The Office of the National Coordinator for Health Information Technology

S&I Framework Initiatives

HIT Standards Committee Update

August 17, 2011

Introduction and Context

- The Standards & Interoperability (S&I) Framework:
  - Creates a collaborative, coordinated, incremental standards process,
  - … guided by the ONC (with input from Federal Advisory Committees),
  - … enabled and led by the an open community of industry participants,
  - … who are interested in solving real-world problems.
- Each S&I Initiative focuses on narrowly-defined, broadly applicable challenge, tackled through a rigorous development cycle including use case development, standards harmonization, testing, pilots and evaluation.
- Today's presentation is a reflection of the ***consensus findings*** of the open community of S&I participants. It represents the tremendous effort, expertise and resourcefulness of the community, for which we are very grateful. We expect that their findings will serve as valuable ***input into*** the HIT Standards Committee process for recommending standards to ONC for Meaningful Use.

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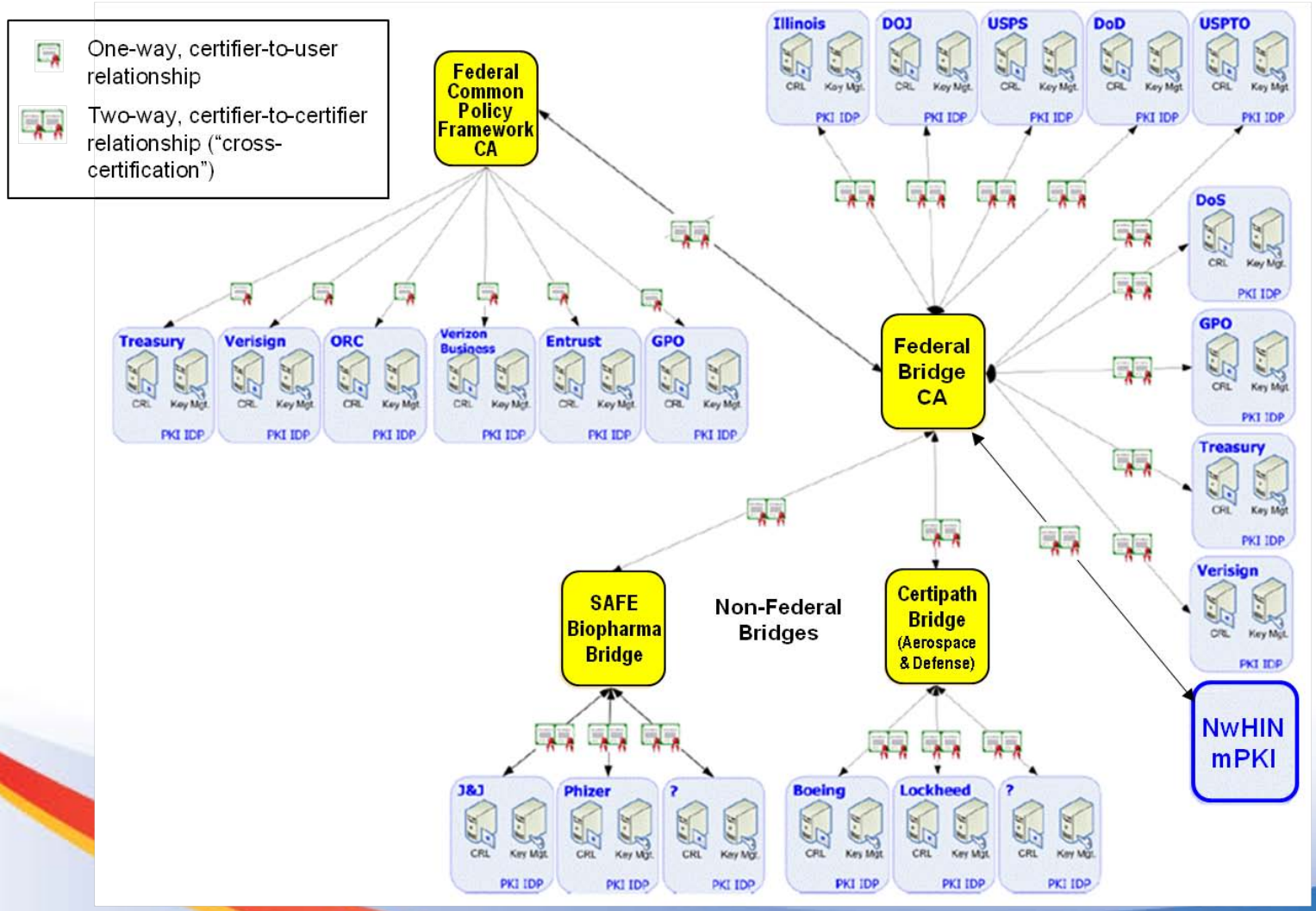
Certificate Interoperability (CI) Final Report

Task for the S&I Framework

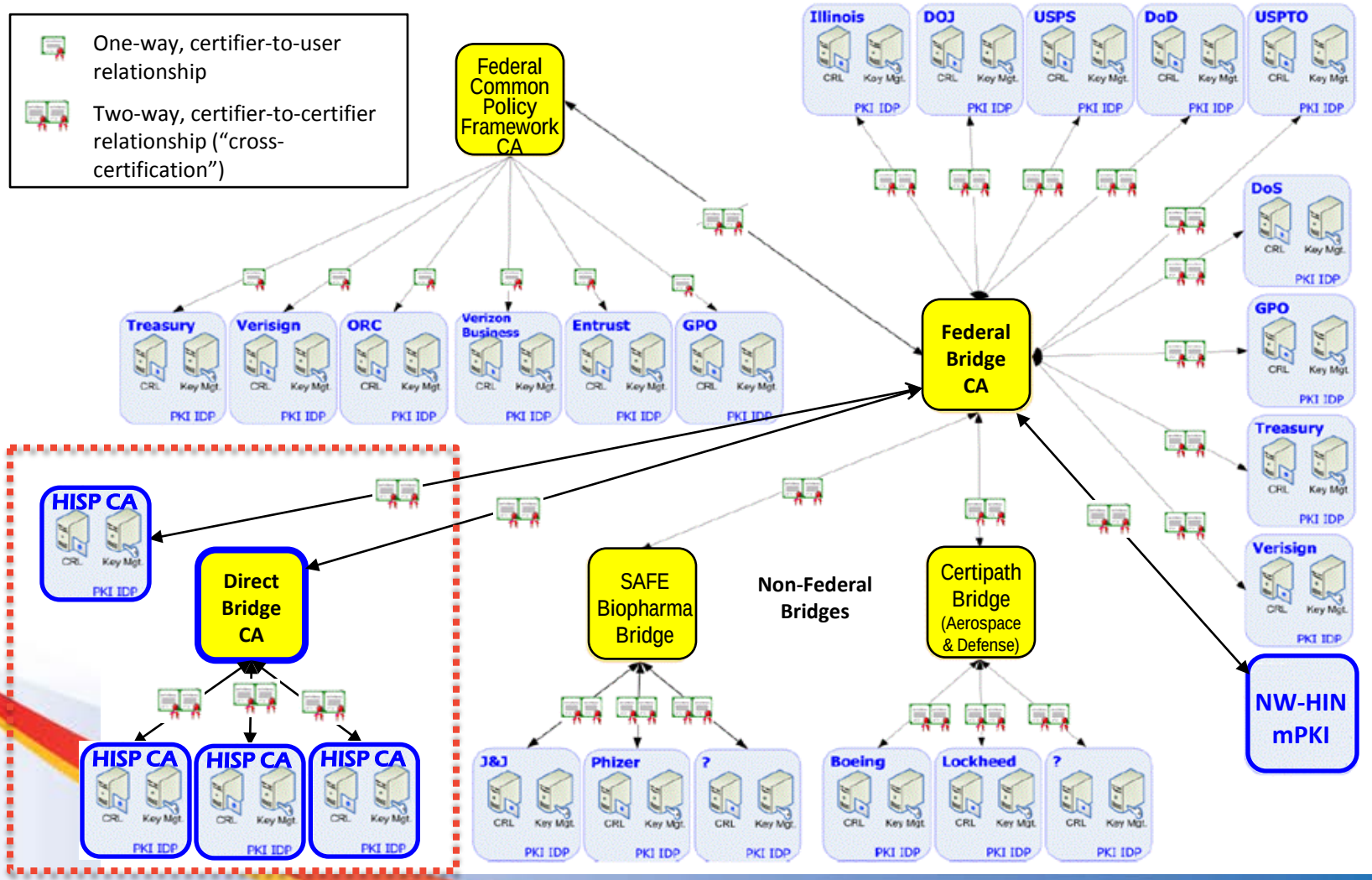
- Recommendation from the HIT Standards Committee to ONC:
  - "To enable Direct users to exchange health information with federal health agencies, the HIT Standards Committee recommends that the ONC investigate architectural and operational alternatives for cross-certifying Health ISPs (HISPs) with the Federal Bridge Certificate Authority, including an examination of potential benefits and implications on cost, market dynamics, and complexity"

Federal PKI Architecture*



*Adapted from *Federal Identity, Credential, and Access Management (FICAM) Roadmap and Implementation Guidance*, Nov 10, 2009

Notional Architecture with Direct Cross-Certification (as presented to HITSC)



*Adapted from *Federal Identity, Credential, and Access Management (FICAM) Roadmap and Implementation Guidance*, Nov 10, 2009

Certificate Interoperability Analysis Process

Step 1

Review Documentation

Certification requirements for…
- Federal Bridge (cross-certification)
- WebTrust
- ETSI

Step 2

Industry Interviews

(Bridges, Certificate Authorities, HIEs, Vendors, Agencies)
- SAFE BioPharma
- REBCA
- NIST
- Verizon Business
- Entrust
- GE Healthcare IT
- HealthBridge
- Lockheed Martin
- Thawte
- Nationwide Health Information Network

Step 3

Comment Period

- Draft Report posted to S&I Wiki for public comments
- Thirteen public comments from several individuals & organizations
- S&I Framework Teams' review of analysis & summary of public comments

Step 4

Address Feedback

- Update to summarize public comments
- Additional research on difference between FBCAs and commercial CAs requirements,
- Additional research on alternatives for cross-certifying HISPs with FBCA with analysis of benefits, cost, market dynamics, and complexity for each option

Today

Present Findings to 8/17 HITSC

FBCA Organizational Certificates

- Current FBCA policy does not issue organization-level certificates, as required by Direct – nor does it address the policies and procedures to verify organizational identities
- ONC staff has met with GSA staff to discuss this gap in policy
- GSA indicates that development of policy for organization identity verification will take 6 – 9 months
- ONC staff will coordinate with GSA on the development of these policies
- The Direct Project Rules of the Road Work Group is developing guidance to Direct Project to ensure that any certificates used in the interim will align with anticipated FBCA policy and comply with commercial best practice

Options for ONC's role

In light of the gap in the availability of organizational certificates, we investigated what support ONC could provide

- **Current state:** Direct participants identify and assess cross-certified CA's to make a purchasing decision
- **ONC provides governance and facilitate market competition to meet needs:** ONC issues guidance that goes beyond the FBCA requirements for certificates and identifies vendors that comply with certificate guidance and are cross-certified with FBCA
- **ONC charters a Bridge:** ONC directly (or contractually) establishes a Bridge that is chartered by the Federal Bridge
- **ONC negotiates an agreement with CAs to obtain discounted certificates:** ONC issues an RFP to select one or more vendors that are cross-certified and meet any additional requirements

Option Comparison Summary

Option for ONC	Pros	Cons
Current State	• Rapid to deploy • Low complexity and low overhead for ONC	• No healthcare root • Higher burden on purchaser to research and acquire CA options • Uncertain impact on certificate costs
Provide Governance and facilitate Market Competition	• Possible limited number of healthcare roots • Purchaser can rely on ONC vetting of vendors • Can require compliance with healthcare policies that go beyond FBCA	• Time and resources to vet CA's ——
Charter a Bridge	• Healthcare root can be established • Can require compliance with healthcare policies that go beyond FBCA • Purchaser can rely on ONC vetting of vendors	• Time and resources to set up and maintain a bridge • Uncertain impact on certificate costs
Negotiate Discounts with CA's	• Possible limited number of healthcare roots • Can require compliance with healthcare policies that go beyond FBCA • Purchaser can rely on ONC vetting of vendors • Reduced certificate costs for purchasers	• ONC responsibility for procurements and contract management • Likely to reduce the number of vendor choices

Implication of Findings

The findings of this initiative suggest that ONC can pursue the following actions:

- Work with GSA to ensure that policies regarding authentication of organizational identity and issuing organizational certificates are developed on an expedited timetable
- Ensure that in the interim Nationwide Health Information Network (including Direct Project) participants acquire and use certificates that align to the maximum extent possible with the Federal PKI policies
- Once Federal policies for authentication of organizational identity are in place, ONC should ensure that Nationwide Health Information Network (including Direct Project) participants have a process for an orderly migration to certificates that are issued by Certificate Authorities cross-certified with the Federal Bridge
- Pursue a longer term strategy to establish a Health bridge that is cross-certified with the Federal bridge

NOTE: For the entire CI report, click here

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Transitions of Care (ToC) Initiative

Value of ToC Initiative

How is the IG valuable in its support of Meaningful Use Stage 1 transitions of care amongst eligible providers, eligible hospitals, and eligible critical access hospitals and what do they stand to gain from the IG?

- Clear implementation guidance for each of the key information exchanges needed in a care transition
- User-friendly tooling and implementation support path to enable easier uptake and adoption
- Clinical perspective included to inform implementation

MEETING THE MISSION:

- Improve the exchange of core clinical information among providers, patients and other authorized entities electronically in support of meaningful use and IOM-identified needs for improvement in the quality of care
- Allow every transition of care to include high quality clinical information that could inform complete reconciled medication, problem, medication reaction, laboratory results, etc.

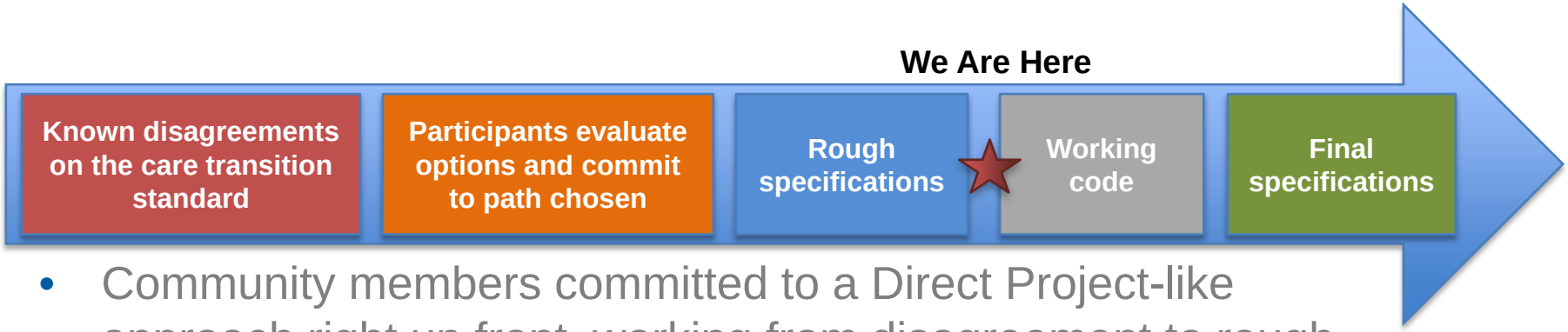
Summary of Decisions

The Community reached consensus on the following:

- HL7 CDA Release 2, specifically the CDA Consolidation ballot results, is the best standard to use in support of meaningful use requirements.
- ToC CIM be used to provide the clinical perspective for care transitions and is mapped to HL7 CDA Release 2.

MEANINGFUL USE REQUIREMENT
Exchange key clinical information among providers of care and with patients and other authorized entities electronically based on level of system capability, i.e., human readable, unstructured text or fully interoperable structured data

Path of Transitions of Care Initiative



- Community members committed to a Direct Project-like approach right up front, working from disagreement to rough consensus.
- We focused on achieving agreement on the following:
  - CDA Findings
  - CDA Tooling and Modeling Support
  - Clinical Information Model Findings
  - Transitions of Care Phase 2 Roadmap

CDA Findings

- Community reached consensus that the HL7 CDA R2 standard is satisfactory and sufficient to accomplish all clinical information exchanges required by the ToC Use Case and can support all exchanges for which a CCR-based transaction might be used
- Substantial library of HL7 CDA R2 templates is being leveraged to expedite completion of ToC IG to promote uptake of CDA use by HIT vendors
- Reference Implementation efforts are focused on the design of a CCR-CCD transformation service as part of the ToC Initiative to facilitate a defined transition path for those providers who will need to move to a CDA-based approach for care transitions
- The community and ONC contractors are collaborating to develop tooling, testing and educational resources to enable both executive guidance and implementation support

Utilizing a single standard minimizes potential misinterpretations from different formats and data structures, streamlines the patient transition process, and increases overall care coordination responsiveness to provide better patient care

Clinical Information Model (CIM) Findings

- Community proposes that the core, priority “A” CIM objects are the data elements that are important in all care transitions
  - Demographics
  - Active Medication List
  - Active Problem List
  - Intolerances including Allergies
- For Stage 2 Meaningful Use and beyond, all certified EHR systems, both hospital and ambulatory, would include an automated upload of priority “A” data elements as discrete data
- Community proposes that priority “B” and “C” data elements are considered optional if not available
- Additional, or variable, data elements that should be included in addition to the core data elements, must be selected by the clinician

ToC CIM and the ToC Implementation Guidance

Phase 1 of ToC Initiative

- Now completed, current versions of the ToC Implementation Guidance and ToC CIM are available for review through the S&I Framework wiki

Phase 2 of ToC Initiative

- Will focus on greenCDA schema development for those CDA sections that are reused across multiple care transitions
- Focus on ToC CIM work to finalize “B”, “C”, and “D” elements as needed

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Laboratory Results Interface (LRI) Initiative

The Value of the IG

How is the IG valuable for clinical labs, patients, providers, and others and what do they stand to gain from the IG?

- Establish a baseline that satisfies current Ambulatory Reporting Requirements and that can accommodate future use cases associated with lab reporting.
- Work is based on existing HL7 Lab Reporting IGs (HITSP, ELINCS, and PH), and based on the "assumptions, solutions, and learnings" of all three.
- S&I Initiative active participants include major labs, ACLA, EHR vendors, SDOs, government agencies, and a variety of implementers and experts.
- Enable a roadmap to future harmonization with the PH IG

MEETING THE MISSION:

To enable ambulatory primary care physicians to receive and meaningfully use standardized, structured electronic lab results.

- Establish the nationwide Implementation Guide for electronic submission of Lab Results to Ambulatory EHRs.
- EHR vendors, LIS vendors and Labs agree that they can implement the IG and use it to transmit and consume lab results without a middleman
- Providers broadly adopt EHRs that conform to the LRI IG - facilitated by Meaningful Use, State HIEs, RECs, and product options in the marketplace

Key Consensus Findings – Implementation Guide

- The community proposes a new IG that will adopt HL7 Version 2.5.1 except where data type, vocabulary, or field definitions in HL7 version 2.7, 2.7.1 or 2.8 provide greater interoperability.
- The community proposes that profiles be used to simultaneously provide constraints while allowing for flexibility to support a higher level of interoperability for labs/EHRs.
- Collaboration involved Lab and EHR, Ambulatory, Acute, and Public Health, drawing on great work done by ELINCS, HITSP, and HL7, to establish an IG that has more buy-in than any one IG could have achieved on its own.
- We asked HL7 to enhance the base standard, which they achieved through the introduction of V2.7.1 features that accommodate segment enhancements and conformance language enhancements. This is similar to support provided when HITSP asked for added field support for V2.5.1.
- Detailed IG and vocabulary findings are posted on the S&I Framework wiki at: http://wiki.siframework.org/LRI+Strategy+and+Consensus+Statement

NEXT STEPS FOR THE IG:

- In early September the IG will go into an out-of-cycle HL7 ballot.
- Planning for testing & implementation pilots is underway and expected to lead to iterative implementation guidance over the next few months.

Key Consensus Findings – Vocabularies and OIDs

- The community proposes LOINC be used for observation identifiers.
- The community proposes SNOMED CT be used for reporting of appropriate lab results, and that SNOMED be piloted for reporting specimen information.
- The community determined that UCUM appears to be viable for reporting Units of Measure but must be piloted before the workgroup can agree on adoption as a standard vocabulary.
  - In the near term, the community proposes that labs be required to transmit textual units of measure in the correct Observation segment.
  - For piloting, the community proposes a series of near term milestones and the development of a 12-24 month timeline.
- The community proposes the adopting of HL7 table content to be used as vocabulary based on the assumption that HL7 Version 2.5.1 standard is the required version in the IG
- The community proposes that ISO OID methodology is to be used to generate Globally Unique IDs; the new implementation guide will post two profiles in order to support the transition from the current practice to the proposed approach.

NEXT STEPS FOR VOCABULARY:

- Define appropriate criteria to evaluate SNOMED CT and UCUM during piloting.
- Launch and iterate through testing and pilots to refine learning and guidance.

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Provider Directories Initiative

Provider Directories (PD) Initiative – *Overview*

- This Initiative addresses the challenge of querying for and obtaining digital certificates and electronic service information to enable health information exchange
- The initiative focused on two use cases:
  1. Discovering digital certificate(s) associated with a known Direct Address
  2. Discovering the Electronic Service Information including Electronic Address with known provider attributes
- Community includes 63 Committed and 55 Non-Committed (i.e., “interested”) participants

FOCUS ON THE MISSION:

- Enable healthcare participants to look up digital certificate information to facilitate secure exchange of information through Direct Project
- Help HIEs/EHRs/PDs to enable query and response for electronic service information including electronic addresses, with corollary benefits to data governance, PD instantiation, HIE/EHR development and deployment, etc.

Discovery of Digital Certificate – *Overview*

- Direct Project Communities of Interest have an urgent and immediate need for common standards for certificate discovery. As a result, the community immediately evaluated current, real-world experience and is presenting the findings
- The community analyzed DNS and LDAP/x.500 (LDAP) standards, including strengths and weaknesses – notably:
  - DNS is being effectively utilized by Direct Project implementers and supports Certificate Discovery to the extent that it has been required so far by Direct Project pilots
  - DNS provides for easy federation and replication of certificate data
  - A significant number of DNS servers do not support CERT records
  - LDAP is currently being used for certificate discovery in a significant number of organizations
  - LDAP has well-established tools for large organizations and large databases
  - LDAP does not have demonstrated federation or universal accessibility as currently deployed

Discovery of Digital Certificate – *Consensus Findings*

- A hybrid DNS/LDAP solution (described on next slide) will take advantage of the strength of each method and in combination cover the individual limitations
- The hybrid approach will allow a greater number of implementers to effectively enable certificate discovery and certificate management
- The Direct Project RI team has examined this approach and agrees that the work required is trivial, and complementary to the current DNS solution
- Several EHR/HIE organizations have volunteered to expend the resources to update the RI and documentation for this solution so that it is broadly available to implementers for free
- Two Direct Project pilot communities have committed to pilot the hybrid solution
- As such, the community suggests that this solution receive due consideration given the value to and interest by implementers, subject to pilot testing

Discovery of Digital Certificate – *Process Flow and Effort Required*

Current DNS resolver

If CERT not found

LDAP resolver

Query DNS SRV record	Query LDAP using anonymous bind

RI currently supports

- Multiple resolvers
- DNS certificate query
- LDAP anonymous bind and certificate query

Work to be completed

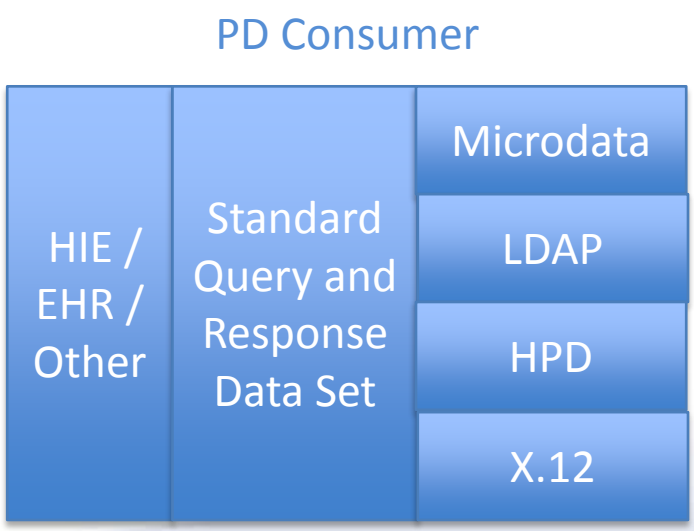
- Implementation guidelines for publishing and discovering LDAP services using the DNS SRV record
- Implementation guidelines for the LDAP query/response schema for digital certificate discovery using an anonymous bind
- Update RI code for discovery of LDAP services using the DNS SRV record for a given domain
- Update RI code for the discovery of a Direct digital certificate stored in LDAP using anonymous bind and the above schema

Query for Electronic Services (including the Electronic Address) – *Overview*

- ***Electronic Service Information*** is the information reasonably necessary to define an electronic destination and its ability to receive and consume a specific type of information (e.g. discharge summary, patient summary, laboratory report). The information should include the destination's electronic address, message framework, payload specification, and required security artifacts.
- Provider Directory Communities of Interest have an urgent and immediate need for provider directory query and response content and vocabulary standards that they can adopt now and will be compatible with any standard that is selected in the future.
- Standardized content and vocabulary are required for HIEs/EHRs/PD to share and utilize data maintained in provider directories
- **However, standards to support queries to provider directories have limited deployment. Broader experience in the use of these standards will provide opportunities for innovation and allow a market-driven evidence-based approach to standards selection**

Query for Electronic Services (including the Electronic Address) – *Data Set Effort*

- The effort utilized the work product completed by the Provider Directory Community of Practice to identify the minimum data set for Provider Directories
- This data set was reviewed, evaluated and updated based on the use case for Electronic Service Discovery and passed consensus vote
- Mapping the dataset, data model and schema – to standards like Microdata, LDAP/x.500, HPD, and ASC X12 – is the first priority and current focus of the initiative
- Community-driven efforts focused on identifying, testing, and evaluating standards for electronic service information discovery are encouraged

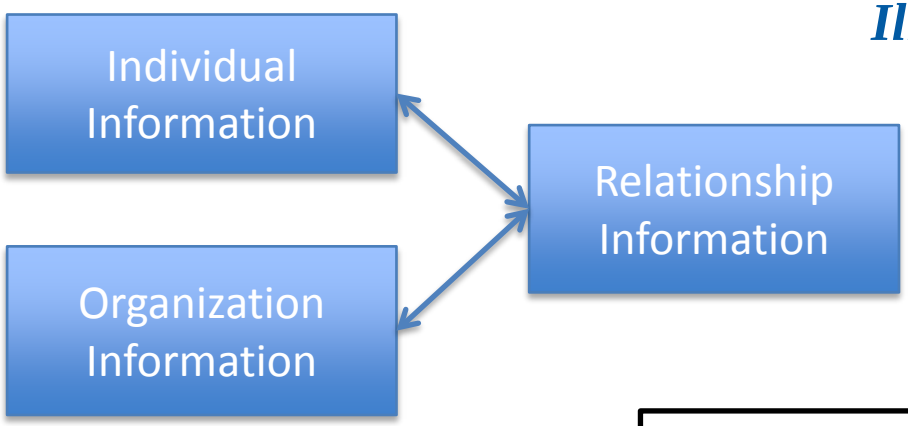


Query for Electronic Services (including the Electronic Address) – *Data Set Detail*

Illustrative

Query

- PD identifier
- Individual, Organization, and Relationship
  - Unique Identifier
  - Name
  - Address
  - Type / Specialty
  - Telephone Number
  - NPI
  - Email
  - Certificate



Response

- PD information
- Individual Information
- Organization Information
- Relationship Information
- Electronic Service Information

Next Steps

Mapping Data Set to:

- Microdata
- IHE HPD
- LDAP / X.500
- ASC X.12

Outcomes:

- Gaps
- Standard Extensions
- Incompatibilities

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Summary of Consensus Findings & Suggested Action Items

Summary & Action Items – *Certificate Interoperability Initiative*

Key Findings:

- There is a gap in Federal PKI policy to address identity validation for organizations requesting server certificates.
- In light of this, the initiative evaluated options for ONC to provide support to the industry

Suggested Actions for HIT Standards Committee:

- Monitor progress of GSA development of policies for organizational certificates
- Confirm that interim certificate practices align with anticipated FBCA policies
- Review transition plan for migration to FBCA organizational certificates
- Monitor development of a Health Bridge

Summary & Action Items – *Transitions of Care Initiative*

Key Consensus Findings

- The CDA Consolidation (HL7 CDA Release 2) ballot results are the best standard to use in support of meaningful use requirements.
- Tooling, testing and educational resources will ease implementation
- The Transitions of Care CIM provides clinical perspective for care transitions and maps to HL7 CDA Release 2.

Suggested Actions for HIT Standards Committee:

- Agree on a standard for care transitions for Meaningful Use Stage 2
- Recommend EHR certification criteria for incorporation and usage of structured care transitions documents

Summary & Action Items – *Lab Results Interface Initiative*

Key Consensus Findings

- The new Lab Results Interface IG leverages profiles to simultaneously provide constraints while allowing for flexibility and higher interoperability.
- LOINC should be used for observation identifiers and SNOMED CT should be used for reporting of appropriate lab results.
- Use of SNOMED for reporting specimen information and UCUM for Units of Measure are likely, but each requires piloting for consensus
  - In near-term, textual units of measure should be transmitted in correct Observation segment

Suggested Actions for HIT Standards Committee:

- Agree on a lab results reporting standard for ambulatory primary care to support Meaningful Use
- Recommend vocabularies or near-term guidance for observation identifiers, lab results, specimen information and units of measure

Summary & Action Items – *Provider Directories Initiative*

Key Consensus Findings:

- Certificate Discovery for Direct Project:
  - A hybrid DNS/LDAP solution allows a greater number of implementers to effectively enable certificate discovery and management
  - Implementers have volunteered to expend the resources to build this solution into the Direct Project RI and to conduct pilots.
- Query for Electronic Services (including the Electronic Address): standards to support queries to provider directories have limited deployment. Broader implementation experience is needed to allow an evidence-based approach to standards selection

Suggested Actions for HIT Standards Committee:

- Agree on an approach (including additional data required and timetable) for recommending:
  - Standards for certificate discovery for Direct Project participants
  - Provider directory query standard(s)

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For more information on S&I Framework activities and detailed consensus findings, please visit: http://wiki.siframework.org