

CDX CONFORMANCE PROFILE

EMR System Conformance – CDA Level 1

[Profile Overview](#)

An outline of the conformance criteria for CDA Level 1 clinical documents that EMR vendors are required to demonstrate within their EMR software applications

Contents

Profile Overview	4
Business Context.....	4
Security Constraints.....	4
Conformance Roles.....	5
Conformance Scope – CDA Levels.....	6
CDA Conformance Keywords.....	7
CDX Conformance Profile Keywords.....	8
Conformance Requirements – Read First	9
Overview.....	9
CDA Compatibility.....	10
CDA Header Discrete Data.....	11
CDA Filing into Document Ontology.....	14
CDA Templates Allowable - EMR to EMR.....	15
CDA Related Documents.....	16
Conformance Session - CDA Level 1	17
01 – Supports BC FIPPA.....	17
02 – Supports receiving, consuming and displaying CDA mandatory header concepts/elements discretely.....	17
03 - Supports receiving, consuming and displaying a CDA where non-mandatory CDA header concepts/elements are omitted or nullFlavor.....	17
04 - Supports receiving, consuming and displaying CDA optional header concepts/elements discretely where possible.....	17
05 - Supports display of narrative or instructional content.....	17
06 - Supports the ability to consume and display the clinical document create date (effectiveTime) from a CDA document received.....	18
07 - Supports the ability to create and display the clinical document received date.....	18
08 - Supports user view of the standardized stylesheet format of the clinical document.....	18
09 - Supports patient matching of received clinical documents via CDX.....	19
10 - Supports the manual remediation of received clinical documents via CDX, where the patient in the CDA clinical document is NOT registered in the destination EMR system.....	19

11 - Supports notification to user when patient demographics in a clinical document(s) (received via CDX) indicates a change from what currently exists in the EMR..... 19

12 - Supports the *soft deletion* of received clinical documents where the *patient is not registered* in the destination EMR system. 20

13 - Supports user awareness of new and un-reviewed clinical documents/results. 20

14 - Supports receiving clinical documents with unknown provider recipients..... 20

15 - Supports receiving clinical documents with only a location recipient. 21

16 - Supports clinical documents with Provider Group recipients. 21

17 - Status of received clinical document is clearly presented to the user. 21

18 - Supports receiving, consuming, and storing discretely the CDA elements that are required to identify, relate and version a clinical document..... 22

19 - Supports replace functionality to ensure most recent version of clinical document is presented to the user. 22

20 - Supports UTF-8 Unicode character set..... 23

21 - Supports the indication of attachment(s) of clinical documents. 23

22 - Supports the receipt of clinical documents with one or more attachments..... 23

23 - Supports clinical document attachments being saved / added to a patient chart. 24

24 - Supports the filing (by LOINC code) of consumed clinical documents, notes and events into a defined filing structure within the patient electronic chart. 24

25 - The list of document templates is dynamic and the EMR system must support the handling of received clinical documents where the LOINC code on the inbound CDA message is *unrecognized*. 24

26 - Supports CDA Level 2 documents..... 24

27 - CDA Level 3 documents handled. 25

28 - System supports the ability to send one or more of the approved E2E templates..... 25

29 - Supports sending clinical documents that adhere to the BC approved LOINC codes..... 25

30 - Supports correct patient selection through appropriate display of patient identifiers when creating clinical documents. 25

31 - Supports the ability for the end user to select and send to CDX subscribed provider recipients..... 26

32 - Supports the ability for the end user to select and send to CDX subscribed provider group (care team) recipients 26

33 - Supports the ability for the end user to select and send to CDX subscribed location recipients 27

34 - Supports the ability for the end user to select to send to non-CDX subscribed recipients..... 27

35 - Supports the display of intended recipients as selected by the user..... 28

36 - Supports the ability to capture and display the code and reason identifying the type of service event that is being documented..... 28

37 - Supports the ability to capture and display the date the service was provided to the patient (service event effectiveTime element).....	29
38 - Supports the ability to create and send the clinical document create date (effectiveTime) with the CDA document.	29
39 - Supports indication of successful submission to the CDX system	29
40 - Supports the ability to create and send the clinical document sent date with the CDA document. ..	29
41 - Supports the ability to determine the distribution status of a document that has been uploaded to CDX.....	30
42 - Supports sending CDA optional header concepts/elements discretely where possible.	30
43 - Supports the creation, maintenance and tracking of clinical document IDs internally, in order to provide ability to relate document versions together.....	30
44 - Supports sending CDA mandatory header concepts/elements discretely.....	31
45 - Supports patient matching criteria for receiving Health Information Systems by including appropriate patient identifiers on outbound clinical documents.	31
46 - Supports the ability to correct and/or update a previously created and sent CDA message/document.	31
47 - Supports storing and sending versioning discrete elements when sending updated clinical documents.	32
48 - Supports capturing and sending the status of the clinical document.	32
49 - Supports the ability for user to cancel clinical documents.....	33
50 - Supports the sending of clinical documents with attachments.	33
51 - Supports approved file formats when sending attachment(s).....	34
52 - Supports file size restriction when sending attachment(s)	34
53 - Supports the ability to relate documents in a workflow.	34
54 - Supports dynamic confirmation of recipient(s) CDX capability.....	34
55 - Supports sending clinical documents as per the BC approved CDA Implementation Guides.....	35
Vendor to complete prior to Conformance	36
Vendor to Complete Table - Document Ontology.....	36
Vendor to Provide Screen Captures	37
APPENDIX:.....	39

Profile Overview

Business Context

The purpose of this document is to outline the conformance criteria for CDA Level 1 clinical documents that EMR vendors are required to demonstrate within their EMR software applications.

Note that the CDX distribution system will currently facilitate the exchange of clinical information based upon CDA templates from the inventory of templates currently captured in the BC CDA Implementation Guide, and for three CDA Level 1 templates in the BC PITO e2e CDA Implementation Guide. In addition to adhering to the conformance outlined in this document, it is expected that the EMR vendor will also ensure that conformance direction/guidance as contained in the following specifications is also reflected within their respective EMR software applications.

Since there is a strong provincial mandate for HIE, EMR vendors should expect that additional CDA templates will be incrementally added to the overall BC inventory of CDA templates. Additionally, currently these specifications provide criteria for only CDA-type messages. As health care information exchange advances, the Health Authorities fully anticipate implementing additional HL7 message types appropriate to their usage.

Type of Transaction	Applicable Specification
Health Authority (HCIS) inbound to EMR system	BC eHR CDA Implementation Guide
EMR system outbound to EMR system	BC PITO e2e CDA Implementation Guide
EMR system outbound to HCIS system	BC PITO e2e CDA Implementation Guide

Security Constraints

Please note: Onboarding to the CDX distribution system is only open to vendors whose EMR systems adhere to the following criteria:

- No storage of Personal Information occurs outside of Canada,
- No distribution or disclosure of Personal Information occurs outside of Canada,
- No access to Personal Information occurs outside of Canada

Conformance Roles

In the electronic exchange of clinical information, there are two key roles:

- 1.1.1. **Originator or Sender:** For example, a provider fills the role of originator when authoring a clinical document, such as a *referral* or *history & physical*, etc. The system in which the clinical document is created/authored has the role of sending/originating system for the clinical document.
- 1.1.2. **Recipient or Receiver:** For example, a provider fills the role of receiver when receiving a clinical document, such as a *consult*. The system in which the clinical document is received and consumed has the role of recipient system for the clinical document.
- 1.1.3. In some instances, roles may overlap for the workflow/process of specific clinical document types. For example, the receiver of a *referral* clinical document becomes the sender when generating an associated/related *consult* document in response to the *referral*. Where roles overlap, they are included in the All Roles section.

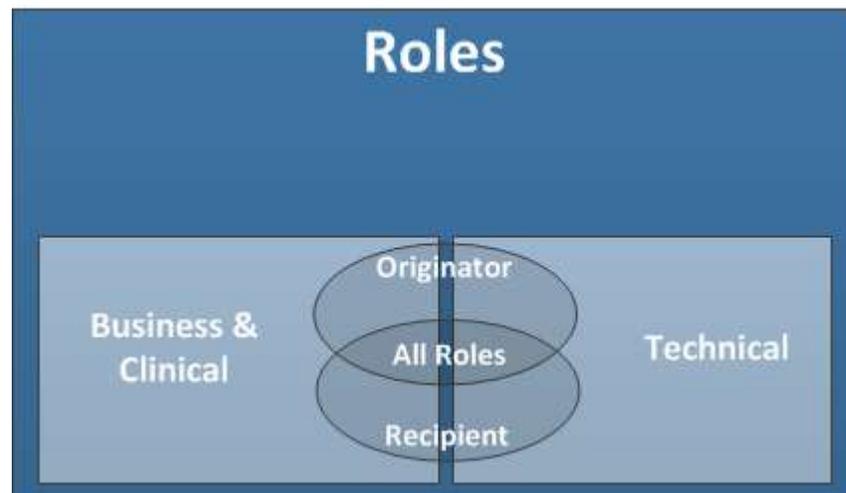


Figure 1: Conformance Roles

Conformance Scope – CDA Levels

The current CDX scope for conformance profiles are structured around the incremental interoperability of the HL7 CDA clinical documents, as follows:

- 1.1.1. CDA Level 1: The simplest form of CDA, which includes the CDA Header plus an unstructured block which could be comprised of plain narrative text, or an attachment (PDF, RTF, JPEG, PNG, TIFF document). This specific profile is limited to evaluating EMR software at this basic level. (Note that attachment size limit is restricted to 50 MB on the CDX platform.)
- 1.1.2. CDA Level 2: The CDA header along with an XML body with defined sections, called “templates.” These templates represent narrative blocks, and are identified by an associated template ID.
- 1.1.3. CDA Level 3: The CDA header, along with an XML body with defined sections. Within at least one of the defined section templates, there are discrete data elements, called “entries.” Entries may use references to relevant codeSystems, such as LOINC, SNOMED-CT-CA, ICD-10-CA, etc.

This specific conformance profile is limited to evaluating EMR software at CDA Level 1. However, EMR systems should be able to receive and render a CDA Level 2 or Level 3 clinical document at CDA Level 1, with the exception of CDA Level 3 Laboratory results. CDA Level 3 Laboratory results must be received and consumed discretely, as outlined in the CDA Level 3 Conformance Profile for Lab.

It is evident that the richness of the clinical data increases with each individual CDA level, as does the interoperable usefulness of that data. While our intention is to expand our delivery of structured information to higher levels, our conformance profiles reflect what is currently available in our HCIS source systems. As new templates are developed, and we move forward in expanding our abilities to send higher levels of CDA documents, additional conformance profiles will be developed.

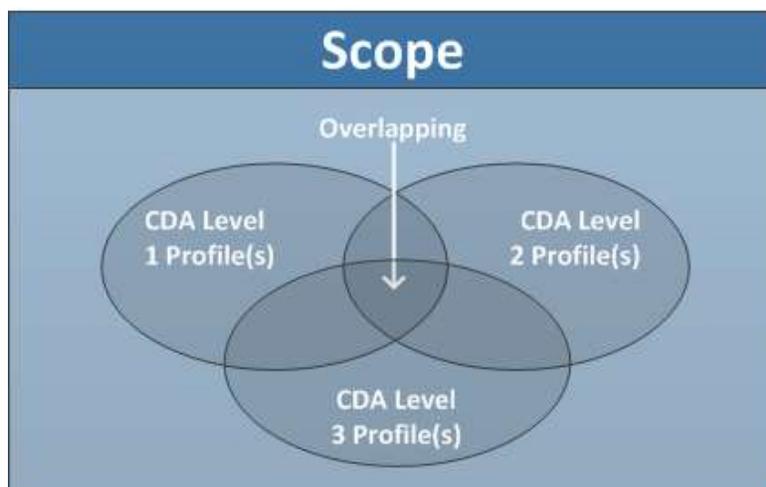


Figure 2: Conformance Scope

CDA Conformance Keywords

Conformance keywords in the BC CDA Implementation Guide adhere to the definition as outlined in the HL7 Version 3 Publishing Facilitator's Guide. Following that provincial direction and adhering to the international HL7 standard, the following Conformance Keywords Definition table outlines the conformance definitions for Clinical Document Architecture (CDA).

Conformance Keyword	Definition
SHALL	An absolute requirement.
SHALL NOT	An absolute prohibition against inclusion.
SHOULD	Recommended. Valid reasons may exist where a decision is made to exclude a particular item, contrary to the specification recommendation to include the item. The full implications of not including a recommended item must be understood and carefully weighed prior to such a decision being made.
SHOULD NOT	Not recommended. Valid reasons may exist where a decision is made to include a particular item, contrary to the specification recommendation against it. The full implications of including an item which is not recommended must be understood and carefully weighed prior to such a decision being made.
MAY/NEED NOT	Truly optional; can be included or omitted as the author decides with no implications.

CDX Conformance Profile Keywords

The conformance keywords used within this document are based upon the HL7 EHR System Functional Model, and are designed to provide a consistent, testable structure to the conformance statements.

The general grammatical structure of a conformance process criteria statement is as follows:

[IF...THEN], the **[SYSTEM | DOCUMENT] [SHALL | SHALL-NOT | SHOULD | MAY] [PROVIDE THE ABILITY TO] ...**

Conformance Process Term	Definition
[IF...THEN]	Is used to qualify a conformance criterion to apply only if a pre-condition exists. For example, if the system supports a specific feature, then a conformance criteria requirement will apply and should be examined. If the system does not support the feature, then the rest of the conformance criteria would not apply and can be safely ignored.
[SYSTEM DOCUMENT]	The SYSTEM or DOCUMENT may be the subject of all the Conformance Criteria. If the criterion applies to a requirement of the originating or recipient system the word “system” will be used to indicate any type of EMR/EHR system. If the criterion applies to the CDA document itself, then the subject of the criteria will specify either the specific document type (discharge summary, anatomic pathology etc.), or a general reference to a CDA document.
[SHALL]	To indicate a mandatory requirement to be followed (implemented) in order to conform. Synonymous with ‘is required to’.
[SHALL-NOT]	To indicate a forbidden action.
[SHOULD]	To indicate an optional recommended action, one that is particularly suitable, without mentioning or excluding others. Synonymous with ‘is permitted and recommended’.
[MAY]	To indicate an optional, permissible action. Synonymous with ‘is permitted’.
[PROVIDE THE ABILITY TO]	Is used when the action described in the conformance criteria may depend on a user intervention. For example, “ <i>the system shall provide the ability to select a patient</i> ” means that a human can use the system to select a patient; versus “ <i>the system shall select a patient</i> ” means that the system will automatically select a patient based on some pre-established criteria.

Conformance Requirements – Read First

Overview

Each of the conformance requirements in the Conformance Statements will be “walked-through” during the EMR vendor conformance session for this specific profile.

In addition to demonstrating conformance to the requirements in the conformance session, the CDX team also requests actual screen captures of specific conformance items. Please see the appropriate section for the complete list of required screen captures.

Within the role column of the session matrix, the requirements are classified as Business, Clinical and/or Technical. In some instances, roles may cross over into all of these areas.

- **Business and Clinical Requirements** – include the expectations of functionality within the receiving system to appropriately receive the CDA documents. The Business and Clinical requirements may not be explicitly outlined in the CDA implementation guides for British Columbia. However, they are assumed to be supported in order to appropriately receive CDA documents that adhere to these specifications.
- **Technical Requirements** – Includes technical requirements of the CDX distribution system, as well as of the CDA implementation guides in British Columbia.

Note that the CDX distribution system will currently facilitate the exchange of clinical information based upon CDA templates from the inventory of templates currently captured in the BC CDA Implementation Guide, and for three CDA Level 1 templates in the BC PITO e2e CDA Implementation Guide.

Since there is a strong provincial mandate for HIE, EMR vendors should expect that additional CDA templates will be incrementally added to the overall BC inventory of CDA templates. As such, we encourage vendors to undertake development in their EMR systems to support the expansion and implementation of additional CDA templates.

CDA Compatibility

This specific conformance profile is limited to evaluating EMR software at CDA Level 1. However, EMR systems should be able to receive and render a CDA Level 2 or Level 3 document at CDA Level 1.

- 1.1.1. CDA Level 1: The simplest form of CDA, which includes the CDA Header plus an unstructured block which could be comprised of plain narrative text, or an attachment (PDF, RTF, JPEG, PNG, TIFF document; 50 MB size restriction). This specific profile is limited to evaluating EMR software for consuming at this basic level.
- 1.1.2. CDA Level 2: The CDA header along with an XML body with defined sections, called “templates.” These templates represent narrative blocks, and are identified by an associated template ID. Although this specific profile is limited to evaluating EMR software for consuming the basic level of CDA Level 1, EMR software will be evaluated for ability to render CDA Level 2 as a CDA Level 1 document.
- 1.1.3. CDA Level 3: The CDA header, along with an XML body with defined sections. Within at least one of the defined section templates, there are discrete data elements, called “entries.” Entries may use references to relevant codeSystems, such as LOINC, SNOMED-CT-CA, ICD-10-CA, etc. Although this specific profile is limited to evaluating EMR software for consuming the basic level of CDA Level 1, EMR software will be evaluated for ability to render CDA Level 3 clinical documents as a CDA Level 1 document. This is with the exception of CDA Level 3 Laboratory Results, which must be received and consumed discretely, as outlined in the CDA Level 3 Conformance Profile for Lab.

CDA Header Discrete Data

All CDA clinical documents have requirements around mandatory and optional discrete data that must be included in the header. Reviewing and validating this common set of data elements in the messages that are received is an essential part of the CDA conformance testing.

It is understood that the various EMR software applications used in BC are at different levels of capability in handling CDA documents, and the data that CDA encapsulates. Additionally, these systems also vary in their approach to how clinical data is captured; some applications rely heavily on free-text and un-coded fields, whereas others have made significant strides in capturing standardized discrete data fields based on codes or standard reference sets. The latter approach obviously supports a higher level of clinical decision support, collaborative care and interoperability.

While respectful of these differences, it is essential for us to maintain a conformance policy and process that demonstrates our commitment to the provincial objective of advancing health information exchange standards and supporting interoperability. Additionally, it is essential that we ensure that the distribution platform that we have developed adheres to a high standard of quality.

EMR Vendors that are not able to achieve discretely consuming the mandatory CDA header elements (see below) are strongly encouraged to have development plans in place to do so.

1. **Patient (or Record Target):** includes patient identifiers, address, telephone, e-mail, patient names/prefix, gender code, birth date/time, language code. May also contain guardian information.
2. **Author:** author of the clinical document, authoring time, provider/author identifier(s), authoring person or authoring device/software name, address, telephone, e-mail.
3. **Custodian:** Is the organization that is in charge of maintaining the original clinical document. This concept contains assigned custodian, custodian organization, custodian organization ID, custodian organization name.

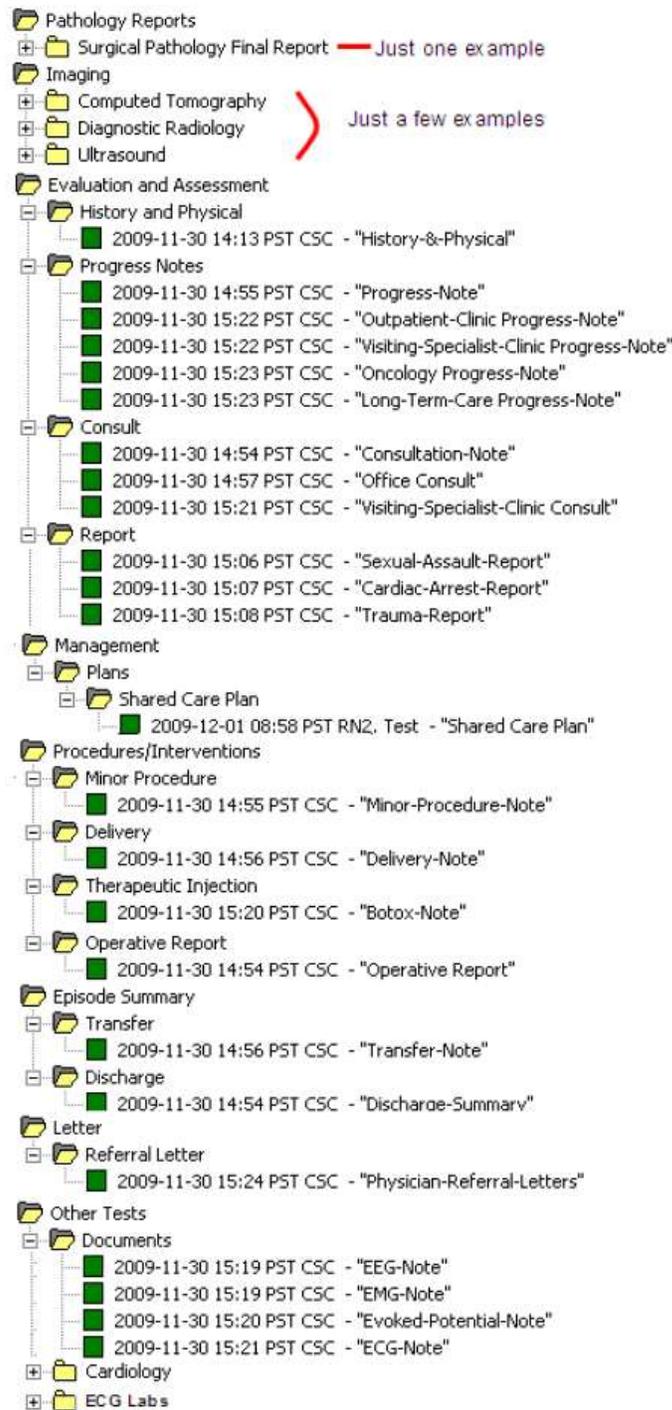
Below is a table view that differentiates which CDA header data elements are mandatory and optional. As noted, where CDA header data elements are mandatory, they **SHALL** be sent, received and consumed as discrete data. For optional CDA header data elements, it is encouraged (but not required) that the data elements are sent, received and consumed as discrete data.

CDA Header Concepts		
Concept	Details	
Record Target (Patient)	A record target (patient) element must be present. The record target documents the patient identifier(s) (mandatory) as well as other details and demographics associated to the patient.	Mandatory
Author	Author information provides demographic information on the author(s) of the document, as well as the software system used to create the document. In some instances, a clinical document has no <i>human</i> author, such as with General Lab Results. In these instances, the authorship is attributed to the software or device by which it is generated, and is captured under <code>assignedAuthor/assignedAuthoringDevice</code> element.	Mandatory
Custodian	CDA R2 requires every document to have a custodian – an organization that is in charge of maintaining the document.	Mandatory
Information Recipient	Information Recipients may be optionally provided, and include the primary receiver - in most cases, the author and/or ordering provider. Other recipients may be defined, and would include any “copy to” recipients.	Optional
Participating Providers	Where a document is providing information related to a specific encounter, the providers associated with that encounter are recorded as participants in the <i>EncompassingEncounter</i> .	Optional
Data Enterer	This participation is where the transcriptionist, if any, is entered. If the data enterer is different from the author, this information should be provided.	Optional
Authenticator	Authenticator is the person or persons who attest to the content of the document.	Optional
Generic Participant	This participant relationship can be used to record roles important to the information in the document instance that are not addressed elsewhere.	Optional
Service Event	Depending on the document type, an instance may contain documentation of a specific service event and the related performers (e.g.: a Procedure Note would document the specific procedure event).	Optional

CDA Header Concepts		
Concept	Details	
Order	This represents the order that is fulfilled by the document instance.	Optional
Related Document	The relatedDocument relationship provides a way for a document instance to point to its ParentDocument.	Optional
Encompassing Encounter	Optionally, information about an encounter and the participating providers may be transmitted as part of the Encompassing Encounter. Depending on the use case, the referring provider, attending provider and other participants may be noted.	Optional

CDA Filing into Document Ontology

Health Information and Electronic Medical Record systems utilize ontologies to organize clinical documents, notes and events into a filing structure. Such ontologies are meant to be user intuitive, with information being located in a standardized structure that makes clinical sense to providers. Here is an example of a standardized ontology:



CDA Templates Allowable - EMR to EMR

The CDX service may be leveraged for EMR to EMR data exchange. Although we anticipate ongoing additions to the overall provincial inventory of EMR to EMR CDA templates, currently EMR systems may only send/receive the following e2e CDA templates at CDA Level 1:

1. Generic Episodic Document (template ID: 2.16.840.1.113883.3.1818.10.1.2)
2. Generic Unstructured Referral (template ID: 2.16.840.1.113883.3.1818.10.1.5)
3. Unstructured Document (template ID: 2.16.840.1.113883.3.1818.10.1.4)

Use of the CDX service for the following e2e templates is prohibited:

1. EMR Conversion
2. Generic Structured Referral
3. Patient Transfer

EMR systems must use the stylesheet provided by the CDX team for standard rendering of all e2e CDA templates received.

CDA Related Documents

Handling Related Documents	
Features Related Document	
<ul style="list-style-type: none"> • Source: HCIS • Example: Transcribed Clinical Document • Type of Correlation: Single value 	<p>HCIS sends HL7 v2 message, which is translated into a CDA before it is sent by CDX to receiving EMR system(s). These HCIS source messages have only a single value that is the same across a set of messages, but by themselves cannot be used to correlate the original document to possible future versions of the document. Rules are applied at the time of CDA creation which allows this correlation.</p>
<ul style="list-style-type: none"> • Source: HCIS • Example: Lab Results • Type of Correlation: Multiple value 	<p>HCIS sends HL7 v2 message, which is translated into a CDA before it is sent by CDX to receiving EMR system(s). These HCIS source messages have multiple values across a set of messages, where the set of messages contains an original message and 1 or more update messages. For example, a single lab message may contain a battery of results, where the common identifiers relate to the individual results, not to the battery or to the message. These common result identifiers cannot be used to correlate the original document to possible future versions of the document. Rules are applied at the time of CDA creation which allows this correlation.</p>
<ul style="list-style-type: none"> • Source: HCIS • Example: Transcribed Clinical Document • Type of Correlation: Single value 	<p>For software that generates CDA documents natively, there is an expectation that they internally create and maintain internal IDs and therefore are capable of relating documents together as noted below.</p> <ul style="list-style-type: none"> • Clinical Document IDs • Order/Referral IDs • Other internal identifiers that relate to system activities/transactions <p>Note: It is suggested that the EMR system generate a GUID for ClinicalDocument/id. However, it is permissible to use an OID such as: (EMR system + clinic + internal document ID) to ensure uniqueness.</p>

Conformance Session - CDA Level 1

01 – Supports BC FIPPA

The system **SHALL NOT** *distribute, disclose, store, or provide any access* to any patient personal information outside of Canada.

02 – Supports receiving, consuming and displaying CDA mandatory header concepts/elements discretely.

The EMR system **SHALL** receive and discretely consume the mandatory CDA header elements, displaying them in the corresponding fields within the EMR system. (see list in Appendix below)

03 - Supports receiving, consuming and displaying a CDA where non-mandatory CDA header concepts/elements are omitted or nullFlavor.

The EMR system **SHALL** be able to receive and consume a CDA where some or all non-mandatory header elements are omitted or nullFlavor, and display the available content to the user

04 - Supports receiving, consuming and displaying CDA optional header concepts/elements discretely where possible.

Wherever the EMR system discretely captures/displays data elements that correspond to optional CDA header elements, the system **SHOULD** discretely consume the optional CDA header elements, displaying them in the corresponding fields within the EMR system.

05 - Supports display of narrative or instructional content.

IF the EMR system receives a CDA message which *contains narrative or instructional content* at the CDA path below:

```
<component typeCode="COMP">  
    <nonXMLBody classCode="DOCBODY" moodCode="EVN">
```

```
<text mediaType="text/plain"
representation="TXT"></text>
</nonXMLBody>
</component>
```

THEN the EMR system **SHALL** support the rendering and display of the narrative text and/or instructional content within their EMR system.

06 - Supports the ability to consume and display the clinical document create date (effectiveTime) from a CDA document received.

When a CDA document is RECEIVED by the system:

- The system **SHOULD** extract the ClinicalDocument/effectiveTime element and populate to the creation date field for the clinical document.

e.g. <effectiveTime value="201210251150-0800"/>

07 - Supports the ability to create and display the clinical document received date.

When a CDA document is RECEIVED by the system:

- The system **SHOULD** generate a clinical document received date.
- The system **SHOULD** display the clinical document received date to the user in the EMR view of the received clinical document.

08 - Supports user view of the standardized stylesheet format of the clinical document.

IF the system receives a CDA clinical document **THEN** the system **SHALL** provide the ability to render the clinical document using the standard XSLT provided by CDX.

09 - Supports patient matching of received clinical documents via CDX.

When CDA documents are received into the EMR, the system **SHALL** (at minimum) evaluate the message header patient demographics and apply 4 point matching criteria to ensure that documents received are attached to the correct patient's chart. The 4 points for matching are:

1. Patient ID (PHN in BC)
2. Patient Last Name
3. Patient DOB
4. Patient Gender

An EMR **MAY** do 5 point matching if their system has this capability. The 5th match point is:

5. Patient First Name

10 - Supports the manual remediation of received clinical documents via CDX, where the patient in the CDA clinical document is NOT registered in the destination EMR system.

IF an incoming CDA document cannot be automatically/system matched to an existing patient record in the EMR system, **THEN** the system **SHALL** provide the ability for the user to manually match the message to an existing patient record. Additionally, the system **SHALL** provide the ability for the user to create a new patient record using the demographics received in the CDA clinical document.

11 - Supports notification to user when patient demographics in a clinical document(s) (received via CDX) indicates a change from what currently exists in the EMR

When CDA documents are received into the EMR system, the system **SHOULD** evaluate the message header patient demographics and provide notification to the user where differences exist from the demographics on file in the EMR for the patient. The system **SHOULD** provide the user ability to manually review, evaluate and update the demographic information in the system based upon review of the differences, where deemed appropriate by the evaluating user.

12 - Supports the *soft deletion* of received clinical documents where the *patient is not registered* in the destination EMR system.

In instances where a clinical document is delivered to a clinic/location in error (e.g. patient has identified a doctor who does/has not actually provided this type of service to the patient), the system **SHALL** provide the ability for the clinical document to be deleted in the application.

Ideally this **SHOULD** be a *soft delete* - where a historical record of the document is maintained in the background. Functionality **SHOULD** be provided to a user to *restore* a soft deleted clinical document when necessary. (e.g. clinical document deleted in error)

13 - Supports user awareness of new and un-reviewed clinical documents/results.

IF the system receives a clinical document **THEN** the system **SHALL** indicate which documents are new and the system **SHALL** indicate which documents have been reviewed.

14 - Supports receiving clinical documents with unknown provider recipients.

IF a document is downloaded to the system where ALL provider recipients are unrecognized by the EMR system, **THEN** the system **SHALL** provide a default user to assign the document to. The system **SHOULD** provide the ability for manual remediation of the document to assign to a provider. The system **SHALL NOT** automatically delete the document without end user review.

Note - CDX will distribute clinical documents using both provider and/or location logic for routing appropriately. If a provider and location is specified the document will be routed to the location only, even if the specified provider does not subscribe to the location.

15 - Supports receiving clinical documents with only a location recipient.

IF a document downloaded to the system has only a location recipient and no provider recipients, **THEN** the system **SHALL** provide a default user to assign the document to. The system **SHOULD** provide the ability for manual remediation of the document to assign to a provider. The system **SHALL NOT** automatically delete the document without end user review.

Note - CDX will distribute clinical documents using both provider and/or location logic for routing appropriately. If a location is specified the document will be routed to that location only.

16 - Supports clinical documents with Provider Group recipients.

IF a document downloaded to the system has a Provider Group as one of the intended recipients, **THEN** the system **SHALL** be able to receive, consume and display the clinical document without error.

The system **SHOULD** be able to display the Provider Group as one of the document's recipients to the end user.

Note: The Provider Group specification can be found in the CDX v3.0 Release Notes

17 - Status of received clinical document is clearly presented to the user.

The system **SHALL** indicate the status of any received clinical document.

The *clinicalDocument/documentationOf/serviceEvent/bccda:statusCode* element determines the document's status. Documents need to be in either final or preliminary state.

Final status codes are:

- aborted
- cancelled
- completed
- held
- new

- normal
- nullified
- obsolete
- signed
- suspended

Preliminary status code is:

- active

18 - Supports receiving, consuming, and storing discretely the CDA elements that are required to identify, relate and version a clinical document.

When a CDA clinical document is received the EMR system **SHALL** consume and store the following elements for the document:

1. ClinicalDocument/id
2. ClinicalDocument/effectiveTime
3. ClinicalDocument/relatedDocument/ParentDocument/id
4. ClinicalDocument/inFulfillmentOf/order/id
5. ClinicalDocument/setId
6. ClinicalDocument/versionNumber

19 - Supports replace functionality to ensure most recent version of clinical document is presented to the user.

IF the EMR system receives a more recent version of a clinical document, **THEN** it **SHALL** replace the default document shown to the EMR user with the more recent version.

A new version of a clinical document can be determined by one or more of the following:

1. Has a ClinicalDocument/**relatedDocument/ParentDocument/id** that is the same as the ClinicalDocument/id of another document in possession.
2. Has a ClinicalDocument/**setID** that matches the ClinicalDocument/**setID** of the document in possession. The most recent version will have the highest ClinicalDocument/**versionNumber**
3. Has at least 1 ClinicalDocument/**infulfillmentOf/order/id** element that matches at least 1 ClinicalDocument/**infulfillmentOf/order/id** of the document in possession.

IF the EMR system receives more than one version of a document **THEN** the system **SHALL** retain and be able to display all previous versions of a document.

20 - Supports UTF-8 Unicode character set.

The system **SHALL** support all UTF-8 Unicode characters. This includes characters in the discrete header data and the body narrative.

21 - Supports the indication of attachment(s) of clinical documents.

IF the system receives a clinical document with one or more attachments **THEN** the system **SHALL** provide a visual indication to the user that attachment(s) are present and how many there are.

22 - Supports the receipt of clinical documents with one or more attachments.

The system **SHALL** provide the ability to receive and view attachments of a CDA message that are in the following file formats:

- JPG
- PNG
- RTF
- PDF
- TIFF

23 - Supports clinical document attachments being saved / added to a patient chart.

The system **SHALL** provide the ability to add or save attachments to the patient chart in the EMR.

24 - Supports the filing (by LOINC code) of consumed clinical documents, notes and events into a defined filing structure within the patient electronic chart.

The EMR system **SHALL** support the filing (by LOINC code) of received clinical documents into defined categories within the system.

25 - The list of document templates is dynamic and the EMR system must support the handling of received clinical documents where the LOINC code on the inbound CDA message is *unrecognized*.

IF the EMR system receives a CDA message which contains a document type *LOINC code that is not recognized*, **THEN** the EMR system **SHALL** support the rendering of the document. The EMR system **SHALL** file the document in an appropriate “default” area in the document ontology.

Additionally, functionality **SHOULD** be provided so that an end user may manually remediate the document to file it in a more appropriate area in the document ontology, if the end user deems appropriate.

26 - Supports CDA Level 2 documents.

The EMR system **SHALL** fully support *receiving and rendering* of a CDA Level 2 clinical document at CDA Level 1.

27 - CDA Level 3 documents handled.

The EMR system **SHALL** fully support receiving and rendering of a CDA Level 3 clinical document at CDA Level 1.

NOTE: This is with the exception of CDA Level 3 Laboratory Results, which must be received and consumed discretely, as outlined in the CDA Level 3 Conformance Profile for Lab.

28 - System supports the ability to send one or more of the approved E2E templates.

The system **SHALL** only send the following e2e CDA templates at CDA Level 1:

1. Generic Episodic Document
2. Generic Unstructured Referral
3. Unstructured Document

29 - Supports sending clinical documents that adhere to the BC approved LOINC codes.

The system **SHALL** only support the sending of clinical documents that are identified by LOINC codes which have been approved for use in BC as per the [BC Document Ontology Implementation Guide](#).

30 - Supports correct patient selection through appropriate display of patient identifiers when creating clinical documents.

When a user generates a clinical document, the system **SHALL** clearly display the patient identifiers on the user's view of the clinical document being generated. The required patient identifiers to be displayed are as follows:

1. Patient PHN
2. Patient Last Name
3. Patient First Name
4. Patient DOB

5. Patient Gender

31 - Supports the ability for the end user to select and send to CDX subscribed provider recipients

When a CDA document is generated by the EMR:

- The system **SHALL** be able to submit a query to the CDX Provider Registry Service, and **SHALL** display the (CDX subscribed provider(s)) results of the query to the end user.
- The system **SHALL** only include providers that are capable of consuming the Document Type (templateId) of the message being sent, in the query results.
 - For example: when sending an e-referral, the sending system **SHALL** first ensure that the recipient is capable of consuming a Generic Unstructured Referral document template.
- The system **SHALL** provide the ability for the end user/sender to pick one or more intended recipient(s) for the document to be delivered to, from the query results.
- The system **SHALL** allow the user to select the correct location from the query results for providers that are subscribed to more than one location.

32 - Supports the ability for the end user to select and send to CDX subscribed provider group (care team) recipients

When a CDA document is generated by the EMR:

- The system **SHOULD** be able to submit a query to the CDX Provider Registry Service, and **SHOULD** display the (CDX subscribed provider group)) results of the query to the end user.
- The system **SHALL** only include provider groups that are capable of consuming the Document Type (templateId) of the message being sent, in the query results.
 - For example: when sending an e-referral, the sending system **SHALL** first ensure that the recipient is capable of consuming a Generic Unstructured Referral document template.

- The system **SHALL** provide the ability for the end user/sender to pick one or more intended recipient(s) for the document to be delivered to, from the query results.
- The system **SHALL** allow the user to select the correct location from the query results for provider groups that are subscribed to more than one location.

Note: Documentation on Provider Groups can be found in the [CDX v3.0 Release Notes](#)

33 - Supports the ability for the end user to select and send to CDX subscribed location recipients

When a CDA document is generated by the EMR:

- The system **SHALL** be able to submit a query to the CDX Clinic Registry Service, and **SHALL** display the (CDX subscribed location(s)) results of the query to the end user.
 - The system **SHALL** only include locations that are capable of consuming the Document Type (templateId) of the message being sent, in the query results.
- For example: when sending an e-referral, the sending system **SHALL** first ensure that the recipient is capable of consuming a Generic Unstructured Referral document template.
- The system **SHALL** provide the ability for the end user/sender to pick one or more intended recipient(s) for the document to be delivered to, from the query results.

34 - Supports the ability for the end user to select to send to non-CDX subscribed recipients.

When the end user is attempting to send a clinical document:

- Where an intended recipients are NOT subscribed to CDX and do NOT appear in the CDX Provider/Clinic Registries, the system **SHALL** allow an intended recipient field to be manually populated by the user
- The EMR system **SHALL** provide indication to the user that a manual process (such as faxing) should be followed to deliver the document

- The EMR system **SHALL** include the non-CDX subscribed providers in the generated CDA message as an intended recipient
- When the document is distributed to a non-CDX recipient through some other means the system **SHOULD** allow the user to manually populate a “Date Sent” field for the clinical document

35 - Supports the display of intended recipients as selected by the user.

When a user has selected the intended recipients for an outbound clinical document:

- The system **SHALL** display the intended recipient(s) within the user’s view of the clinical document being generated as a record of who the document will be sent to.
- The system **SHALL** provide clear indication to the user that the clinical document will be sent electronically for the intended recipients that are subscribed to the CDX service
- The system **SHALL** provide clear indication to the user that the clinical document will **NOT** be sent electronically for intended recipients **NOT** subscribed to the CDX service

36 - Supports the ability to capture and display the code and reason identifying the type of service event that is being documented.

When a CDA clinical document is generated:

- the system **SHOULD** provide the ability for the user to enter the type of service (service event code element) related to the event that triggered the creation of the associated clinical document
- the system **SHOULD** include the service event code element in any outbound CDA clinical document in *documentationOf\serviceEvent\code*

37 - Supports the ability to capture and display the date the service was provided to the patient (service event effectiveTime element)

When a CDA clinical document is generated:

- the system **SHOULD** provide the ability for user to enter the date of service (service event effectiveTime element) related to the event that triggered the creation of the associated clinical document
- the system **SHOULD** include the service event effectiveTime element in any outbound CDA clinical document in *documentationOfServiceEvent\effectiveTime*

38 - Supports the ability to create and send the clinical document create date (effectiveTime) with the CDA document.

When a CDA document is generated by the system:

- The system **SHALL** generate a document creation date.
- The system's document creation date **SHALL** be populated into the CDA mandatory effectiveTime element for all outbound CDA documents.

NOTE: The creation date of a document represents the date the user initiated the document, which may or may not be the same date as the document is actually sent from the system.

39 - Supports indication of successful submission to the CDX system

When a CDA document is successfully received by the CDX system:

- The system **SHALL** provide a message to the user indicating that the clinical document has been successfully delivered to the CDX service, and is awaiting retrieval by the intended recipient.

40 - Supports the ability to create and send the clinical document sent date with the CDA document.

When a CDA document is SENT by the system:

The system **SHOULD** automatically populate a "Date Sent" field for the clinical document.

the system **MAY** include the document sent date in the narrative text section of the outbound CDA document, preferably at the bottom of the narrative text section on all outbound CDA documents.

Note: The creation date of a document represents the date the user initiated the document, which may or may not be the same date as the document is actually sent from the system.

41 - Supports the ability to determine the distribution status of a document that has been uploaded to CDX.

The EMR system **SHOULD** support logic to query the CDX Distribution Status Service using the Document ID to retrieve the status of a clinical document.

The Document ID is assigned at the time a document is created by the EMR.

The EMR **SHALL** appropriately consume/present the status(es) from CDX.

For example checking the status of an e-Referral and showing it as sent to all recipient clinics.

42 - Supports sending CDA optional header concepts/elements discretely where possible.

Wherever the EMR system discretely captures data elements that correspond to optional CDA header elements, the system **SHOULD** send the optional CDA header elements.

43 - Supports the creation, maintenance and tracking of clinical document IDs internally, in order to provide ability to relate document versions together.

Use Case: Original clinical document, natively generated

When a CDA document is generated the EMR system **SHALL** create, maintain, store and send the following elements:

1. *ClinicalDocument/id*
2. *ClinicalDocument/effectiveTime*

IF the system chooses to utilize the `setId` and `versionNumber` elements **THEN** the system **SHALL** create, maintain and store the following elements:

1. *ClinicalDocument/setId*
2. *ClinicalDocument/versionNumber*

44 - Supports sending CDA mandatory header concepts/elements discretely.

The EMR system **SHALL** send the mandatory CDA header elements. (see list in Appendix below)

45 - Supports patient matching criteria for receiving Health Information Systems by including appropriate patient identifiers on outbound clinical documents.

When CDA documents are sent from the EMR system, the system **SHALL**, at a minimum, contain in the message header the patient demographics to ensure that documents sent have the ability to be attached to the correct patient's chart in the receiving system.

The 5 patient matching points are:

1. Patient PHN
2. Patient Family Name
3. Patient Given Name
4. Patient DOB
5. Patient Administrative Gender

46 - Supports the ability to correct and/or update a previously created and sent CDA message/document.

- The system **SHOULD** provide the user the ability to edit/update CDA clinical documents which have already been sent.
- The edited/updated information in the clinical document **SHOULD** be clearly identifiable

- The updated document **SHALL** indicate the parent document.
- Historical versions of the document **SHALL** be accessible to be viewed by the user.

47 - Supports storing and sending versioning discrete elements when sending updated clinical documents.

(Use Case: Updated clinical document, natively generated)

When an EMR system is sending an updated CDA document the EMR system **SHALL** create, maintain, store and send the following elements:

1. *ClinicalDocument/relatedDocument/parentDocument/id* element (RPLC)

IF the system chooses to utilize the *setId* and *versionNumber* elements **THEN** the system **SHALL** create, maintain and store and send the following elements:

1. *ClinicalDocument/setId*
2. *ClinicalDocument/versionNumber*

48 - Supports capturing and sending the status of the clinical document.

The EMR system **MAY** send the document status in the *ClinicalDocument/documentationOf/serviceEvent/bccda:statusCode* element.

IF the EMR system sends a preliminary clinical document **THEN** the EMR system **SHOULD** send the status code:

- Active

IF the EMR system is sending a clinical document in a final state **THEN** the EMR system **SHOULD** omit the *statusCode* element, or the system **MAY** send one of the following codes:

- aborted
- cancelled

- completed
- held
- new
- normal
- nullified
- obsolete
- suspended

The system **SHALL NOT** send any status codes other than those specified above.

49 - Supports the ability for user to cancel clinical documents.

The system **MAY** provide functionality which allows the user to cancel a document that has been created and sent.

IF the system provides the functionality to cancel a document, **THEN** the system **SHALL** include the code "cancelled" or "aborted" in the *documentationOf/serviceEvent/bccda:statusCode* element and **SHOULD** also include an indication of this in the narrative body.

IF the system provides the functionality to cancel a document, **THEN** the system **SHALL** also send a CDA to any intended recipients of the original clinical document to indicate that the clinical document is now in a cancel status.

50 - Supports the sending of clinical documents with attachments.

IF the system is using CDX to send CDA documents, **THEN** the system **MAY** provide ability for the user to add one or more attachments to outbound clinical documents.

IF the system chooses to implement the sending of attachments, **THEN** the system **SHALL** adhere to the CDX Multiple Attachment Specification as found on BCCDX.ca

51 - Supports approved file formats when sending attachment(s).

IF the system is using CDX to send CDA documents, **THEN** the system **SHALL** restrict the attachments to the following file formats: .jpg, .tiff, .png, .rtf, and .pdf

52 - Supports file size restriction when sending attachment(s)

IF the system is using CDX to send CDA documents, **THEN** the system **SHALL** restrict the size of the attachment(s) to less than 50 MB.

*50 MB is the current maximum total allowable message size in CDX (this 50 MB includes the message and all attachments.)

53 - Supports the ability to relate documents in a workflow.

(Use Case: Clinical documents associated by workflow, such as referral/consultation)

When CDA documents representing part of a clinical workflow are generated in the EMR (such as an order/request (e.g. referral) the EMR system **SHALL** create, maintain, store and send *ClinicalDocument/inFulfillmentOf/order/id*

When a response (e.g. consult)) to an order/request document is generated the EMR system **SHALL** preserve, store and send the requesting document's *ClinicalDocument/inFulfillmentOf/order/id*

(Set to unique order ID or referral ID from generating system. If not available, populate with ClinicalDocument/id)

54 - Supports dynamic confirmation of recipient(s) CDX capability

The sending system **SHALL** support dynamically confirming recipients' CDX capability (CDX subscription status, location, and template capability) immediately prior to sending the clinical document to the CDX distribution system.

The system **SHALL NOT** submit the clinical document to the CDX system, if **NONE** of the originally selected recipients are capable of receiving the document through CDX.

55 - Supports sending clinical documents as per the BC approved CDA Implementation Guides.

IF the system chooses to send E2E clinical documents through the CDX distribution system, **THEN** the system **SHALL** generate CDA Level 1 documents conformant to the BC eHR CDA Implementation Guide and selected items in the BC PITO e2e CDA Implementation Guide.

Note: In the case of discrepancy between the two IGs the BC eHR CDA IG is preferred

Vendor to complete prior to Conformance

Vendor to Complete Table - Document Ontology

Health Information and Electronic Medical Record systems utilize ontologies to organize clinical documents. Although efforts are being made in the international (etc.) community to provide standards around ontology in Health Information and Electronic Medical Record systems, it may be some time before published standards are available. In the absence of such standards, we would like to get a high level view into how EMR software handles the ontology for the clinical documents *we distribute*. In that regard, please complete the following table:

EMR Ontology Feedback	
Clinical Document	Filed where in EMR Ontology/Filing Structure?
Procedure Note	
Discharge Summary	
Diagnostic/Medical Imaging	
Progress Note	
History & Physical	
Consultation	
Referral	
Care Plan	
Admission and Discharge Notification documents.	

Vendor to Provide Screen Captures

Please provide EMR screen captures which show how the EMR handles the following:

EMR Document Handling & Rendering	
1.	Demonstration of how messages that cannot be matched to a patient are presented to users
2.	Demonstration of partial match of demographics for a patient with the option to update the patient demographics
3.	Provide the data mapping of CDA header data elements to EMR data elements in receiving a clinical document.
4.	A corrected clinical document, both before and after the correction.
5.	An appended clinical document, both before and after the document has been appended.
6.	Display of the user view of the CDX standard XSLT stylesheet for a CDA Level 1 Health Authority inbound clinical document.
7.	Display of the user view of the CDX standard XSLT stylesheet for a CDA Level 1 e2e inbound clinical document.
8.	The high level table view (ontology) of a patient's clinical documents. Note: The table view refers to a table of clinical documents for one or more patients.
9.	A new (un-reviewed) message as it is presented to the user in the EMR
10.	The presence of a CDA Level 1 transcribed report
11.	The presence of a CDA Level 1 Medical/Diagnostic imaging document type
12.	The presence of a CDA Level 1 Admission Notification document.
13.	The presence of a CDA Level 1 Discharge Notification document.
14.	Demonstration of how CDA messages/documents with unrecognized LOINC codes are placed in an appropriate "default" area of the document ontology
15.	The presentation of a CDA clinical document with an attachment, and multiple attachments.
16.	The presentation of attachments being saved/added to the patient chart.

EMR Document Handling & Rendering	
17.	The presentation of outbound clinical document with an attachment, where the attachment is being evaluated for correct file format and size restriction.

APPENDIX:

#02 & #44: CDA Mandatory Header Elements

(elements in **bold** are displayed by stylesheet)

- realmCode
- typeId
- templateId
- **id**
- **code** (sort of displayed by stylesheet, since its the same as title)
- **title**
- **effectiveTime**
- confidentialityCode
- languageCode
- recordTarget/./**id (PHN)**
- recordTarget/./name/**family**
- recordTarget/./name/**given** (1st occurrence)
- recordTarget/./**administrativeGenderCode**
- recordTarget/./**birthTime**
- author/**time**
- author/./id
- author/./**family** (if person)
- author/./**given** (1st occurrence) (if person)
- custodian/./**id**
- component/**nonXMLBody/text** (unless a reference to an attachment)

#32:

Provider Group documentation can be found in link below.

https://bccdx.ca/Documents/CDX%20v3.0%20Change%20Notice%20for%202016%20August%2018_Infrastructure.pdf