

The Direct Project Overview

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Abstract: The Direct Project specifies a simple, secure, scalable, standards-based way for participants to send authenticated, encrypted health information directly to known, trusted recipients over the Internet. This document provides a general overview of the Direct Project: its goals, limitations, use cases, and how it fits into broader exchange standards already in place.

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1. What is the Direct Project?

1.1 Introduction

Today, communication of health information among healthcare organizations, providers, and patients is most often achieved by sending paper through the mail or fax. The Direct Project seeks to benefit patients and providers by improving the transport of health information, making it faster, more secure, and less expensive. The Direct Project will facilitate “direct” communication patterns with an eye toward approaching more advanced levels of interoperability than simple paper can provide.

The Direct Project specifies a *simple, secure, scalable, standards-based* way for participants to send authenticated, encrypted health information *directly to known, trusted recipients over the Internet.*

The Direct Project focuses on the technical standards and services necessary to securely push content from a sender to a receiver and not the actual content exchanged. However, when these services are used by providers and organizations to transport and share qualifying clinical content, the combination of content and Direct-Project-specified transport standards may satisfy some Stage 1 Meaningful Use requirements. For example, a primary care physician who is referring a patient to a specialist can use the Direct Project to provide a clinical summary of that patient to the specialist and to receive a summary of the consultation.

Additional information on the Direct Project, such as workgroups, models, standards, services, reference implementation and documentation, can be found at <http://www.nhindirect.org>. Many of the terms used in this document are defined in the Glossary in the Appendix.

1.2 Assumptions

The Direct Project allows secure communication of health data among health care participants who already know and trust each other and thus is bound by a set of simplifying assumptions. The Direct Project assumes that the sender is responsible for several minimum requirements before sending data, including the collection of patient consent where appropriate. These requirements may or may not be handled electronically, but they are handled nonetheless, even when sharing information today via paper or fax. For example, a sender may call to ask whether a fax was sent to the correct fax number and was received by the intended receiver. This is sometimes referred to as “out of band” verification.

The following assumptions provide context for the Direct Project’s standards and services:

- **Policy guidance** for Direct Project exchange will be provided by the [Nationwide Health Information Network Workgroup of the HIT Policy Committee](#) and will not be decided within the Direct Project itself. Organizations must choose the policies and practices that support their specific environments.
- Direct Project exchange will **conform to applicable federal and state laws**, including but not limited to those related to security and privacy of protected health information.¹

¹ Since Federal laws do not currently mandate any particular transport standards, the standards specified by the Direct Project cannot be inherently noncompliant in regards to transport.

- As required by law or policy, the Sender has obtained the patient's **consent** to send the information to the Receiver. Therefore, the Sender and Receiver know that the patient's privacy preferences are being honored.
- The Sender of a Direct message has determined that it is **clinically and legally appropriate** to send the information to the Receiver through out-of-band means.
- The Sender has determined that the Receiver's **address** is correct.
- The Sender has communicated to the receiver, perhaps out-of-band, the **purpose** for exchanging the information.
- The Sender and Receiver **do not require common or pre-negotiated patient identifiers**. Similar to the exchange of fax or paper documents, there is no expectation that a received message will be automatically matched to a patient or automatically filed in an EHR.

The Direct Project solution provides a way to communicate in a secure, encrypted, and reliable way, as described in the detailed Direct Project technical specifications. These specifications can validate the identity of the sender and ensure the authenticity and integrity of the content sent, but they do not assert that the sender or receiver has met the policy assumptions mentioned above.

1.3 Scope Limitations

The Direct Project does not target complex scenarios, such as an unconscious patient who is brought by ambulance to an Emergency Department. In the unconscious patient scenario, a provider in the ED must “search and discover” whether this patient has records available from any accessible clinical source. This type of broad query is not a simple and direct communication pattern, and therefore it requires a more robust set of health information exchange tools and service that the Direct Project does not provide. The Direct Project does not embody a model of pulling information.

The Direct Project focuses on the *transport* of health information, but Direct alone does not produce “interoperability.” Interoperability enables two or more disparate systems to communicate information meaningfully, and it requires three prerequisite predefined components: Transport, Content, and Vocabulary. In order for systems to interoperate, they must determine

- how they will send and receive their messages (e.g., Direct Project-specified transport),
- the structure and format of their exchanged content (e.g., a Continuity of Care Document), and
- what terms they will use within their content (e.g., SNOMED Clinical Terminology).

The Direct Project provides only the first of these three prerequisite components.

2. How will Direct Project Exchange be Used?

2.1 Common Scenarios

The Direct Project standards and services can be adopted by any organization or person (such as a physician or a patient) seeking to implement simple direct point-to-point electronic communications. For some providers, these communications are part of satisfying Stage 1 Meaningful Use objectives. The Direct Project can also help improve business processes for a practice, or empower patients and families by supporting efficient exchange of health information using widely available technology.

This technology can range from certified comprehensive EHRs, to individual EHR modules, to Personal Health Records, to other technology that is not part of an EHR or PHR – such as a simple e-mail client or web browser – that can communicate health information securely. Direct human interaction with data may

be involved on both ends of the communication: for example, a physician who composes an e-mail to another physician and attaches a clinical document which the physician on the other end receives and opens. Human interaction may be involved on only one end of the communication: for example, an EHR that automatically generates an e-mail message and send it to a patient who opens it and reads its contents. No human interaction or intervention may be involved in the exchange at all: for example, an EHR that automatically communicates with a health information exchange repository or another EHR, automatically routing and/or storing the message without being viewed by anyone as it is being done. It is important to note, however, that the “entirely automated” scenario requires more than the minimum required data to be sent for effective processing within the business workflow.

Direct messages can carry patient-specific or non-patient-specific content. A sample set of scenarios (called “user stories”) that can be enabled using the Direct Project’s standards and services are listed below.

Priority One

Stories that support Stage 1 Meaningful Use and are targeted for implementation in the first implementations of the Direct Project

- Primary care provider refers patient to specialist including summary care record
- Primary care provider refers patient to hospital including summary care record
- Specialist sends summary care information back to referring provider
- Hospital sends discharge information to referring provider
- Laboratory sends lab results to ordering provider
- Transaction sender receives delivery receipt
- Provider sends patient health information to the patient
- Hospital sends patient health information to the patient
- Provider sends a clinical summary of an office visit to the patient
- Hospital sends a clinical summary at discharge to the patient
- Provider sends reminder for preventive or follow-up care to the patient
- Primary care provider sends patient immunization data to public health

Priority Two

Stories that are prioritized for early implementation but have potentially complex dependencies on additional policy considerations

- Provider or hospital reports quality measures to CMS
- Provider or hospital reports quality measures to State
- Laboratory reports test results for some specific conditions to public health
- Hospital or provider send chief complaint data to public health
- Provider or hospital sends update to regional or national quality registry
- Pharmacist sends medication therapy management consult to primary care provider
- A patient-designated caregiver monitors and coordinates care among 3 domains
- A Provider EHR orders a test
- A patient sends a message to the provider

Priority Three

Other high priority use cases

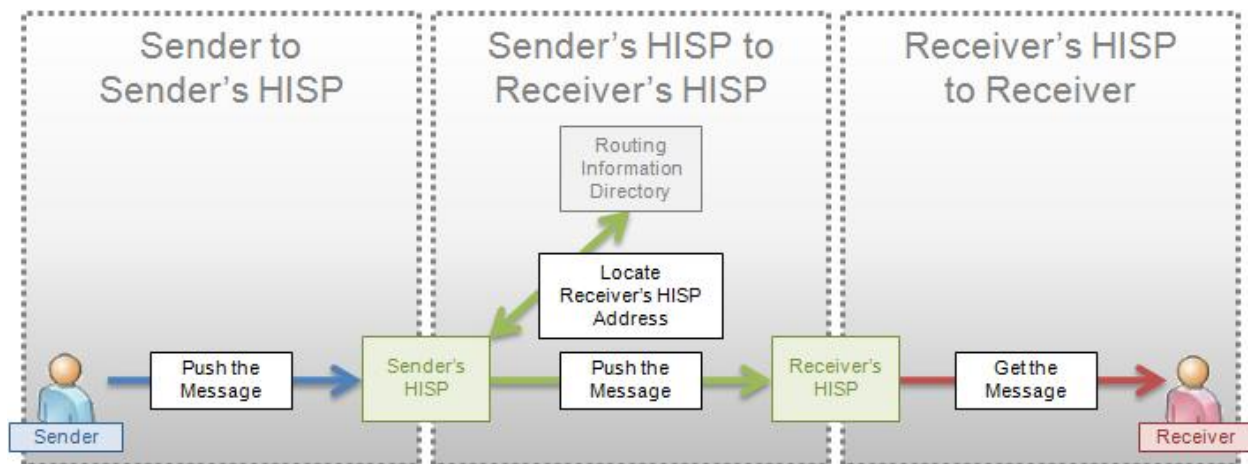
- Transaction sender receives read receipt
- State public health agency reports public health data to Centers for Disease Control

The analysis of user stories leads to common patterns that are required to satisfy them. Some of these patterns include

- A need to uniquely and contextually identify the Sender of the health information
- A need to uniquely and contextually identify the Receiver of the health information
- A need to deliver health information from the Sender
- A way to separate the routing of the health information from the clinical content, which includes formal as well as informal types of content (for example, simple text narrative, or formal structured documents such as a CCD or CCR or a lab test result)
- Security that establishes and verifies trust between the participants and protects the content being transferred from inappropriate disclosure or tampering

2.2 Support of the User Stories

The Direct Project Abstract Model below was created to represent the flow of information from one party, a sender, to another party, the receiver. The Abstract Model forms the basis of the Direct Project's technical specifications and provides a common framework for stakeholders to investigate Direct Project standards and services in the context of the user stories. The concepts and acronyms on this diagram are then defined and explained through the examples below.



The Direct Project Abstract Model

The Abstract Model introduces the concept of a HISP, or Health Information Service Provider. A HISP is not necessarily a separate business or technical entity; instead, it is a logical concept that encompasses certain services that are required for Direct Project exchange but *may* be performed or handled by a party other than the sender or receiver, depending on the deployment option chosen by the implementation.

The model is deliberately abstract to avoid declaring that there is only one way to implement each arrow or to embody each concept. To illustrate the abstract model, we explore two of the Priority One user stories, but the flexibility surrounding the Direct Project's specifications means that these stories are merely possibilities in the various options for actual deployment.

Example: Primary care provider refers patient to specialist including summary care record

Starting on the left of the diagram,

1. Sender to Sender's HISP

Primary care physician Dr. B. Wells is the Sender who initiates a message using technology such as an EHR. In this example, she has referred one of her patients to a gastroenterology specialist,

Dr. G. Aye, and she would like Dr. Aye to have some background information about the patient. She uses her EHR to generate a clinical summary and sends it to Dr. Aye using a Direct Project address that Dr. Aye gave her. Her EHR system authenticates to establish its identity² to a HISP, then it encrypts and sends (pushes) the message including the clinical summary to her HISP.

2. Sender's HISP to Receiver's HISP

Dr. Wells' HISP, after locating the address of the Receiver's HISP, must communicate with the Receiver's HISP through similar steps of authentication, encryption and message transmission. Once the message has arrived at the Receiver's HISP, it needs to be delivered to the intended recipient.

3. Receiver's HISP to Receiver

Dr. Aye doesn't have an EHR, but he already uses e-mail software³ that is capable of handling secure (encrypted) messages. Dr. Aye's e-mail software authenticates to the HISP that Dr. Aye is using to provide him with Direct Project services and gets the message, displaying it within an inbox of messages. Dr. Aye has chosen to keep multiple e-mail accounts to separate his Direct messages from his normal e-mail, so his inbox contains only clinical messages sent via the Direct Project. He sees the message from Dr. Wells. Dr. Aye uses the procedure that his e-mail software requires to open encrypted e-mails, in order to open the attached clinical summary. He sees Dr. Wells' description of the patient's problems, medications, allergies, and recent diagnostic tests, and he is now well briefed for the patient's visit later today.

Example: Hospital sends health information to a patient

Some details that are the same as the previous example are not repeated here.

1. Sender to Sender's HISP

Patient M. Powered has recently completed a hospitalization stay at Premiere Memorial Hospital, and he'd like to get a copy of his clinical information and discharge summary. He asks Premiere to send his information to his personal health record, and he provides a Direct address he's received through his PHR: m.powered@SuperPHR.com. A Health Information Management professional at Premiere, Meg Wreckerds, uses the hospital EHR to select documents to send to a patient. She selects both a Continuity of Care Document and a dictated Discharge Summary document, enters M. Powered's Direct address, and sends the message with the documents attached.

2. Sender's HISP to Receiver's HISP

In this example, Premiere Hospital's EHR is hosted by their EHR vendor's data center, which has built-in HISP capabilities. The HISP locates the SuperPHR HISP address and sends the message to the PHR's HISP.

3. Receiver's HISP to Receiver

In this example, there is no human intervention on the receiving end. Rather, the PHR, which is also hosted in a data center, is "listening" for messages and directing them to the appropriate patients' records. Upon receiving the documents, the PHR software detaches them from the message, decrypts them, and stores them in the "incoming documents" folder for the patient

² Analogous to a user logging on to a system, but in this case it is one system authenticating to another

³ such as Outlook, Thunderbird, etc.

associated with the Direct address in the message. Later, when M. Powered logs into SuperPHR, he reviews the documents and has the option to select data from the Continuity of Care Document and add it to the appropriate section of his PHR.

2.3 Technical Implementation

In general, a Direct Project implementation is responsible for packaging message content, securing it, and transporting it from one location to another.

- Content is packaged using MIME and, optionally, XDM.
- Confidentiality and integrity of the content is handled through S/MIME encryption and signatures.
- Authenticity of the Sender and Receiver is established with X.509 digital certificates.
- Routing of messages is handled through SMTP.

3. The Direct Project and Other Health Information Exchange Models

3.1 The Direct Project and the Nationwide Health Information Network

The Direct Project is an integral component of a broader national strategy to have an interconnected health system through a Nationwide Health Information Network. The Nationwide Health Information Network is being developed “to provide a secure, nationwide, interoperable health information infrastructure that will connect providers, consumers, and others involved in supporting health and healthcare. This critical part of the national health IT agenda will enable health information to follow the consumer, be available for clinical decision making, and support appropriate use of healthcare information beyond direct patient care so as to improve health.”⁴ The Nationwide Health Information Network initiative has four major components:

- Nationwide Health Information Network Exchange **Specifications** support secure information exchange between health information organizations (HIOs). One important aspect of this health information exchange is the ability to identify a common patient even without a common patient identifier and to search for and exchange records about patients. This capability goes beyond the “simple, direct, among known participants” scope of the Direct Project. Exchanges between HIOs are not limited to “direct” messages or “known participants.” For example, the emergency department that treats a patient who was vacationing did not have a prior relationship with the patient’s providers, and none of the previous providers directed a message to the ED. The specifications do not address how information is exchanged *within* a single HIO.
- Nationwide Health Information Network **CONNECT** is an open-source reference implementation that embodies the standards and services to support the existing Nationwide Health Information Network Exchange specifications. It helps those who wish to use or build upon it, but anyone can also choose to develop his own software to implement these specifications.
- The Nationwide Health Information Network **Exchange** is a “Limited Production Exchange” among a group of HIOs that have come together under a standard policy framework to exchange data using the Exchange specifications mentioned above. Some Nationwide Health Information Network Exchange implementations have used CONNECT, and others have developed their own software. Organizations may use some or all specifications without formally being part of the

⁴ “Nationwide Health Information Network: Background and Scope.” *Health Information Technology*. The Department of Health and Human Services. Retrieved 10/8/2008. <http://www.hhs.gov/healthit/healthnetwork/background/>

Exchange. In order to participate formally in the Exchange, an organization needs to complete an “on-boarding” process that consists of:

- Application for participation with a sponsoring Federal Agency
 - Execution of the Data Use and Reciprocal Support Agreement (DURSA)
 - Completion of required testing and validation of the Exchange services
 - Acceptance by the Nationwide Health Information Network Cooperative, which operates the Exchange
- **The Direct Project** complements existing Nationwide Health Information Network Exchange Specifications, CONNECT, and the Nationwide Health Information Network Limited Production Exchange. It is a project, with a beginning and an end, to draft the specifications and services (including open-source reference implementations) that address simple, direct communication between known participants. The Direct standards and services can be implemented by any two participants, organizations or a community without a central governance structure

The goal of the Direct Project is to coexist gracefully with health information exchange services based on the existing Nationwide Health Information Network standards and services. The Nationwide Health Information Network is expected to ultimately include the standards and services developed by the Direct Project, in addition to the standards and services it includes already. Any HIO can choose to support both Direct and existing Nationwide Health Information Network Exchange specifications to connect as many participants as possible. To support information exchange between those who implement Direct exchange and those who use existing Nationwide Health Information Network specifications and standards, the Direct Project provides an option to convert messages between senders and receivers who support different protocols.

3.2 The Direct Project and other health information exchanges beyond the Nationwide Health Information Network

EHRs and existing organizations such as HIOs exchange information in various ways. Some use standards related to, but not identical to, those used in the Nationwide Health Information Network Exchange, and some use other mechanisms. They may use mechanisms (e.g., IHE’s XDS integration profile) for “pull” use cases *within* an HIO, which are out of scope for both the Direct Project and the Nationwide Health Information Network Exchange Specifications.

An HIO is not required to support the Direct Project services and specifications. However, the Direct Project offers capabilities that can optionally be used by an HIO to complement existing approaches:

- The Direct Project can be used by HIOs to implement use cases that require a push model to complement their pull model.
- HIOs that are currently using other standards or proprietary communication mechanisms can replace or augment these mechanisms with the subset of Direct Project specifications based on e-mail.
- Organizations already using the XDR integration profile from IHE will be able to use Direct Project conversion specifications to communicate with sources and destinations that do not support XDR.

Interoperability standards and initiatives provide the foundation for exchange, but they do not limit the ability of HIOs to innovate or offer additional value-added services. For example, some HIOs may offer common provider directories for participants to look up Direct addresses; some may offer translation

between different protocols, formats, and vocabularies; some may aggregate data for quality or public health reporting; or some may offer other complementary services that are beyond the scope of the Direct Project or the Nationwide Health Information Network Exchange.

4. The Direct Project Organization and Participation

The Direct Project is an open government initiative⁵ started by the Department of Health and Human Services' [Office of the National Coordinator](#) for Health Information Technology. The policy direction for the Direct Project is provided by the Nationwide Health Information Network Workgroup of the HIT Policy Committee, and oversight related to technology standards is provided by the HIT Standards Committee.

Standards and services used in the existing Nationwide Health Information Network Exchange were developed under recent federal contracts and designed for a robust type of health information exchange. Analysis of these standards by Wes Rishel and David McCallie in late 2009 highlighted the need for "simple interoperability" among healthcare providers to enable simpler point-to-point communication. In response, the Nationwide Health Information Network Workgroup recommended the creation of additional specifications to include *simple, direct, secure standards for point-to-point messages*. The Implementation and Adoption Workgroup of the HIT Standards Committee endorsed this idea of "simple interoperability" by noting that "one size does not necessarily fit all." The Direct Project was launched to complement and extend the suite of existing specifications by focusing on these simpler scenarios.

The Direct Project provides multiple avenues for organizations to contribute to the development of standards and services. To facilitate effective coordination and expedited development of standards and services, the Direct Project is organized into multiple workgroups, each with a dedicated set of goals and timelines.

The workgroup collaboration is facilitated by use of a wiki⁶ (<http://www.nhindirect.org>), by weekly and monthly meetings, and by blogs and discussion lists. Currently the Direct Project has more than 200 participants from over 50 different organizations. These participants include EHR and PHR vendors, medical organizations, systems integrators, integrated delivery networks, federal organizations, state and regional health information organizations, organizations that provide health information exchange capabilities, and health information technology consultants. Many Direct Project participants are also active in standards organizations such as HL7, IHE, ASTM, and others.

5. The Direct Project Implementation

Organizations that create initial implementations of the Direct Project's standards and services via the project's conformance testing process are the enablers of the Direct Project. Examples of such organizations include EHR, PHR, and other HIT vendors, health information exchange organizations, and integrated delivery networks. In addition to these organizations, the Direct Project is organizing real-world pilots to demonstrate health information exchange using Direct standards and services.

⁵ See <http://www.whitehouse.gov/open> for more information about the Obama administration's intent to promote transparency, participation, and collaboration in government.

⁶ A wiki is a website with user-maintained content, such as Wikipedia. The Direct Project wiki contains the latest information and much more detail about the project than can be included in an Overview.

To help the Direct Project's implementers, an open-source reference implementation of the Direct standards and services is being implemented under the guidance of the Direct Project.

6. For Further Reading

More documentation surrounding the topics introduced in this whitepaper can be found on the Direct Project's wiki at <http://nhindirect.org/For+furthereading>.

Appendix: Glossary

- Abstract Model** The basis of the Direct Project's technical specifications, the abstract model provides a common framework for stakeholders to investigate Direct standards and services
- ARRA** American Recovery and Reinvestment Act of 2009, also known as the "economic stimulus package." It includes a bill called HITECH, which provides incentives to providers and hospitals to adopt Health Information Technology.
- Authenticate** To verify an identity prior to granting access or asserting trust
- CCD** Continuity of Care Document, an XML-based standard that specifies the encoding, structure, and semantics for a document that summarizes a single patient's clinical information
- CCR** Continuity of Care Record, an XML-based standard that specifies a way to create a clinical summary of a patient's information
- Certificate Authority** Issues digital certificates in a public key infrastructure environment
- CMS** Centers for Medicaid and Medicare Services
- Content** The health information being communicated, which is independent of the technical mechanism used to move it
- Direct Address** Used to identify an endpoint (a Sender or Receiver) when information is exchanged. The Direct Address has two parts, a Health End Point Name and a Health Domain Name, for example, drbob@samplehisname.org.
- Direct Message** The content of the information being transferred from the Sender to the Receiver. The Direct Message is similar to a package that is sent from one person to another via the postal service, such as the content within an envelope or a box
- DNS** Domain Name System, an Internet system to translate human-readable names into Internet addresses
- DURSA** Data Use and Reciprocal Support Agreement, a comprehensive agreement that governs the exchange of health data between participants in the Nationwide Health Information Network Exchange
- EHR** Electronic Health Record, a computerized system for recording, storing, producing, and using electronic patient medical and health information

Health Domain Name The delivery location for messages to an individual Direct HISP, the HISP portion of a Direct Project Address

Health End Point The delivery location for messages to an individual Direct user, the user portion of a Direct Project Address

HIO Health Information Organization, an organization that holds patient information and/or provides services to allow members of the organization to exchange health information

HISP Health Information Service Provider, the entity that is responsible for delivering health information as messages between senders and receivers over the Internet.

HITECH Health Information Technology for Economic and Clinical Health Act, a bill that, as a part of the American Recovery and Reinvestment Act of 2009, aims to advance the use of health information technology such as electronic health records

HITPC Healthcare IT Policy Committee, a federal advisory committee charged with making recommendations to the National Coordinator for Health IT surrounding standards, implementation specifications, and certifications criteria in order to shape a nationwide infrastructure for the adoption of healthcare information technology and the exchange of meaningful patient medical information

HITSC Healthcare IT Standards Committee, a federal advisory committee charged with providing standards guidance and testing infrastructure to support the recommendations of the HIT Policy Committee

HL7 Health Level 7, an international standards organization that develops and publishes voluntary consensus technical standards

IDN Integrated Delivery Network, a network of healthcare organizations organized under a parent holding company that provides a continuum of healthcare services

IHE Integrating the Healthcare Enterprise, a group of healthcare industry stakeholders that promotes and defines coordination of established standards to provide meaningful and effective information exchange

Meaningful Use Often abbreviated as MU, defined in the Final Rule from CMS published in July, 2010 under the ARRA HITECH provisions

MIME Multipurpose Internet Mail Extensions, an Internet standard that extends e-mail to support content beyond simple ASCII plaintext data

Nationwide Health Information Network A set of standards, services and policies that enable secure health information exchange over the Internet

Nationwide Health Information Network CONNECT Open source software that embodies the standards and services to support Nationwide Health Information Network specifications

Nationwide Health Information Network Exchange A diverse set of federal agencies and non-federal organizations that have come together to securely exchange electronic health information using the Nationwide Health Information Network specifications

Nationwide Health Information Network Specifications Specifications of the core Nationwide Health Information Network services and standards enabling such functions as locating patients at other participating healthcare organizations. These specifications must be used by Nationwide Health Information Network Exchange participants and may be used by others.

Nationwide Health Information Network Workgroup Part of the federal Health IT Policy Committee

ONC Office of the National Coordinator for Health Information Technology in the Department of Health and Human Services, the principal Federal entity charged with coordinating nationwide efforts to promote the use of health information technology

PHR Personal Health Record, an electronic health record managed by a patient. A PHR may be “connected”, opening a patient-friendly portal to information ultimately owned by a healthcare organization, care provider, or insurance company; or it may be “unconnected,” providing a patient-owned space for storing and editing personal medical information.

Receiver Actor in the Direct workflow who receives the message content. A Receiver may be a person or a larger business entity.

Reference Implementation Open-source software that implements the Direct Project specifications. There may be multiple reference implementations using different technologies (e.g., .NET, Java), and a reference implementation is not normative as the specifications are.

Sender Actor in the Direct workflow who originates the message content. A Sender may be a person or a larger business entity.

S/MIME Secure/Multipurpose Internet Mail Extensions, a Internet standard for securing MIME data. S/MIME provides privacy and data security through encryption; and authentication, integrity assurance, and non-repudiation of origin through signing.

SMTP Simple Mail Transport Protocol, an industry standard for transporting e-mail

XDM The IHE Cross-Enterprise Document Media Interchange integration profile, a specification for the exchange of electronic health record documents on portable media. XDM provides an option for zipped file transfer over e-mail, which is very relevant to the Direct Project specifications.

XDR The IHE Cross-Enterprise Document Reliable Interchange integration profile, a specification for the interchange of electronic health record documents through reliable point-to-point network communication, based on a push of information

XDS The IHE Cross-Enterprise Documenting Sharing integration profile, a specification for managing the sharing, finding, and retrieval of electronic health record documents among a defined group of healthcare enterprises

X.509 Digital Certificates A standard for asserting that an entity is who it purports to be. The standard is strictly hierarchical, where a trusted entity asserts the identities of a set of child entities, which can make further assertions, ad infinitum.