



*An Overview of Direct Secure  
Messaging, MU Requirements,  
Use Cases and  
CLIA/Delivery Notification*  
ONC State HIE / NILA Workgroup

August 20, 2013

- What is Direct Secure Messaging (DSM)?
- Direct Workflow Scenarios
- Other Health Care Use Cases for Direct
- The Business Case for Lab Result Delivery and Direct
- CLIA Requirements and Delivery Notification
- Labs Over Direct Pilots and Tool Kit

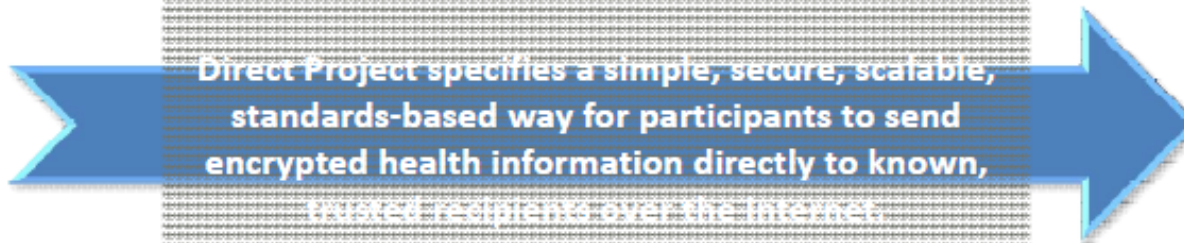
- Establish a consistent level of understanding on the topics of Direct Secure Messaging (DSM), lab related use cases and CLIA requirements for DSM
- Equip stakeholders with the understanding of this technology as a tool for exchange and to facilitate conversations between labs and HIEs.

# Direct Secure Messaging

## Secure Internet-based Direct Communications



b.wells@direct.aclinic.org



h.elthie@direct.ahospital.org

- **Simple.** Connects healthcare stakeholders through universal addressing using simple push of information.
- **Secure.** Users can easily verify messages are complete and not tampered with in travel.
- **Scalable.** Enables Internet scale with no need for central network authority.
- **Standards-based.** Built on common Internet standards for secure e-mail communication.

## Direct Addresses

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- Direct Addresses are used to route information
  - Look like email addresses
  - Used only for health information exchange

[b.wells@direct.aclinic.org](mailto:b.wells@direct.aclinic.org)

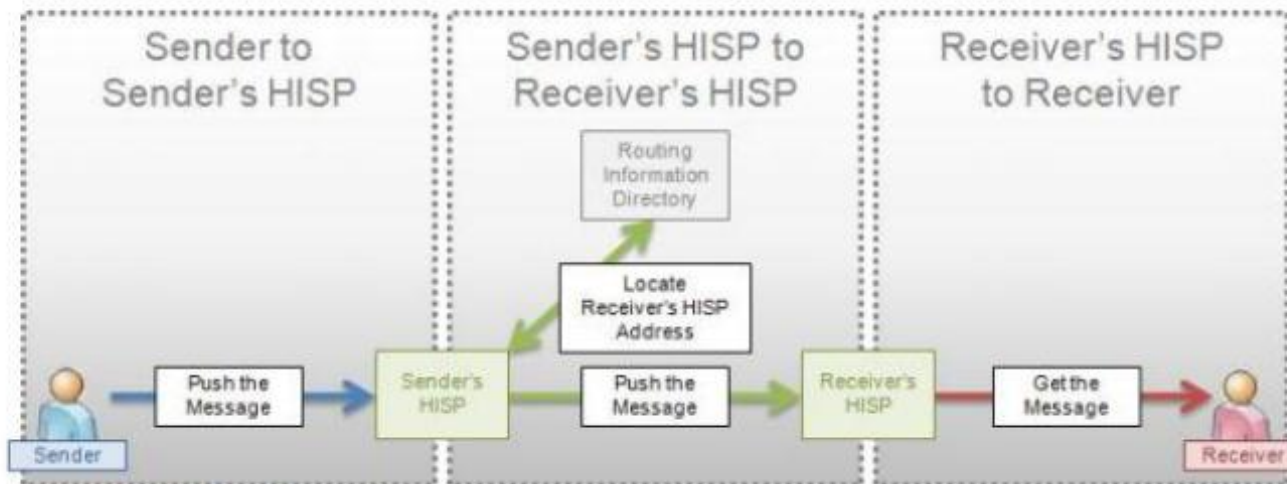


The diagram shows the email address [b.wells@direct.aclinic.org](mailto:b.wells@direct.aclinic.org) with brackets underneath. A bracket under 'b.wells' is labeled 'Endpoint'. A bracket under '@direct.aclinic.org' is labeled 'Domain'. A larger bracket under the entire address is labeled 'Direct Address'.

- An individual may have multiple Direct addresses

- HISP = Health Information Service Provider
- HISPs enable their members to communicate using Direct. HISPs .....
- Provide Direct Addresses
- Publish digital certificates
- Route Direct messages
- Depending on implementation model (e.g., web portal), possibly store Direct messages

## What is a HISP?



*The Direct Project Abstract Model*

In brief, the essence of a HISP's duties are to:

- Package message content using MIME and, optionally, XDM.
- Secure the confidentiality and integrity of the content by handling it through S/MIME encryption and signatures.
- Ensure the authenticity of the sender and receiver via X.509 certificates.
- Route messages through at minimum SMTP (other protocols allowed by mutual consent between HISPs)



- **Transport**

- Secure Health Transport specifications detail how to use SMTP, S/MIME, and X.509 digital certificates to securely transport health information over the Internet
- *Applicability Statement for Secure Health Transport*  
<http://wiki.directproject.org/Applicability+Statement+for+Secure+Health+Transport>

- **Certificate Discovery**

- HISPs must support a mechanism for certificate discovery
- The *Applicability Statement* details how to do so using DNS and DNS CERT records

- **Trust Models (*emerging area*)**

- Security profile, including authentication and encryption of data at rest
- Trustworthiness of associated CAs and RAs
- Identity verification or proofing

- **Registration Authority (RA)**
  - Collects information for the purpose of verifying the identity of an individual or organization (i.e., identity proofing)
  - Produces certificate requests based on gathered attributes
  
- **Certificate Authority (CA)**
  - Digitally signs certificate requests
  - Issues digital certificate that ties a public key to the gathered attributes

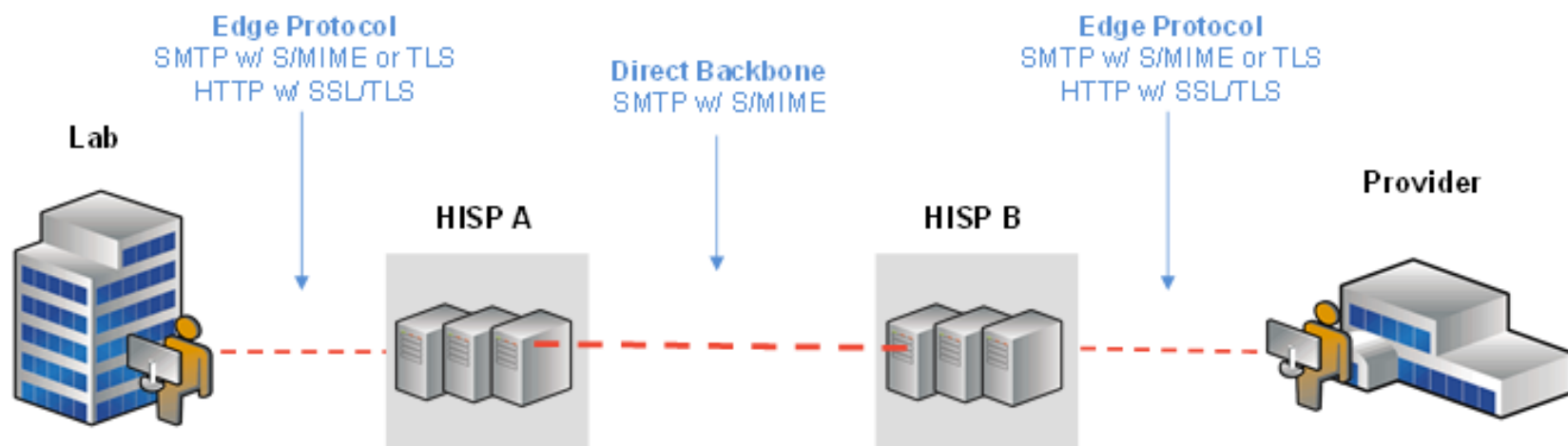
Two types of trust when talking about certificates:

1. Technical trust that comes from using digital certificates
  - The Sender has a strong mathematical certainty that only someone controlling the Receiver's private key (presumably the Receiver) can view the message
  - The Receiver has a strong mathematical certainty that only someone controlling the Sender's private key (presumably the Sender) sent the message
  - Both Sender and Receiver have confidence that nothing happened to the message in transit (e.g., tampering, disclosure, etc.)
2. Trust that the parties involved in communication are who they say they are.

# Direct Workflow Scenarios for Lab Result Delivery

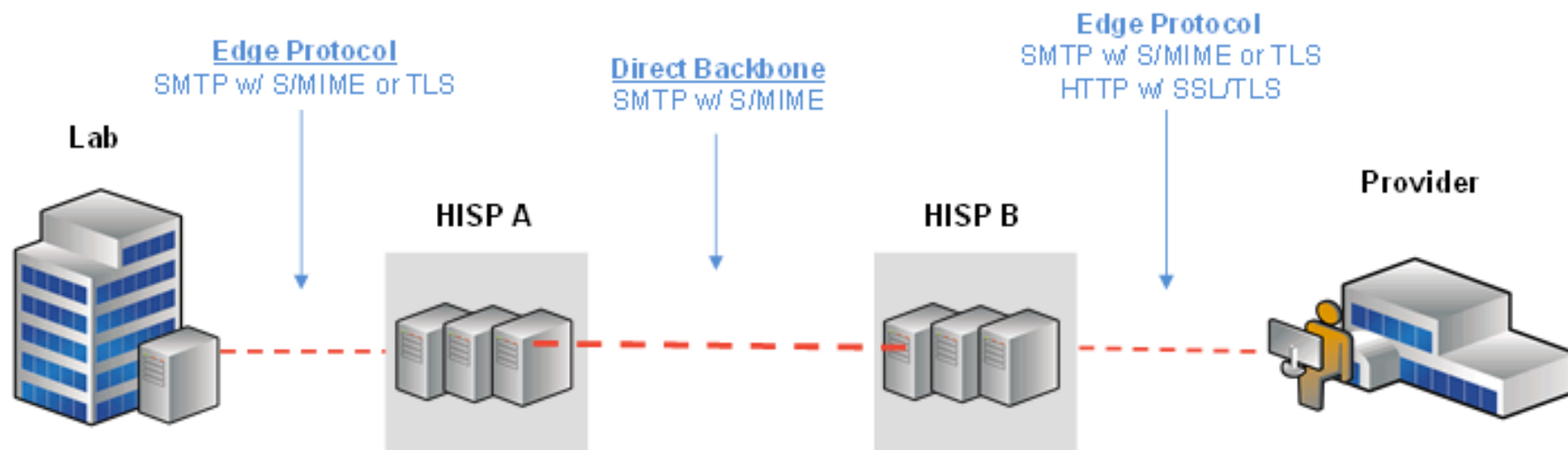
## Scenario 1: Manual Unstructured

In this first scenario, the lab end-user creates a Direct message and attaches a LIS-generated 'print image' (i.e. PDF unstructured document) of the lab results in a desktop email client or webmail portal. On the other side of the transaction, the provider end-user receives the Direct message with the PDF attachment in a desktop email client or webmail portal and manually enters results into an EHR.



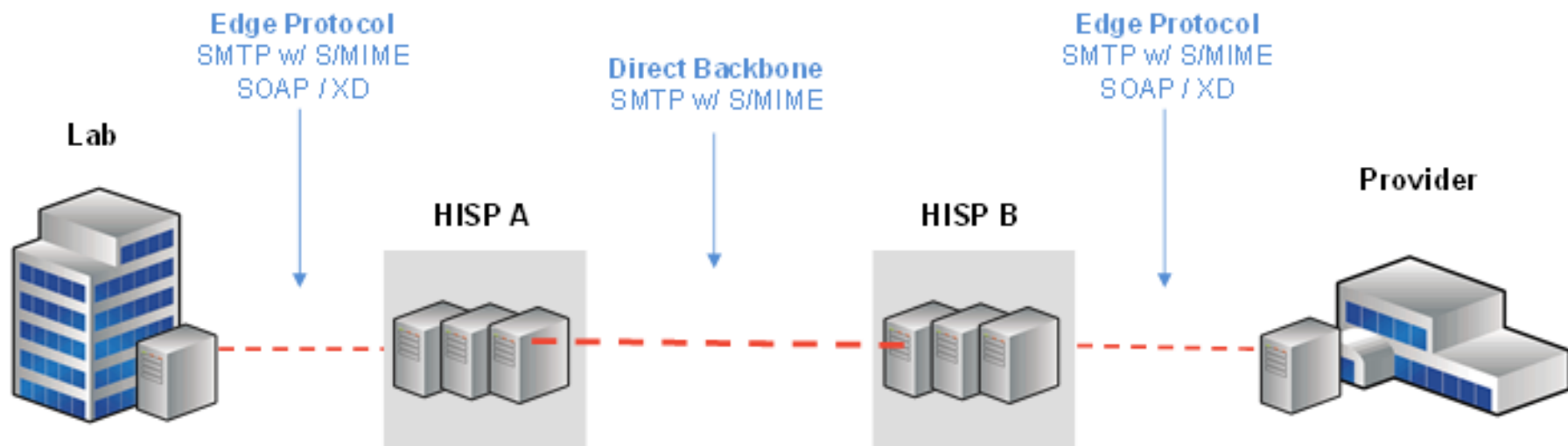
## Scenario 2: Partially Automated Unstructured

In this scenario, the LIS programmatically generates a 'print image' (i.e. PDF unstructured document) of the results, creates a Direct message, attaches the results and sends to the HISP. On the other side of the transaction, the provider end-user receives the Direct message with the attached PDF document in a desktop email client or webmail portal and manually enters results into an EHR.



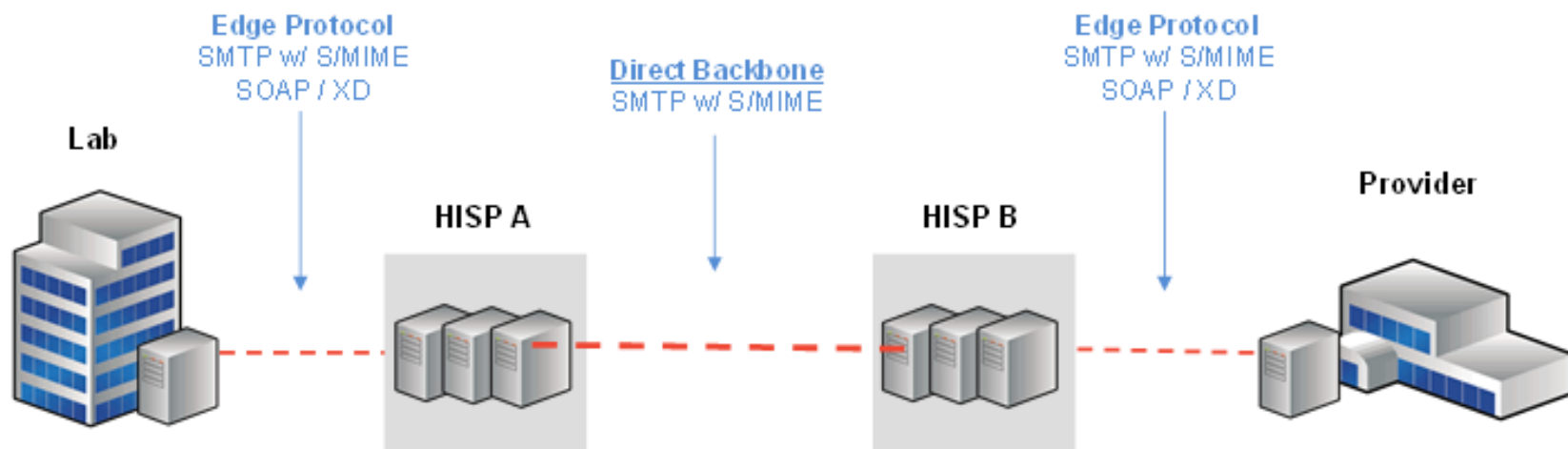
## Scenario 3: Automated Structured

In the third scenario, the LIS programmatically generates a structured message (i.e. HL7) based on national standards and sends the message to the HISP. On the receiving end of the transaction, the ordering provider's EHR receives the message and stores structured data in the EHR.



## Scenario 4: Automated Structured Lab Results Interface (LRI)

In the fourth scenario, the LIS programmatically generates an LRI IG-compliant structured (i.e. HL7) message and sends to the HISP. On the other side of the transaction, the ordering provider's EHR receives an LRI-compliant message and automatically stores structured data in the EHR.



**\*Note:** Edge protocols (e.g., SMTP, SOAP, HTTP, etc) are up to the discretion of the HISP and may come in many forms other than those listed in the scenarios.



# Other Health Care Use Cases for Direct

- Patient referrals between PCP and Specialists
- Transitions of care (hospital ER or IP, nursing home, PCP).
- Hospital sends patient health information to the patient
- Provider sends a clinical summary of an office visit to the patient
- Hospital ADT alerting to providers.
- Any electronic exchange of PHI.
  - Care management
  - Quality review organizations
- Public health reporting (immunizations...etc.)
- Interstate exchange
- Emergency/disaster response
- Department of Corrections
- Behavioral Health collaboration

# The Business Case for Lab Results Using Direct

- ONC identified lab result interoperability as one of the top priorities for State HIE grantees.
- Implementation of Direct secure messaging is a phase one priority for State HIE grantees.
- Structured Lab result delivery using Direct is a lower cost technology to support the lower volume small / rural providers vs dedicated interfaces.
- Supports providers (clients) in achieving Meaningful Use requirements.

# Why Direct for Lab Delivery?

## Benefits and Barriers

### Benefits

- Direct secure messaging is a **low-cost, scalable, standardized** solution to get labs connected to providers where there are no existing point-to-point interfaces.
- Direct w/ delivery notifications functionality is **CLIA-compliant** and helps labs stay competitive in an evolving marketplace.
- All providers will have Direct functionality in their CEHRT.
- Potential to either “level the playing field” for all labs.
- Does not require a Business Associates agreement.

### Barriers

- Limited technical and workflow integration between the LIS and Direct HISPs.
- Funding for small independent labs, (hospitals have MU, national labs have deeper pockets and point-to-point solutions).
- Potential to block the market for those labs who cannot adopt a solution.
- National labs have NOT shown much interest in Direct as they have point-to-point solutions already in their markets.

# CLIA Requirements and Delivery Notification

# What is CLIA?

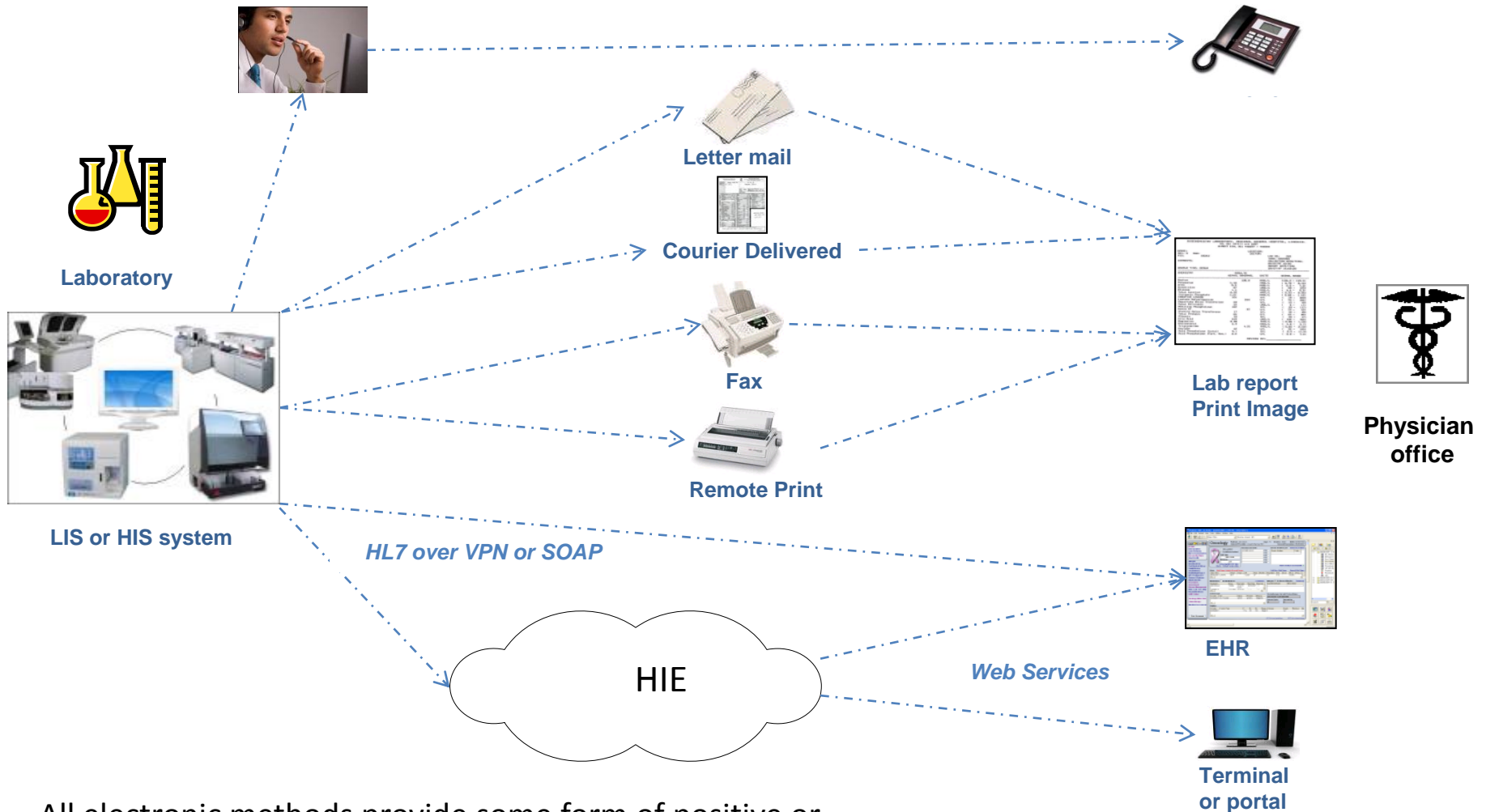
- Congress passed the **Clinical Laboratory Improvement Amendments (CLIA)** in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed.
- The **Centers for Medicare & Medicaid Services (CMS)** regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA).
- Exempt states – New York, Washington

- Timely and predictable acknowledgement of result delivery success or failure
  - Under CLIA, labs are responsible for delivering reports to the Final Report Destination, and must know when report delivery has succeeded or failed
  - Existing mechanisms for report delivery provide timely and predictable acknowledgement of success and failures



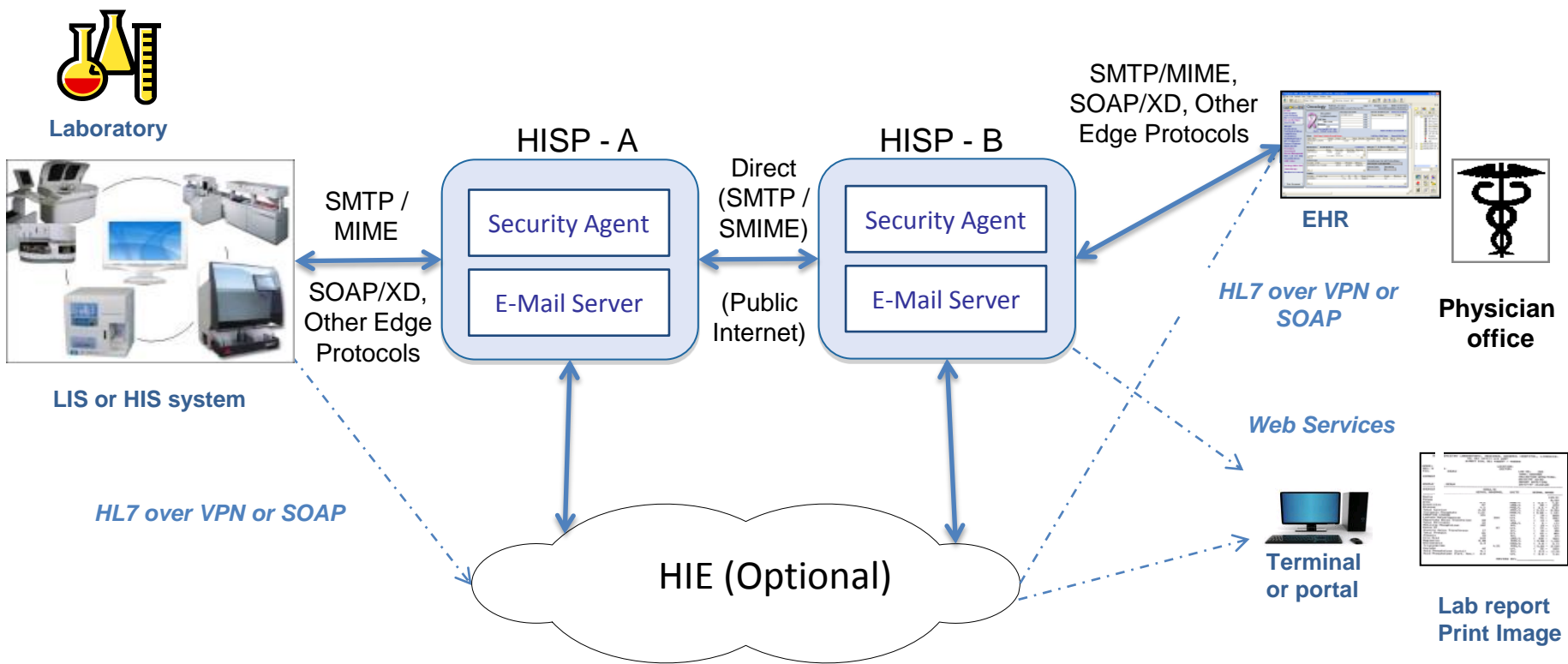
# Laboratory Results Reporting Today

Putting the I in HealthIT   
www.HealthIT.gov



All electronic methods provide some form of positive or negative acknowledgement of receipt

# Laboratory Results Reporting via Direct



Multiple paths are possible depending on the specific implementation of Direct

- How can labs confirm receipt?
- How can labs assure timely delivery?

# Delivery Notification

## *Implementation Guidance*

- Direct Project's *Applicability Statement for Secure Health Transport* specification allows for acknowledgements of delivery success or failure, but does not **require** them
  - Security/Trust Agents (STAs), such as HISPs, that receive a Direct Message **MUST** acknowledge successful receipt and trust verification of a Message by sending a Message Disposition Notification (MDN) with a *processed* disposition (i.e., a *processed* MDN)
  - STAs / HISPs **MAY** issue other notifications under other conditions but are not required to do so

# Direct – Laboratory Reporting Workgroup

- ONC formed a workgroup including labs, accrediting agencies, and CLIA
  - Members include: ONC, LabCorp, Quest, Methodist Hospital, Pathology Inc., College of American Pathologists (CAP), CMS/CLIA
- Charge:
  1. Identify any regulatory and operational issues with Direct that prevent or limit adoption by clinical laboratories for transmitting the “Report of Record” to the Final Report Destination
  2. Identify mitigation strategies for each of the issues
  3. For regulatory issues, work with ONC and CMS/CLIA to ensure that, where appropriate, guidance is issued to accrediting agencies to enable the use of Direct for lab reporting
- Outcome:
  - Implementation Guide was created and directed at HISP vendors
  - Guide details how to implement timely, predictable acknowledgement of positive or negative delivery within a Direct context

- Guide details how to implement timely, predictable acknowledgement of positive or negative delivery within a Direct context
- Requires HISPs to indicate successful or failed delivery to destinations
- Guide details how to request destination delivery notifications, what constitutes a delivery “success” or “failed” notification, and the responsibilities of the Sending and Receiving HISPs around these notifications
- Guide provides use cases that illustrate when and under what circumstances “success” and “failed” notifications could be sent

**1. *What constitutes a “reasonable timeframe” for result delivery?***

**A:** In the context of lab reporting, a Sending HISP serving a lab should wait for a destination delivery notification no longer than 1 hour before declaring the transmission a failure unless otherwise specified within an SLA with the lab.

**2. *Instead of these notifications, wouldn’t issuing “read receipts” suffice?***

**A:** No. Labs must know in a predictable, timely manner when delivery has succeeded or failed. There is no guarantee as to when a message will be read or if it will be read, thereby resulting in a receipt, and read receipts provide no mechanism for indicating delivery failure.

**3. *Beyond the Implementation Guide, are there any other requirements that must be fulfilled in order to transmit lab reports using Direct?***

**A:** Yes. All STAs/HISPs must comply with Direct Project’s *Applicability Statement*, and parties must continue to meet all their responsibilities as applicable under HIPAA, CLIA and associated guidance, and state and federal law.

# Labs Over Direct Pilots

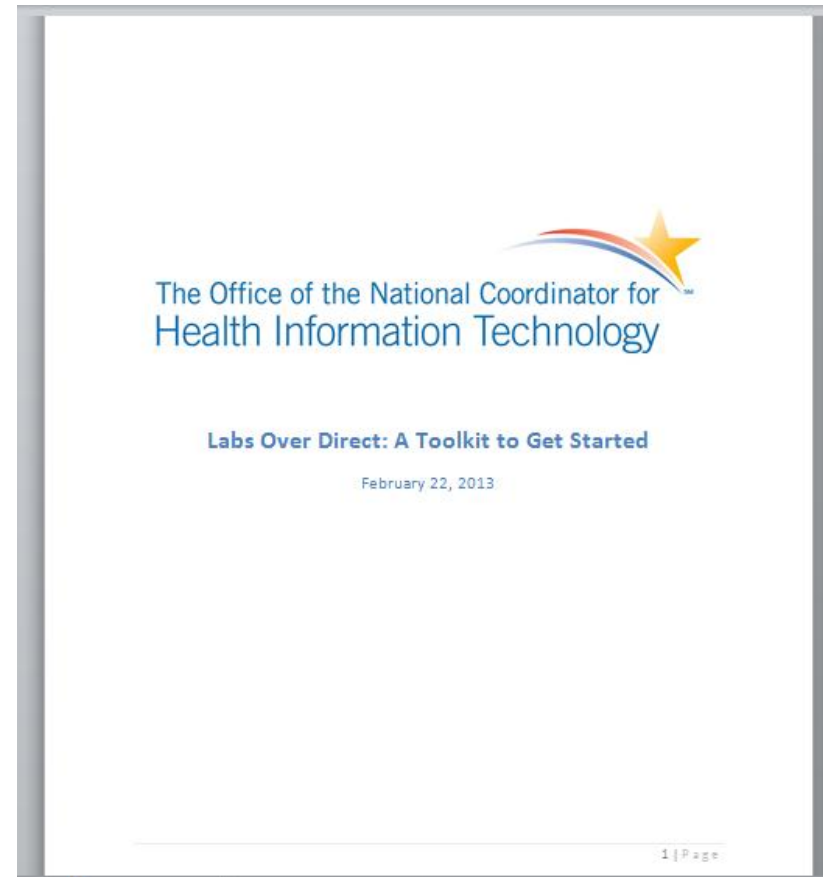


- Pilots were introduced at the ONC Lab Summit – May 2012
- Pilot Projects Kick-off – June 2012
- Implementation and Testing of Delivery Notifications – Fall 2012

<p><b>Alaska Team Lead: Paul Cartland</b></p> <p>AK Department of Health and Social Services (State HIE)            AK Anchorage Neighborhood Health Clinic            AK Fairbanks Hospital            AK State Public Health Laboratories            Orion Health            Chemware            Cognosante            Providence Medical Center</p>	<p><b>Hawaii Team Lead: Greg Suenaga</b></p> <p>Hawaii Health Information Exchange (State HIE)            Clinical Laboratories of Hawaii, LLP            Hawaii Beacon North            HI Beacon WellLogic provider            Medicity            Wellogic</p>	<p><b>Florida Team Lead: Walt Culbertson</b></p> <p>FL Agency for Health Care Administration (State HIE)            FL Care360 provider            IOS Health Systems            Harris Corporation            MedPlus, Inc.            Quest Diagnostics            FL Health Management Associates</p>
<p><b>North Carolina Team Lead: Keith Scott</b></p> <p>NC Dept of Health and Human Services (StateHIE)            Orion Health            Solstas Lab Partner</p>	<p><b>Guam Team Lead: Ed Cruz</b></p> <p>Office of the Governor of Guam (State HIE)            GU provider            Diagnostic Laboratory Services            Apenimed            Medicity            Atlas</p>	<p><b>West Virginia Team Lead: Kathy Moore</b></p> <p>WV Premier Medical Group            WV Preston Taylor            Grafton City Hospital            Orchard Software Corporation            Truven (formerly Thomson Reuters)            West Virginia Health Information Network</p>

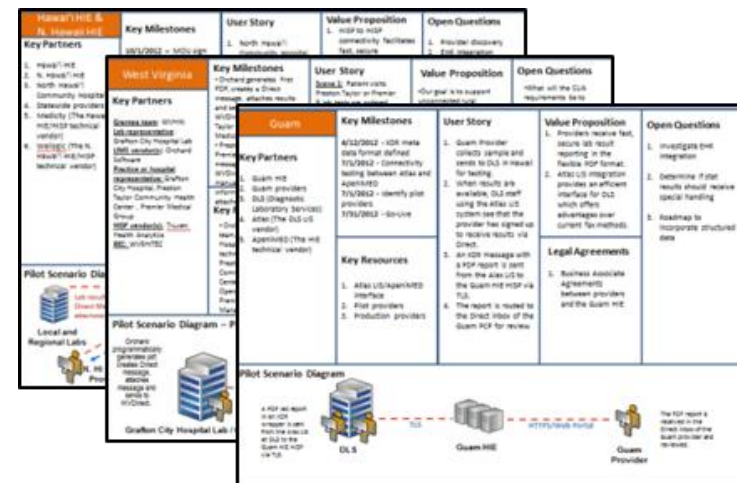
# What is the Lab Pilot Toolkit?

- The toolkit is designed as a “how to” guide for planning and implementing your own labs over Direct pilot project to help accelerate lab interoperability in your state or community.
  - It draws from the experiences and lessons learned from the Labs Over Direct Pilot Teams (from AK, FL, GU, HI, NC, and WV).
  - It also contains useful documents and strategies.
- The information that is provided will help you to better understand promising practices, strategies and tactics that health information exchanges, sub-state exchanges and other stakeholders are using to enable lab exchange over Direct secure messaging.
- *The toolkit is available for download on the [HITRC](#).*



# How is the Lab Pilot Toolkit Organized?

- The Lab Pilot Toolkit is organized chronologically by suggested steps to take to get started with your own pilot. It contains the following sections:
  - **Planning a Labs Over Direct pilot**
    - *Describes the steps needed to identify potential partners and define project goals*
  - **Operationalizing pilots**
    - *Describes the essential components of a functional project plan and legal considerations*
  - **Implementation and testing**
    - *Presents test scripts that can be used to ensure the implementation meets requirements outlined in the Delivery Notification Implementation Guide.*
  - **Pilot evaluation and expansion of services to other labs**
    - *Presents key takeaways from the six lab pilot teams*



- Labs Over Direct Toolkit and related materials  
<http://hitrc-collaborative.org/confluence/display/hiecoplabinteroperability/Labs+Over+Direct+Toolkit>
- Direct Project Wiki  
<http://wiki.directproject.org>
- *Applicability Statement for Secure Health Transport* – the normative specification defining Direct transport  
<http://wiki.directproject.org/Applicability+Statement+for+Secure+Health+Transport>
- *Implementation Guide for Delivery Notification in Direct* – the guide defining positive and negative delivery notifications  
<http://wiki.directproject.org/file/detail/Implementation+Guide+for+Delivery+Notification+in+Direct+v1.0.pdf>
- Direct Project Implementation Geographies Workgroup – regular meetings of communities and vendors that are implementing or have implemented Direct  
<http://wiki.directproject.org/Implementation+Geographies>
- Direct Project Reference Implementation Workgroup – Java and C# open source software implementations of Direct Project specifications  
<http://wiki.directproject.org/Reference+Implementation+Workgroup>

# Questions?