



HL7 Informative Document: C-CDA Rubric,
Release 1
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HL7 Informative Ballot

Sponsored by:
Structured Documents Work Group
Patient Care Work Group

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Following is a non-exhaustive list of third-party terminologies that may require a separate license:

Terminology	Owner/Contact
Current Procedures Terminology (CPT) code set	American Medical Association https://www.ama-assn.org/practice-management/cpt-licensing
SNOMED CT	SNOMED International http://www.snomed.org/snomed-ct/get-snomed-ct or info@ihtsdo.org
Logical Observation Identifiers Names & Codes (LOINC)	Regenstrief Institute
International Classification of Diseases (ICD) codes	World Health Organization (WHO)
NUCC Health Care Provider Taxonomy code set	American Medical Association. Please see www.nucc.org . AMA licensing contact: 312-464-5022 (AMA IP services)

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1 Overview

This document contains rubric criteria created through an ongoing project in the HL7 Structured Documents Work Group (SDWG), originating in 2016. Throughout 2018 a group of HL7 members created a new set of rubrics to add to the original rubric. This project identified key problematic areas in real system generated C-CDA documents where similar data was consistently represented differently or incompletely. Variably constructed data removes the ability to reliably share and compare data, adversely impacting interoperability. The hope is that the rubric will promote best practices by allowing providers and health IT developers to identify and resolve issues of C-CDA document data representation in their health IT systems thereby promoting interoperability and use of clinical data received in C-CDA documents.

A subset of the rubric criteria are utilized to identify best practice tests and quantitative scoring criteria in the Office of the National Coordinator for Health IT (ONC) [C-CDA Scorecard](#). The ONC C-CDA Scorecard is designed to allow implementers insight into C-CDA implementations and highlights areas of improvement which can be made today to move the needle forward. The intent is to add these additional rubrics to the ONC Scorecard.

In order for these rubric criteria to be more exposed, members of SDWG suggested it would be a good idea to put the rubric criteria through an Informative Ballot.

1.1 Need

There is an industry need for disparate systems to be able to communicate with each other. End users can use tools that utilize these rubric criteria to determine the quality of their C-CDA applications, leading to quality improvement discussions with their vendors. The Informative Ballot will help gain widespread consensus on the appropriateness of the rubric criteria.

1.2 Note to Balloters

When commenting on the Criteria, please be as specific as possible. For instance:

- Provide suggested wording if you want to see a proposed criteria revised
- Please provide a clear rationale for why you are requesting a particular change
- If a significant criteria seems to be absent, please provide the criteria text and justification of the need

2 C-CDA Rubric

2.1 Explanation of the Rubric Criteria

The rubric criteria are a set of rules that go above and beyond EHR certification. They are meant to be utilized in best practice testing tools to provide feedback to industry and help drive the EHR vendor community towards consistent implementation of the C-CDA standard.

There are two types of Rubric criteria identified:

- **Required** – All tools adopting this criteria should throw an error.
- **Informational** - All tools adopting this criteria should throw a warning, not an error.

2.2 Required Rubric

REQUIRED RUBRIC		
Section/Entry/Header	Rubric	Description
Patient Demographics	Patient Date of Birth should be valid and properly precisioned	The Patient's date of birth has to have a value which has a precision at least to the day.
	Patient's alternative names such as birth name, previous name should exist in its own name element independent of the legal name.	Patient's alternative names such as birth name, previous name should exist in its own name element independent of the name element representing a legal name.
Encounters	EffectiveDate/Time elements should have the right time and time zone offsets	EffectiveTime elements in the section are expected to have time offsets along with the date and are typically nonzero time offsets. In addition they are expected to have the time zone information for proper interpretation. For e.g. if the time is being defaulted to 000000 for hours, minutes and seconds for multiple entries it might be worth checking if the data was entered properly. Also if the time offsets are present without a time zone, the time may be interpreted incorrectly, hence time zones should be specified as part of

REQUIRED RUBRIC		
Section/Entry/Header	Rubric	Description
		the time element.
	EffectiveDate/Times for all historical activities should be within the lifespan on the patient	EffectiveDate/Times for historical events should be greater than the patient's date of birth and less than the earliest of current time or patient's date of death.
	Encounter date/time and ID in the header are also in an EncounterActivity	Check if the Encounter date/time and ID in the header is present in one of the EncounterActivity entries in the Encounter section of the body.
	Check if an Encounter is present	If an encompassingEncounter is present in the header, then check whether there is an encounter in the Encounter section (not a null flavor)
	Encompassing encounter is present in Encounter documents	Check whether the encompassing encounter is present in all encounter based documents i.e. Discharge Summary, Referral Note, etc. (do not ding if using CCD/Care Plan)

REQUIRED RUBRIC		
Section/Entry/Header	Rubric	Description
	The Display Names used by the structured data should conceptually align with the meaning of the code	Each of the code systems, value sets specified by the C-CDA IG refers back to standard terminologies like SNOMED-CT, LOINC, RxNorm, ICD9, ICD10. When codes from these code systems are used to represent structured data the short or long description assigned in the code system for the code should be used in the display name of the code element in the C-CDA document
	Each entry has to be linked to related narrative text	Each entry should have a text element with a reference that is linked to the corresponding narrative text in the section.text.
Allergies	AllergyObservation entry has a reaction	Allergy Observation entry must have a reaction. Require a nullFlavor if not known.
	EffectiveDate/Times for all historical activities should be within the lifespan on the patient	EffectiveDate/low for historical events should be greater than one year prior to the patient's date of birth and effectiveTime/high less than the earliest of current time or patient's date of death.
	The Display Names used by the structured data should conceptually align with the meaning of the code	Each of the code systems, value sets specified by the C-CDA IG refers back to standard terminologies like SNOMED-CT, LOINC, RxNorm, ICD9, ICD10. When codes from these code systems are used to represent

REQUIRED RUBRIC		
Section/Entry/Header	Rubric	Description
		structured data the short or long description assigned in the code system for the code should be used in the display name of the code element in the C-CDA document
	Each entry has to be linked to related narrative text	Each entry should have a text reference that is linked to the narrative text in the section.
	Allergen representation is correct	The narrative name of the Allergen should represent the conceptual meaning of the code in the entry
	Author entry includes a last modified date	Author entry must include at least a timestamp with information of the last modified date and be present within the Allergies entry, which could be at the concern or observation level.
	Allergies should be structured with the correct code systems	Allergies should be structured in UNIL, NDF-RT, SNOMED or RxNorm
Problems	EffectiveDate/Time elements have the right time and time zone offsets - This should be removed.	EffectiveTime elements in the section are expected to have time offsets along with the date and are typically nonzero time offsets. In addition they are expected to have the time zone information for proper interpretation. For e.g. if the time is being defaulted to 000000 for hours, minutes and seconds for multiple entries it might be worth checking if the data was entered properly. Also if the time offsets are present without a time zone, the time may be interpreted incorrectly, hence time zones should be specified as part of

REQUIRED RUBRIC		
Section/Entry/Header	Rubric	Description
		the time element
	EffectiveDate/Times for all historical activities should be within the lifespan on the patient	EffectiveDate/low for historical events should be greater than one year prior to the patient's date of birth and effectiveTime/high less than the earliest of current time or patient's date of death. When the subject is the patient, the previous statement should be true.
	The Display Names used by the structured data should conceptually align with the meaning of the code.	Each of the code systems, value sets specified by the C-CDA IG refers back to standard terminologies like SNOMED-CT, LOINC, RxNorm, ICD9, ICD10. When codes from these code systems are used to represent structured data the short or long description assigned in the code system for the code should be used in the display name of the code element in the C-CDA document
	Problem Concern effective times reflect the appropriate problem concern status	A Problem Concern of completed or suspended should have a Problem Concern effectiveTime/high value present. Similarly a Problem Concern which is Active shall not have a Problem Concern effectiveTime/high value.

REQUIRED RUBRIC		
Section/Entry/Header	Rubric	Description
	Problem Observation value shouldn't be the same as Problem Observation code	The problem observation value should not be set to the problem observation code (problem type value set)
	The Problem narrative representation should be correct	The narrative name of the Problem should represent the meaning of the code in the Problem Observation value
	Author entry includes a last modified date and be present in the Problems entry	Author entry must include the most recent author with at least a timestamp with information of the last modified date and be present within the Problems entry, which could be at the concern or observation level.
	Narrative name of the problem should relate to the meaning of the code in the value	The narrative name of the Problem should represent the meaning of the code in the Problem Observation value
	Each entry has to be linked to related narrative text	Each entry should have a text reference that is linked to the narrative text in the section.
Medications	Medications effective/time should minimally be represented to the day, but should reflect more specific time when such time is available (e.g., reflecting hospital MAR time specificity)	EffectiveTime elements in the section are expected to have time offsets if a more specific time is given (e.g. HHMMSS) For e.g. if the time is being defaulted to 000000 for hours, minutes and seconds for multiple entries it might be worth checking if the data was entered properly. Also if the time offsets are present without a time zone, the time may be interpreted incorrectly, hence time zones should be specified as part of the time element

REQUIRED RUBRIC		
Section/Entry/Header	Rubric	Description
	EffectiveDate/Times for all historical activities should be within the lifespan on the patient.	EffectiveDate/low for historical events should be greater than one year prior to the patient's date of birth and effectiveTime/high less than the earliest of current time or patient's date of death.
	The Display Names used by the structured data should conceptually align with the meaning of the code.	Each of the code systems, value sets specified by the C-CDA IG refers back to standard terminologies like SNOMED-CT, LOINC, RxNorm, ICD9, ICD10. When codes from these code systems are used to represent structured data the short or long description assigned in the code system for the code should be used in the display name of the code element in the C-CDA document
	Medications should be coded with RxNorm SCD, SBD, GPCK, or BPCPK codes	C-CDA medication lists should contain medications coded as RxNorm Semantic Clinical Drugs, Semantic Branded Drugs, and packs. This means prescribable products on the level of 'loratadine 10mg oral tablet
	Immunizations should be represented in the Immunizations section.	Immunizations should be recorded using the Section Code 11369-6 within the document.
	Substance administration effectiveTime should match the narrative	The Substance administration/effectiveTime @xsi:type = pivl should agree with the Free Text Sig information.
	Substance administration effectiveTime	The Substance administration/effectiveTime @institution specified should agree with the Free Text Sig

REQUIRED RUBRIC		
Section/Entry/Header	Rubric	Description
		information
	Medications should have Free Text Sig entry.	Medications should have a free text sig entry to communicate medication instructions to providers and patients.
	The Author should include a timestamp and modified date in the Medication Activity entry	Author entry must include at least a timestamp with information of the last modified date and be present within the Medication Activity entry.
	Name of the drug should agree with the coded entry	The narrative name of the drug should represent the conceptual meaning of the code in the entry
	The substance administration/route code should reconcile with the medication consumable	
	The substance administration status code should not conflict with the medication status observation	
	Medication status end time should be later than the document creation date	When Medication status is active the high time should be in the future relative to the document generation date or the effectiveTime/high could be not present
	Machine readable should align with the narrative	The machine readable doseQuantity should agree with the Free Text Sig information
	Each entry has to be linked to related narrative text	Each entry should have a text reference that is linked to the narrative text in the section.

REQUIRED RUBRIC		
Section/Entry/Header	Rubric	Description
Immunization	Immunizations effective/time should minimally be represented to the day, but should reflect more specific time when such time is available (e.g., reflecting hospital MAR time specificity)	EffectiveTime elements in the section are expected to have time offsets if a more specific time is given (e.g. HHMMSS) For e.g. if the time is being defaulted to 000000 for hours, minutes and seconds for multiple entries it might be worth checking if the data was entered properly. Also if the time offsets are present without a time zone, the time may be interpreted incorrectly, hence time zones should be specified as part of the time element
	EffectiveDate/Times for all historical activities should be within the lifespan on the patient.	EffectiveDate/low for historical events should be greater than one year prior to the patient's date of birth and effectiveTime/high less than the earliest of current time or patient's date of death.
	The Display Names used by the structured data should conceptually align with the meaning of the code.	Each of the code systems, value sets specified by the C-CDA IG refers back to standard terminologies like SNOMED-CT, LOINC, RxNorm, ICD9, ICD10. When codes from these code systems are used to represent structured data the short or long description assigned in the code system for the code should be used in the display name of the code element in the C-CDA document
	The narrative should align with the meaning of the coded entry	The narrative name of the Immunization should represent the concept meaning of the code in the entry

REQUIRED RUBRIC		
Section/Entry/Header	Rubric	Description
	Each entry has to be linked to related narrative text	Each entry should have a text reference that is linked to the narrative text in the section.
Social History	EffectiveDate/Time elements have the right time and time zone offsets if the precision is proposed to the minute.	Social History elements are often less precise. Do not over specify the precision. For e.g. if the time is being defaulted to 000000 for hours, minutes and seconds for multiple entries it might be worth checking if the data was entered properly. Also if the time offsets are present without a time zone, the time may be interpreted incorrectly, hence time zones should be specified as part of the time element
	EffectiveDate/Times for all historical activities should be within the lifespan on the patient.	EffectiveDate/low for historical events should be greater than one year prior to the patient's date of birth and effectiveTime/high less than the earliest of current time or patient's date of death.
	The Display Names used by the structured data should conceptually align with the meaning of the code.	Each of the code systems, value sets specified by the C-CDA IG refers back to standard terminologies like SNOMED-CT, LOINC, RxNorm, ICD9, ICD10. When codes from these code systems are used to represent structured data the short or long description assigned in the code system for the code should be used in the display name of the code element in the C-CDA document
	Smoking status observation Template Id should be present in CCD and Referral Note.	Smoking status observation should be present. This is an observation with observation.code=72166-2

REQUIRED RUBRIC		
Section/Entry/Header	Rubric	Description
	Birth Sex has to be recorded as a social history observation.	C-CDA documents should capture birth sex as a social history observation independent of the Administrative Gender element in the US-Realm Header.
	Each entry has to be linked to related narrative text	Each entry should have a text reference that is linked to the narrative text in the section.
Laboratory Tests and Results	EffectiveDate/Time elements have the right time format and time zone offsets	EffectiveTime elements in the section are expected to have time offsets along with the date and are typically nonzero time offsets. In addition they are expected to have the time zone information for proper interpretation. For e.g. if the time is being defaulted to 000000 for hours, minutes and seconds for multiple entries it might be worth checking if the data was entered properly. Also if the time offsets are present without a time zone, the time may be interpreted incorrectly, hence time zones should be specified as part of the time element
	EffectiveDate/Times for all historical activities should be within the lifespan on the patient.	EffectiveDate/low for historical events should be greater than one year prior to the patient's date of birth and effectiveTime/high less than the earliest of current time or patient's date of death.

REQUIRED RUBRIC		
Section/Entry/Header	Rubric	Description
	The Display Names used by the structured data should conceptually align with the meaning of the code.	Each of the code systems, value sets specified by the C-CDA IG refers back to standard terminologies like SNOMED-CT, LOINC, RxNorm, ICD9, ICD10. When codes from these code systems are used to represent structured data the short or long description assigned in the code system for the code should be used in the display name of the code element in the C-CDA document
	Lab Result values should use preferred UCUM units for the specific lab test.	Lab Result values should use preferred UCUM units
	The effectiveTime is an interval that spans the effectiveTimes of the contained result observations.	The effectiveTime interval in the Result Organizer must encompass the effectiveTimes of the observations within the organizer.
	If observation value is recorded as a PQ datatype and if present, the observation range should be coded as an "IVL_PQ"	If observation value is recorded as a PQ datatype and if present, the observation range should be coded as an "IVL_PQ" (a parse-able range high/low attributes instead of narrative text).
	Each entry has to be linked to related narrative text	Each entry should have a text reference that is linked to the narrative text in the section.

REQUIRED RUBRIC		
Section/Entry/Header	Rubric	Description
Vital Signs	EffectiveDate/Time elements have the right time format and time zone offsets	<p>EffectiveTime elements in the section are expected to have time offsets along with the date and are typically nonzero time offsets. In addition they are expected to have the time zone information for proper interpretation.</p> <p>For e.g. if the time is being defaulted to 000000 for hours, minutes and seconds for multiple entries it might be worth checking if the data was entered properly. Also if the time offsets are present without a time zone, the time may be interpreted incorrectly, hence time zones should be specified as part of the time element</p> <p>Note: Organization should consider taking points away if it fails more than once as there's a chance someone input 12:00:00 and it fails</p>
	EffectiveDate/Times for all historical activities should be within the lifespan on the patient	EffectiveDate/low for historical events should be greater than one year prior to the patient's date of birth and effectiveTime/high less than the earliest of current time or patient's date of death.
	The Display Names used by the structured data should conceptually align with the meaning of the code.	Each of the code systems, value sets specified by the C-CDA IG refers back to standard terminologies like SNOMED-CT, LOINC, RxNorm, ICD9, ICD10. When codes from these code systems are used to represent structured data the short or

REQUIRED RUBRIC		
Section/Entry/Header	Rubric	Description
		long description assigned in the code system for the code should be used in the display name of the code element in the C-CDA document
	The Vital Sign Observation entries should use the right LOINC codes to represent the type of vital sign being captured	Each of the vital sign observation present in the document should use the recommended LOINC codes to represent the vital sign
	Each of the Vital Sign Observation should use the recommended UCUM units to represent the vital sign measurement result.	The recommended UCUM units should be used to represent the Vital Sign result values as part of the observation.
	The EffectiveDate/Time elements for the Vital Sign Organizer must encompass the underlying observations.	The EffectiveDate/Time elements of the Vital Signs Organizer cannot be out of sync with the Vital Signs Observation. Each of the Observation's EffectiveTime/low >= Organizer's EffectiveTime/low and Observation's EffectiveTime/high should be <= Organizer's EffectiveTime/high
	Vital signs and results should use a LOINC Code.	A LOINC Code must be used when coding vital signs and results.

REQUIRED RUBRIC		
Section/Entry/Header	Rubric	Description
	BMI should match height and weight	
	Vital signs and results should use a LOINC Code	
	Each entry has to be linked to related narrative text.	Each entry should have a text reference that is linked to the narrative text in the section.
Procedures	The Display Names used by the structured data should conceptually align with the meaning of the code.	Each of the code systems, value sets specified by the C-CDA IG refers back to standard terminologies like SNOMED-CT, LOINC, RxNorm, ICD9, ICD10. When codes from these code systems are used to represent structured data the short or long description assigned in the code system for the code should be used in the display name of the code element in the C-CDA document
	Procedures should be structured with the correct code system	Procedures should be structured in CPT, CDT-2, ICD-9, ICD-10, SNOMED, HCPCS or LOINC
	Each entry has to be linked to related narrative text	Each entry should have a text reference that is linked to the narrative text in the section.
Goals	Each goal must be related to a specific health concern	If there's a goal you must be able to tell what health concern(s) the goal is related to (Care Plan Document Type specific rubric for now, but will throw a warning for

REQUIRED RUBRIC		
Section/Entry/Header	Rubric	Description
		CCD, Referral Note, Progress Note and Discharge Summary - may ding for all document templates in the future)
	Each intervention must relate to a specific goal	If there's an intervention you must be able to tell what goal(s) the intervention is related to (Care Plan Document Type specific rubric for now, but will throw a warning for CCD, Referral Note, Progress Note and Discharge Summary - may ding for all document templates in the future)
Miscellaneous	All Template Ids for C-CDA and Supplemental IGs should be correct	All Template Ids should be Valid for C-CDA and Supplemental IGs. If there is a valid template ID, but doesn't align with above then provide an Informational message saying it's an unrecognized template ID.
	Documentcode should specify a valid document type	The clinicalDocument.code that specifies the document type should come from one of the concepts or value sets specified by C-CDA.
	If observation value is recorded as a PQ datatype and if present, the observation range should be coded as an "IVL_PQ"	If observation value is recorded as a PQ datatype and if present, the observation range should be coded as an "IVL_PQ" (a parse-able range high/low attributes instead of narrative text).
	The identifiers used within a CDA document should be unique within the same document. Reoccurrences of an identifier should	Instance Identifiers should be unique for distinct acts. Encounters could have same ids when referencing the same encounter.

REQUIRED RUBRIC		
Section/Entry/Header	Rubric	Description
	represent the same instance of the item in the document.	

2.3 Informational Rubric

Note: The rubric listed below are informational only. All tools adopting this criteria should throw a warning not an error.

INFORMATIONAL RUBRIC		
Section/Entry/Header	Rubric	Description
Laboratory Tests and Results	Lab results should be expressed with preferred LOINC codes which are published as the top 2000 LOINC codes from Regenstrief.	Lab results should be expressed with LOINC codes.
Problems	All problem codes should be expressed with core subset of SNOMED codes	All problem codes should be expressed with core subset of SNOMED codes
Medications	The substance administration/route code must not conceptually conflict with the narrative sig	

3 References

- C-CDA Rubric Project Page - http://wiki.hl7.org/index.php?title=CCDA_Scorecard_Rubric_Update
This link is where the current rubric is located, where you can find more information about the process for creating a rubric, and where you can find call information.
- C-CDA Product Page - http://www.hl7.org/implement/standards/product_brief.cfm?product_id=492

The Consolidated CDA (C-CDA) implementation guide contains a library of CDA templates, incorporating and harmonizing previous efforts from Health Level Seven (HL7), Integrating the Healthcare Enterprise (IHE), and Health Information Technology Standards Panel (HITSP). It represents harmonization of the HL7 Health Story guides, HITSP C32, related components of IHE Patient Care Coordination (IHE PCC), and Continuity of Care (CCD).

- **ONC C-CDA Scorecard** - www.healthit.gov/scorecard
The C-CDA Scorecard leverages the work completed by an ONC-funded grant — [SMART \(Substitutable Medical Apps Reusable Technologies\)](#) and promotes best practices in C-CDA implementation by assessing key aspects of the structured data found in individual documents. It is a tool designed to allow implementers to gain insight and information regarding industry best practice and usage overall. It also provides a rough quantitative assessment and highlights areas of improvement which can be made today to move the needle forward.