



Legal and Policy Issues of Electronic Patient Records

Development of Multilateral Agreements Among Providers and Users of Health Information

April 28, 2006

Allen Briskin
Davis Wright Tremaine LLP
allenbriskin@dwt.com



Development of Multilateral Agreements Among Providers and Users of Health Information

Structural Considerations

- ◆ Data User Agreement for sharing patient health information among providers and others
- ◆ Parties include data providers, data recipients and centralizing organization (*e.g.*, RHIO or SNO)
- ◆ Agreement is multilateral
 - ❖ Agreement between data provider or recipient and RHIO/SNO (bilateral)
 - ❖ Agreement among data providers and data recipients (multilateral)
 - ❖ Terms apply to individuals working on behalf of data providers and recipients (*i.e.*, authorized users)
- ◆ Design of Data User Agreement to accommodate future network expansion or connection to others (*e.g.*, regional, national, etc.)



Development of Multilateral Agreements Among Providers and Users of Health Information

Structural Challenges

- ◆ New agreement among parties who have existing relationships, agreements, attitudes
 - ❖ Professional providers, as individuals and groups
 - ❖ Institutional providers
 - ❖ Payors
 - ❖ Business relationships and competition among participants
- ◆ Development and administration at local level (RHIOs and SNOs)
- ◆ Future interface with larger network, among RHIOs and SNOs
- ◆ Need for common framework (*i.e.*, terms that apply to all)
- ◆ Need for regional or local specifics
- ◆ Need to address specific participants' concerns (one size not fitting all)



Development of Multilateral Agreements Among Providers and Users of Health Information

Development Process

- ◆ Need for parties to approach this relationship differently
- ◆ Top down vs. bottom up
- ◆ What about the armies of lawyers?
- ◆ Crucial development of trust
 - ❖ Participants' acceptance of common terms
 - ❖ Participants' acceptance of a smaller agenda
 - ❖ Arrangement in which health care consumers will participate
- ◆ Some “special deals” will be justified
- ◆ The terms will start changing tomorrow



Development of Multilateral Agreements Among Providers and Users of Health Information

Managing Resources

- ◆ Simplifying process for negotiating large numbers of agreements
- ◆ Standard terms that apply to all parties
- ◆ Flexibility to negotiate unique agreements with specific parties
- ◆ Simplifying process for making changes
- ◆ The role of stakeholders to help simplified process is accepted
 - ❖ Stakeholders' representatives (*e.g.*, contract development group)
 - ❖ Not necessarily the same as the governing body
 - ❖ Data users, data recipients, individual providers, small providers, institutional providers, payors, thought leaders
 - ❖ And consumers



Development of Multilateral Agreements Among Providers and Users of Health Information

A Structure for the Agreement

- ◆ Common framework (*e.g.*, “national” terms that apply to all RHIOs/SNOs and all participants)
- ◆ Regional or local terms and conditions (which incorporates the Common Framework)
- ◆ Specific data user agreement (which incorporates the regional/local terms and conditions, and thus incorporates the common framework)
 - ❖ “Just sign here”
- ◆ Exceptions negotiated with specific participants, but must be consistent with common framework and regional/local terms and conditions
- ◆ Agreements with necessary third parties (*e.g.*, vendors, funders, etc.)



Development of Multilateral Agreements Among Providers and Users of Health Information

Mechanism for Amendments

- ◆ Predictable and unpredictable change
- ◆ New technology
- ◆ New legal issues
- ◆ New consumer (“political”) issues
- ◆ New participants or other parties
- ◆ The “book club” model
- ◆ Opting out
- ◆ Using stakeholder participation process to minimize opting out



Development of Multilateral Agreements Among Providers and Users of Health Information

Legal Context

- ◆ HIPAA (privacy and security)
- ◆ State laws regarding disclosure and use of health information
- ◆ Federal Stark/Anti-Kickback Laws; State anti-self referral and anti-kickback laws
- ◆ Liability to patients and other participants
- ◆ Impact of tort reform
- ◆ Intellectual property rights
- ◆ Mandates from funding sources



Development of Multilateral Agreements Among Providers and Users of Health Information

Network-wide Issues

- ◆ Who may participate
- ◆ Standards for data providers
- ◆ Permitted and prohibited disclosures and uses of information
- ◆ Compliance with laws, generally
- ◆ Privacy and security standards
- ◆ Interoperability and other technical standards
- ◆ RHIO or SNO functionality
- ◆ Liability to patients & other participants; insurance; indemnification
- ◆ Participants' obligations to comply with network's terms and conditions



Development of Multilateral Agreements Among Providers and Users of Health Information

Regional or Local Issues

- ◆ Compliance with state and local laws
- ◆ Additional terms not prohibited by or inconsistent with network's terms and conditions
- ◆ Permitted and prohibited uses
- ◆ Nature and scope of RHIO's/SNO's system (technology) and services
- ◆ Participants requirements for technology and services
- ◆ Process for selecting participants
- ◆ Responsibility for individual users: certification, supervision, training, etc.
- ◆ Compliance with specific agreements (*e.g.*, vendor agreements and licenses)
- ◆ Reporting obligations



Development of Multilateral Agreements Among Providers and Users of Health Information

Regional or Local Issues

- ◆ Operational issues
- ◆ Governance
- ◆ Termination
- ◆ Those I haven't thought of
- ◆ What the stakeholders tell us
- ◆ What the "outsiders" tell us



Development of Multilateral Agreements Among Providers and Users of Health Information

Learnings

- ◆ Effective stakeholder participation is crucial
 - ❖ Composition of stakeholder group
 - ❖ Collaborative process
 - ❖ Acquiring expertise
 - ❖ Knowing when not to listen to the experts
- ◆ “Leave your lawyer at home”
- ◆ “Client” delivers work plan