## Agenda

<table>
<thead>
<tr>
<th>Time</th>
<th>Item</th>
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<tbody>
<tr>
<td>11:00am</td>
<td>Welcome Scott Christman, CHeQ</td>
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<tr>
<td>11:05am</td>
<td>Introductions Participants</td>
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<tr>
<td>11:30am</td>
<td>Responsibility Sharing Between HIOs and Vendors Bill Beighe, CAHIE</td>
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<tr>
<td>11:30am</td>
<td>Lunch sponsored by Pillsbury</td>
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<tr>
<td>12:30pm</td>
<td>Essential Documents Allen Briskin, JD, Pillsbury</td>
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<tr>
<td></td>
<td>• HIE policies and procedures</td>
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<td>• Aaron Seib, CalOHII</td>
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<td>12:30pm</td>
<td>Educational Materials – “Why HIE?” Leah Hart, CHeQ</td>
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<tr>
<td>2:00pm</td>
<td>California Trust Framework (CTF): RIM Cothren, PhD, CHeQ</td>
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<td></td>
<td>• Update on the CTF Pilots</td>
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<td>• Inter-HIO exchange</td>
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<tr>
<td>2:20pm</td>
<td>• Wrap-up</td>
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<tr>
<td>2:55pm</td>
<td>Wrap-up</td>
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California Health eQuality Program (CHeQ)

- Implementing California’s Health Information Exchange (HIE) programs with California Health and Human Services Agency (CHHS), under state’s Cooperative Grant Agreement with federal Office of the National Coordinator for Health Information Technology (ONC)

- CHeQ promotes coordinated health care for Californians by catalyzing the adoption and implementation of Health Information Exchange by:
  - Building a trusted exchange environment that enables inter-organizational and interstate exchange while respecting and protecting patient privacy
  - Supporting uniform standards for exchanging health information
  - Improving public health capacity
  - Accelerating HIE implementation by supporting regional HIE initiatives
Introductions

Please have one representative from each organization share the following:

- Planned service area
- Participants in attendance
- Status update
Emerging HIE Forum: Beyond Technology

Responsibility Sharing Between HIOs and Vendors

Bill Beighe

August 27, 2013
Bill Beighe

• CIO of Santa Cruz Health Information Exchange
• General manager of Axesson
• Co-Chair CAHIE
• CHeQ Advisory Committee
• SCHIE
  • Operating Since 1996
  • Full Service Model
  • Multi-Stakeholder – Open to all
  • 300K Patients
  • 8 Million Clinical Documents
  • 380 Interfaces
  • NHIN I Pilot 2006 (and 3 more plus production)
  • Direct Pilot 2010 and 2012 plus production
  • CalOHII Consent Project
Agenda

• Key Definitions
• 3 Approaches to HIE Involving a HIO/HISP
• HIE Reality Check
• Standards & Interoperability
• Checklist for a Health Information Exchange Organization
Key Definitions

• HIE = The act of exchanging health information
• RHIO = Regional Health Information Exchange Organization
  • Often used synonymously with HIO
  • Serves a medical trading area
  • Connects with other RHIO and HIO (aspirational)
    • Intro to CAHIE
    • NwHIN Direct
    • NwHIN Connect and HealtheWay

• Requires:
  • Local governance (not likely outsourced)
  • Local operations support (possibly outsourced)
# Key Definitions

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<tr>
<th>Name</th>
<th>Description</th>
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| HIE Software Vendor         | Organizations such as Mirth, Orion, ICA, Optum, Medicity.  
  • These organizations typically sell software and optionally hosting services.  
  • The RHIO provides operational support and more that we will cover in our checklist exercise.  
  • The RHIO provides local governance. |
| HIE Services Provider       | Organizations such as OCPRHIO, Axesson.  
  • These organizations typically offer HIE services including software, hosting and operational support for a monthly fee.  
  • The RHIO provides local governance. |

This is not an endorsement of any of the vendors or organizations listed. Bill Beighe is the General Manager of Axesson.
3 Approaches to HIE Involving a HIO/HISP

• **Push** – not simply a point-to-point connection
  • Interface delivering HL7 (hopefully)
  • HIO may or may not do message transformation
  • Can be unidirectional or bidirectional
  • NwHIN Direct is a form of Push

• **Pull** – aka Query
  • Commonly deployed as a portal to one or many data sources
  • NwHIN Connect is a form of Pull

• **Full Service**
  • All above plus
  • Master Patient Index
  • Results Delivery
  • Alerts and automated workflow responses
  • Provider and Entity Directory
  • Clinical Data Repository (Federated, Hybrid or Centralized)
  • Analytic Support
  • Customizations to support local workflow
Reality Check

• Data Drives Usage
• The Integration Imperative
  • Application Integration
  • Workflow Integration (Flexibility)
• Local Support Critical
  • Operational and Governance
• Standards Present Challenges
  • Have holes and are not widely or consistently adopted
• Interoperability 2020 ??
  • True Interoperability is aspirational
CCD our Savoir – NOT Today!

• A CCD – C32 lists 17 sections
• If you have seen 1 CCD you have seen 1 CCD
  • Meaningful Use requires 4 of 17
  • Interop Work Group activity 2011 / 2012
  • Beacon CCD
  • VA CCD
• MU Stage 1 requires: Problems, Lab Results, Medications and Medication Allergies
• Key Data needed to provide care usually missing
  • History of Present Illness
  • Chief Complaint
  • Incomplete / unstructured medication information
Stage 2 – A Step towards Interoperability

- Common MU Data Set
- Consolidated CDA Template Support Required

A CDA document using CCD templates

A CDA document using CCD templates plus others

CCD
- Demographics
- Allergies
- Family History
- Social History
- Vital Signs
- Medications
- Problems
- Payer

CDA
- Chief Complaint
- Discharge
- Diagnosis
- Transport
- Mode of
- Surgical Finding
- Discharge Diet

New Section...
Consolidated CDA Templates Required by MU 2

- CCD
- Consultation Note
- Diagnostic Imaging Report
- Discharge Summary
- H&P
- Operative Note
- Procedure Note
- Progress Note
Closing Thoughts

• High-Level RHIO Business Model
  • RHIO runs HIO
  • RHIO hires HIE Service Provider

• ACO and Value Based Payment is coming, will the RHIO be a vital partner or will it become irrelevant

• On to the Checklist
Essential Documents

- Aaron Seib, CalOHII
- Allen Briskin, JD at Pillsbury
August 27, 2013

Model Modular Participants Agreements
California’s eHealth Vision:

Improve the health and well-being of all Californians
California’s eHealth Goals:

- **Enhance** individual and population health outcomes through results-oriented programs.
- **Ensure** secure data access that protects patient privacy and data integrity.
- **Engage** patient and families as partners in care.
Agenda

- Overview of Release 2
  - Briefly provide context regarding Participant Agreements.
  - Describe how Release 2 of the MMPA was developed.
  - Describe the intended use of the MMPA.
  - Overview of the MMPA
  - Describe the current status of the
What is a Participants Agreements?

- What are Participant Agreements and why are they important to the California eHealth Vision?
- Participants Agreement – the contract between an HIO and its Participants, the purchaser of the HIO’s service offerings.
- Participants Agreements describe the obligations of both parties and are essential to describing the rules of the road.
- Since the service offerings of each HIO is different and how those service offerings are delivered differ there is no one size fits all contract that can be proposed.
Frequently cited as a barrier to exchange

- Pain Point – Why?
- For emerging HIOs these contracts are costly to develop and finalize.
- For Participants the variance between Agreements increases the difficulty in evaluating them and ultimately executing them.
- Significant elapsed time lost to legal review.

CalOHII heard from all types of Stakeholders that the participant’s agreement was an area where the community could benefit from a tool – perhaps a Model Participants Agreement?
But why is this so hard?

- If you have seen one HIO, you’ve seen one HIO
- There are many mechanisms to enable appropriate health information exchange
- Many HIOs offer multiple mechanisms to enable health information exchange depending on the use case and customer needs
- These compounded differences and the complexity of the learning curve makes it difficult for any single organization to support the resource requirements to readily master all of the details.
- Even a task force supported by the State had to make some simplifying assumptions...
Iterative Development

- MMPA Release 1.1
  - Formed Task Force in July 2012
  - Drafted straw-man and iterated numerous times
  - 30 day comment period; input incorporated
  - Presented Candidate version to CalOHII
  - Released by CalOHII in September 2012

- MMPA Release 2.0
  - Following same pattern of development
  - Currently seeking public comment
  - Cut-off date for public comment is May 30, 2013

- MMPA Release 2.1
  - Available now
# MMPA R2 Task Group Members Included

<table>
<thead>
<tr>
<th>Allen Briskin <em>(Co-Chair)</em></th>
<th>Austin O’Flynn <em>(Co-chair)</em></th>
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<tbody>
<tr>
<td>Pillsbury, Winthrop, Shaw, Pittman, LLP</td>
<td>Senior Counsel, Dignity Health</td>
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<tr>
<th>Jana Aagaard</th>
<th>Alice Leiter</th>
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<tr>
<td>Of Counsel to Dignity Health</td>
<td>Policy Counsel, Center for Democracy and Technology</td>
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<td>Law Office of Jana Aagaard</td>
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<tr>
<th>Sergio Bautista</th>
<th>Bill Beighe</th>
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<tr>
<td>CFO\COO</td>
<td>Chief Information Officer</td>
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<tr>
<td>Community Health Alliance of Pasadena</td>
<td>Santa Cruz Health Information Exchange</td>
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<tr>
<th>Paul Budilo</th>
<th>Richard Swafford, PhD</th>
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<tr>
<td>Executive Director</td>
<td>Executive Director</td>
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<td>OCPRHIO</td>
<td>Inland Empire Health Information Exchange</td>
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<tr>
<th>Martin Love</th>
<th>Michael Smith</th>
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<tr>
<td>Chief Executive Officer</td>
<td>Director of Operations</td>
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<td>North Coast Health Information Network</td>
<td>HealthShare Bay Area</td>
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<tr>
<th>John R. Christiansen</th>
<th>Dr. Lisa Scott</th>
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<tr>
<td>Christiansen IT Law</td>
<td>Deputy Compliance Officer</td>
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<tr>
<th>James Killeen, MD</th>
<th>Hugo Von Bernath</th>
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<tr>
<td>University of San Diego</td>
<td>Healthcare Information Resource Center</td>
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<tr>
<td>Dept. of Emergency Medicine</td>
<td>Office of Statewide Health Planning and Development (OSHPD)</td>
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<tr>
<th>Cassie McTaggart</th>
<th>Kerry Cataline</th>
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<tr>
<td>Cal OHII Division Chief</td>
<td>Cal OHII Branch Chief</td>
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<tr>
<td>Health Information and Policy Standards</td>
<td>Health Information and Policy Standards</td>
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Release 2.0 MMPA Task Force

Task Force Goals

- Build on the framework of the first release, working on Task Force prioritized topics:
  - Update release 1.1 to reflect HIPAA Omnibus Rule released January 23, 2013
  - Review and extend MMPA with regards to the increasing pervasiveness of agreements between HIOs to facilitate Statewide Health Information Exchange
Summary of changes in Release 2.0

- Changes required as result of HIPAA Omnibus rule
  - Following significant discussion the Task Force decided the best way to incorporate the Omnibus requirements were to modify the MMPA to separate the Business Associates Contract (aka BAA) to a separate Exhibit.
  - The changes to BAA found in Release 1 would be significant and real world experience using Release 1 indicated a strong rational for separating the BAA to a stand alone exhibit.
  - Other changes to R1 found in R2 as a result of the Omnibus rule included:
    - Modification to Sec. 9.2 regarding Breach notifications
    - Modification to Sec. 10 referring to Exhibit X, effectively replacing the BAA from Release 1.1
    - others
Summary of changes in Release 2.0

Changes made in relation to “Other HIOs”

- Release 1.1 included the concept of “Other HIOs” and provided a baseline framework to incorporate the condition where the HIO that is the subject of the Participants Agreement enables its participants to exchange with “other HIOs”.
- In setting the priorities for release 2 the Task Force wanted to expand on this area to reflect the increased prevalence of these relationships.

Changes found in Release 2 as a result include

- Updates to some definitions, Additional Alternatives regarding Section 2.2 and increased guidance in related footnotes; plus
- The commissioning of an analysis of extant InterHIO agreements by CalOHII for the Task Force (more on this later).
Disclaimer

The MMPA is for informational purposes only and should not be construed as legal advice or policy of the State of California.

The California Office of Health Information Integrity (CalOHII) makes no warranties, expressed or implied, regarding errors or omissions and assumes no legal liability or responsibility for loss or damage resulting from the use of information contained within.

Each HIO’s Participants’ Agreement will need to address the unique circumstances created by its own organization, the operations conducted, the particular range of services offered, the particular technology used, the regulatory environment in which it operates, and other factors it determines appropriate.
**Intended use**

- The MMPA is a tool to aid you. It does not eliminate the need to work with legal counsel.
- For those of you who are currently developing Participants Agreements we hope this is helpful in accelerating the process.
- For those of you who are potential Participants, we hope this tool helps you evaluate the agreements of HIOs you’re working with.
- As we move toward enabling inter-HIO exchange we hope that the MMPA facilitates the process of verifying alignment of any HIO’s Terms and Conditions to this common baseline in order to minimize the need for point-to-point agreements between HIOs.
- The theory is that having a reference point we can Index Participants Agreements and ultimately simplify the comparison of terms and conditions and enable the acceleration of HIE Adoption at the participant level and across HIOs.
In order to give you more perspective on the key subjects that you should consider as you draft your PAs....
Emerging HIE Forum

Key Subjects for Agreements for Health Information Exchange

Allen Briskin

August 27, 2013
The purpose of this presentation is to inform and comment upon recent developments in health law. It is not intended, nor should it be used, as a substitute for specific legal advice – legal counsel may only be given in response to inquiries regarding particular situations.
Overview of Data Sharing Agreements

■ Definitions
■ Administration of agreements
■ Who may use; rules for use
■ Rights to use system, services and data
■ Obligations of data providers and data recipients
■ Obligations of HIO; HIO’s services
■ Applicable policies and procedures
■ Technology
■ Privacy and security
■ Economic relationship
■ Compliance, enforcement, protection of parties’ legal interests
Definitions

- Important terms used in the contract
- Interplay with terms that have a specific meaning in related contexts
  - Applicable laws and regulations, *e.g.*, HIPAA, CMIA, etc.
  - Grant and demonstration project requirements
  - Others
- “Nonstandard” definitions can create “more work”
- Making choices about where those nonstandard definitions are worth the extra work
Administration of Data Sharing Agreements

- How HIE will
  - Develop and enter into agreements
  - Develop and adopt policies and procedures
  - Manage agreements
  - Manage changes

- Role, if any, of participants in governance
- Who may be a participant
- HIO’s enforcement powers
- Termination of participation
Who May Use HIO’s System; Rules for Use

- Who may be a participant
- Who may be an authorized user
- Roles & responsibilities of authorized users
- Passwords & other security measures
- Training & monitoring of authorized users
- Legal responsibility for authorized users’ actions and for use of their accounts or credentials
Rights to Use System, Services & Data

- Rights of participant and its authorized users to use HIO’s system, services and patient data so obtained
- Legal nature of rights
- Permitted and prohibited uses of system and services
- Permitted and prohibited access of data
- Permitted and prohibited uses of data
Obligations of Data Providers

- Rights granted to HIO and to participants to access and use patient data
- Type(s) and scope of patient data to be provided
- Measures to assure accuracy, completeness and timeliness of data provided
- Responsibility for consequences resulting from provision of inaccurate or incomplete data
Obligations of Data Recipients

- Responsibilities for selection, training, monitoring and disciplining authorized users
- Permitted and prohibited uses of patient data
- Responsibility for use of patient data
- Responsibility for actions taken (or not taken) based upon patient data obtained
Obligations of HIO

- Participants’ rights to use system, services and data
- Technology, if any, provided by HIO
- Maintenance of system
- Service standards
- Training
- Support
- Auditing, information collection, reporting
- Business associate obligations
Policies and Procedures

- Applicable policies and procedures
  - Developed by (unique to?) HIO
  - Developed by others
- Process for development and maintenance of policies and procedures
- How changes to policies and procedures will be made
- Role of participants in development and maintenance of policies and procedures
- Obligations of participants to comply with policies and procedures
Technology

- (Assuming that HIO will provide technology)
- Description of technology
- Meeting of minimum standards
- Participants’ rights to use technology
- Limitations on rights to use technology
- Participants’ obligations, if any, to make arrangements with others
- Participants’ obligations, if any, to provide own technology or infrastructure
Privacy and Security

- HIO’s obligations as a business associate
- Privacy and security policies that apply to access and use of system, services and patient data
- Obligations of HIO and participants to prevent data breaches, to report breaches and other events to each other, and to respond otherwise
- Measures to prevent damage to system and patient data
Economic Relationship

- Usage or other fees
- When fees can change, and how
- Other charges that can apply
- Consequences for failure to pay when due
- Participants’ responsibility for other expenses of participation
Enforcement; Transparency, Oversight & Accountability

- Measures to build and maintain trust among HIO and participants
- Obligations to indemnify others for acts and omissions
- Programs to enhance transparency, oversight, enforcement and accountability among participants and HIO
- Compliance with laws, generally (and business associate obligations noted above)
Protection of Parties’ Other Legal Interests

- Preserving confidentiality of proprietary information (different from patient data)
- Disclaimers of liability, allocations of legal responsibility, and other measures to prevent inappropriate legal claims
- Obligations to purchase and maintain insurance
- Indemnification obligations
- How agreements and policies and procedures will be interpreted
Wrap Up and Questions
Thank you

Allen Briskin

allen.briskin@pillsburylaw.com
Educational Materials

- Leah Hart, Communications at CHeQ
HIO Communications

HIO Marketing

- Why HIE?
- One sheets/Ads
- Journalistic Articles
- HIE Definitions/Acronyms
- Suggestions?

How can we help you?
Our success...
Our problem...

- Still creating stovepipes of data...
  ...now bounded by community and enterprise HIOs.
- The cost of inter-HIO data sharing agreements is too high.
A solution...

- **Trust**
  Trusted exchange among community and enterprise HIOs.

- **Scalable Trust**
  Trusted exchange among community and enterprise HIOs *without point-to-point data sharing agreements*. 
What do you need for trusted exchange?

- Know your conversation is not overheard.
- Know who you are talking to.
- Know who you are talking about.
- Know there is consent for your conversation.
California Trust Framework

Policies, practices, and technologies...
...that enable and promote trusted exchange...
...among community and enterprise HIOs and HIE service providers...
...without the need point-to-point data sharing agreements.
California Trust Framework

**Components:**

- **Trust Community** based on consensus policies and practices.
- **Multipart Data Sharing Agreement** rather than individual point-to-point agreements within the Trust Community.
- **Digital Certificates** to establish secure exchange with other members of the Trust Community.
- **Provider Directories** that identify individuals with whom to exchange information.
Using National Standards

*Exchange between HIOs is based on:*

- Direct specifications... 
  ...for simple push exchange (mostly) between individuals.

- Exchange (aka NwHIN) specifications... 
  ...for query/response exchange between organizations, and 
  ...for push exchange between organizations 
  ...with explicit authorization and patient matching.

- Healthcare Provider Directory specifications... 
  ...to discover addresses of individuals and organizations for 
  exchanging information.
Technical Approach

- Trust Bundles
  - New national standard for managing digital certificates and establishing participation in Trust Communities.

- Federated Provider Directories
  - Allowing widespread discovery of providers within Trust Communities.
  - Distributing management to ensure the information is accurate.

*Keeping the infrastructure lightweight!*
## Pilot Participants

<table>
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<th>Direct Track</th>
<th>Exchange Track</th>
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<td>Inland Empire HIE</td>
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<td>NCHIN*</td>
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<td>Santa Cruz HIE</td>
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<td>Sujansky &amp; Associates</td>
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<tr>
<td>UC Davis Health System</td>
<td>UC Davis Health System</td>
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* Also a NATE member.
Timeline

1. Established baseline Trust Bundle service. See [http://bundles.hiecosystem.net/ca/](http://bundles.hiecosystem.net/ca/)
2. Established baseline Provider Directory services. See [http://cheq.wikispaces.com/Provider+Directory](http://cheq.wikispaces.com/Provider+Directory)
4. Finalizing consensus policies and practices for Exchange.
5. Finalizing consensus policies and practices for Provider Directories.
6. Started the on-boarding process for Direct.
What this means to you...

- Allows you to focus on regional exchange to meet immediate community needs.
- Prepares for the future, when you can exchange with...
  - your neighboring communities,
  - overlapping enterprise exchanges,
  - federal agencies, and
  - exchanges across the country
...simply by joining Trust Communities.
Related activities...

- Know your conversation is not overheard.
- Know who you are talking to.
- Know who you are talking about.
- Know there is consent for your conversation.

Focus of HealtheWay
Pilot with OCPRHIO
Related activities...

“Creating a California trust framework based on national standards and protocols for trusted exchange and to create pathways to ensure that all providers can connect to and use Direct and HealtheWay’s eHealth Exchange.”

- Informed by the pilot.
Related activities...

- Focus on interstate exchange.
  - Provided much of the baseline thought for our trust framework.

- Establishing Trust Communities:
  - For provider exchange for treatment purposes, and
  - For patient engagement using PHRs.
Related activities...

- Focus on compliance testing for Direct and Exchange specifications.
- Drafted extension to HPD.
- Conducting a pilot test of provider directories for ONC.
Related activities...

- Focus on query/response exchange.
  - Although it supports other processes.
- Establishes trust through a multiparty agreement.
  - Driven by federal agency participation.
  - Basis for much of our agreement.
Related activities...

- Focus on Direct as a sole means of exchange.
- Establishes trusted transport through accreditation of business processes.
Questions

For more information, see:
http://cheq.wikispaces.com/Trust+Framework
Contact Information

Robert M. Cothren, PhD

Technical Director, California Health eQuality
Institute for Population Health Improvement
UC Davis Health System

916-731-1375
robert.cothren@ucdmc.ucdavis.edu
http://www.ucdmc.ucdavis.edu/iphc/Programs/cheq/
Next Emerging HIE Forum
Thursday, November 14th
In conjunction with the HIE Stakeholder Summit, November 15th

More information to be announced

HIE Stakeholder Summit details:
http://www.ohii.ca.gov/calohi/eHealth/NewsEvents/2013HIEStakeholderSummit.aspx
Thank You!