

Legal/Policy Advisory Group

May Meeting

May 28, 2013



Agenda

Project Update

Phase 1 Consent

HISP-to-HISP Exchange

Next Steps

Phase 2 overall timeline

Mass HIway Phase 2 high level project schedule

Activity	Target date
Submit IAPD to CMS	Dec 2012
CMS approval of Phase 2 IAPD	April 2013 Completed
Phase 2 contract (or change order) executed	April 2013 May 2013
Go-live - Public Health - Immunization Registry Node	April 28 2013 Completed on 4/28/13
Go-live - Public Health - Reportable Lab Results (ELR) Node	April 28 2013 Completed on 4/28/13
Testing - Public Health - Syndromic Surveillance Node	April 12 2013 May 24, 2013
Testing - EOHHS – Children’s Behavioral Health (CBHI) Node	May 24, 2013
Go-live for Phase 2, Release 1 (Other Public Health interfaces)	May – Oct 2013
Go-live for Phase 2, Release 2 (CDR, EMPI, RLS, Consent)	Oct 2013 – Mar 2014

Current Status

There are a number of organizations technically connected to the Hlway, and production transactions are starting to grow

- One million+ cumulative transactions have been transacted over the Hlway production system
- In May alone the Hlway has transacted:
 - 500K+ discharge/ED summaries and HL7 labs from Tufts Medical Center to Network Health
 - 40K+ CCDs from BIDMC to MAeHC Quality Data Center
 - 400+ HL7s from BIDMC to DPH Immunization Registry (stage)

MeHI Implementation Grant Program should accelerate demand for Hlway services

MeHI Grants Will Generate Demand for Hlway Services

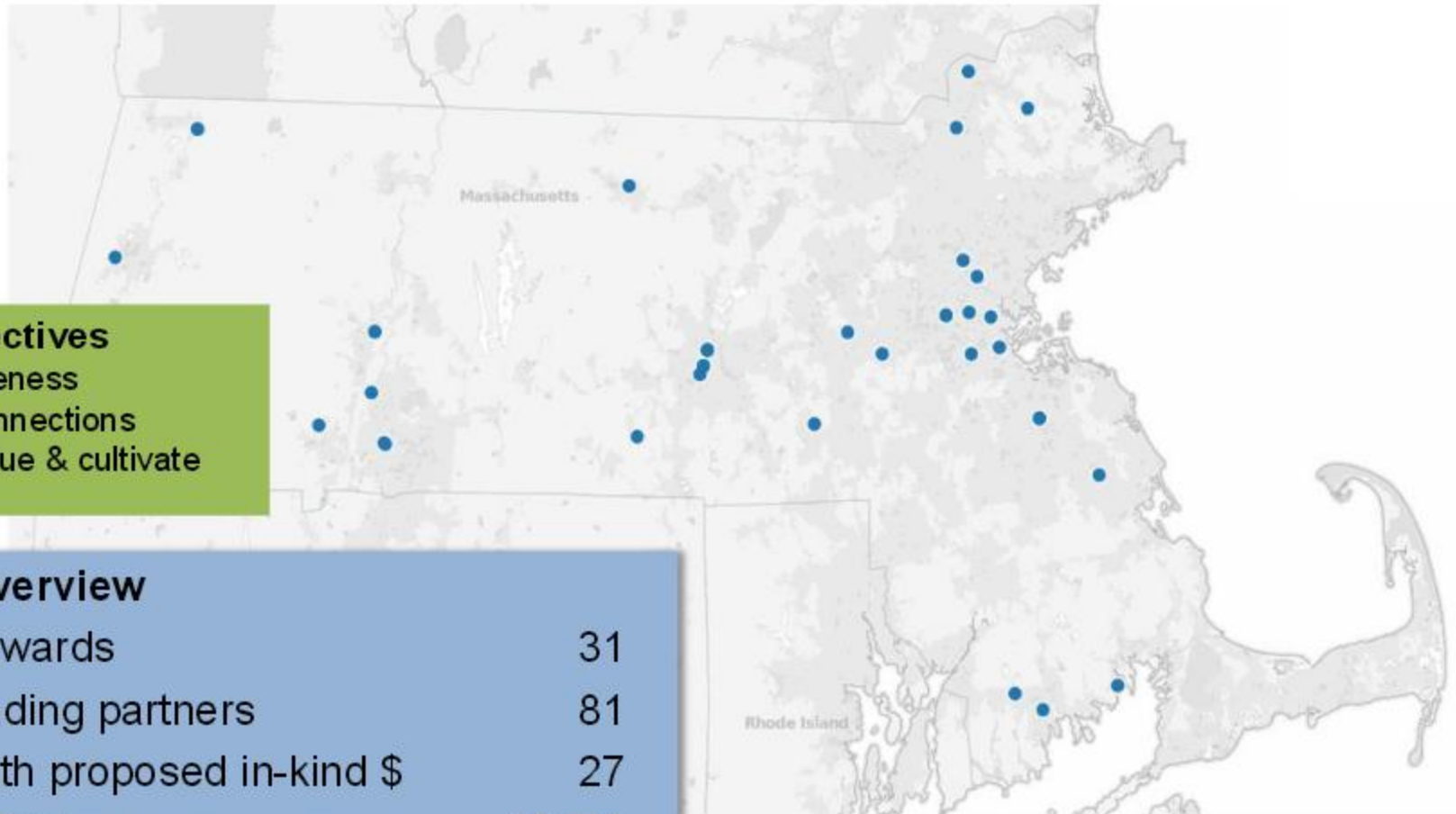
Hlway Implementation Grants

Grant Objectives

- 1. Build awareness
- Catalyze connections
- Build the value & cultivate 'stories'

Grants Overview

Planned Awards	31
Unique trading partners	81
Awards with proposed in-kind \$	27
Grant funding	\$2.2M



Map plotting 'primary applicants' of grants awarded

Agenda

Project Update

Phase 1 Consent

HISP-to-HISP Exchange

Next Steps

Consent for Phase 1 Services

Despite the fact that Phase 1 services are essentially “a step up from faxing”, there is some confusion in the market about consent requirements for the Hlway

Chapter 224 requires that patient has ability to “opt-in” and “opt-out” of HIE, however:

- Language was not updated from Chapter 305 (passed in 2008) and thus does not reflect new HIE architecture and more mature industry understanding of HIE and consent
- Hlway Phase 1 is basically secure email – highly circumscribed activity with no patient data repositories or query capabilities
- Law does not define key terms
 - “Opt-in” not defined at all
 - Implied definition of “opt-out” is not consistent with standard industry definition

Implementing Phase 1 Consent

Most large organizations and many small ones already opt-in patients for information-sharing

- Usually incorporated in “consent to treat” – sometimes bound with consent for treatment, sometimes separated
- Often does not distinguish mode of communication – authorizes sharing regardless of mode

A proposed operational approach for Phase 1 consent would be:

- Opt-in should include an actual consent for information-sharing that specifically names the MA Hlway as a mode of exchange
 - Not just a notice such as NPP; shouldn’t remain silent on MA Hlway
- An example that would cover this and is aligned with many current consent workflows:
 - Consent to treat that includes information-sharing with other providers
 - Update to NPP to list MA Hlway as a mode of exchange
- EOHHS is in process of evaluating this definition and options for providing greater clarity to the market

Leveraging current “consent to treat” and NPP to also cover Hlway opt-in would likely work for most larger entities but many small practices do not have formal “consent to treat”

- Some small practices may have to begin a more formalized consenting process to accompany their NPPs
- EOHHS in process of evaluating ability to provide examples to assist process

Key Questions on Phase 1 Consent

What issues and concerns do you have regarding the Phase 1 consent process?

What additional guidance or facilitation can EOHHS provide to assist with this process?

Agenda

Project Update

Phase 1 Consent

HISP-to-HISP Exchange

Next Steps

HISP Definition

What is a HISP?

- An organization that provides security and transport services for directed exchange based on the Direct protocol
- The term HISP does not have any authoritative meaning outside of the directed exchange protocol described in the [Applicability Statement for Secure Health Transport \(July 2012\)](#)
- 2014 Certification Standards cover EHRs, not HISPs

What does a HISP do?

- Assurance
 - Provide assurance of identity of participant (entities and individuals) and justification for participation in a trust community
 - Issue and maintain Direct email addresses to participants (entities and individuals)
- Security
 - Associate each email address with at least one security certificate and assure Direct-compliant payload encryption as specified by each addressee
 - Maintain a keystore of public keys discoverable to other HISPs through industry-standard protocols (e.g., DNS, LDAP, other)
- Standards
 - Process Direct-compliant messages to and from assigned addressees using SMTP/SMIME (and optionally, XDR/SOAP), signed and encrypted using X509 certificates

Breakdown in the HISP model

A key goal of the Direct Project was to have *federated, scalable trust* whereby each HISP maintains a trust fabric through contracts *within* the HISP, but requires no further trust fabric formalities *between* HISPs:

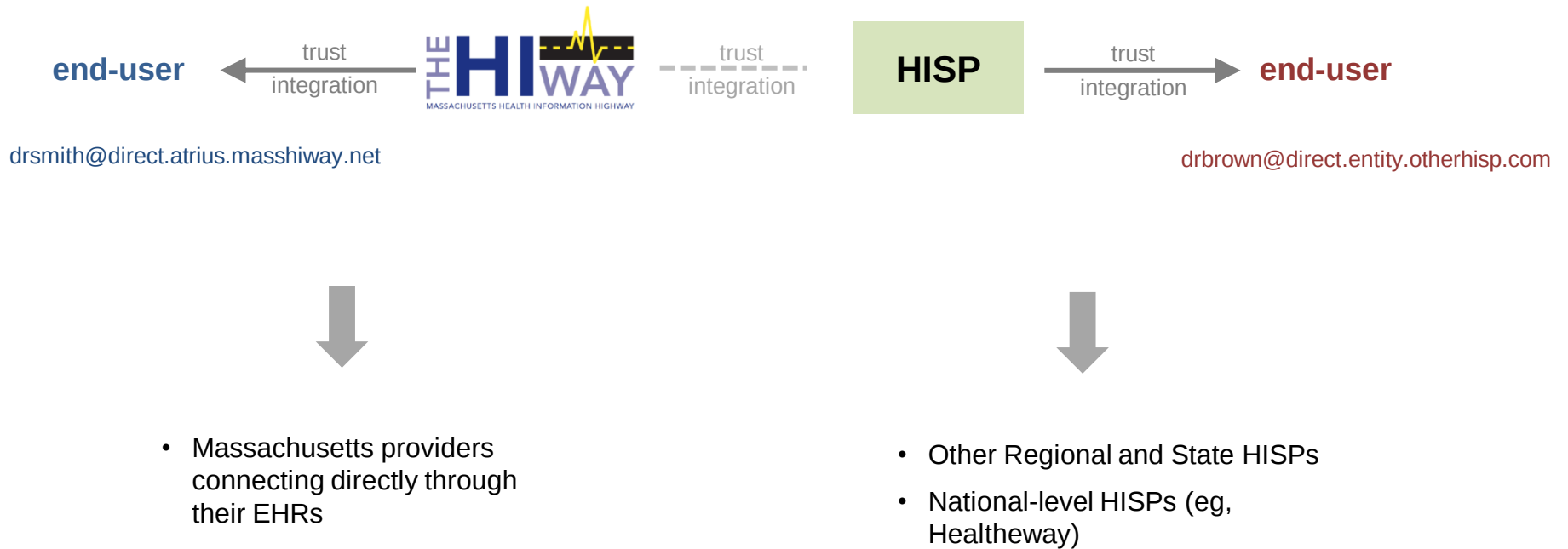
- Core HISP functions should be well-understood and transparent
- Inter-HISP trust not needed due to end-to-end encryption
- Applies only to directed exchange functions – not defined for other functions such as query
- Relies on end-users' trust across HISPs (i.e., end-users in one HISP accept trust established to end-users in other HISPs)
- Services integration (provider directory, certificate exchange, etc) does not require complex business and technical agreements

Yet, in reality, we have encountered a number of operational issues that weren't fully recognized at the time that Direct was specified

- There is no statutory or regulatory oversight of HISPs – standards apply to EHRs, NOT to HISPs
- Wide variety of models claiming to be HISPs – non-compliance with Direct specifications as well as allowable variations within the Direct-project specification
- Inconsistent trust fabric requirements – wide variety of within-HISP trust models that at a minimum require diligence before enabling cross-HISP exchange
- Scope of HISP activities – some HISPs perform more functions than just directed exchange, such as query-based transactions
- Technical integration – provider directory integration is not standardized, requiring detailed and ad hoc integration approaches

There is no standard definition of a HISP, so will have to make up our own operational definition

The original HIway HISP concept



Need for HISP-to-HISP policies

Original HISP concept envisioned HISPs as facilitators that would not require any type of HISP-to-HISP contracts

- “there should be no need for HISPs to require contractual relationships as a precondition for exchange using Direct Project compliant implementations”
- In practice, HISP-to-HISP contracts are proliferating

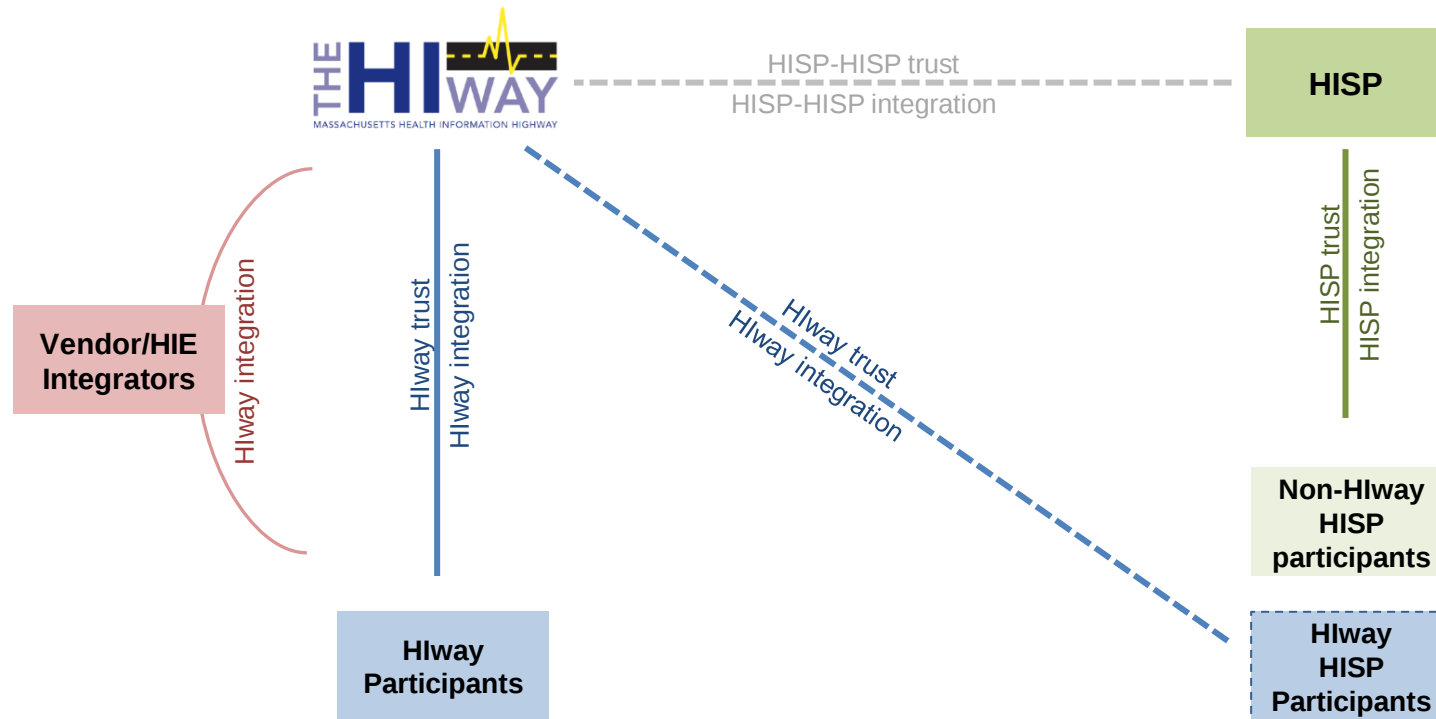
The proliferation of HISP models wouldn't be as big an issue EXCEPT for the fact that many Massachusetts providers may only be able to connect to the Hlway via HISP-HISP arrangements

- Some will be forced to by their EHR vendors (eg, eCW, Cerner)
- Others may choose to through local HIEs and nationwide networks (eg, Surescripts)

This adds policy, contract, and technical complexity to the Hlway model

- Trust/assurance approach
- Revenue model
- Service model (e.g., provider directory robustness and completeness, uniform Direct address domains, etc)

Need to define policy and technical approaches to variety of HISP models that exist in the market



Hlway Participant: sign Hlway PA on behalf of all end-users, validated through Hlway RA, cert through Hlway CA; Hlway issues direct addresses

Vendor/HIE Integrator: do not sign Hlway PA on behalf of end-users but provide single node of connection to the Hlway; end-users validated through Hlway RA, cert through Hlway CA; Hlway may or may not issue Direct addresses

HISP: self-contained trust community with own eligibility and participation requirements and own RA and CA and Direct addressing implementations

Many types of organizations that Hlway needs to consider

	Type	Description	Example
Hlway Participant	Basic entity Participant	Organizations that provide single type of health care services	practice, hospital, nursing home
	Complex entity Participant	Organizations that provide continuum of health care services	Partners, BID, Baystate
	Local HIE Participant	HIE organization that provides Hlway contractual representation and technical integration services to multiple Hlway-qualifying entities	Holyoke PVIX?
Vendor/HIE Integrator	Local HIE Integrator	HIE organization that provides Hlway technical integration services to multiple Hlway-qualifying entities	Wellport? PVIX?
	Vendor Integrator	EHR vendor that provides Hlway technical integration services to multiple Hlway participants	
HISP	Local HIE HISP	HIE organization that provides HISP-HISP contractual and technical integration services to multiple Hlway-qualifying entities	?
	EHR vendor HISP	EHR vendor that provides HISP-HISP contractual and technical integration services to multiple Hlway-qualifying entities and non-qualifying entities	eCW, Cerner
	Nationwide network HISP	HIE network vendor that provides HISP-HISP contractual and technical integration services to multiple Hlway-qualifying entities and non-qualifying entities	Surescripts
	State-sponsored HIE HISP	State-sponsored HIE that provides HISP-HISP technical integration services on behalf of multiple entities based outside of Massachusetts	NHHIO, RIQI
	PHR HISP	PHR vendor that provides HISP-HISP technical integration services on behalf of patients	HealthVault, No More Clipboards

Key areas to address in policy, contract, and technical requirements

Type	Contracts	Trust/ Assurance	Pricing	Certificate Authority	Provider Directory	Technical standards
Hlway Participant	• Hlway PA	• Hlway diligence process • Issues Hlway Direct addresses	• Pays Hlway fees	• Accepts Hlway as Certificate Authority	• Hlway Provider Directory as truth source	• Hlway integration requirements (transport, PD, certificates)
Vendor Integrator	• Technology Integrator agreement • Participants sign Hlway PA	• Hlway diligence process • Issues Hlway Direct addresses	• No charge to Vendor • Participants pay Hlway fees	• Accepts Hlway as Certificate Authority	• Hlway Provider Directory as truth source	• Hlway integration requirements (transport, PD, certificates)
HISP	• HISP-HISP agreement • Hlway PA?	• Hlway HISP requirements? • Issues HISP Direct addresses	• No charge to HISP? • Participant fees?	• HISP is Certificate Authority • Xcertify – all Participants or Hlway qualified only?	• HISP Provider Directory as truth source • Integration with Hlway PD	• SMTP/SMIME • Provider directory Pub/Sub and/or WS integration • Xcertification of root certificates

Is Direct Trust the answer?



Trust community that agrees upon common technical, business, and legal standards

- Formed to head off proliferation of one-off bilateral contracts among HISPs
- Received ONC grant to further work in security and trust “rules of the road”

62 members as of May 2013

- Of relevance to Hlway: eCW, Cerner, Surescripts, RIQI, Orion, Symantec

Three elements:

- Framework with consensus policies – currently X509 Certificate Policy and Federation Agreement
- Accreditation through EHNAC (First 4 vendors just certified including Cerner and Surescripts)
- Trust Anchor Bundle Distribution Service
 - Collection of trust anchors (root certificates) that meet common set of minimum policy requirements within a Trust Community Profile
 - Trust community profile – policies and requirements on selected organizations getting together for specific use cases

What Direct Trust does not answer

Direct Trust is not (yet) a magic bullet

- Still have relatively limited membership
- Only 8 trust anchors from 5 organizations included at present – relevant to Hlway: Cerner, Surescripts, RIQI
- Robustness and consistency of policies still being developed

Variations in eligibility and participation requirements

- They have a model trust agreement, but participants seem to be customizing it according to local policies and desires

Implicitly assumes complete end-user trust across HISPs

- We would still have to define policy/technical approaches for segregating MA providers from others, if that becomes our policy

Relatively few trust bundles defined at present

- But that should grow rapidly over time

Many policy and technical issues still not ready for prime time

- Requirement that Hlway work within Direct Trust governance and working group structure to bring the model to industry readiness

Key Questions on HISP-to-HISP Policies

Are there organization/contracting variants that were not identified?

Given that Phase 1 service is essentially secure email, what are the main trust issues that need to be addressed?

- Eligibility criteria and uses?
- Alignment of policies and procedures?
- Access to provider directory?
- Other?

Agenda

Project Update

Phase 1 Consent

HISP-to-HISP Exchange

Next Steps

Next steps

Next steps

- Key points and recommendations synthesized and provided back to Advisory Group for final comments
- Presentation materials and notes to be posted to EOHHS website
- Next Legal & Policy Advisory Group Meeting – June 18, 2013, 2:30-4pm.
 - MMS Plymouth Conference Room
 - Conference line: (866) 792-5314, Code: 7814347906#
- Next HIT Council – June 3, 2013, 3:30-5:00 One Ashburton Place, 21st Floor

HIT Council meeting schedule, presentations, and minutes may be found at <http://www.mass.gov/eohhs/gov/commissions-and-initiatives/masshiway/hit-council-meetings.html>