

***HEALTH INFORMATION EXCHANGE:  
The Road from Policy and Technology  
Decision-Making to Multi-Lateral HIE  
Agreement***

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# The Challenge of Developing Policies to Complete the Model Contract

- ◆ Connecting for Health's Common Framework is a starting point
- ◆ Common Framework's Model Contract for HIE was designed to be 60-40 solution
  - ❖ the Model identifies policy decisions to be addressed by each HIE Network
  - ❖ the Model assumes that national policies would be adopted by each HIE Network—these policies have yet to be established
- ◆ In the absence of national policies, to make the Model useful now, an HIE Network needs to address all of the policy topics identified in the Model
- ◆ The challenge is to develop and implement mechanisms for policy decision-making



# Core Concepts

- ◆ **Participants** – sources and recipients of health information
- ◆ **Authorized User** – individual who uses the HIE Network on behalf of a Participant
- ◆ **HIE Network** – in the Model, this is the “sub-network organization” (“SNO”), which brings together Participants
- ◆ **Participation Agreement** – Links Participants to the HIE Network, wherein Participants agree
  - ❖ To create and use a shared technology for HIE
  - ❖ To follow common policies and procedures that enable HIE
  - ❖ To accept specified consequences for failure to follow policies and procedures



# Essential Decisions

- ◆ Structure – what terms go into
  - ❖ the Participation Agreement
  - ❖ Manuals
  - ❖ Separate agreements (e.g. technology license)
- ◆ Policies
  - ❖ Privacy and security
  - ❖ User authentication and responsibility
  - ❖ Risk management, insurance, indemnification
  - ❖ Business associate responsibility
  - ❖ Governance/mechanism for amending the Participation Agreement and related manuals



# Designing a Decision-Making Process

- ◆ Subject matter dependent
- ◆ Identify representative stakeholders
- ◆ Assign responsibility for first-draft or recommendations
- ◆ Convene consensus bodies by subject matter
- ◆ Policy-making body
  - ❖ reviews
  - ❖ reconciles different subjects where necessary
  - ❖ finalizes
- ◆ Governing body adopts



# Guidance Available from the Common Framework

- ◆ Policy Documents: Three Categories
  - ❖ Background Document
    - P-1: Privacy Architecture for a Networked Health Care Environment
  - ❖ Specific Policy Documents
    - P-2 through P-8: Model privacy policies, notification and consent, correct matching, authentication, patient access, audits, and breaches
  - ❖ Sample Contract Language
    - M-1: Contract Topic List
    - M-2: Model Contract



# Sample Policy Documents

Sample policy language

CFH Recommended policy

Incidents to the covered entity.<sup>13</sup> See relevant sample contract excerpts below:<sup>14</sup>

Section 8.03 Report of Improper Use or Disclosure. [The SNO] agrees promptly to report to a [Participant] any use or disclosure of the [Participant's] PHI not provided for by this Agreement of which [the SNO] becomes aware.

and

Section 8.14 HIPAA Security Rule Provisions.

- (a) ...
- (b) [The SNO] agrees promptly to report to a [Participant] any Security Incident related to the [Participant's] ePHI of which [the SNO] becomes aware.

Similarly, each Participant must agree to inform the SNO of any serious breach of confidentiality. It is not necessary for a Participant to inform the SNO of minor breaches of confidentiality (unless there is otherwise a serious breach to the SNO). While it is difficult to define what would rise to the level of a "serious" breach, SNOs and Participants might decide that the breaches of

From P8 - Breaches, p. 4

Model Terms and Conditions	Notes
<p><b>4.7 Participant's Other Rights to Terminate Registration Agreement.</b> How a Participant may cease to be a Participant, generally.</p> <p><b>Alternative One: Participant may terminate at any time without cause.</b> A Participant may terminate its Registration Agreement at any time without cause by giving notice of that termination to [SNO Name].</p> <p><b>OR</b></p> <p><b>Alternative Two: Participant may terminate without cause with prior written notice.</b> A Participant may terminate its Registration Agreement at any time without cause by giving not less than _____ days prior notice to [SNO Name].</p> <p><b>OR</b></p> <p><b>Alternative Three: Participant may terminate as of the next anniversary of having entered into the Registration Agreement.</b> A Participant may terminate its Registration Agreement at any time without cause effective as of the next anniversary of the effective date of the Participant's Registration Agreement, by giving not less than _____ days prior notice to [SNO Name].</p> <p><b>OR</b></p> <p><b>Alternative Four: Participant may terminate for cause (may be combined with Alternatives Two or Three and/or Five).</b> A Participant may terminate its Registration Agreement upon [SNO Name]'s failure to perform a material responsibility arising out of the Participant's Registration Agreement, and that failure continues uncured for a period of sixty (60) days after the Participant has given [SNO Name] notice of that failure and requested that [SNO Name] cure that failure.</p> <p><b>OR</b></p> <p><b>Alternative Five: Participant may terminate for specified cause (may be combined with Alternatives Two or Three and/or Four).</b> A Participant may terminate its Registration Agreement upon a Serious Breach of Confidentiality or Security, as described in Section 9.3 (<u>Reporting of Serious Breaches</u>), when such Serious Breach of Confidentiality or Security continues uncured for a period of sixty (60) days after the Participant has given [SNO Name] notice of that failure and requested that [SNO Name] cure that breach.</p>	<p>The SNO may wish to allow Participants to terminate their participation freely at any time, or to require that termination be preceded by a substantial period of advance notice, or to require that Participants maintain their participation for a year (or longer) at a time.</p> <p>If the SNO wishes to limit further certain Participants' (e.g., certain data providers) rights to terminate their participation, the SNO may provide for such special terms in written Registration Agreements described in Section 4.2 (<u>Registration by Agreement</u>).</p> <p>If the SNO places limits upon the Participant's right to terminate, the SNO may wish to provide for the Participant's right to terminate based on the SNO's failure to perform. The Model provides a simple "termination for cause" provision. The SNO may wish to qualify a Participant's right to terminate, e.g., by providing in addition that if the SNO's failure to perform is one that the SNO cannot reasonably cure within the specified period, then the termination will not take effect so long as the SNO commences and diligently pursues work to cure the failure.</p>



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Agency for Healthcare Research and Quality  
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# Other Resources

- ◆ Fair Information Practice Principles
- ◆ Organisation for Economic Co-operation and Development
  - ❖ Fair Information Practices
  - ❖ Guidelines on Protection of Privacy and Transborder Flows of Personal Data
- ◆ 1995 Canadian Standards Association Model Code for the Protection of Personal Information
- ◆ HIPAA
- ◆ State laws



# Getting Started

- ◆ Identify key initial policies
  - ❖ Scope of information to be included
    - Initially
    - Long-term
  - ❖ Who will have access
  - ❖ Under what circumstances will access be granted
  - ❖ For what purposes will access be granted
  - ❖ At what level(s) will auditing take place
- ◆ Confirm that your technology solutions will enable these policies
- ◆ Create a “cheat sheet” for this information that will guide the efforts that will follow



# Privacy and Security

- ◆ Privacy and security concerns
  - ❖ Misuse of data; commercial, government, criminal
  - ❖ Security breaches
  - ❖ Data quality issues
  - ❖ Other harmful consequences; stigma, exposure, embarrassment
- ◆ Use of privacy and security architecture to establish trust
- ◆ Integration of privacy and security architecture with applicable laws and regulations



# Privacy and Security Principles

- ◆ Principles for privacy and security architecture
  - ❖ Openness and transparency
  - ❖ Purpose specification and minimization
  - ❖ Collection limitation
  - ❖ Use limitation
  - ❖ Individual participation and control
  - ❖ Data integrity and quality
  - ❖ Security safeguards and controls
  - ❖ Accountability and oversight
  - ❖ Remedies



# Sample Privacy and Security Policy from Common Framework

- ◆ 100: Compliance with law and policy
- ◆ 200: Notice of Privacy Practices



# Sample Privacy and Security Policy from Common Framework - 300

- ◆ Patient Participation and Control of Information
  - ❖ Choice not to have information included
  - ❖ Effect of choice
  - ❖ Revocation of decision
  - ❖ Documentation of patient decisions
  - ❖ Reasonable and appropriate processes to enable the exercise of patient choice
  - ❖ Assurance that coverage or care will not be withheld based on choice



# Sample Privacy and Security Policy from Common Framework - 400

- ◆ Uses and Disclosures of Health Information
  - ❖ Compliance with law
  - ❖ Permitted purposes
  - ❖ Compliance with HIE Network and Participant policies
  - ❖ Accounting of disclosures
  - ❖ Audit logs
  - ❖ Uniform authentication requirements
  - ❖ Access to own information



# Sample Privacy and Security Policy from Common Framework - 500

- ◆ 500: Information Subject to Special Protection
- ◆ 600: Minimum Necessary



# Sample Privacy and Security Policy from Common Framework - 700

- ◆ Workforce, Agents, Contractors
  - ❖ Access to system – limited to those with legitimate need
  - ❖ Training – Participant must train
  - ❖ Discipline – Participant must discipline its Authorized Users for failure to follow policies, procedures
  - ❖ Non-compliance – To be reported



# Sample Privacy and Security Policy from Common Framework

- ◆ 800: Amendment of Data – comply with applicable laws
- ◆ 900: Requests for Restrictions – comply with patient requests
- ◆ 1000: Mitigation – mitigate and take appropriate remedial action in the event of improper disclosure or use



# User Authentication and Responsibility

- ◆ Identity
- ◆ Identifier -- must be unique
- ◆ Authentication
  - ❖ HIE Network-level
  - ❖ Participant-level
- ◆ Authorization
  - ❖ Tied to Users
    - Roll-based
    - Request-based
  - ❖ Breaking the glass



# Risk Management, Insurance and Indemnification

- ◆ HIE Network's own coverage
  - ❖ Cyberliability – technology failures
  - ❖ Professional errors and omissions expanded coverage
- ◆ Participant insurance requirements
  - ❖ Specific (minimum standards and amounts)
  - ❖ General (customary coverages)
- ◆ Indemnification
  - ❖ State law – basic rule
  - ❖ May be modified to shift responsibility
    - Malpractice
    - Breaches



# Business Associate Responsibility

- ◆ Correctly identify who is and who is not a Participant's business associate
- ◆ Stream-line business associate contracting mechanism
- ◆ HIE Network's responsibility for managing business associate relationship creation
  - ❖ obtaining agreements
  - ❖ enforcing agreements
  - ❖ remediation



# Technology Licensing

- ◆ Identifying the HIE Network's role with respect to HIE technology
- ◆ Legal relationships will be driven by technology solution(s) selected
- ◆ Licensing structure
  - ❖ HIE Network as the vendor/Participants as licensees
  - ❖ HIE Network as master licensee/Participants as sub-licensees
  - ❖ Participants as direct licensees of third-party vendor



# Structural Considerations

- ◆ Manage resources in negotiating participation agreements
  - ❖ Multilateral nature of the agreement
  - ❖ Acknowledge advantages and disadvantages of traditional relationships and contracting strategies
  - ❖ Standard terms that apply to all parties
  - ❖ Flexibility to negotiate unique agreements with specific parties
- ◆ Stress importance of role played by stakeholders' representatives (e.g., Management Committee) to assure document structure and process is and remains reasonable



# Simple Process for Making Changes

- ◆ Management Committee approves changes
- ◆ Changes required by law are automatic
- ◆ Ministerial changes imposed by Management Committee to take effect as needed
- ◆ Super-majority required for “material” changes
  - ❖ Changes apply unless you opt-out by terminating your participation
    - Long lead time for termination
    - Permits Management Committee time to revisit changes



# About Pilots

## ◆ Benefits

### ❖ Limited scope

- Subject matter
- Participants

### ❖ Opportunity to test

- Technology
- Policies

- Initial policy-making needs to occur: Access – what, who, when, what for?

## ◆ Simplified documentation

## ◆ Commitment of the parties to see it through

## ◆ Evaluate results and build on experience



# Common Framework Resources

- ◆ All materials are available without charge at [www.connectingforhealth.org](http://www.connectingforhealth.org)
- ◆ Discussion forum for registered users is available at [www.healthit.ahrq.gov](http://www.healthit.ahrq.gov)
- ◆ Software code available from regional sites: Regenstrief, MASHare, OpenHRE
- ◆ E-mail to [info@markle.org](mailto:info@markle.org)
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