

# HITSP/C32 Test Package Registration and Medication History

Version 2.0.4  
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## Package Contents

- A folder (HITSP\_C32\_templates) containing Schematron entity files for testing HITSP/C32 documents.
- A copy of the HITSP/C32 profile (2007-11-29 v2.0.4) downloaded from the HITSP repository at ANSI.
- A folder (HITSP\_C32\_examples) containing sample XML files that are valid CCD documents and an XML transform ( HumanViewCCD.xsl) for transforming the XML files into human readable output files.
- A folder (cdar2c32) containing the original HL7 CDA/R2 schema along with NIST produced schema extensions as permitted by CCD and as indicated by the HITSP/C32 profile of CCD.
- A Schematron schema (HITSP\_C32.sch), derived from the enclosed entity files, for testing HITSP/C32 validation of a CCD document.
- A NIST Disclaimer file (please read).
- This file (in word and pdf formats) describing the contents of the package.

## Schematron Entity Files

The HITSP/C32 specification v2.0.4 defines 17 templateIds. NIST has defined one schematron entity file for each of these templateIds. If a CCD instance document claims conformance to HITSP/C32 then the existence of one templateId (2.16.840.1.113883.3.88.11.32.1) is required in the root ClinicalDocument element. The other templateIds are optional.

The HITSP/C32 profile is not yet clear on whether or not C32 data element rules should be enforced in the absence of explicit C32 templateIds for elements other than the root ClinicalDocument. Since all HITSP/C32 data elements are identifiable whether or not a C32 templateId is present, the rules for each C32 data element are always executed. This differs from the way profile rules are checked for CCD and IHE profiles. One difference is that a user will get Warnings and guidance Notes for all C32 data elements present in a C32 document, whereas CCD and IHE schematron rules do not raise warnings or guidance when an explicit templateId is not present. Another difference is that sometimes a C32 Error will be raised for a C32 data element even in the absence of an explicit C32 templateId for that data element. Such Errors can

easily be changed to Warnings if the evolving HITSP/C32 profile determines that Errors shall not be raised in the absence of explicit C32 templateIds.

## **CDA R2 and CCD Validation**

All of the sample documents (except those with specific extensions) are valid CDA/R2 documents that validate to the XML schema provided with the CDA/R2 specification from HL7. In addition, most of the sample documents validate as both CDA/R2 and ASTM/HL7 CCD documents according to the CDA/R2 and CCD validators available at the NIST and Alschuler Associates web sites:

NIST <http://xreg2.nist.gov:8080/hitspValidation/validation.jsp>  
Alschuler Associates <http://www.alschulerassociates.com/validator/> .

Exceptions are the one document with identified HITSP/C32 extensions (CCD\_HITSP\_C32\_Test1), which raises CDA/R2 errors for those extensions, and the example document (CCD\_Meds\_Procs\_SupplyErrors.xml) that highlights what are believed to errors in the CCD schematron rules at both sites.

## **HITSP/C32 Validation at NIST web site**

NIST has a new experimental web site to check validation of various CDA profiles and guidelines, especially those produced by HITSP Patient Care. The URL is:

<http://xreg2.nist.gov/cda-validation>

This site explains the CDA Guideline Validation project at NIST and includes pointers to the NIST validation page referenced above. The Schematron entity files and schemas included with this package are implemented at this site.

## **Sample HITSP/C32 Documents**

### **CCD\_HITSP\_C32\_C27.xml**

This document was derived from the sample CCD clinical document provided with the CCD package downloaded from the HL7 web site. NIST modified the header content in several ways to abide by HITSP/C32 and HITSP/C27 specifications. It carries exactly one HITSP/C32 templateId (2.16.840.1.113883.3.88.11.32.1) on its root element. This document would validate as a HITSP/C32 document if C32 rules were not checked in the absence of explicit C32 templateIds, but it raises 27 Errors and multiple Warnings and guidance Notes when checked against all rules in the C32 profile.

### **CCD\_Minimal\_No\_C32\_templateIds.xml**

This document was produced with minimal content as allowed by the CDA/R2 schema and the CCD validation rules. It does not contain any HITSP/C32 templateIds. When checked for HITSP/C32 validation at the NIST web site it raises an Error indicating that the root HITSP/C32 templateId (2.16.840.1.113883.3.88.11.32.1) must be present on the ClinicalDocument element before a document can claim C32 conformance. It also raises 7 other Errors and 8 Warnings associated with that templateId.

#### CCD\_Minimal\_ALL\_C32\_templateIds.xml

This document was produced with minimal content as allowed by the CDA/R2 schema and the CCD validation rules. It has CDA and CCD template ids in its root ClinicalDocument element. It also carries all 17 HITSP/C32 template ids on the same root element, only one of which is in the correct location. This document produces approximately 25 HITSP/C32 errors, mostly from HITSP/C32 templateIds placed in incorrect locations and missing content required by a given templateId. It also produces multiple Warnings and guidance Notes.

#### CCD\_HITSP\_C32\_Test1.xml

This document is a modification of the above sample documents to correct most of the errors and some of the warnings. It contains nearly all of the HITSP/C32 templateIds (correctly positioned) and thus applies all of the rules contained in the 17 entity files included in this package. It would validate as a HITSP/C32 document if rules were not checked in the absence of explicit HITSP/C32 templateIds, but with complete checking produces 8 Errors. When a CCD section had multiple entries at least one of the entries was left without a C32 templateId to generate an Error and at least one entry was left with non-fixed Warnings to alert the user to missing Required-if-Known (R2) content. It produces about 70 HITSP/C32 warnings of this type. It also produces more than 100 Notes to point out optional C32 data elements that are not included in the document.

#### CCD\_Meds\_Procs\_SupplyErrors.xml

This document was produced to highlight what are believed to be errors in the CCD schematron rules implemented at both the NIST and Alshuler Associates CCD validation sites. When checked against the CCD validation rules it produces two CCD SHALL violations and one SHOULD violation that appear to be incorrect. A joint process among NIST and Alshuler Associates is underway to address these and other potential CCD validation issues. It produces only one validation Error when checked against the HITSP/C32 validation rules because it does not contain the required HITSP/C32 templateId on its root element.

#### CCD\_HITSP\_C32\_Medications.xml

This document was prepared to concentrate only on the Medications section of the HITSP/C32 specification. The purpose was to provide a conforming HITSP/C32 document that contains a Medications section with all CCD Medications options present in the document. It validates cleanly to all HITSP/C32 validation rules. It produces 18 Warnings, primarily to identify elements that use a nullFlavor rather than a specific code recommended for Required-if-Known (R2) or Optional (O) C32 data elements. It produces lots of Notes, including optional additional items that could have been included in the Medications data elements. It is NIST intent to use this document as a template for producing randomized samples that will validate to CCD and/or HITSP/C32 Medication sections. In addition, this document raises some of the same CCD validation rule issues as does the CCD\_Meds\_Procs\_SupplyErrors document above.