HEALTH LEVEL SEVEN
Electronic Health Record Technical Committee
Structured Documents Technical Committee

Draft Standard for Trial Use:
HL7 Implementation Guide for CDA Release 2: Reference Profile for EHR Interoperability, Release 1
A Profile of the HL7 Electronic Health Record Interoperability Model (EHR/IM) DSTU

Collaboration

This Reference Profile is the result of an ongoing collaboration between the HL7 Electronic Health Record, Security and Structured Documents Technical Committees.

Glossary

CDAr2	HL7 Clinical Document Architecture Release 2
DSTU	HL7 Draft Standard for Trial Use
EHR	Electronic Health Record
EHR/IM	Electronic Health Record Interoperability Model Draft Standard for Trial Use, March 2007
EHRS/FM	Electronic Health Record Functional Model, normative standard, March 2007
HL7	Health Level Seven, an ANSI accredited standards developer

Section 1: Background

The HL7 Electronic Health Record Technical Committee is focused on standards applicable to EHR Systems and EHR Records.

The EHR System Functional Model describes functional characteristics (functions) of EHR Systems. EHR Systems conform to functional profiles of the EHRS/FM. The EHRS/FM is a normative HL7/ANSI Standard, published March 2007.

The EHR Interoperability Model describes characteristics of interoperable EHR Records. An EHR Record is a persistent artifact which may be independent of the EHR or other System from which it originated. The EHR/IM is an HL7 Draft Standard for Trial Use, published March 2007.

As the EHR/IM was developed the obvious question arose, given this set of record interoperability requirements, what implementation strategy might be considered for the Common EHR Record Unit? Although the EHR TC considered alternatives CDAr2 was the obvious and immediate candidate. Rather than invent something new, why not re-purpose HL7's long-standing document architecture as an implementation strategy for the Common EHR Record Unit? Thus this Reference Profile was initiated.

Section 2: Purpose

The Reference Profile shows how attributes of the HL7 CDAr2 fulfill requirements of the Common EHR Record Unit, per the HL7 EHR Interoperability Model DSTU.

Section 3: Scope

- The Reference Profile is offered as a Draft Standard for Trial Use.
- The Reference Profile shows how CDAr2 could be used to implement the Common EHR Record Unit, as specified in EHR/IM Sections 3 & 4.
- The Reference Profile crosswalks EHR Record interoperability requirements, as specified in EHR/IM Column B Assertions and Characteristics, to corresponding CDAr2 attributes.
- For each designated CDAr2 attribute, the Reference Profile specifies its testability criteria.
- Of the fifty-six (56) total requirements specified, fifty-one (51) are fulfilled by CDAr2 and are subject of this Profile, with five (5) remaining requirements to be taken up in future collaborative work of the HL7 EHR, Structured Documents and Security Technical Committees.

Section 4: Future Work

As outlined above, most EHR/IM Common EHR Record Unit requirements are supported by attributes of CDAr2. Collaboration will continue between the EHR, Structured Documents and Security Technical Committees to resolve the remaining issues.

Here is a summary of outstanding items:

EHR/IM Ref	EHR Interoperability Requirement	
3.18.2	Access control for record creation/amendment	To be considered in future collaboration between Electronic Health Record, Structured Documents and Security TCs.
3.19.3	Point of record access/use audit	
3.19.5	Point of record transmittal or disclosure audit	
3.19.6	Point of record receipt audit	
3.19.7	Point of record de-identification, aliasing audit	

Section 5: Key to Profile

Col	Description
A	EHR/IM Reference Number
B	EHR/IM Record Interoperability Assertion or Characteristic (Requirements Statement)
C	CDAr2 Attribute
D	Testability Criteria, if formalized

Section 6: Reference Profile for EHR Interoperability

The following table matches/specifies Common EHR Record Unit requirements (per EHR/IM Sections 3&4) with CDAr2 Attributes which fulfill/enable those requirements:

EHR/IM ID	HL7 EHR/IM Interop Assertion/Requirement (from EHR/IM Column B)	HL7 CDAr2 Attribute/Notes	Testability Criteria
EHR Interoperability Model Section 3 - Act Record (Common EHR Record Unit)			
3	An Act is documented by an Act Record instance.		
3.1	An Act/Act Record instance is uniquely identifiable.	Clinical Document ID	/ClinicalDocument/id
3.2	An Act Record is persistent legal evidence of Act occurrence.	legalAuthenticator	/ClinicalDocument/legalAuthenticator/signatureCode[@code="S"]
3.3	An Act Record is a unit of record of the Health Record.	informationRecipient	/ClinicalDocument/informationRecipient[@typeCode="HLTHCHRT"]
3.4	An Act Record is comprised of multiple attributes (elements).	<Yes!>	fn:count(/ClincalDocument/component/structuredBody/component/section/entry/observation) > 1
3.5	An Act Record may contain attributes:		
3.5.1	Current to the Act	ClinicalDocument EncompassingEncounter	/ClinicalDocument/componentOf/encompassingEncounter
3.5.2	Of an historical nature	Observation/effectiveTime SubstanceAdministration/effectiveTime Supply/effectiveTime Procedure/effectiveTime Encounter/effectiveTime Act/effectiveTime	/ClinicalDocument/component/structuredBody/component/section/entry//*[(self::observation|self::supply|self::substanceAdministration|self::procedure|self::encounter|self::act)]/effectiveTime
3.6	An Act Record is (one of):		
3.6.1	Patient related and patient identifiable.	recordTarget	/ClinicalDocument/recordTarget/patientRole/id
3.6.2	Not patient specific.		/ClincalDocument/recordTarget/PatientRole/id[@nullFlavor="NI"]

EHR/IM ID	HL7 EHR/IM Interop Assertion/Requirement (from EHR/IM Column B)	HL7 CDAr2 Attribute/Notes	Testability Criteria
3.6.3	Patient related but aliased.	Patient/name - flagged as alias	/ClinicalDocument/recordTarget/patientRole/patient/name[use="A"]
3.6.4	Patient related but anonymized.	Patient/name - flagged as alias	/ClinicalDocument/recordTarget/patientRole/patient/name[@nullFlavor]
3.7	An Act Record is (one of):		
3.7.1	A non-attestable unit of the health record	CDA only requires the potential for authentication, documents can be created without actual authentication.	
3.7.2	An attestable (signature specific) unit of the health record, which is (one of):	CDA specifies the potential for authentication.	
3.7.2.1	Attested by one or more Actor(s)/ Author(s)	authenticator legalAuthenticator	/ClinicalDocument/authenticator/signatureCode[@code="S"] | /ClinicalDocument/legalAuthenticator/signatureCode[@code="S"]
3.7.2.2	Not yet attested	The absence of authenticator or legal authenticator or X (required) signatureCode indicates a document has not been attested.	/ClinicalDocument/authenticator/signatureCode[@code="X"] | /ClinicalDocument/legalAuthenticator/signatureCode[@code="X"]
3.8	An Act Record has (may have):		
3.8.1	One or more originating Actor(s)/Author(s)	Author	/ClinicalDocument/author
3.8.2	One or more amending Actor(s)/Author(s)	This would be the Author on the amending CDA document instance.	/ClinicalDocument/author
3.9	An Act Record is sourced by an originating application.	custodian CustodianOrganization	/ClinicalDocument/custodian/assignedCustodian/representedCustodianOrganization/id
3.10	An Act Record allows revision by additive amendment only.	relatedDocument	/ClinicalDocument/relatedDocument[typeCode="APNS"]
3.10.1	Each Act Record amendment may include a reason for amendment	This could be specified as an optional section in the amendment document via implementation guide,	
3.11	An Act Record is timestamped according to:	*The document has a timestamp.*	

EHR/IM ID	HL7 EHR/IM Interop Assertion/Requirement (from EHR/IM Column B)	HL7 CDAr2 Attribute/Notes	Testability Criteria
3.11.1	Act Date/Time	Observation/effectiveTime SubstanceAdministration/effectiveTime Supply/effectiveTime Procedure/effectiveTime Encounter/effectiveTime Act/effectiveTime	/ClinicalDocument/component/structuredBody/component/section/entry//*[(self::observation|self::supply|self::substanceAdministration|self::procedure|self::encounter|self::act)]/effectiveTime
3.11.2	Act Duration	Observation/effectiveTime (interval) SubstanceAdministration/effectiveTime (interval) Supply/effectiveTime (interval) Procedure/effectiveTime (interval) Encounter/effectiveTime (interval) Act/effectiveTime (interval)	/ClinicalDocument/component/structuredBody/component/section/entry//*[(self::observation|self::supply|self::substanceAdministration|self::procedure|self::encounter|self::act)]/effectiveTime/[count(low|high|center|width) > 0]
3.11.3	Act Record Origination Date/Time	ClinicalDocument/effectiveTime	/ClinicalDocument/effectiveTime
3.11.4	Act Record Amendment Date(s)/Time(s)	relatedDocument	/ClinicalDocument/[relatedDocument/@typeCode="APND"]/effectiveTime
3.12	An Act Record is oriented to physical locations:		
3.12.1	Act Location	EncompassingEncounter/location	/ClinicalDocument/componentOf/encompassingEncounter/location
3.13	An Act Record is originated/amended at a specific device and network location.	assignedAuthor[assignedAuthoringDevice]/addr	/ClinicalDocument/component/structuredBody/component/section/entry//*[(self::observation|self::regionOfInterest|self::observationMedia|self::supply|self::substanceAdministration|self::procedure|self::encounter|self::organizer|self::act)]/id
3.14	An Act Record may contain uniquely identified multi-media elements.	ObservationMedia linkHtml	/ClinicalDocument/component/structuredBody/component/section/entry//*[(self::observationMedia]| /ClinicalDocument/component/structuredBody/component/section//*[(self::linkHtml]

EHR/IM ID	HL7 EHR/IM Interop Assertion/Requirement (from EHR/IM Column B)	HL7 CDAr2 Attribute/Notes	Testability Criteria
3.15	An Act Record may contain uniquely identified document elements.	Document/relatedDocument/ParentDocument reference/ExternalDocument - May refer to Act IDs??	/ClinicalDocument/relatedDocument/parentDocument/id | /ClinicalDocument/component/structuredBody/component/section/entry//*[(self::reference/externalDocument]/id
3.16	An Act Record may be signed or attested as complete, by declaration or by algorithmic measure.	legalAuthenticator <also Template Constraints>	/ClinicalDocument/legalAuthenticator/signatureCode[@code="S"]
3.17	An Act Record may be designated as accurate, by declaration or by algorithmic measure.	legalAuthenticator <also Template Constraints>	/ClinicalDocument/legalAuthenticator/signatureCode[@code="S"]
3.18	An Act Record may embed access controls to allow only permitted:		
3.18.1	Record access/view	ClinicalDocument/confidentialityCode - Note CDA provides basic confidentiality codes at the document and section levels.	/ClinicalDocument/confidentialityCode
3.18.2	Record creation/ amendment	Not currently supported in CDA – will be considered in future collaboration between EHR, SD and Security TCs.	
3.19	An Act Record has an embedded audit trail, tracing:		
3.19.1	Original record content along with each successive amendment, timestamped	ClinicalDocument/effectiveTime	/ClinicalDocument/effectiveTime
3.19.2	Point of record creation and amendment	ClinicalDocument/effectiveTime	/ClinicalDocument/effectiveTime
3.19.3	Point of record access/use	Not currently supported in CDA – will be considered in future collaboration with EHR, SD and Security TCs.	
3.19.4	Point of record content translation	ClinicalDocument/relatedDocument/ParentDocument <Document Originator Application Role>	/ClinicalDocument/relatedDocument/[@typeCode="XFRM"]/id

EHR/IM ID	HL7 EHR/IM Interop Assertion/Requirement (from EHR/IM Column B)	HL7 CDAr2 Attribute/Notes	Testability Criteria
3.19.5	Point of record transmittal or disclosure (to external entity)	Not currently supported in CDA – will be considered in future collaboration between EHR, SD and Security TCs.	
3.19.6	Point of record receipt (from external source)	Not currently supported in CDA – will be considered in future collaboration between EHR, SD and Security TCs.	
3.19.7	Point of record de-identification, aliasing	Not currently supported in CDA – will be considered in future collaboration between EHR, SD and Security TCs.	
3.19.8	Point of record completion	legalAuthenticator	/ClinicalDocument/legalAuthenticator/[signatureCode/@code="S"]/time
3.19.9	Point of record attested accurate	authenticator/time legalAuthenticator/time	/ClinicalDocument/authenticator/time | /ClinicalDocument/legalAuthenticator/time
3.20	An Act Record may be:		
3.20.1	Part of a patient encounter	EncompassingEncounter	/ClinicalDocument/componentOf/encompassingEncounter
3.20.2	Related to an identified patient problem	<Observation within "Chief Complaint" or "Reason for Referral" Section>	
3.20.3	Related to a specific order or care plan	ClinicalDocument/inFulfillmentOf/Order	/ClinicalDocument/inFulfillmentOf/order/
EHR Interoperability Model Section 4 - Act Record Attributes			
4	[Per 2.3 & 3.4] An Act Record is comprised of multiple attributes (elements).	Observation/referenceRange/ObservationRange Substance/Adminstration Supply Procedure Encounter	/ClinicalDocument/component/structuredBody/component/section/entry//*[(self::observation/referenceRange/observationRange|self::supply|self::substanceAdministration|self::procedure|self::encounter|self::act)]

EHR/IM ID	HL7 EHR/IM Interop Assertion/Requirement (from EHR/IM Column B)	HL7 CDAr2 Attribute/Notes	Testability Criteria
4.1	An Attribute is uniquely identifiable.	Observation/id RegionOfInterest/id ObservationMedia/id SubstanceAdministration/id Supply/id Procedure/id Encounter/id Organizer/id Act/id	/ClinicalDocument/component/structuredBody/component/section/entry//*[(self::observation|self::regionOfInterest|self::observationMedia|self::supply|self::substanceAdministration|self::procedure|self::encounter|self::organizer|self::act)]/id
4.2	An Attribute has a data type.	<Yes!>	
4.3	An Attribute is (one of):		
4.3.1	Computable	<Based on Data Type> Example: Observation/statusCode	
4.3.2	Non-computable	<Based on Data Type> Example: Observation/text	
4.4	An Attribute may have (one or more):		
4.4.1	Unit of measure	Observation/value (PQ data type) Supply/quantity	/ClinicalDocument/component/structuredBody/component/section/entry//*[(self::observation/value/@xsi:type="PQR"|self::supply/quantity)]
4.4.2	Reference range	Observation/referenceRange/ObservationRange	/ClinicalDocument/component/structuredBody/component/section/entry//*[(self::observation/referenceRange/observationRange)]
4.4.3	Expiration date/time or duration	EffectiveTime	/ClinicalDocument/component/structuredBody/component/section/entry//*[effectiveTime]
4.5	An Attribute may be encoded according to:		
4.5.1	Industry standard coding/classification scheme	<Any attribute of CE and CD data type>	
4.5.2	Local coding/classification scheme	<Attribute with CWE constraints are extensible>	

EHR/IM ID	HL7 EHR/IM Interop Assertion/Requirement (from EHR/IM Column B)	HL7 CDAr2 Attribute/Notes	Testability Criteria
4.6	An Attribute may be translated from one code set to another with:		
4.6.1	Industry standard mapping scheme	<Any attribute of CE and CD data type>	
4.6.2	Local mapping scheme	<Attributes with CE/CD which include translations>	
4.7	An Attribute may embed access control parameters to allow only permitted:		
4.7.1	Attribute access/view	Note CDA provides basic confidentiality codes at the section level, not at the entry level.	
4.7.2	Attribute edit	N/A - CDA does not specify this behavior.	