If You Build It, They Will Come...But Then What? Corporate Structure, Governance, Funding and Legal Agreements for RHIOs

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The models and processes by which the organizations involved in a RHIO conduct business have not been standardized. The founders of these organizations must determine the best form of legal agreements to share data, operating rules, governance, financial structure and incorporation models. More than 100 regional health information networks must considered the foundation on which to build a national health information network.

- Interpret key legal RHIO Agreements (vendor agreements, data source agreements, participation agreements)
- Analyze sources of funding
- Apply RHIO Governance Models
If You Build It, They Will Come... But Then What?
Corporate Structure, Governance, Funding and Legal agreements for RHIOs

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HiMSS RHIO Symposium

If You Build It, They Will Come... But Then What?

Corporate Structure, Governance, Funding and Legal Agreements for RHIOs

Key Issues in the Formation of an RHIO

- Purpose
- Participants and Leadership
- Business Strategy
- Corporate Structure, Organization, Tax Status and Funding
RHIO = ROI + Shared Benefits

No ROI + Shared Benefit = No RHIO

For Purposes of Nomenclature, RHIO = HIN

Purpose

- Why should the RHIO exist?
- Who will benefit? (not just profit)
- What is the RHIO intended to do?
- What are the Medical/Social/Political/Economic Reasons for RHIO?

Participants and Leadership

- Who gets to Play and on What Basis?
- Will leadership be:
  - Ordained by the organizers?
  - Determined by Investment?
  - Democratic?
  - Representative of Stakeholders?
- Relationship to Payor, Provider, Consumer and Political Communities?
- What economic incentives drive participation?

Who Pays:
Payers or Providers?
Business Strategy

• What will RHIO actually do?
  – Operate a health information network?
  – Community Health Data interchange?
  – Create Provider to Provider Network?
  – Fund Physician EMRs?
  – Link Payors and Providers for PBHFs?
  – Patient Access

• Big Bang Strategy – or – How do You Eat an Elephant?

Business Strategy

• Projected capital and operating revenue needs?
• Where is Your Business Plan?
• Anticipated sources of capital investment and operating revenue?
  – Grants?
  – User Fees?
  – Taxes?
  – Strategy?

• Valuation?
  – Operating Characteristics?
  – Revenue Streams?
  – Investment by Potential Beneficiaries?
  – Subscription Model?

Corporate Structure, Governance, Organization and Tax Status

• Need to reflect:
  – Goals and purposes of the RHIO
  – Projected capital needs and
    – Revenue
  – Depend upon corporate structure and political climate
  – Non-profits easiest to form and may include a variety of participants,
  – Tax exempt, may also qualify for grants and ability to borrow through a
    government authority.
  – But RHIO = RUL = benefits:
    – Easier to attract investment from entities with an economic interest in RHIO
    – Foundation and success, thus need for profit, or hybrid mode.

Funding for RHIO Operations

from cost savings
Examples That Work

- Kaiser/VA
- BCBSDE + Christiana Care
- BCBS TX
- Santa Barbara
- Health Bridge
- Peace Health
- INPC/Regenstrief
- Florida Medicaid Prescribing

Privacy/Security

- HIPAA and State Laws
- Medicare, Medicaid and VA
- Federal and State Drug and Alcohol Laws
- HIV Information
- Mental Health Records

Privacy/Security

- HIPAA
  - Privacy Rules Facilitate Transmission of Data for Treatment
  - More Limited for Payment and Operations
  - Security – Consistency with Current Standards
Privacy/Security

- HIPAA Security
  - Administrative, Physical and Technical Safeguards
  - Audit Controls
  - Access Controls
  - Authentication
  - Certification

Liability and Indemnification

- Key Issues:
  - Content
  - Practice Enhancements/Evidence Based Medicine
  - UMD/DM/CM
  - Pay for Performance
  - Duty to Consult
  - Fraud and Abuse Implications

Liability

- Content:
  - Origination
  - Quality/Accuracy/Integrity
  - Amendments/Additions/Disputations
Liability

- But Innovation Leads to Higher Expectations
  Consider:
  - *Helling v. Carey* (Glaucoma Testing)
  - *Shannon v. McNulty* (Nurse Call Center)
  - Fetal Monitoring Cases
  - X-Ray Cases

Fraud & Abuse

3 Laws
- Anti-Kickback Law
- Stark Physician Anti-Referral Law
- False Claims Act

Stark - Exceptions

Anti-Kickback Law – Safe Harbors

MMA – Mandates OIG Promulgate
  Exceptions and Safe Harbors for
  E-Prescribing
Proposed Stark Exceptions

- MA/Medicaid Electronic Prescribing Exception
- Pre-HIPAA Consensus Electronic Health Records Exception
- Post-HIPAA Operational Electronic Health Records Exception

Proposed Safe Harbors

- MA/Medicaid Electronic Prescribing Safe Harbor
- Pre-HIPAA Consensus Electronic Health Records Safe Harbor
- Post-HIPAA Consensus Electronic Health Records Safe Harbor

Proposed Stark Exceptions/
Proposed Safe Harbors

- Similar Structures
- Standards for Donated Technology
- Permissible Donors and Recipients
- Volume or Value Prohibition
- Value of Protected Technology

Presenters

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KEY RHIO AGREEMENTS

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Agenda

- Definition of a RHIO
- Business Associates
- Conduits and Gateways
- Participant Agreements
- Risk Analysis

What is a RHIO?

- Organization that facilitates electronic exchange of information among healthcare entities.
- Can be composed of providers, providers and plans, or others
### What is a RHIO?

- Promotes use of standard formats, interoperable systems, common consultants or vendors, and common approaches to privacy and security.

### RHIO Data

- Central warehouses of PHI disfavored
  - Ownership
  - Control
  - Privacy Issues
  - Public Trust

### RHIO Data

- Current trend is that participating organizations retain and maintain their own protected health information with no central repository
Data Storage and Access

- RHIO can facilitate "point to point" connectivity between participants (NEHEN)
- RHIO also can implement Master Patient Index to facilitate location of PHI relating to an individual at several data sources and consolidation of PHI from several sources into one report (Meds Info ED, RxGateway)

RHIO Functions

- Transmission of PHI to manage care
- Development of longitudinal records and reports
- Integration of PHI from a record at one location to a record at another location

RHIO Agreements

- RHIO as Business Associate
- Service Providers/Vendors
- Participants
- Gateways & Conduits

RHIO IS NOT A GOVERNMENT ENTITY
Business Associates

- HMO might be a business associate of all participating covered entities
- BA must implement reasonable and appropriate administrative, physical and technical safeguards to protect confidentiality of e-PHI
- BA must ensure that any agent, including a subcontractor, agrees to implement reasonable and appropriate safeguards

Business Associates

- BA must report any security incident of which it becomes aware to the CE
- Authorization of termination for material breach

Service Providers/Vendors

- Almost certainly BA's to Participants
- Example: Record Locator Service operating an MPI
- Filtering Service
- Provide Services, Software or both
Participants
- Can be Data Sources, Data Users or both
- Data Users want access, Data Sources demand safeguards
- Participant Agreements must be based on a privacy-compliant use case.

Conduit
- Facilitates connectivity only, usually with encryption. Does not use or disclose PHI
- No BA requirements per HIPAA
- Consider security requirements
- Confirm status as conduit, not BA

Privacy Compliance
- Develop System of Permissions Suited to Permitted Purpose, Type of Data and Data Sources
  - Treatment is most permissive
  - Special rules for Sensitive Information
  - Public Perception Issues
  - Rules for Plan Data Different than for Provider Data—per State law
Perform Risk Analysis

- Sensitive or Specially Protected Data?
- Direct Connections to e-PHI or “Always On” Connections?
- Volume of Data?
- Other Risk Factors?

Is Obeying the Rules Enough?

- “We Comply with HIPAA” language?
- Consider impact of breach
- Ability to authenticate, monitor and sanction data users and their workforces
- Strategic Partners
  - Payers and Providers
  - Physicians—Medical Staff

Trading Partner Risk Profile

- Criticality of Data
- Probability of Adverse Event
- Ease of Access
- Resources to Implement Safeguards
- Trust But Verify
Selected Issues

- Incident reporting – timing and content
- Authentication Methods
- Access controls
- Identity management policies

Selected Issues

- Audit requirements
- Outsourcing
- Site Visits
- Security Collaboration

Indemnification Clauses

- IP infringement, privacy breach, others?
- Like insurance, with no premium, no reserves, no limits
- Consider: is it worth anything? Do you want to give it?
- Add: carve outs, notice, control of defense
- Insurable?
Partnering Issues

- Big versus small
- Essential but non-compliant
- Risk management philosophy

Questions?

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