How 21st Century Technology May Affect Informed Consent for HIE

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Introduction

- Background: How Did We Get Here?
- The Consent Dilemma
- The New Health Care Paradigm
- Balancing Competing Interests
- Lessons Learned
- Trends and Emerging Consent Solutions

Background: Pre-HIPAA

- Before HIPAA, some states required patient consent to release health information

- HIPAA created national recognition of issue of consent to release health information and other patient rights in their health information

Background: Post-HIPAA

- Purposes of administrative simplification:
  - Improve efficiency and effectiveness of health care system by standardizing the electronic exchange of administrative and financial data
  - Reduce administrative costs through streamlining
  - Protect security and privacy of patient health care information from unauthorized access or disclosure, alteration, destruction, or loss

HIPAA Privacy Standards

- Created a federal threshold level of privacy protection for health information
- Some states have greater privacy protections
- Only applies to “covered entities” (health care providers, health plans, clearinghouses)

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Objectives of HIPAA Privacy Standards

- Health information should be used only for health purposes
- Organizations entrusted with individuals' health information should safeguard its privacy
- Consumers should have some control over when and how their confidential medical information is used
- Each of these concepts appears in Markle and DHHS Privacy Principles

HIPAA Privacy Loopholes

- Marketing allowed without authorization
- Data mining
- Employers, PHR vendors are not covered entities
- Definitions of treatment, payment, and health care operations are incredibly broad
- **Consumers don’t know what they don’t know!**

DHHS Privacy Principles (12/08)

- Based upon Markle Foundation Principles
  - Openness and transparency; data quality and integrity; individual access; correction; limits on collection, use, and disclosure; safeguards; accountability; individual choice
- "Over time, consumer confidence in the handling of health information is likely to grow just as consumer confidence in online banking has grown, but that won't happen without similar protections and transparency about the use of their information" (former Sec'y Leavitt)

Road to the NHIN

- April 2004: George W. Bush called for widespread adoption of EHRs so every American could have a personal EMR by 2014

- Since 2004, significant progress made toward the NHIN

- Numerous federal, state, and private initiatives researching, discussing, and planning for increased EHR adoption → increased electronic exchange of information → ultimately, leading to the NHIN

Road to the NHIN

- However, obstacles to the NHIN remain, including:
  - Standards for data exchange
  - Significant EHR adoption among physicians
  - Lack of enforcement of privacy and security violations
  - Variations in state privacy and security laws, including consent requirements and practices

The Consent Dilemma

- State laws vary widely regarding whether and what consent is needed to exchange health information
- What amount of choice should consumers have regarding the release of their health information into and through an interoperable EHR?
- What approach to consent will further both EHR adoption and intrastate and interstate health information exchange?

Health Information Security and Privacy Collaboration (HISPC)

- North Carolina participated in a four-state collaborative evaluating these questions as part of HISPC Phase 3
- Intrastate and Interstate Consent Policy Options Collaborative's work addressed "lack of policy standardization" barrier identified in Phase 1:
  - Overlapping, conflicting state and federal laws and policies regarding patient consent to disclose information, including "sensitive" information

HISPC

- HISPC: Starting in 2006, ONC-funded project initially involving 34 states and territories
- Phase 1 identified barriers to health information exchange and proposed solutions
- Phase 2 reviewed high priority areas for collaboration to develop common solutions
- Phase 3 further developed those solutions and created replicable tools to reduce barriers

Intrastate Consent Evaluation

- What level of individual consent to **electronic** exchange of health information is required/should be allowed?
  - NC law does not directly address this issue – it is assumed same as for paper exchange
  - Should HIPAA serve as a “floor” for consent to exchange information through an HIO (so release for TPO automatically allowed)?
  - Should there be two consents – one to permit release of information into the HIO/to RLS, and another to permit exchange of information for certain defined purposes?

Real World Answers

- Markle Foundation/Connecting for Health Common Framework:
  - No prior consent should be required to have information included in a record locator service (RLS) index
  - However, recommends notice to patients that provider participates in the RLS, and offer an opportunity to **opt out** of the RLS
- Rhode Island HIE: **Opt In With Restrictions**
  - Two-part consent: (1) enroll in the HIE and (2) indicate which providers may access their data through the HIE

Intrastate Consent Evaluation

- Looked at five possible consent options for consumers in North Carolina
  - No choice *(info automatically included & exchanged)*
  - Opt In *(info not automatically included; consumer must consent)*
  - Opt In w/Restrictions *(info not automatically included; consumer may consent for some but not all exchanges)*
  - Opt Out *(info automatically included; consumer must refuse consent)*
  - Opt Out w/Exceptions *(info automatically included; consumer may refuse consent for some but not all exchanges)*

Intrastate Consent Evaluation

- *Looking beyond opt-in and opt-out*: how much **flexibility** should consumers have in permitting the sharing of their health information by entities that hold their information?
  - What level of specificity or "granularity" should be permitted? Should consumers be allowed to authorize release of lab results to one physician but not another, or info regarding some health problems to one physician but all to another?
  - Does system have this capability? If so, who tracks this?
  - What about highly sensitive information?
- More flexibility → more complexity

Intrastate Consent Evaluation

- For what purposes should consumers be allowed to withhold consent to—or be required to permit—release of information?
  - Treatment, payment, health care operations
  - Research
  - Marketing
  - Bioterrorism
  - Public health
  - Health oversight
  - Uses required by law

- Who educates consumers about their consent options?

Real World Answers

- National Committee on Vital and Health Statistics:
  - Recommends consumers have limited right to control/block access to their information
  - Based upon categories of consent:
    - Types of data (by condition)
    - Recipients of data (by provider)
    - Uses of data (primary or secondary)

Real World Answers

- Delaware Health Information Network: **Opt In With Restrictions** model
- Iowa is considering **opt out** or **opt out with exceptions** options (all information would be included in the HIE system, but consumers may restrict how it is shared)

Intrastate Consent Evaluation

- If consumers have no/limited choice about participating in an HIO, how to protect against possible negative outcomes?
  - Identity theft
  - False positive lab tests
  - Abusive spouse/ex-spouse seeking custody
  - Physician/practitioner who no longer treats patient
  - Misuse (sale/firing based on health status)

Intrastate Consent Evaluation

- Evaluated each consent option in five scenarios:
  - Lab Results
  - Outpatient Care Coordination
  - Reportable Disease
  - Minor Seeking STD Testing
  - Substance Abuse Consultation

Intrastate Consent Evaluation

- Explored how different consent options would affect quality of care provided, business impact (including cost) on providers, confidence in HIE, and liability of providers
- Created summary of findings and summary of pros and cons of each consent option in the various scenarios

Interstate Consent Evaluation

- Explored legal mechanisms to resolve conflicts between state privacy laws:
  - What law would apply to consumer health information created in state A, stored or accessed electronically by a HIO in state B, and disclosed to or accessed by an entity in state C?
- Mechanisms reviewed: Model Act, Uniform Law, Interstate Compact, Conflict of Law

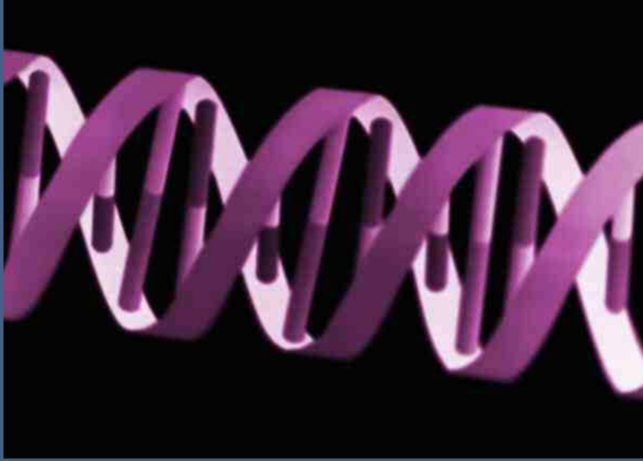
Interstate Consent Evaluation

- Uniform Law
  - Legislative proposal approved by NCCUSL for adoption by states *in its entirety*
- Model Act
  - Legislative proposal approved by NCCUSL for adoption by states; may or may not be adopted in its entirety
- Interstate Compact
  - Voluntary agreement between 2+ states designed to meet common problems; require US Congressional approval; if adopted, would supersede state laws
- Choice of Law
  - Provision states could adopt to specify which state's law governs consent when PHI needs to be exchanged among organizations in different states with conflicting consent requirements

20th Century Health Care

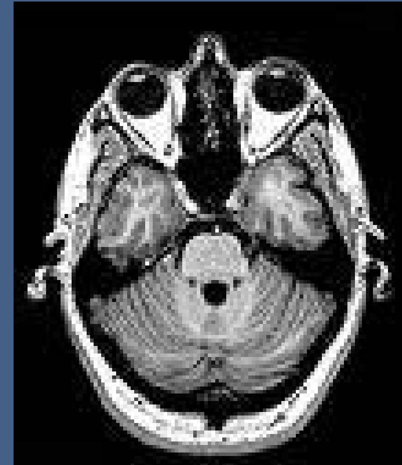
- 1-on-1 physician-patient relationship
- Paper records
- Incident-by-incident decisions
- Point-to-point exchanges

The New Health Care Paradigm—21st Century Health Care

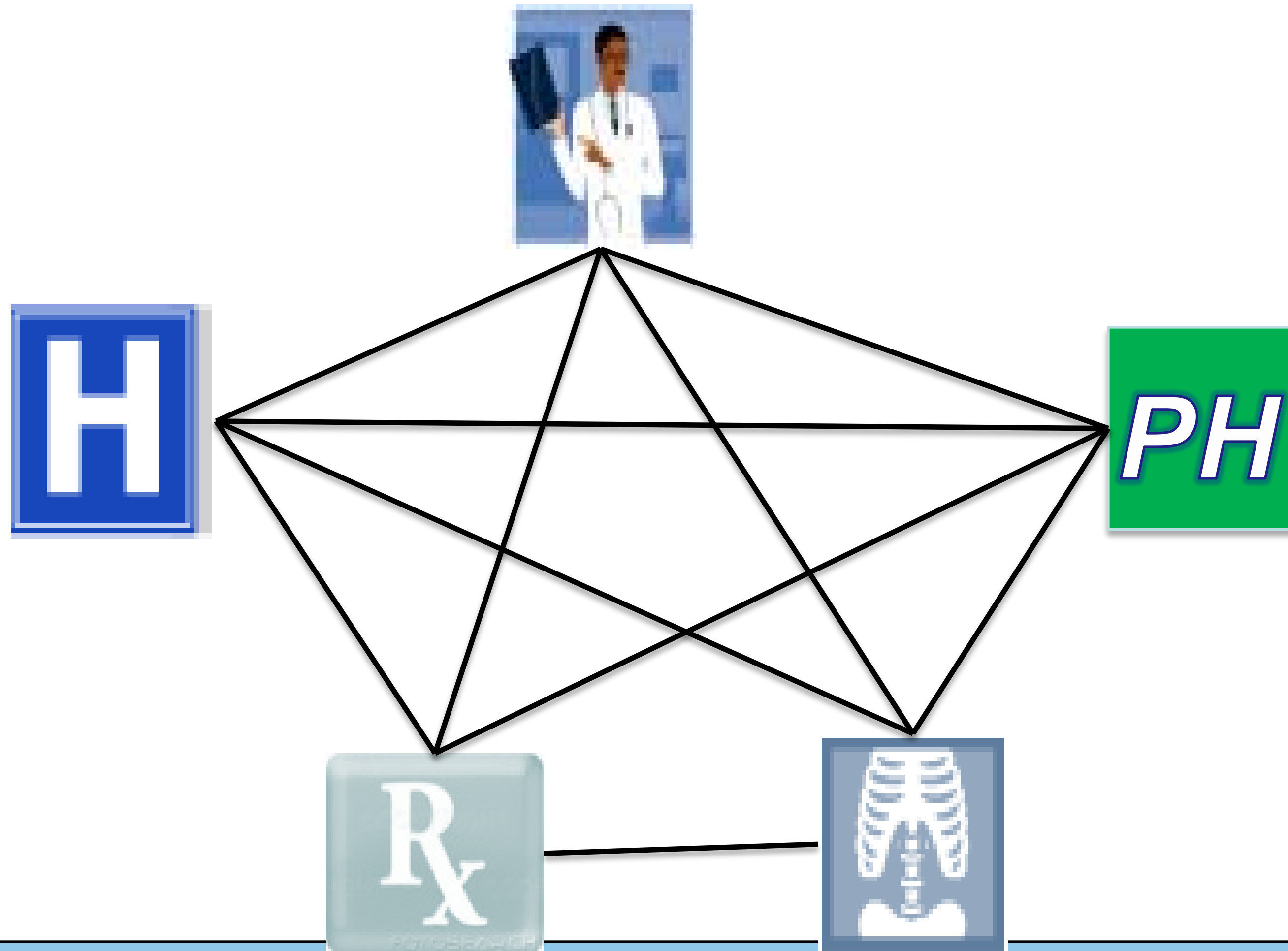


- Multiple providers
- Coordination of care
- Electronic records
- Interconnected, interoperable

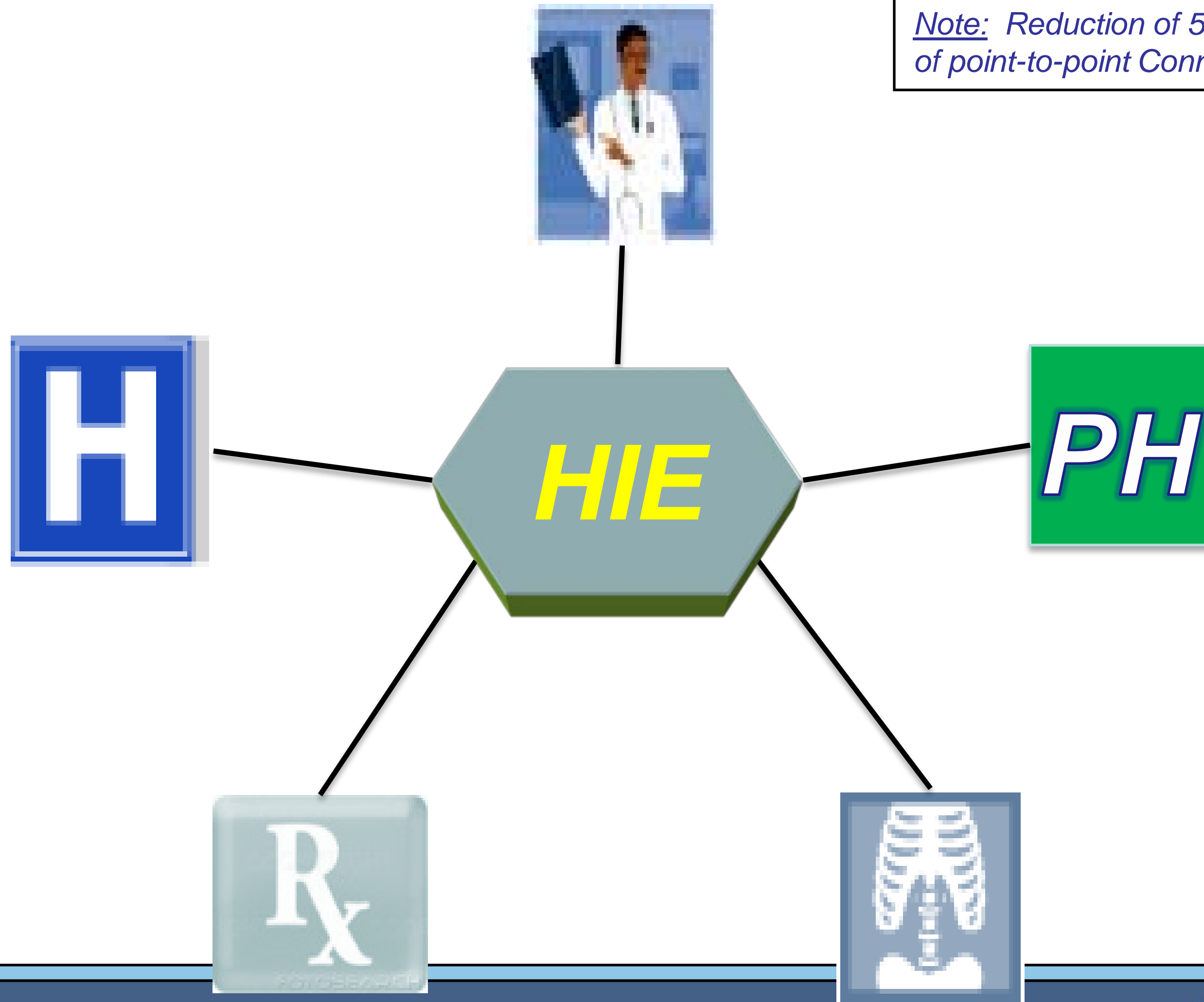
- Many-to-many
- PHRs, health record banks
- HIOs, RHIOs



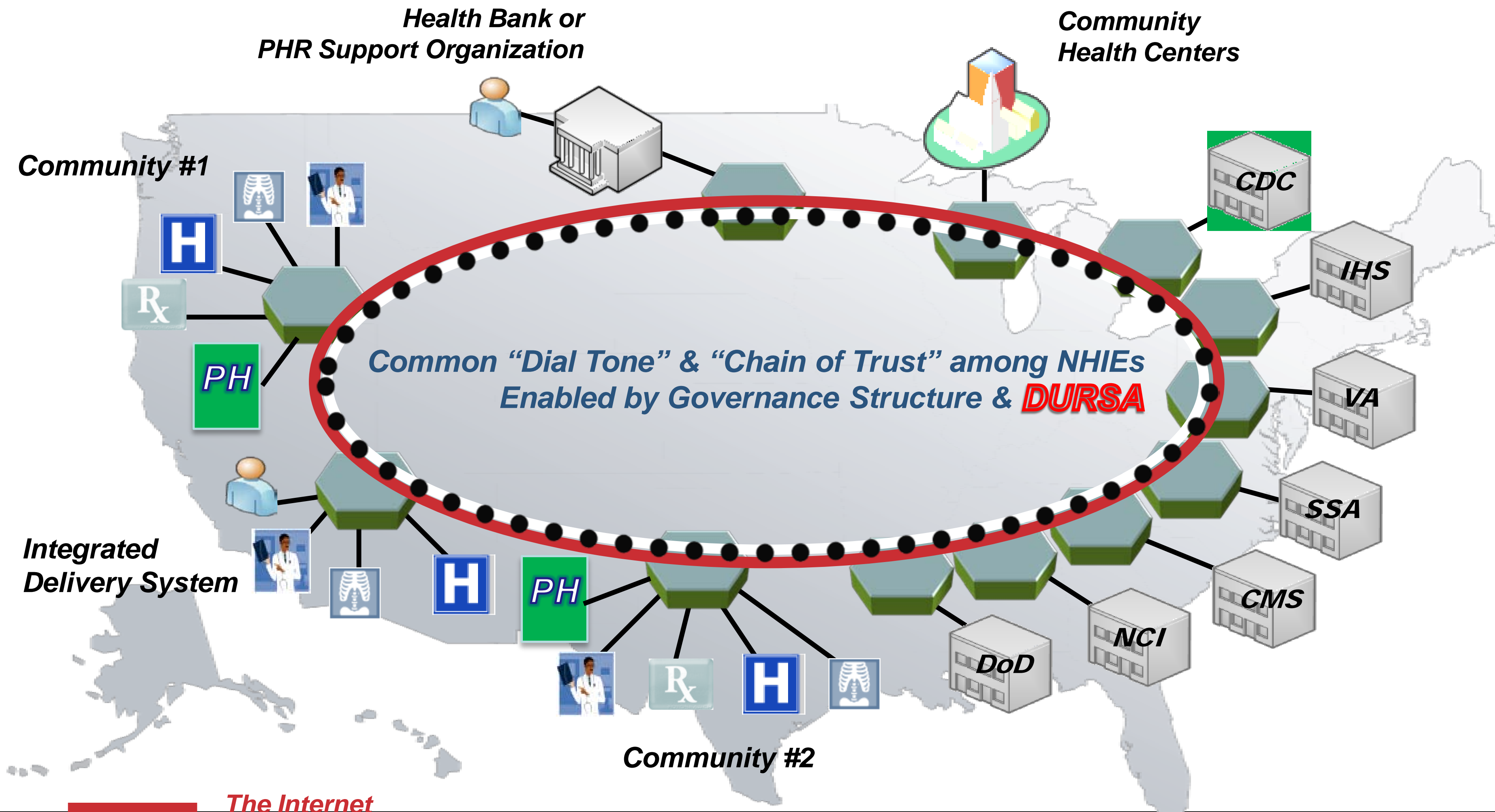
*The Old Health Care Paradigm



*The New Health Care Paradigm: HIE "Utility"(example)



*NHIN "Network of Networks"



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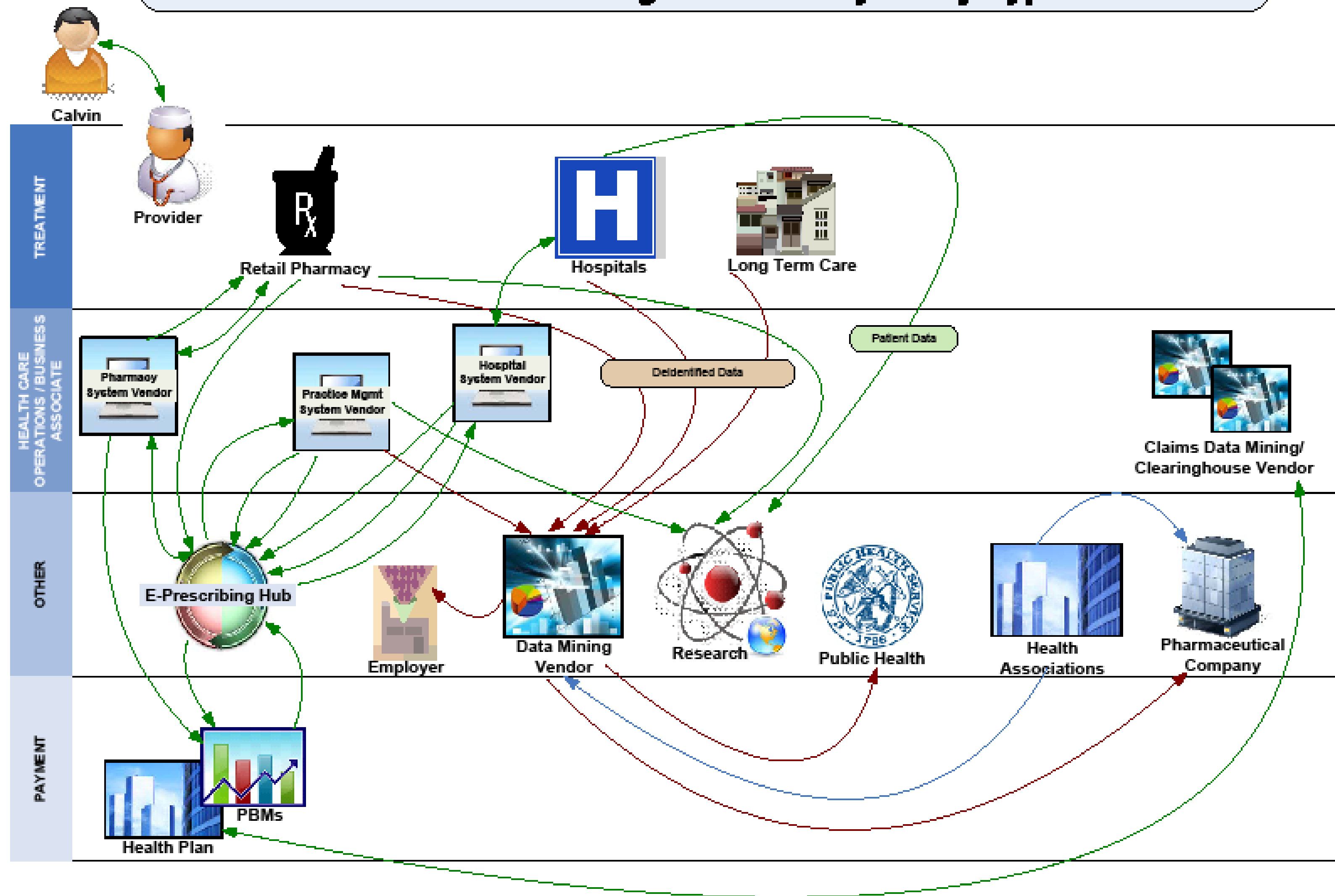
Use of ePrescribing Data Flow by Entity Type



NC HISPC 3 Intrastate Findings

- As amount of consumer consent decreases, amount of consumer participation in HIE likely decreases **unless significant consumer and provider education on protections and how info will be used**
- As amount of consumer consent increases, amount of consumer trust in HIE increases, but provider concern about quality and quantity of data increases → provider confidence in HIE decreases
- As amount of consent decreases, amount of time and money required to educate and change current processes decreases
- As amount of consent increases, lesser liability for violation of consent laws and possibly lesser malpractice liability
- As sensitivity of info increases, greater consumer sense of risk and lower confidence that their info will be protected

NC HISPC 3 High-Level Intrastate Findings

- Stakeholders want **consistent** policy to avoid delayed treatment and potential liability → legislation required?
- "All or nothing" consent (opt in/opt out) initially may result in fewer records, especially for those with sensitive conditions
- NC stakeholders demonstrated strong support for at least some consumer choice about release of health info

HISPC 3 Interstate Findings

- To eliminate **all** barriers to HIE between states, need all 50 states to adopt a consistent approach
- The mechanism should be **uniform** in its approach
- For this reason, Model Act and Choice of Law would be ineffective
- Interstate Compact and Uniform Law could work
  - Provide for most standardized approach, and legally binding
  - Permit input by key stakeholders—transparency and consensus-building
  - Flexibility to quickly address policy and technology changes
  - Lengthy implementation time frame (3 to 9 years)

Balancing Competing Interests

- Consumers vs. providers
- Granular consent vs. no choice
- Less info exchanged vs. more info exchanged
- Policy vs. technology considerations
- Uneducated consumers vs. educated consumers

- Quality of care and trust in HIE are NOT incompatible → technology and policy can accommodate both

Balancing Competing Interests

- In a networked health care environment, consent to release information likely will need to be **informed** consent in order to encourage use of and trust in the technology
- Greater enforcement of privacy and security laws is needed to provide confidence to both consumers and providers
- Electronic exchange of health information requires commitment to privacy principles and perhaps certified exchange mechanisms
- TRUST→ requires a balancing of interests
- Likely will need a single consent standard for a HIO, state, or region

Trends & Emerging Consent Solutions

- States/HIOs appear to favor opt in or opt out
- A few provide for granular consent (DHIN, RIHIE)
- Some have more than one consent option
- Number of patients opting out generally small
- MH/SA/HIV status often not included
- Sharing generally permitted for treatment

Trends & Emerging Consent Solutions

- Technology is gaining on granularity
- In some states (NY), one-to-one exchanges don't require consent (treated like paper exchange)
- NCVHS and others suggest that instead of granular consent, perhaps rely on increased enforcement and improved technology for privacy protections
- NCVHS: for missing/sequestered health data, consider notice to requestor that info missing
  - Mention category of info or not?

Next Steps

- Investigate/test technological feasibility of electronic consent directives
- Investigate/pilot whether interstate compact may be an effective mechanism for HIE between states
- Pilot NCVHS recommendation: permit individuals to restrict exchange of their info by categories (domestic violence, genetic info, mental health/substance abuse, reproductive info)

Selected Resources/Links

- eHI, www.ehealthinitiative.org
- Markle Foundation, Consumer Consent to Collections, Uses, and Disclosures of Information, http://www.connectingforhealth.org/phti/docs/CP3.pdf
- Markle Foundation, Notification and Consent When Using a Record Locator Service, http://www.connectingforhealth.org/commonframework/docs/P3_Notification_Consent.pdf
- NCHICA, www.nchica.org
- NCVHS, Recommendations on Privacy and Confidentiality, 2006 – 2008, http://www.ncvhs.hhs.gov/privacyreport0608.pdf
- Rosati, Kristen, Consumer Consent for Health Information Exchange: An Exploration of Options, http://www.ehealthinitiative.org/assets/Documents/ConsumerConsentforHealthInformationExchange-AnExplorationofOptions.pdf
- RTI International, HISPC Materials, http://www.rti.org
- SLHIE, www.slhie.org

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