

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

Electronic Health Record 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 purposes;
- 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 (HIE) 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).

This specification does not support the exchange of metadata associated with the exchanged documents. It is important to note that it recommends (i.e., does not mandate) its use and provides a minimal metadata specification.

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 (email with metadata) specifications.

XDM and XDR support the exchange of metadata in addition to the exchanged document. Both standards use the same metadata definition.

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.

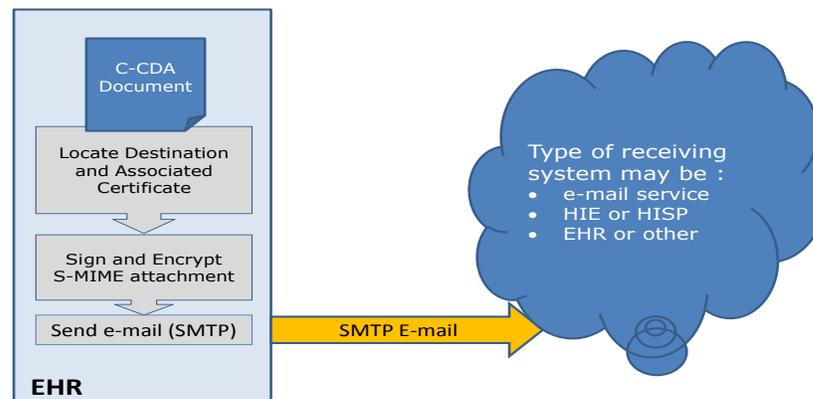
This standard is not at a level where healthcare metadata is being exchanged as it is used as a transport under XDR.

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.

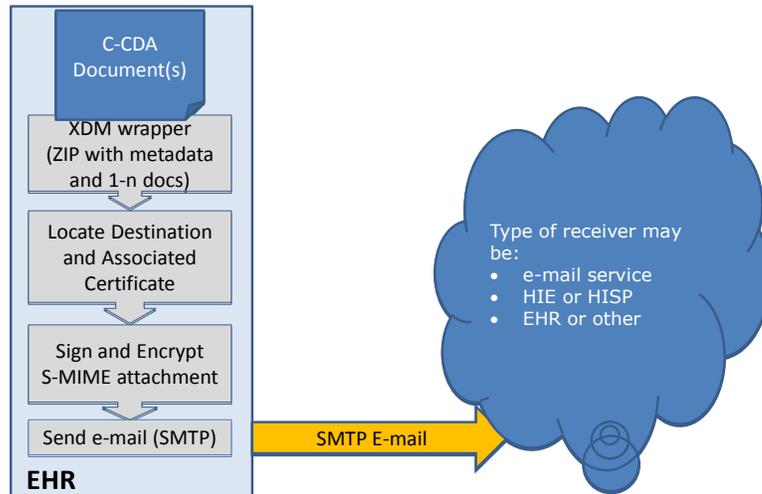
2.1 Send

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



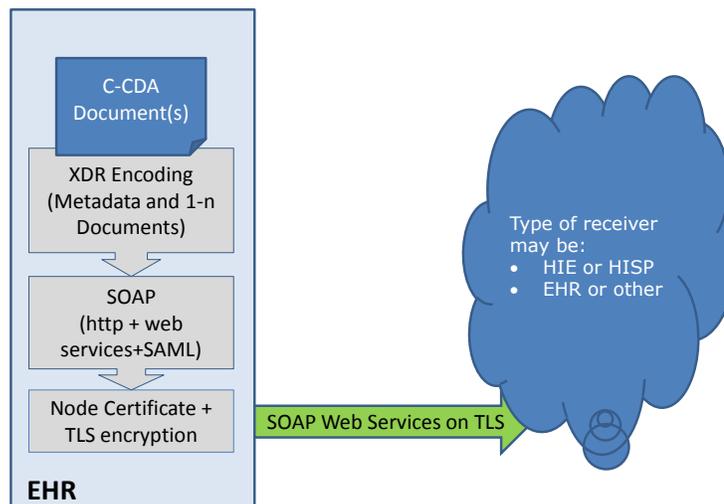
- The conveyance of metadata is not required, but may be supported optionally with the use of the (a+b) combination below.

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



- The XDM Wrapper combines metadata along with one or more C-CDA documents.

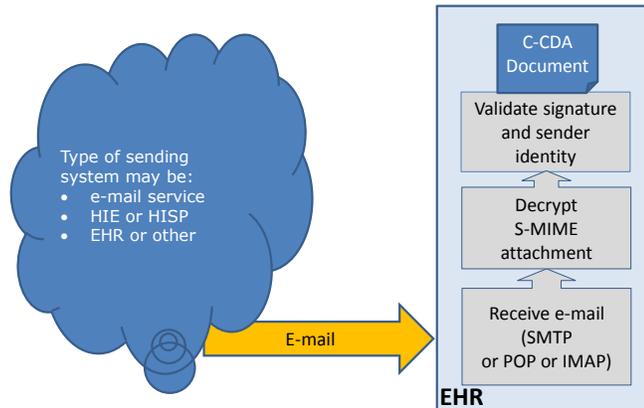
• **EHR Supporting SOAP with XDR (b+c)**



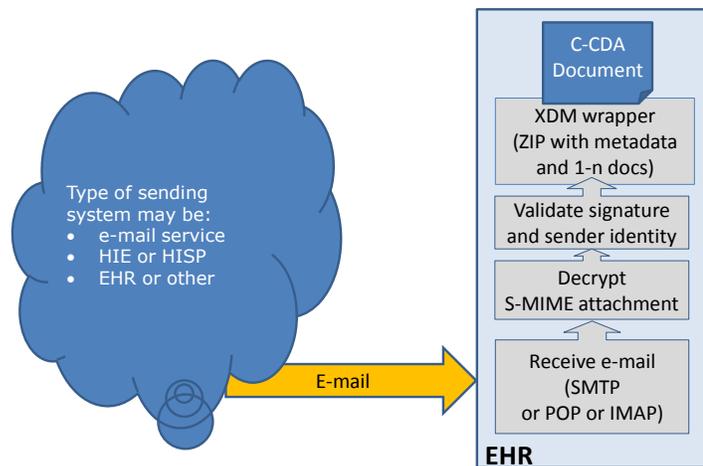
- XDR relies on SOAP (Web services) and not Email as transport. However, it offers the same ability to wrap the C-CDA document(s) with associated metadata and place it in the SOAP message.

2.2 Receive

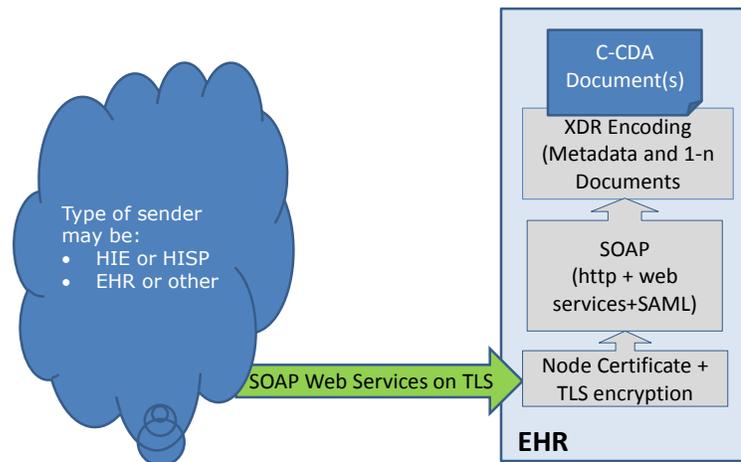
- **EHR Supporting Direct-only SMTP (a)**



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



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



3. EHR Certification Requirements

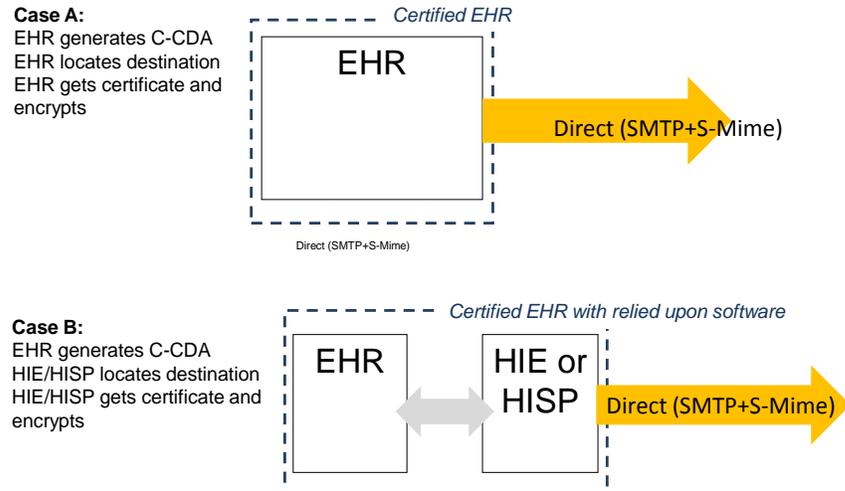
3.1 Send

1. Required Certification: (a) Direct SMTP Only

EHR vendors have a variety of implementation strategies, as long as an S-MIME encrypted email 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 email 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 third party operating as “relied upon software” for the capability to locate a destination direct email 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 third party HISP is not considered a certified solution (see Case B in figure below).

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



Note: There is no requirement for a sender to use email delivery notification. Only receivers are required and tested to respond to email 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 to wrap the C-CDA document(s) with associated metadata and place it in the S-MIME attachment.

The same variants in implementation (Cases A and 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) for the receiver are:

1. better management/routing of the document; and
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 email 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 receivers (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 email is received. This can be realized for example by:

- Bundling by the EHR vendor of the capability to receive an SMTP (as email server or STA) and to decipher the S-MIME attachment (often incorrectly called a HISP-like functionality), enabling a POP or IMAP service to pull email from a specific email 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 third party operating as "relied upon software" the capability to receive an SMTP Email 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 third party HISP is not a certified solution.

Note that when acquiring the EHR alone, using it in conjunction with a different email 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) are:

- The receiver can better manage/route the document without having to open it;
- 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.

XDR relies on Web services and not on email 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 (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 receivers (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 (EPs) 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 **[(I)(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 consistent with the NWHIN / eHealth Exchange (e.g., XCA/XDS queries, as referenced from their 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 transfers 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; or
 - 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.

Note that under scenario 2.b. above, the provider still must possess CEHRT that is certified to (a) DIRECT, even though it is not used to achieve the threshold measurements for transitions of care. The software developer cannot completely carve out (a) Direct from its module offered as (a) Direct, and (b+c) XDR (with SOAP) are part of the same certification criterion. To accommodate that the provider in those situations does not have to fully implement and pay for HISP services they are not using, ONC clarified the concept of right of possession. This is further defined and clarified in ONC's [FAQ #21](#).

ONC in its communication has been recommending that EHRs implement the optional (b+c) to provide more flexibility to providers. See ONC's December 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) in 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).

Note that the sending provider is not measured on the recipient consuming the transmission, only that the transmission successfully arrived at its intended destination. Also note that the receiving provider does not have a transitions of care measure.

5. Value-Added workflows leveraging XDM/XDR metadata

1. Recommendations to HISP/HIEs Implementers
 - a. When a HISP/HIE receives metadata from an EHR connected via (a+b) Direct with XDM or via (b+c) SOAP with XDR, it should forward unchanged this metadata to other HITPS/HIE using (a+b) Direct with XDM.
 - b. When a HISP/HIE receives metadata from another HISP/HIE using (a+b) Direct with XDM, it shall forward unchanged this metadata to either another HISP/HIE using (a+b) Direct with XDM or to an EHR if connected via either (a+b) Direct with XDM or via (b+c) SOAP with XDR.
 - c. Only when neither the next HISP nor the receiving EHR, should a HISP/HIE revert to using (a) Direct only and discard the received metadata.
2. Recommendations to EHRs Implementing the (a+b) XDM or (b+c) XDR MU2 Options
 - a. When an EHR has been certified with one or both of the transport options: (a+b) Direct with XDM or via (b+c) SOAP with XDR, it should populate the metadata with the data values identified below. This will enable any EHR supporting the MU2 optional transports to receive a transition of care patient summary in the context to enhance its user experience and workflows.

- b. The sending EMR shall populate the following metadata. Each of the documents (transition of care C-CDA and referral letter) will be associated with their document specific metadata as defined below. In addition, the submission set metadata recommended content is defined below.

	Transition of Care Care Summary	Transition of Care Referral Letter
DocumentEntry classCode	Summary	Request
DocumentEntry formatCode	C-CDA	PDF
DocumentEntry healthcareFacilityTypeCode	Primary Care	Primary Care
DocumentEntry practiceSettingCode	(Specialty Code*)	(Specialty Code*)
DocumentEntry sourcePatientId	Source Patient Id	Source Patient Id
DocumentEntry sourcePatientInfo	Last, First, DoB, Gender	Last, First, DoB, Gender
DocumentEntry typeCode	Care Summary	(coded LOINC doc type*)
(Other elements required – See R below-e.g. identifiers-technical)		

Submission Set

SubmissionSet author:authorTelecommunication	Tel number of sender
SubmissionSet contentTypeCode	(coded LOINC doc type*)
SubmissionSet intendedRecipient	(Same as Direct Address)
SubmissionSet patientId	Source Patient Id
SubmissionSet limitedMetadata	(If XDM)
(Other elements required – See R below-e.g. identifiers-technical)	

Using this metadata, the receiving entity may:

- Automatically match the patient to a locally known patient;
- Automatically route the request to the internal target department based on the LOINC Document Type of the referral letter without opening any of the documents;
- Call the sender (phone number in metadata), if the documents received cannot be processed (in case or errors) and timely action is needed;
- Link a referral request with a referral response (include a referral ID)

3. The following terminology value sets are recommended:

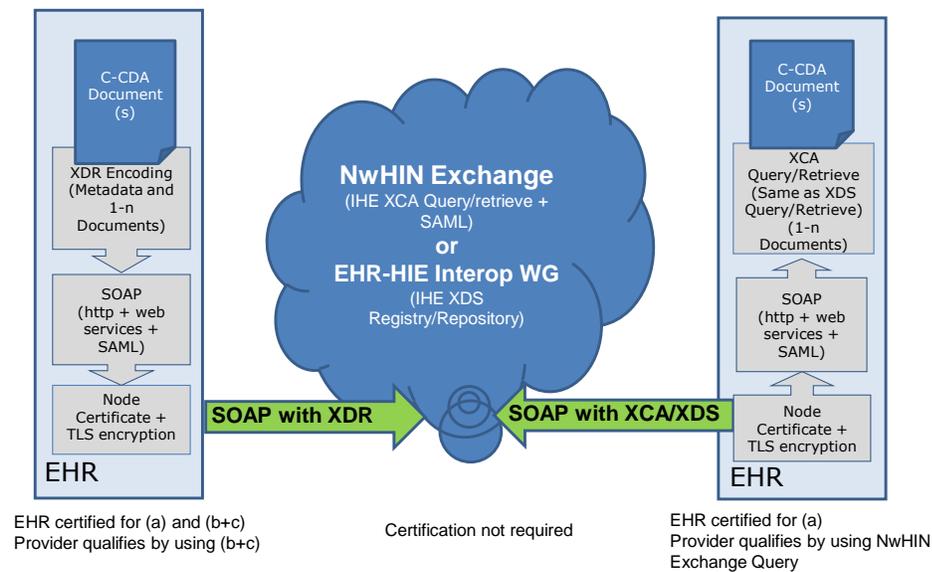
- a. Specialty Code Value Set
 - i. Suggest to identify a small subset from SNOMED-CT
- b. Referral Document Type Code Value Set
 - i. Suggest identifying a small subset from LOINC.

6. Analysis of Some Infrastructure Deployment Models in the Context of MU Stage 2

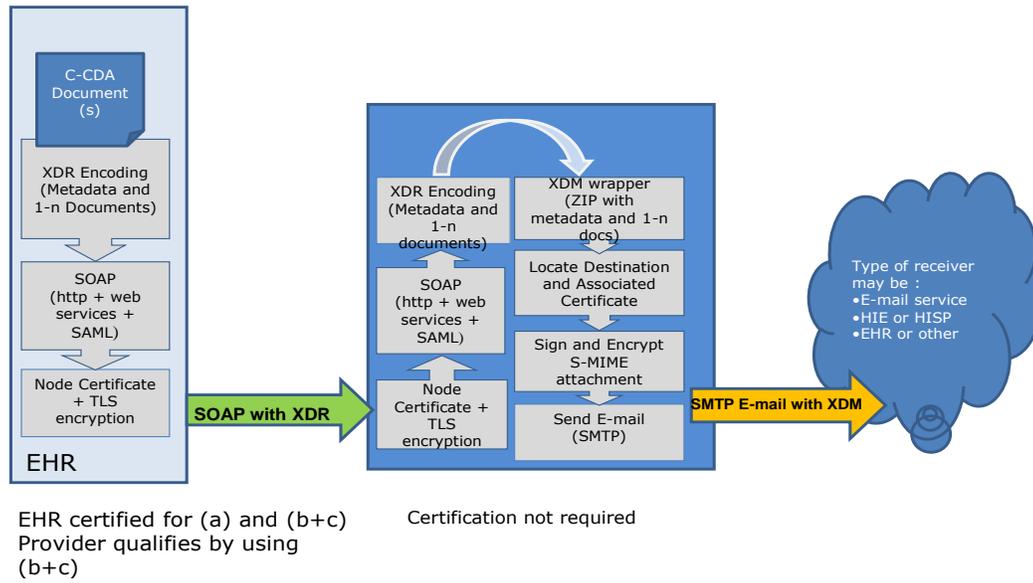
It is not the purpose of this document to fully analyze the large variety of health information exchange infrastructures that may be deployed to support qualified physicians and hospitals. A few typical cases are highlighted in this section.

6.1 Typical IHE XDS or XCA-Based Communication Infrastructure (per EHR-HIE Interoperability Workgroup and eHealth-NwHIN Exchange)

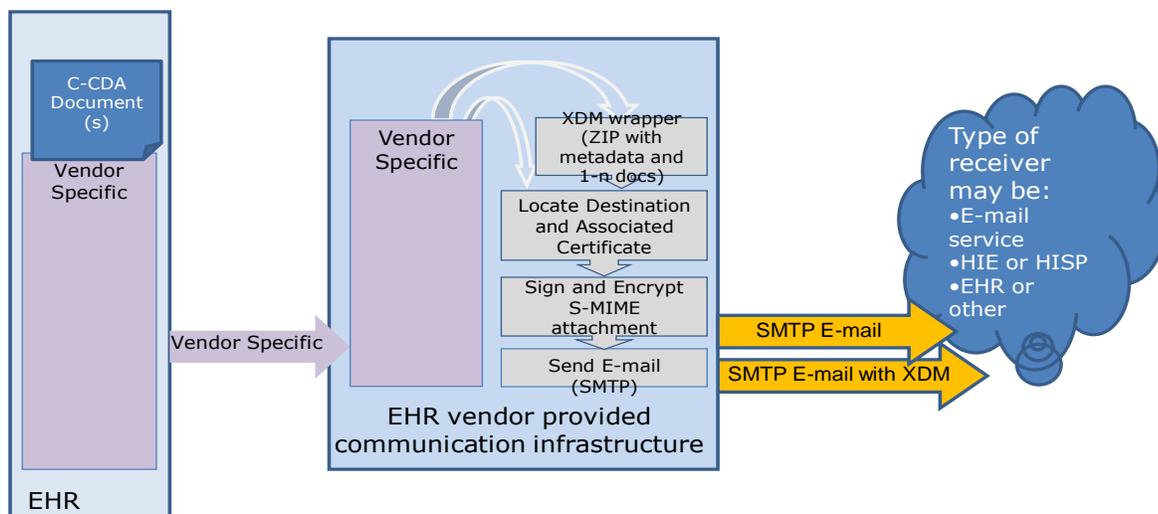
Typical IHE XDS or XCA based communication infrastructure
(per EHR-HIE Interoperability WG and eHealth-NwHIN Exchange)



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



6.3 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)

7. Addressing Considerations for Direct Transport

One of challenges with the deployment of the Direct transport paradigm is the ability to address the message to the correct party. Building up 'my contact list' of reliable and valid addresses will be a learning experience for everybody involved.

As we have seen with email, the use of personal/local directories will be common place, but we do expect that HIEs and other national/regional entities will (begin to) provide directory services for look-up of their provider's relevant contact address(es).

Based on practical use cases, we must recognize that messages will not only be sent from one person to another person, but from a person to an organization, organization to person, or organization to organization. The following use cases may illustrate this further.

- A primary care physician (PCP) wants to refer a patient, on a non-urgent basis, to a *specific* specialist. The PCP will select that specialist from the Directory and send the referral C-CDA message directly to that specialist.

- The same PCP wants to refer another patient on a semi-urgent basis (i.e., to be seen within the next few days) to an X type specialist. The PCP is unsure which specialist will have availability during the desired timeframe and therefore selects the desired X type specialty organization for the patient to be seen by the first available specialist within the practice and sends the C-CDA Direct message to that specialty organization.
- When a patient is admitted to a hospital for a planned elective procedure, a similar clinical summary could be sent to the hospital (e.g., the admission office) to be put into the hospital's EHR, and be made available to the patient's treating clinicians.
- Upon discharge to home, the C-CDA message would be sent via Direct to the patient's PCP. However, if the patient was discharged to a skilled nursing facility or to a rehabilitation facility, the message could be sent via Direct to that organization.

Staffing and workflows of the provider organization/practice/hospital will determine who sends and who will receive and appropriately distribute Direct messages within the recipient EHR.

For further information and considerations, including HDPPlus, see the *Statewide Send and Receive Patient Record Exchange* and its *Technical Specification Appendix, HDPPlus RDB Implementation Guide*, issued by the EHR/HIE Interoperability Workgroup. These can be obtained using their [documentation web page](#).

Appendix A: What is the XDM or XDR Metadata?

XDM and XDR metadata follows the same specification that is originally found in the IHE Technical Framework for the XDS (cross-enterprise document sharing), as well as XDR and XDM profiles. The full metadata definition may be found in the IHE ITI Technical Framework Volume 3 (Section 4.1.7). On the basis of this general definition, a minimal metadata definition was introduced by IHE as a Supplement on Metadata-Limited Document Sources which aligns with the minimal metadata definition initially introduced by the ONC Applicability Statement for Secure Health Transport (incorporated by reference in § 170.299).

The following table provides a complete list of the available metadata. Note that only 11 data elements that are quite trivial are required, the vast majority being qualified for XDR and XDM as "Required if Known (R2)". The next section analyzes a limited number of use cases where the use of a small subset of these would provide significant value-added capabilities for the clinician workflows.

	XDS	XDR	XDM
DocumentEntry author: authorPerson	R	R2	R2
DocumentEntry classCode	R	R2	R2
DocumentEntry confidentialityCode	R	R2	R2
DocumentEntry creationTime	R	R2	R2
DocumentEntry entryUUID	R	R	R
DocumentEntry formatCode	R	R2	R2
DocumentEntry healthcareFacilityTypeCode	R	R2	R2
DocumentEntry hash	R	N/A	R
DocumentEntry languageCode	R	R2	R2
DocumentEntry mimeType	R	R	R
DocumentEntry patientId	R	R2	R2
DocumentEntry practiceSettingCode	R	R2	R2
DocumentEntry limitedMetadata	N/A	R	N/A
DocumentEntry serviceStartTime	R2	R2	R2
DocumentEntry serviceStopTime	R2	R2	R2
DocumentEntry sourcePatientId	R	R2	R2
DocumentEntry sourcePatientInfo	O	R2	R2
DocumentEntry size	R	N/A	R
DocumentEntry typeCode	R	R2	R2
DocumentEntry uniqueId	R	R	R2
DocumentEntry URI	R	N/A	R
SubmissionSet author: authorPerson	R	R2	R2
SubmissionSet author:authorTelecommunication	O	R2	R2
SubmissionSet contentTypeCode	R	R2	R2
SubmissionSet entryUUID	R	R	R
SubmissionSet intendedRecipient	R2	R2	R2
SubmissionSet patientId	R	R2	R2
SubmissionSet limitedMetadata	N/A	R	N/A
SubmissionSet sourceId	R	R	R
SubmissionSet submissionTime	R	R	R
SubmissionSet uniqueId	R	R	R
Folder codeList	R	R2	R2
Folder entryUUID	R	R	R



Folder patientId	R	R2	R2
Folder uniqueId	R	R	R

R= Required to be sent O=Optional to be sent R2= Required to be sent if known