with the letter of the law
- Specific laboratory tests are not included in SPI
- Substance abuse observations are “watermarked” to deter secondary disclosure
- This was deemed the most pragmatic choice given the nature of source data systems

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MAeHC - Consumer Advocacy

- Local and national consumer advocacy groups on Security and Privacy Committee
- Deeply involved in definition of patient consent communications, forms
- Participating in customization of Wellogic's patient portal from privacy perspective
- Have been great champions of benefits to patients of HIE

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MAeHC - Opting In/Out

- Entity-by-entity, or globally for all entities in a community
- Patients are assumed to have opted out until they indicate otherwise
- On opt in, SPI begins to flow from that entity to the community
- On opt out, SPI stops flowing from that entity to the community - and if no flow has occurred, master patient index is also purged of that patient’s information

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MAeHC - Opting In/Out …

- Newburyport
  - – Patients initially opted out
  - – Globally opt in at any participating care providing organization
  - – Globally opt out at any time from any participating care providing organization

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MAeHC - Opting In/Out …

- Brockton
  - – Patients initially opted out
  - – Opt in at a participating care providing organization for that organization's SPI
  - – Globally opt out at any time from any participating care providing organization

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MAeHC - Securing Consumer Buy-In

- Consumer Council formed in each community with broad representation
- Demonstration of exchange, provider, and patient portals to illustrate use
- Focus groups to refine consent messaging

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MAeHC - Securing Consumer Buy-In …

- Design materials to reach all patient segments and test materials with focus groups and community leaders
- Design more detailed materials targeted at providers so they have correct and complete information know when patients inquire
- Engage community leaders to use existing effective communication channels
- Create a central hotline and/or website to alleviate providers’ education burden

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MAeHC - Securing Consumer Buy-In …

- MAeHC focus group recommendations
  - Emphasize *benefits* over *risks*
    - How does this help me? (Benefits)
    - What else should I know? (Risks)
  - Clarify HIE boundaries
    - Who does NOT have access
      - Employers, insurance companies, federal government
    - What information is NOT included
      - SSN, financial information, detailed medical notes
    - State and Federal laws DO apply
      - HIPAA, HIV-status disclosure, etc.

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MAeHC - Where to Manage Consent

- Within each care providing organization?
  - – Within practice / hospital EHR
  - – Severe system limitations
- At the “center”
  - – Desire for patient data to not leave “the four walls” without consent

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MAeHC - Where to Manage Consent …

- MAeHC chose to manage consent “inside the four walls” but “centrally”
- Inexpensive relay servers placed inside care providing organizations with clinical systems that do not manage adequately
- Web-based consent management solution with electronic feed from mail survey vendor

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3. **How did MAeHC implement a solution?**

MAeHC’s EHR Rollout

- Electronic Health Records (EHRs) in each practice
- “Inside the four walls”
  - Improved availability of patient information
  - Support for safer, more cost effective decisions
  - Improved operational efficiency
  - Impact on the bottom line

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However, Stand Alone EHRs …

- Continue to perpetuate fragmented patient records “outside the four walls”
- Leave room for substantial improvement in care, operational efficiency gained by data sharing
- Lay foundation for scalability, cost savings potential of healthcare transaction aggregation
- Do not tap into benefits of improved patient-provider collaboration

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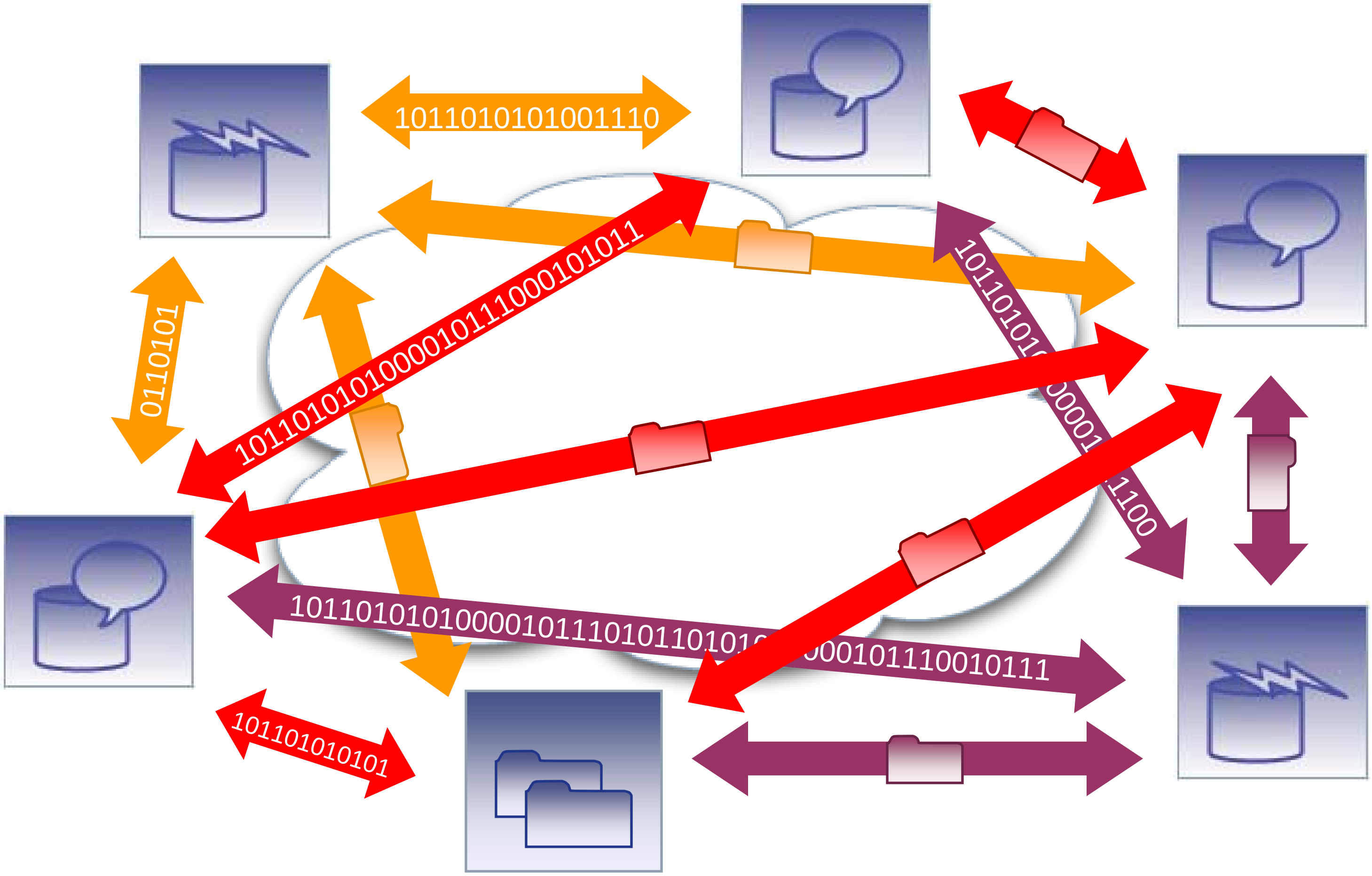
Care Community Without HIE



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MAeHC’s HIE Rollout

- The Health Information Exchange provides the community “glue”
- “Outside the four walls”
  - Only if there is patient consent per organization
  - Shared Patient Information (SPI) is available to authorized users across the community
  - In addition to secure messaging, communitywide referrals, forms routing, anytime-anywhere e-prescribing
  - A central point for key healthcare transactions
  - And a patient portal for enhanced patient participation

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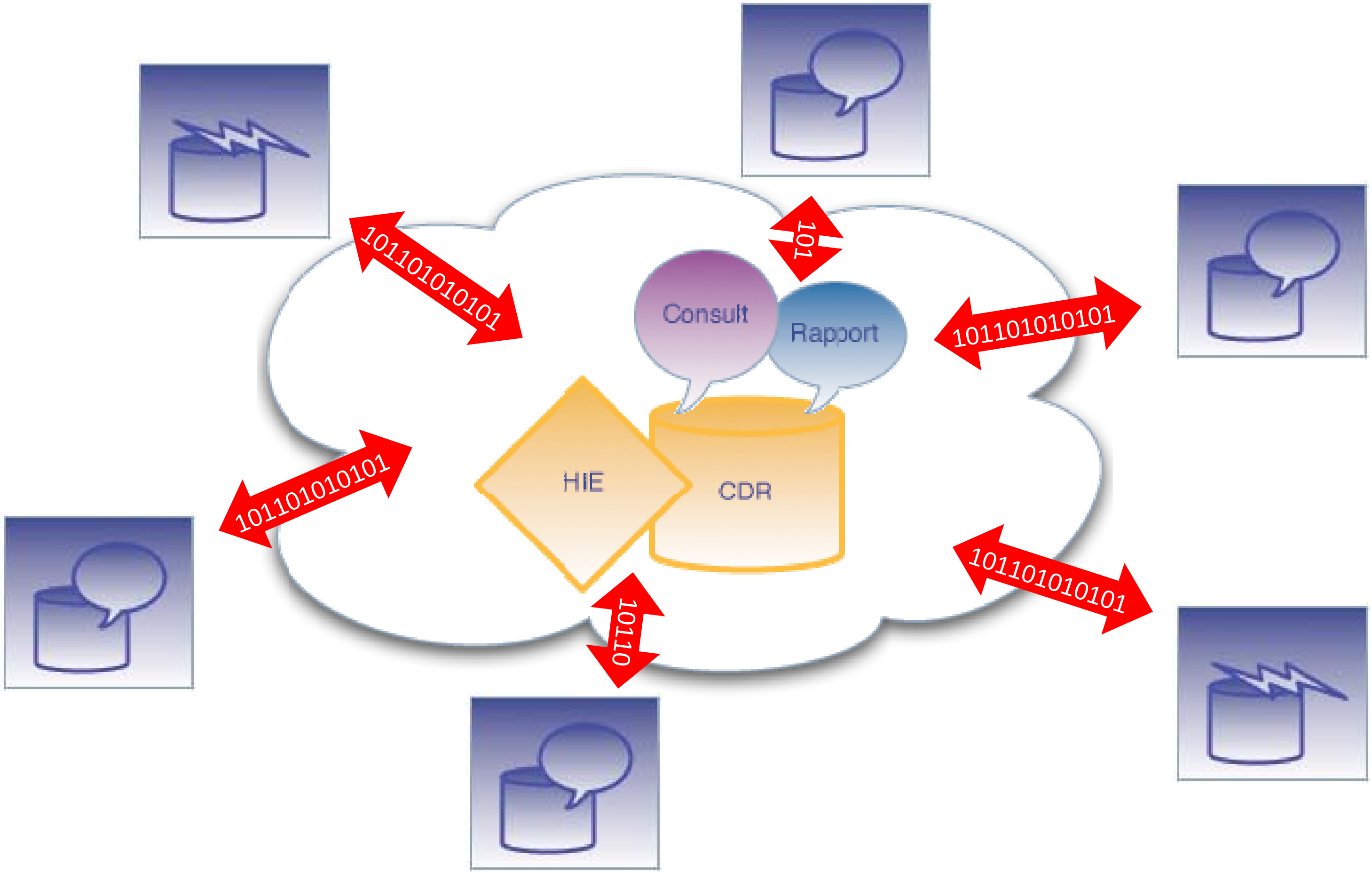
Care Community with HIE



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MAeHC - HIE Approach …

- Federated model providing autonomy for participating organizations
  - Preferred “internal” EHRs are enhanced with “Shared Patient Information”
  - “Native” features of EHRs are leveraged for decision support
- Routine routing of traditional healthcare transactions
  - No special consents required
  - Local community care standards determine result destinations
- Centralized repository of Shared Patient Information (SPI)
  - Available under umbrella of patient consent
  - Leverages industry standards with great guidance from HITSP
- Central repository for studies and reporting

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MAeHC HIE Approach: Hybrid Model

- Some data lives in Wellogic HIE center, some at individual practice EMRs
- Data in center can be pulled into EMRs
- Select data (SPI) that lives in the EMRs is pushed to the center at the completion of each visit

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MAeHC - HIE Components

- Organization Registry
- Provider Registry
- Patient Registry
- Consent Management
- Transaction Exchange
- SPI Repository
- Provider Portal
- Patient Portal
- Utilization Reporting
- Population-Based Reporting

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MAeHC - Consent Lessons *Being* Learned

- Implementing consent “as a right to be earned” is difficult
  - Consumer concerns
  - System limitations
- State regulations create variances that inhibit common models across regions
- Viable models require great adaptability and consensus building among vendors, care providers, consumers, and communities
- The long-term benefits appear to greatly outweigh the cost relative to consent “as a given”

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Discussion

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Thank You!

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