

Davis Wright Tremaine LLP 

**2004 HIT Summit
Governance – Key Legal Issues**

Gerry Hinkley
Lawyer

Davis Wright Tremaine LLP
gerryhinkley@dwt.com
415-276-6530



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Form follows objectives - 1

- **Access** – Available to serve all residents in the community
- **Accountability** – Quantifiable goals to be reported on to ensure accountability to users, funders, the public and other constituents
- **Input** – Ensure appropriate input from users, advocates, consumers and others in the ongoing development of the program

2



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Form follows objectives - 2

- **Policy/Systems Reform** – Desire to advocate for policy and system reforms that improve the way programs operate at the local, state and national levels
- **Purchasing Power** – Use group purchasing power to ensure that it is in the best possible position when negotiating the purchase of services from vendors and consultants.

3



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Form follows objectives - 3

- **Partnering** – Work closely with other organizations that share its mission to improve and streamline eligibility and enrollment processes for state and federally-funded programs.
- **Timing** – Immediate or incremental
- **Financing** – Users, others

4



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Organizational steps

- Convene constituencies
- Get organized
- Plan operations
- Secure funding
- Be inclusive
- Implement
- Operate

5



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Governance Principles – Choice of entity

- Partnership/LLC
- Corporation
- Public Authority

6



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Tax Status

- Taxable
- Tax-exempt
 - 501(c)(3)/509(a)(2)
 - 501(c)(4)

7



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Governance Principles - Membership

- The collective entities and individuals who
 - establish
 - maintain
 - changegovernance structure
- Clout, representation

8



Governance Principles – Governing body, officers

- How constituted – background, skills
- Responsibilities
 - program development
 - financial model and performance
 - vendor relationships
 - financial performance
- Size, terms, compensation, independence, relationship to management, time commitment, self-critical examination

9



Governance Principles – Role of stakeholders

- Membership
- Governing body
- Advisory bodies

10

Sample Governance Models

Question	Indiana Health Information Exchange, Inc. (IHIE)¹	MA-SHARE, a Program of the Massachusetts Health Data Consortium	Santa Barbara County Care Data Exchange, Inc. ("Exchange")²
<p>What does it do?</p>	<p>IHIE is a community health information network working to establish a clinical data repository in electronic format, to be used for population-based research and clinical decision research. IHIE seeks to collect and aggregate the data, mapping all terms using a standardized method. IHIE was initiated in central Indiana, but ultimately seeks to extend nationwide. IHIE seeks to use the database to improve health care delivery and research.</p>	<p>MA-SHARE (Simplifying Healthcare Among Regional Entities) seeks to promote the inter-organizational exchange of healthcare data using information technology, standards and administrative simplification, in order to make accurate clinical health information available wherever needed in an efficient, cost-effective and safe manner. Specifically, MA-SHARE seeks to foster improvements in community clinical connectivity, allowing appropriate sharing of inter-organizational healthcare data among the various participants in the healthcare system, including patients, doctors and other practitioners, hospitals, government, insurers, HMOs and other payors.</p>	<p>The Exchange operates an interactive, Internet-based, peer-to-peer computer system³ and clinical search engine to assist physicians, caregivers, and consumers in Santa Barbara County ("Participants") to locate and facilitate the sharing of patient data held by multiple health care organizations with disparate health information computer applications, at the point of care. By making the system available to all authorized users, the Exchange seeks to increase the quality, safety and efficiency of care delivery.</p>
<p>How is it organized?</p>	<p>IHIE is a non-profit 509(a)(3) supporting organization to charitable nonprofits including: public health institutions,</p>	<p>MA-SHARE is a regional collaborative initiative operated as an Advisory Committee to the Board of Directors of the Massachusetts Health Data</p>	<p>The Exchange is organized as a collaborative public-private arrangement that is guided by a 501(c)(3) California nonprofit public benefit corporation.</p>

¹ Teleconference with Micky Tripathi, Boston Consulting Group (617)973-6081.

² Teleconference with Nicholas Augustinos, CareScience, Inc. (415) 546-3046.

³ The peer-to-peer system negates any need to place all shared files on a central database or server. Instead, members of the peer-to-peer network can pull those files off of each other's individual computers and access them through the Internet.

Question	Indiana Health Information Exchange, Inc. (IHIE) ¹	MA-SHARE, a Program of the Massachusetts Health Data Consortium	Santa Barbara County Care Data Exchange, Inc. (“Exchange”) ²
	<p>academia and government, operated as follows:</p> <ul style="list-style-type: none"> • There is a 15 member Board of Directors representing the 13 founding institutions; • Board members include: the Indiana Health Commissioner; the dean of Indiana University School of Medicine, the CEO of the Regenstrief Institute (health care policy) and the CEOs of the five largest hospitals in Indiana; • The Board purposely excludes representation from the medical device and pharmaceutical industry as well as insurers. 	<p>Consortium, a 501(c)(3) organization (the “Consortium”)</p> <p>There are 25 members of the MA-SHARE Advisory Committee, seven of whom are members of an Executive Sub-Committee, (of which several are funders of MA-SHARE) as follows:</p> <ul style="list-style-type: none"> • 1 seat for the Consortium’s Chairman of the Board (who is also President of the Consortium and a member of the Executive Sub-Committee); • 1 seat for the CIO Forum of the Consortium; • 3 seats representing hospitals in Massachusetts (two of whom are also members of the Executive Sub-Committee); • 3 seats representing health plans in Massachusetts (two of whom are also members of the Executive Sub- 	<ul style="list-style-type: none"> • The Care Data Exchange Council (the “Council”), which acts as the governing body of the Exchange, meets monthly to determine the business and operating policies of the Exchange, set priorities for its expansion, development and communication strategies and provide legal and business oversight. • Any organization with a direct role in the delivery, operation or purchase of healthcare services in Santa Barbara County may become a Participant in the Exchange by entering into a Care Data Exchange User Agreement with the Council. The agreement sets forth the rights and responsibilities of the parties, almost like a software license agreement, without binding them together under any specific corporate structure.

⁴ One vote per Key Participant is the voting arrangement originally devised for the Council. Mr. Augustinos was not certain whether this structure has changed over time.

⁵ Following is a listing of each **Alliance**, its **anchor** and the other Participants, respectively: **Lompoc**, The Lompoc Valley Community Healthcare Organization, Federal Correction Complex, Lompoc Hospital District, Lompoc Public Health Department, the Santa Barbara Regional Health Authority, Valley Medical Group, Vandenberg Airforce Base; **Sansum**, Sansum-Santa Barbara Medical Foundation Clinic, UNILAB Corporations, University of California, Santa Barbara, Cottage Health System, local pharmacies; **Midcoast**, MidCoast IPA, Catholic Health Care West Marion Medical Center, Meridian Health Care Management, UNILAB Corporations; **Santa Barbara Regional Health Authority**, Santa Barbara Regional Health Authority, Lompoc Valley Community Health Organization, Sansum-Santa Barbara Medical Foundation Clinic, Santa Barbara Dept. of Public Health, Santa Barbara City Medical Society, Santa Barbara Neighborhood Health Clinics.

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	<p>Committee);</p> <ul style="list-style-type: none"> • 3 seats representing physicians in Massachusetts (one of whom is on the Executive Sub-Committee); • 3 seats representing State Government (one of whom is on the Executive Sub-Committee); • 3 seats for other healthcare organizations in Massachusetts; and • 5 other seats (representing employers, academia, technology association, the state legislature and consumers). <p>MA-SHARE has a CEO who is also on the Board of Directors of the Consortium.</p> <p>The MA-SHARE operating model is generally conceived as that of a facilitator and incubator, in which projects exploring healthcare data connectivity will be undertaken in order to develop, pilot and demonstrate new healthcare information technologies across communities and enterprises. MA-SHARE solicits proposals from healthcare organizations interested in piloting clinical information technology projects, which are reviewed by MA-SHARE staff and the Advisory Committee.</p>	<ul style="list-style-type: none"> • Each of the founding health care entities participating in the Exchange (the “Key Participants”) has one representative, with one vote on the Council.⁴ • Key Participants and Participants are loosely organized into four “Care Data Alliances,” according to mutual information technology goals. The structure is designed to enable collaboration but allow each organization to achieve its unique strategic priorities. Each Alliance is led by an anchor entity, which is one of the Key Participants.⁵ • Two advisory committees, the Technical Advisory Committee and the Clinical Advisory Committee, composed of representatives from each Alliance, provide guidance to the Council on technical and advisory issues, respectively. 	

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How was it formed?	<p>Micky Tripathi, who is President (and acting CEO until a replacement is identified), launched IHIE.⁶</p> <p>IHIE was developed from and is reflective of the clinical perspective. Launched through Indiana University's efforts to share electronic medical records, IHIE will build on what IU achieved, becoming the sales and marketing arm of the enterprise.</p> <p>Mr. Tripathi recommended answering the question of governance by posing the following questions:</p> <ul style="list-style-type: none"> (a) what do you want to do? (b) what is the organization that you can create to enable that? (c) who are your initial participants and why? (d) what do they have to gain from participating? (e) who is your core 	<p>MA-SHARE was initially formed with lead grants from two Massachusetts healthcare organizations of \$35,000 each to initiate a new community clinical connectivity initiative being spearheaded by the Consortium.</p> <p>The Consortium Board of Directors instructed the Consortium CEO to investigate governance models for MA-SHARE, so as to clarify its relationship to the Consortium and to create a proper basis for MA-SHARE's operations.</p> <p>With the lead grants, the Consortium convened the seven member MA-SHARE Executive Sub-committee made up of executive level healthcare leaders and charged with identifying the critical operating issues for the entity (over a two-month period).</p> <p>The Consortium subsequently extended invitations to community leaders to participate in the 25 member Advisory Committee, consisting of representatives from hospitals, physician organizations,</p>	<p>Initially, CHCF funded a six-month feasibility study, conducted by David J. Brailer, M.D., Ph.D., to evaluate the general potential for regional data sharing.</p> <p>Based on the feasibility study, CHCF provided a \$10 million grant to Dr. Brailer and CareScience, Inc. (the entity that built the Exchange software) to establish a Program Management Office to oversee the implementation, governance, legal and regulatory issues of building the Exchange.</p> <p>To begin, the Exchange had no legal form. Rather, it began as a "handshake council" that operated in conjunction with CareScience as its project manager. To enable participation by the Participants, Care Science operated as the "hub," bound to each Participant "spoke" by a Care Data Exchange User Agreement.</p>

⁶ Mr. Tripathi is a consultant for Boston Consulting Group and is performing the search for the new CEO. He is also a "governance health leader" at the upcoming National Health Information Initiative conference, July 20-23, where he will be speaking on the topic of governance and health information.

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	<p>community?</p> <p>In developing the IHIE, Mr. Tripathi determined there was a need to identify who would pay for the services. He envisioned:</p> <ul style="list-style-type: none"> (1) patient identified data, for sale to hospitals via a clinical messaging system and delivery to physicians in office, electronically; (2) a single system across Indiana, which every physician may access; (3) aggregate (de-identified) data, for sale to academia and the pharmaceutical industry. 	<p>other healthcare providers, health plans, state government, academia, employers, the CIO Forum, and the Consortium.</p>	
<p>Where is it in the formation process?</p>	<p>The entity is formed (and recently expanded when several suburban hospitals became members). However, it has not yet begun operations. (See “How was the transition managed?”)</p>	<p>Formation of the Advisory Committee (and executive Sub-Committee) is complete.</p>	<p>The Council has taken the place of CareScience as the “hub.” The role of CareScience is now limited to that of technical provider, through an “arms length” contract with the Exchange.</p> <p>As existing User Agreements between the Participants and CareScience expire, Participants will enter into a new User</p>

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How is it funded?	<p>Thus far, the organization has been funded through grants from BioCrossroads, the Regenstrief Institute and other funders.</p> <p>Under the IHIE business model, users will pay a fee to access the database. To determine an appropriate price, IHIE created a Return On Investment model, working directly with hospitals. IHIE identified what it thought a particular hospital would spend in specified categories, e.g., X dollars to mail test results, then determined how IHIE could deliver the same service for less money and, in that process, began to create a customer base.</p>	<p>MA-SHARE began formal operations with the aid of a \$500,000 grant from Blue Cross and Blue Shield of Massachusetts and additional support from Partners Healthcare System, Harvard Pilgrim Health Care, Tufts Health Plan, Fallon Health Plan and Neighborhood Health Plan.</p> <p>As a subcommittee of the Consortium, continued operations are funded through the Consortium.</p>	<p>Agreement with the Council. New Participants will contract directly with the Council.</p> <p>The Council is in the process of developing a new form of User Agreement.</p> <p>In addition to the grants CHCF made to conduct the feasibility study and to fund the project through a program office of CareScience, CHCF also provided grants to Key Participants to enable their early participation in the project. (<i>See also</i>, "How was it formed?")</p> <p>As a 501(c)(3) organization, the Exchange is organized to allow for the continued receipt of grant money, both from CHCF and other funders, including the Key Participants.</p> <p>The Council is now in the process of determining how to obtain continued funding from nonprofits, the government and, eventually, Participants. CareScience has determined a proposed price for Participants to join the Exchange. Although at this stage of development, in order to encourage participation, the Council does not want to charge</p>

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How was the transition managed?	No, separate transitional organization was formed. Initially, IHIE’s attorneys developed a Memorandum of Understanding, to which the participants agreed.. Mr. Tripathi has managed the organization from inception and will remain as acting CEO until a successor has been identified. (See also “How was it formed?”)	No, separate transitional organization was formed. (See also “How was it formed?”)	participants any fee, a user fee may be imposed in the future.
What is/has been the use of consultants?	Micky Tripathi	None. (See “What is/has been the use of paid staff?”).	Although not technically consultants, CHCF made grants to Dr. Brailer and CareScience. (See also “How was it formed?”)
What is/has been the use of paid staff?	The CEO is paid. (Before assuming the CEO position, Mr. Tripathi worked with BioCrossroads of the Central Indiana Corporate Partnership, ⁷ which is funding his position for six months as an in-kind donation). Board members are unpaid.	The Consortium engaged professional staff to support the MA-SHARE effort.	The staff of the CareScience Program Office was paid through the CHCF grant. (See also “How was it formed?”) Mr. Augustinos did not identify whether any Board Members on the Council or its staff is paid or by whom.

⁷ BioCrossroads also paid for IHIE’s attorneys.

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	Currently IHIE has one paid employee and expects to hire and pay more staff in the future.		