EHR∧
HIMSS Electronic Health Record Association

Practical Guidance to Implement Meaningful Use Stage 2 Secure Health Transport for Certification and Meaningful Use

EHR Association
Standards and Interoperability Workgroup

1. Introduction

Meaningful Use (MU) Stage 2 introduces three transport standards for use in healthcare information transport. The purpose of this paper is to:

- Summarize the transport standards and their purpose

- Provide practical guidance to apply one or more of these standards in a MU Stage 2 implementation from a software developer perspective seeking to meet certification

- Highlight the flexibility allowed by MU Stage 2 in the ways providers may qualify in deploying health information exchange with a certified EHR

2. Summary of Certification Requirements

Section 170.202 of the final rules for Stage 2 certification identifies three transport standards adopted for healthcare messaging. They are:

1. ONC Applicability Statement for Secure Health Transport (incorporated by reference in § 170.299)

   This specification discusses the Direct protocol for provider-to- provider messaging. The core component in the technology stack is standard, secure email (SMTP/SMIME).

2. ONC XDR and XDM for Direct Messaging Specification (incorporated by reference in § 170.299)

   This specification discusses the application of XDR and XDM to the direct messaging environment and the interaction between the primary Direct Project environment, which uses SMTP and RFC 5322 to transport and encode healthcare content, and the XDR (Web Services push) and XDM (E-mail with metadata) specifications. ONC Transport and Security Specification (incorporated by reference in § 170.299).

3. Standard. ONC Transport and Security Specification (incorporated by reference in § 170.299)
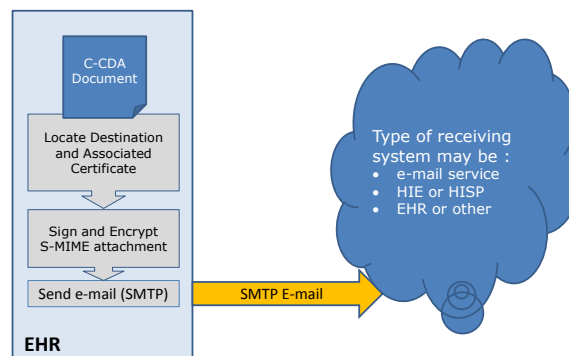
This document defines the primary set of Web Services-based (SOAP) security and transport protocols needed to establish a messaging, security, and privacy foundation for health information exchange.

The above three standards are related and may be combined in three ways, as defined in 45CFR 170.314 (b) (1) (i) A, B, C and 170.314 (b) (2) (ii) A, B, C. These three combinations are labeled: **(a), (a + b), and (b + c).**
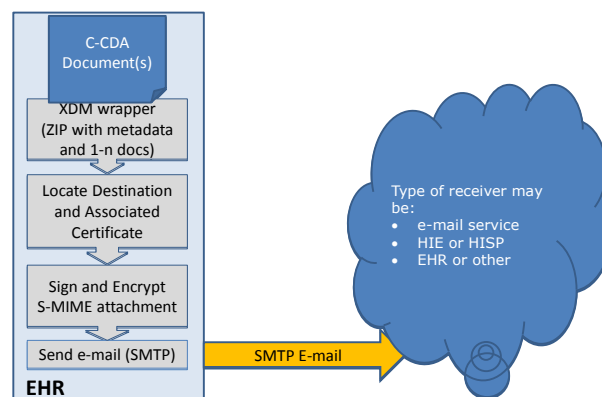
The following diagrams describe the main steps to produce, transmit, and receive a document for each of these combinations.

2.1 Send
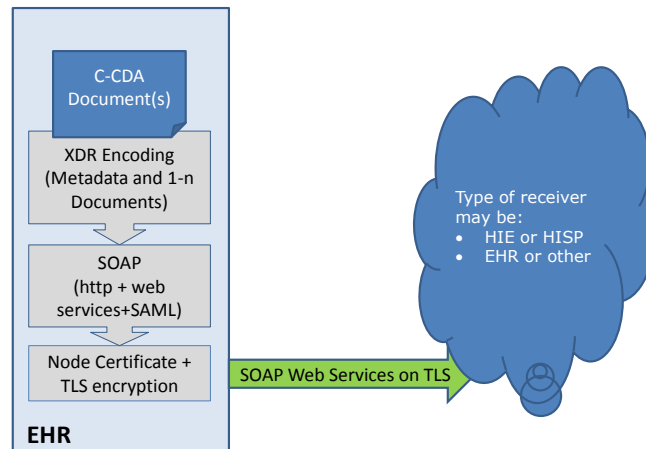
- **EHR Supporting Direct-only SMTP (a)**

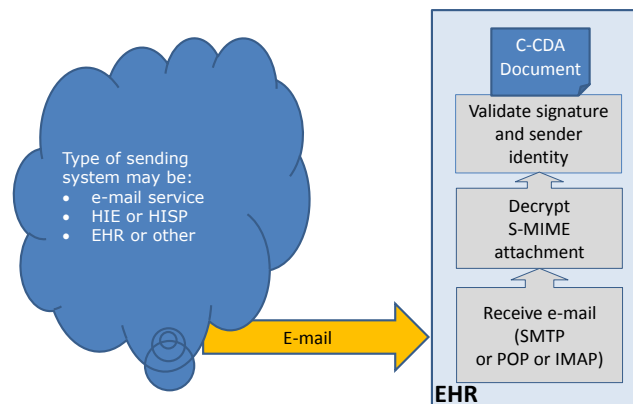- **EHR Supporting Direct with XDM (a+b)**

Practical Guidance to Implement Meaningful Use Stage 2   February 5, 2013
Secure Health Transport for Certification and Meaningful Use

- **EHR Supporting SOAP with XDR (b+c)**

C-CDA Document(s)

XDR Encoding (Metadata and 1-n Documents)

SOAP (http + web services+SAML)

Node Certificate + TLS encryption

EHR

SOAP Web Services on TLS

Type of receiver may be:
- HIE or HISP
- EHR or other

2.2 Receive

- **EHR Supporting Direct-only SMTP (a)**

Type of sending system may be:
- e-mail service
- HIE or HISP
- EHR or other

E-mail

C-CDA Document

Validate signature and sender identity

Decrypt S-MIME attachment

Receive e-mail (SMTP or POP or IMAP)

EHR

- ## EHR Supporting Direct with XDM (a+b)

Type of sending system may be:
- e-mail service
- HIE or HISP
- EHR or other

E-mail →

EHR

C-CDA Document

XDM wrapper (ZIP with metadata and 1-n docs)

Validate signature and sender identity

Decrypt S-MIME attachment

Receive e-mail (SMTP or POP or IMAP)

- ## EHR Supporting SOAP with XDR (b+c)

Type of sender may be:
- HIE or HISP
- EHR or other

SOAP Web Services on TLS →

EHR

C-CDA Document(s)

XDR Encoding (Metadata and 1-n Documents

SOAP (http + web services+SAML)

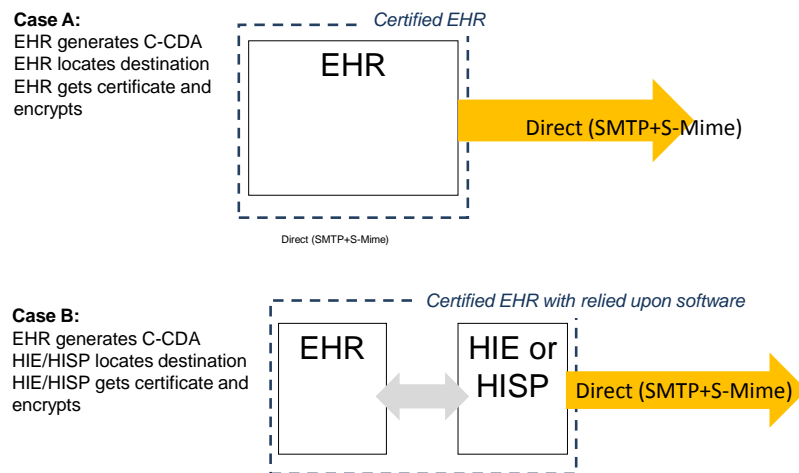Node Certificate + TLS encryption

3. EHR Certification Requirements

3.1 Send

1. **Required Certification: (a) Direct SMTP Only**
   EHR vendors have a variety of implementation strategies, as long as an S-MIME encrypted E-mail is received by the test tool. This can be realized for example by:

   1. Bundling by the EHR vendor of the capability to locate a destination direct E-mail address and association of the signing/encryption certificate (often incorrectly called HISP-like functionality) with the EHR module supporting the criterion requiring transport. This capability may reside within the EHR (see Case A in figure below) or be externally operated by the EHR vendor (see Case B in figure below).

   2. Partnering by the EHR vendor with a 3rd party operating as "relied upon software" for the capability to locate a destination direct E-mail address and association of the signing/encryption certificate. When this specific combination of the two is certified for (a) then the EHR alone or in conjunction with a different 3rd party HISP is not a considered a certified solution (see Case B in figure below).

Implementation Strategies for Direct (a) and (a+b)

Case A:
EHR generates C-CDA
EHR locates destination
EHR gets certificate and encrypts

Certified EHR

EHR

Direct (SMTP+S-Mime)

Direct (SMTP+S-Mime)

Case B:
EHR generates C-CDA
HIE/HISP locates destination
HIE/HISP gets certificate and encrypts

Certified EHR with relied upon software

EHR

HIE or HISP

Direct (SMTP+S-Mime)

Note: There is no requirement for a sender to use E-mail delivery notification. Only receivers are required and tested to respond to E-mail delivery notifications requests. CMS stated that the sender must know that the transition of care document was received, but no technical requirements are specified.

2. **Optional Certification: (a+b) Direct with XDM**

This certification is optional in addition to (a), **not** instead of (a), as (a) is minimally required.

This certification is identical to (a) and only involves the addition of the ability wrap the C-CDA document(s) with associated metadata and place it in the S-MIME attachment.

The same variants in implementation (Cases A & B in figure) may be used as described under (a).

The benefits of this approach over the (a) result from the inclusion of metadata (for either non-CDA and CDA documents, as well as multiple documents) that the receiver can use to:

1. Better manage/route the document without having to open it
2. Improved privacy and security management without having to open the document

Note: In order to enhance interoperability between (a) sources and (a+b) receivers, we suggest that any implementation of (a) may be designed to receive (a+b) by ignoring the XDM wrapper and the metadata, if not used. This provides compatibility between (a) and (a+b) considering that the certification of (a+b) without also being certified for (a) is not permissible.

3. **Optional Certification: (b+c) XDR (with SOAP)**

This certification is optional in addition to (a), **not** instead of (a), as (a) is minimally required.

In this scenario, XDR relies on SOAP (web services) and not E-mail as transport. However, it offers the same ability to wrap the C-CDA document(s) with associated metadata and place it in the SOAP message. Note that this is not an S-MIME attachment but the SOAP attachment method supported by all SOAP stacks.

The benefits of this approach over the (a) are:
- Gives independence from HIE/HISP/Receivers (if they are capable of XDR receive) in that an EHR need not be certified with the relied upon HIE/HISP chosen by the provider
- Provides metadata for receiver(especially with non-CDA documents and multiple documents) to improve their ability to manage/route the document(s)
- Provides compatibility with an IHE XDS Provide and Register transaction (share documents in an HIE)

3.2 Receive

1. **Required Certification: (a) Direct SMTP Only**
   EHR vendors have a variety of implementation strategies, as long as an S-MIME encrypted E-mail is received. This can be realized for example by:

   - Bundling by the EHR vendor of the capability to receive an SMTP (as E-mail server or STA) and to decipher the S-MIME attachment (often incorrectly called a HISP-like functionality) and enabling a POP or IMAP service to pull E-mail from a specific E-mail service mailbox and to check the signature and decipher the S-MIME attachment. These receive capabilities may be offered within the EHR or operated independently by the EHR vendor.

   - Have the EHR vendor partner with a 3rd party operating as "relied upon software" the capability to receive an SMTP E-mail and decipher the S-MIME attachment. The specific combination of the two is certified for (a). The EHR alone or in conjunction with a different 3rd party HISP is not a certified solution.

     Note that when acquiring the EHR alone, using it in conjunction with a different E-mail service than the one it has been certified with is not considered a certified solution.

2. **Optional Certification: (a+b) Direct with XDM**
   This certification is optional in addition to (a), **not** instead of (a), as (a) is minimally required.

   This certification for receive is identical to (a) and only involves the addition of the ability to unwrap the C-CDA document (one or more) and associated metadata and extract it in the S-MIME attachment. The same variants in implementation may be used as for (a).

   The benefits of this approach over the (a) result from the inclusion of metadata (for either non-CDA and CDA documents, as well as multiple documents) that the receiver can use to:
   - Better manage/route the document without having to open it
   - Improved privacy & security management without having to open the document

   Note: In order to enhance interoperability between (a) sources and (a+b) receivers, we suggest that any implementation of (a) may be designed to receive (a+b) by ignoring the XDM wrapper and the metadata, if not used. This provides compatibility between (a) and (a+b) considering that the certification of (a+b) without also being certified for (a) is not permissible.

Practical Guidance to Implement Meaningful Use Stage 2 February 5, 2013
Secure Health Transport for Certification and Meaningful Use

3. **Optional Certification: (b+c) XDR (with SOAP)**

This certification is optional in addition to (a), **not** instead of (a), as (a) is minimally required.

XDR relies on Web services and not on E-mail as transport. However, it offers the same ability to extract from the SOAP message. This is not an S-MIME attachment but the attachment method of SOAP. The wrapped content that includes C-CDA documents (one or more) and associated metadata to facilitate the routing of the documents without any need to parse their content.

The benefits of this approach over the (a) are:
- Gives independence from HIE/HISP/Receivers (if they are capable of XDR receive) in that an EHR need not be certified with the relied upon HIE/HISP chosen by the provider
- Provides metadata for receiver(especially with non-CDA documents and multiple documents)
- Provides compatibility with an IHE XDS Provide and Register transaction (share documents in an HIE)

4. Provider Requirements for Deploying an EHR to Qualify for MU Stage 2

The EHR Incentive Program for MU Stage 2 Final Rule describes in § 495.6(j)(14) for eligible providers (EP) and § 495.6(l)(11) for eligible hospitals (including critical access hospitals, EHs and CAHs) the measurements:

*(A) Subject to paragraph (c) **[of/in]** this section, the **[EP/EH or CAH]** that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50 percent of transitions of care and referrals,*

*(B) Subject to paragraph (c) in this section, the **[EP/EH or CAH]** that transitions their patient to another setting of care or provider of care provides a summary of care record for more than 10 percent of such transitions and referrals either:*

(1) Electronically transmitted using Certified EHR Technology to a recipient; or

(2) Where the recipient receives the summary of care record via exchange facilitated by an organization that is a NwHIN Exchange participant or in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network;

*(C) Subject to paragraph (c) of this section an **[EP/EH or CAH]** must satisfy one of the following:*

*(1) Conducts one or more successful electronic exchanges of a summary of care record meeting the measure specified in paragraph **[(l)(11)(ii)(B)/(j)(14)(ii)(B)]** of this section with a recipient using technology to receive the summary of care record that was designed by a different EHR developer than the sender's EHR technology certified at 45 CFR 107.314(b)(2); or*

(2) Conducts one or more successful tests with the CMS designated test EHR during the EHR reporting period.

This allows for transport mechanisms described in this document, based on ONC's 2014 Edition Final Rule, to meet the target measurements, as well as those used by intermediaries who are approved by NwHIN / eHealth Exchange, e.g., XCA/XDS queries, as referenced from the NwHIN / eHealth Exchange WIKI pages (http://exchange-specifications.wikispaces.com/home) and the Message Platform page in particular (http://exchange-specifications.wikispaces.com/Messaging+Platform+Home).

Therefore, the provider must interface its EHR with other providers with which it is performing transfer of care. Two cases are worth considering:

1. If the provider uses a service offered by the EHR vendor (as relied upon software), no further analysis is needed. This relied upon software/service, along with the EHR, must have been certified to (a), and optionally to (a+b) or (b+c). No other choices are acceptable.
2. If the provider wishes to use another HIE/HISP service than the one chosen by the EHR vendor when it certified to (a) Direct, either:
   a. the provider needs to certify with the selected HIE/HISP on their own, or with assistance from the EHR vendor.
   b. The provider needs to connect its EHR using (b+c) to the HIE/HISP (no need for self-certification, but this implies that the EHR was certified to (b+c) and that the HIE/HISP supports (b+c) which is likely.

No other choices are acceptable. ONC in its communication has been recommending that EHRs implement the optional (b+c) to provide more flexibility to providers. See ONC Dec 19, 2012 Presentation to NeHC at:
http://www.nationalehealth.org/ckfinder/userfiles/files/Helping%20Providers%20Meet%20Direct%20Requirements%20for%20Meaningful%20Use%20Stage%202.pdf

For receipt, the requirements for the providers in the CMS regulations are quite flexible. Only the ability to consume C-CDAs (as well as CCD and CCR for backward compatibility) is required. A provider is explicitly qualified to receive C-CDA with other solutions than (a), (a+b) or (b+c) on its EHR, such as using the eHealth (previously called NwHIN) Exchange which relies on a query for documents on SOAP (IHE XCA Query Retrieve which is the same as XDS Query Retrieve, plus SAML).

No measure is defined on receipt of transfer of care.

If an EHR is certified with (a), the EHR must be delivered with this (a) capability as used for certification even though the provider may be only using (b+c).
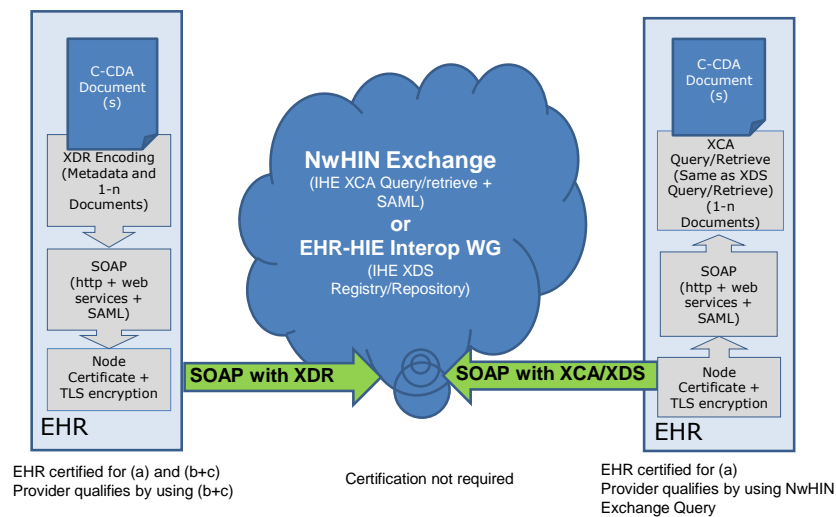
5. Analysis of Some Infrastructure Deployment Models in the Context of MU Stage 2

It is not the purpose of this document to fully analyze the large variety of health information exchange infrastructures that may be deployed to support qualified physicians and hospitals.
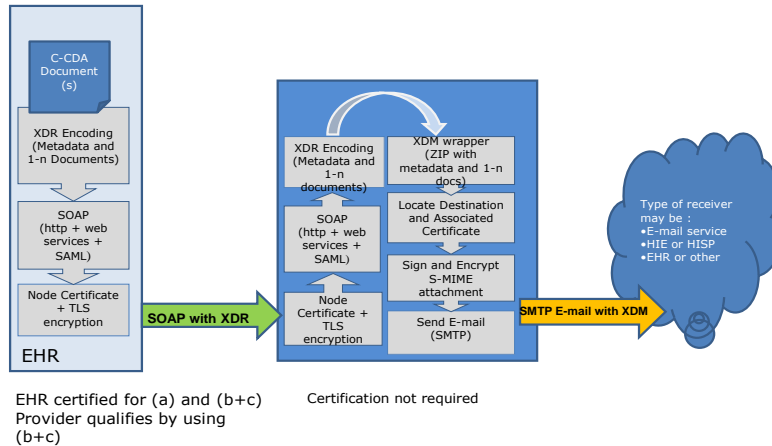
A few typical cases are highlighted in this section.

5.1 Typical IHE XDS or XCA based communication infrastructure (per EHR-HIE Interoperability WG and eHealth-NwHIN Exchange)

Typical IHE XDS or XCA based communication infrastructure
(per EHR-HIE Interoperability WG and eHealth-NwHIN Exchange)

Practical Guidance to Implement Meaningful Use Stage 2   February 5, 2013
                       Secure Health Transport for Certification and Meaningful Use

5.2 XDR Gateway to (a+b) DIRECT with XDM (b+c)

EHR certified for (a) and (b+c)
Provider qualifies by using (b+c)

Certification not required

5.3 EHR Vendor Provided Communication Infrastructure in an MU Stage 2 Context

EHR and supporting communication infrastructure certified together for (a) and (a+b)
Provider qualifies for using either (a+b) or (a)