eHealth Exchange™

Content Testing
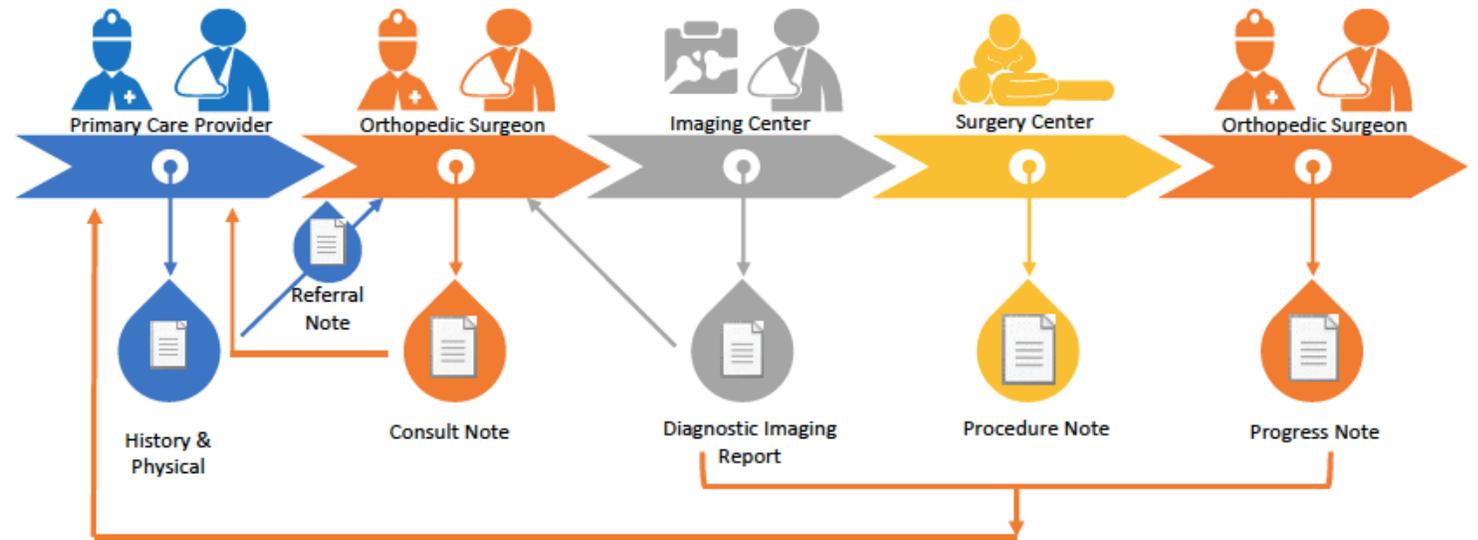
Program Overview

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Program Review

- Background

- Content Testing Program Details
  - Content Testing Documentation Package
  - Content Testing Process
  - Content Testing Tooling
  - Future Content Testing Milestones/Timeline

Use Cases: C-CDA: Exchanging the Patient's Story

- Today, most of the clinical data exchanged by systems leverages ONLY the CCD

- Many documents are not created by a human but by a machine on demand when queried. Data should be exchanged using appropriate document types.

http://www.himss.org/library/c-cda-documents-building-blocks-meaningful-exchange

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Why is using the right type of document important?

- Each CDA Document is designed to address a specific purpose
  - Use Cases should be reviewed to determine appropriate documents for use to support optimal patient care
  - Documents need to fit the situation
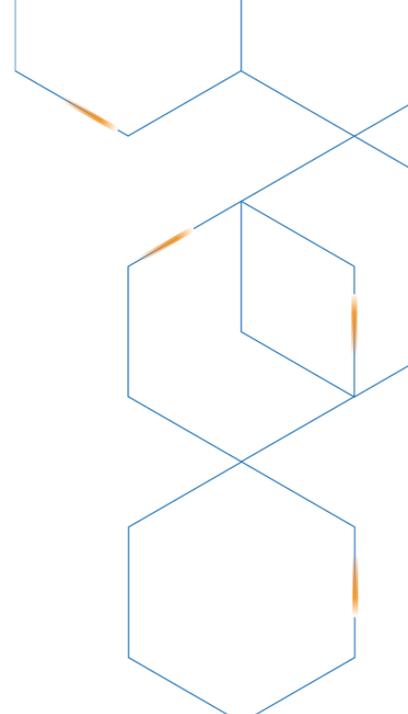 - Share information that is relevant and pertinent

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Why is using the right type of document important?

- Establish the right context for the information being shared
    - Information about multiple encounters
    - Information about a single encounter
    - Information about a service(s) within an encounter
    - Information that is related to a specific order
    - Patient generated information vs. Clinician or System generated data

	Admission Diagnosis	Admission Meds	Advance Directive	Allergies & Intolerances	Anesthesia	Assessment & Plan
Assessment	Chief Complaint Reason for Visit	Chief Complaint	Complications	Course of Care	DICOM Object Catolog	Discharge Diagnosis	Discharge Diet
Discharge Medications	Encounters	Family History	Fetus Subject Context	Findings	Functional Status	General Status	Goals
Health Concerns	Health Status Eval/Outcomes	History Past Illness	History Present Illness	Hospital Consultations	Hospital Course	Hosp. Disch. Instructions	Hosp. Disch. Physical
Hosp. Disch. Studies Sum.	Immunizations	Implants	Instructions	Interventions	Medical (Gen) History	Medical Equipment	Medications Administered
Medications	Mental Status	Nutrition	Objective	Observer Context	Operative Note Fluids	Op Note Surgical Proc.	Payers
Physical Exam	Plan of Treatment	Planned Procedure	Postoperative Diagnosis	Postprocedure Diagnosis	Preoperative Diagnosis	Problem	Procedure Description
Procedure Disposition	Procedure Est. Blood Loss	Procedure Findings	Procedure Implants	Procedure Indications	Procedure Specimens	Procedures	Reason for Referral
Reason for Visit	Results	Review of Systems	Social History	Subjective	Surgery Description	Surgical Drains	Vital Signs

http://www.himss.org/library/c-cda-documents-building-blocks-meaningful-exchange

Transfer Summary

REQUIRED:

- Allergies & Intolerances
- Assessment
- Medications
- Problem
- Reason for Referral
- Results
- Vital Signs

OPTIONAL:

- Admission Diagnosis
- Admission Meds
- Advance Directive
- Assessment & Plan
- Course of Care
- Discharge Diagnosis
- Encounters
- Family History
- Functional Status
- General Status
- History Past Illness
- History Present Illness
- Immunizations
- Medical Equipment
- Mental Status
- Nutrition
- Payers
- Physical Exam
- Procedures
- Review of Systems
- Social History

CCD

REQUIRED:

- Allergies & Intolerances
- Medications
- Problem
- Procedures
- Results
- Social History
- Vital Signs

OPTIONAL:

- Advance Directive
- Encounters
- Immunizations
- Family History
- Functional Status
- Medical Equipment
- Mental Status
- Nutrition
- Payers
- Plan of Treatment

http://www.himss.org/library/c-cda-documents-building-blocks-meaningful-exchange

C-CDA R2.1 Document Types (12 Total)

- Consultation Note
- Continuity of Care Document (CCD)
- Diagnostic Imaging Report
- Discharge Summary
- History and Physical
- Operative Note
- Procedure Note
- Progress Note
- Unstructured Document

- Care Plan
- Referral Note
- Transfer Summary

- **New USCDI v1 Data Classes:**

- USCDI V1.0 Added/Expanded these 3 Data Classes

Patient Demographics
- Current Address
- Previous Address
- Phone Number
- Phone Number Type
- Email Address

Clinical Notes
- Consultation Note
- Discharge Summary Note
- History & Physical
- Imaging Narrative
- Laboratory Report Narrative
- Pathology Report Narrative
- Procedure Note
- Progress Note

Provenance
- Author Time Stamp
- Author Organization

Industry-Wide Content Pain Points

OPTIONALITY
More than one way to do things and inconsistent implementations across vendors
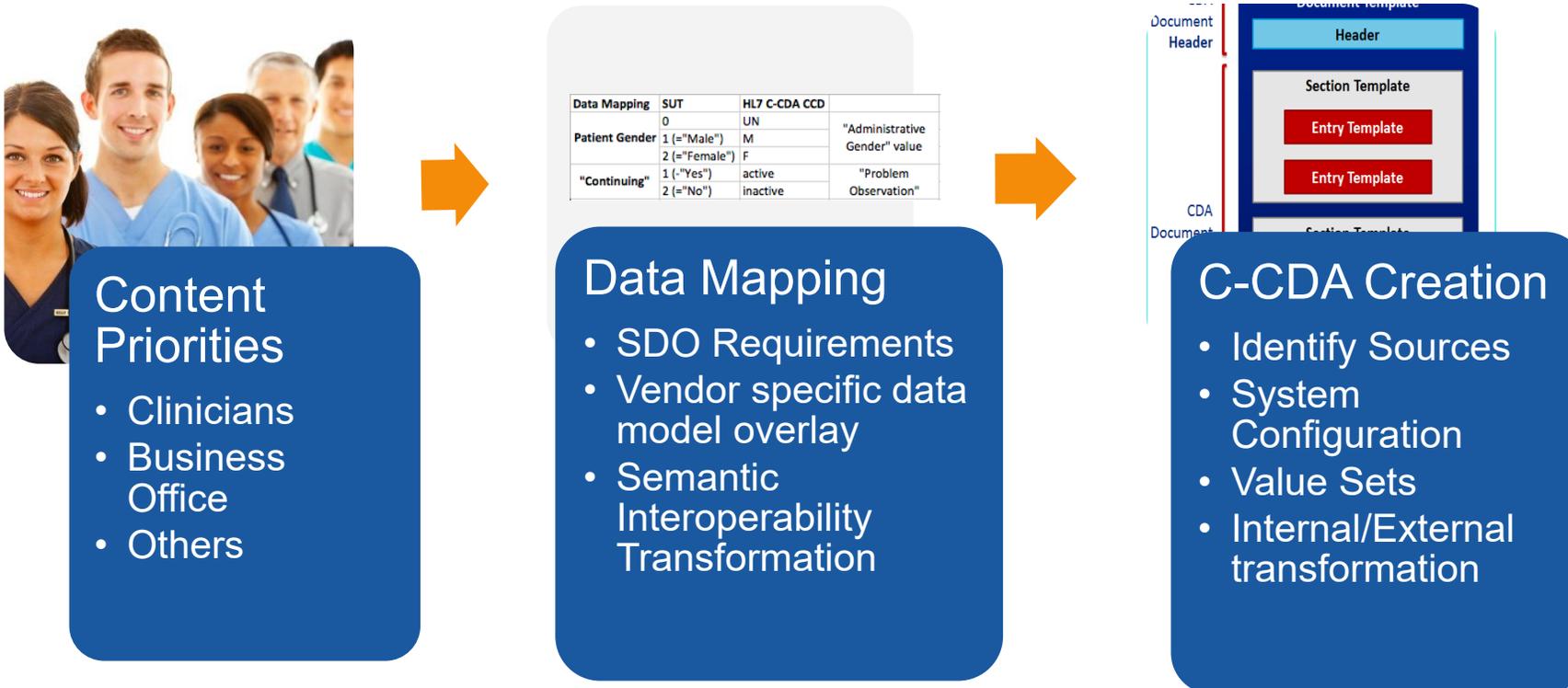
TERMINOLOGY
Inconsistent terminology usage

COMPLEXITY
The C-CDA standard is difficult to understand and consume and is lacking in clearly documented examples

SPECIFICATION AMBIGUITY

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Process for Creating Consistent & Robust HL7 C-CDAs

Content Priorities
- Clinicians
- Business Office
- Others

Data Mapping
- SDO Requirements
- Vendor specific data model overlay
- Semantic Interoperability Transformation

C-CDA Creation
- Identify Sources
- System Configuration
- Value Sets
- Internal/External transformation

Validated Product Vendors – Required Testing

- All current Validated vendors are required to test
  - Create Test Cases (Using Vendor Supplied Test Data – No PHI please)
  - Receive Test Cases (R2.1 Documents)
- New Vendors seeking Product Validation will be required to provide one or more content samples as follows:
  - Samples for testing for each version of HL7 specification they support (R2.1 or USCDI v1)
  - Samples of each document type they support for their customers on an ongoing basis as new documents are added (CCD, Discharge Summary, Progress Note, etc.)

Participant Content Testing Requirements

- All current Participants will be required to test
  - Create Test Cases (Using Participant specified Test Data – no PHI)

- New Participants seeking to onboard will be required to provide one or more content samples from each Document Source in their community:
  - All Document Sources will be required to provide samples for testing for each version of HL7 specification they support (HL7 C-CDA R2.1 or USCDI v1)
  - All Document Sources will be required to provide samples of each document type they support in production on an ongoing basis resulting in continuous testing (CCD, Discharge Summary, Progress Note, etc.)
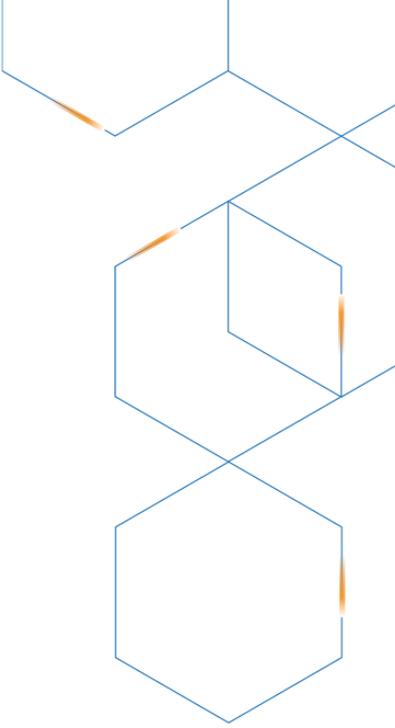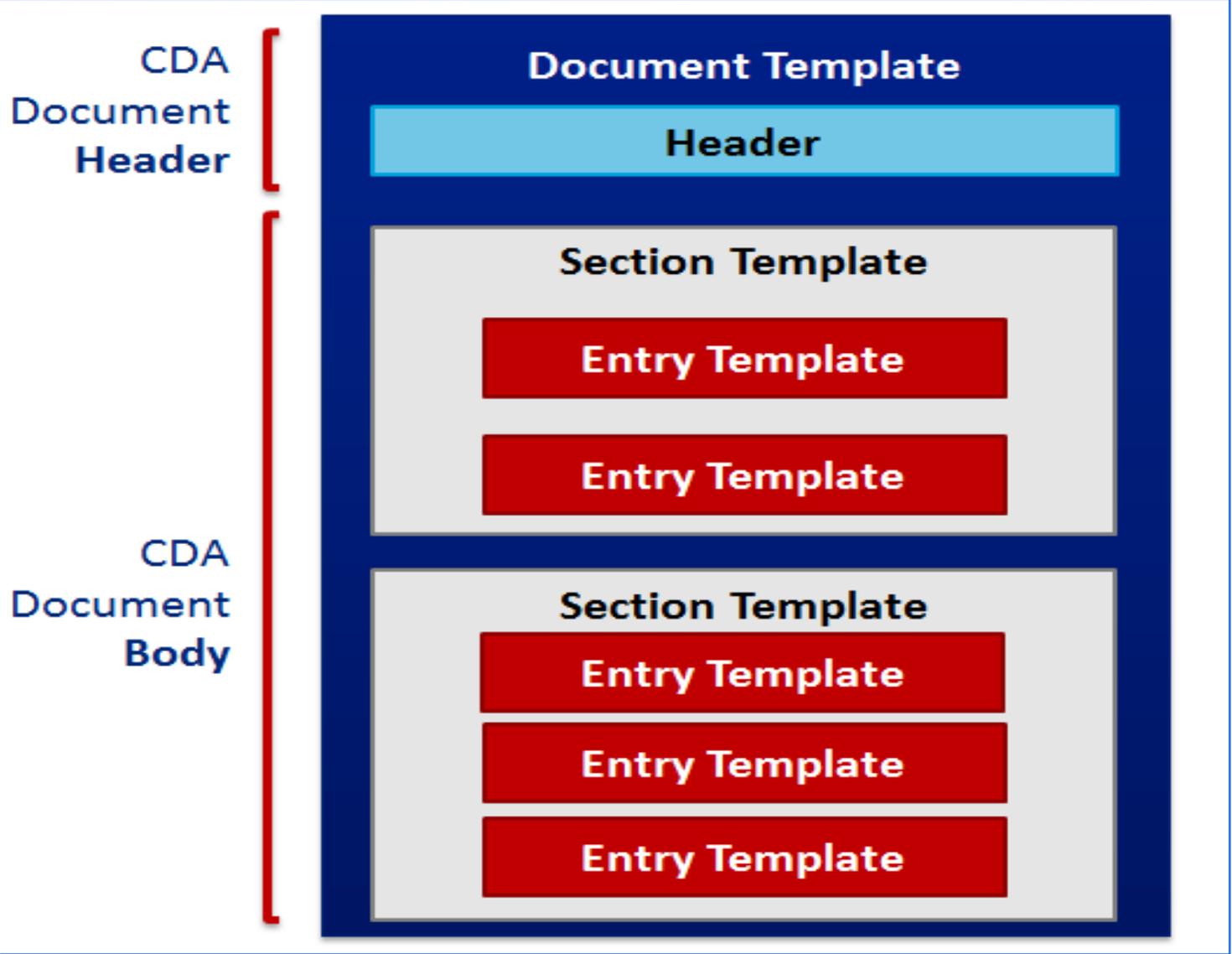
Content Testing Tooling

ART DÉCOR/GAZELLE OBJECTS CHECKER

- Hosted by IHE Services as part of the IHE International Scheme Testing

- Tooling was piloted in April 2015 and is ISO 17025 Compliant for Conformity Assessment

- Covers only HL7 C-CDA CCD R2.1 and USCDI v1 versions

- Found to report on warnings and errors not found by other testing tooling (https://gazelle.ihe.net/cda/cda-basic-req.pdf)

- More information on the tooling can be found in Appendix B of the eHealth Exchange Content Testing Guide 2018 v1.0

Content Testing Survey/Application

- eHealth Exchange Content Testing Survey form
- **Required** to gain access to tooling
- One form per organization
- Asks for all source systems expected to be tested
- Asks for additional details useful for trading partners to know
  - Some details may be published in the eHealth Exchange Directory in the future

Process to Report Questions, Issues, Defects

- Email one question/issue/defect per email to
  - testing@ehealthexchange.org

- Provide as much information as possible including:
  - Screenshots
  - Testing Permanent Link with Issue
  - Reference details for specification questions/issues

File Name: patient_CCDA_CCD_R2_1_altered.xml
OID : 1.3.6.1.4.1.12559.11.28.1641
Schematron : N/A (Version N/A)
Schematron Validation Result : N/A
Validation Date : 1/29/18 6:01:04 PM (CET GMT+0100)
Model Based Validator : HL7 - C-CDA R2.1 - Meaningful Use Stage 3 (Version N/A)
Model Based Validation Result : FAILED SC
Permanent link : https://gazellecontent.sequoiaproject.org/EVSClient/detailedResult.seam?type=CDA&oid=1.3.6.1.4.1.12559.11.28.1641
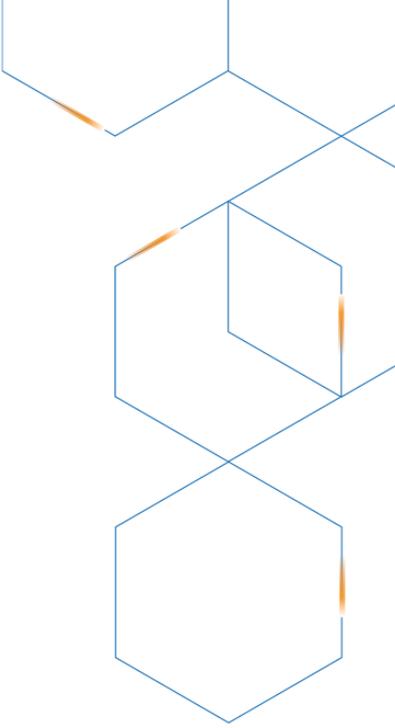**Data Visibility :** Private - Owned By kstevenson / DOD

< observation classCode="OBS" moodCode="EVN">

↑ (4/105)	Test	ccda212265	E - 4
↓	Location	/ClinicalDocument/component/structuredBody/component[6]/section/entry[86]/organizer/component[0]/observation	
	Description	In Vital Sign Observation (V2), in /hl7:observation[hl7:templateId/@root='2.16.840.1.113883.10.20.22.4.27'], the element(s) hl7:value SHALL not have nullFlavor (mandatory) (Item : CONF:1098-7305)[Constraint...] [Assertion...]	

```
<templateId root="2.16.840.1.113883.10.20.22.4.27" extension="2015-08-01"/>
<id extension="00" root="2.16.840.1.113883.3.42.126.100001.19" />
<code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" code="39156-5" displayName="BMI" />
<text><reference value="#vitals-86"/></text>
<statusCode code="completed" />
<effectiveTime nullFlavor="NI"/>
<value nullFlavor="NI" xsi:type="PQ" />
```
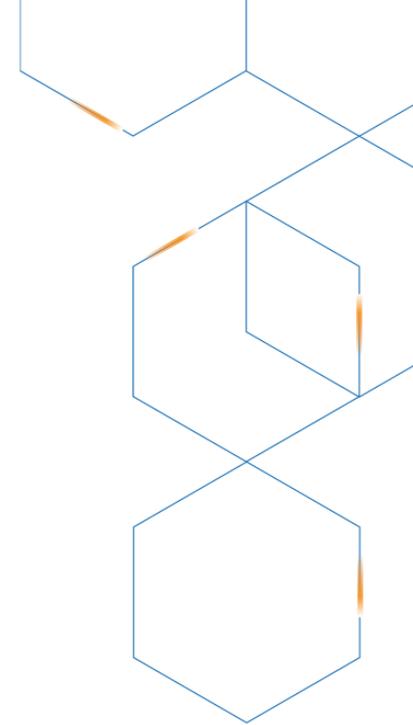
</observation>

8. **SHALL** contain exactly one [1..1] value with @xsi:type="PQ" (CONF:1098-7305).
    a. This value **SHALL** contain exactly one [1..1] @unit, which **SHALL** be selected from ValueSet <u>UnitsOfMeasureCaseSensitive</u> urn:oid:2.16.840.1.113883.1.11.12839 **DYNAMIC** (CONF:1098-31579).

I believe the nullFlavor should be allowed for the "value" element since it isn't specifically not allowed. In particular, CONF:1098-7305 requires that the "value" element be present with @xsi:type="PQ", but doesn't state that nullFlavor cannot be used.

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Value Sets
https://vsac.nlm.nih.gov/

Requires UMLS license/account

Testing Program Requirements – Proposed Changes

	Baseline Testing - Participants	eHealth Exchange Validated Product	QTS Basic	QTS Intermediate	QTS Advanced
Criteria	• Participant successfully completes eHealth Exchange Transport and Security Tests	• Vendor successfully completes eHealth Exchange Product Testing • Participant has decreased testing requirements if using a validated product	• Is an eHealth Exchange Validated System • Uses a Standardized Configuration • Has a minimum of 4 Production Participants completing testing w/no failures • No outstanding technical issues • Recognized as a Federal Fast Track (or equivalent) program partner	Has satisfied ALL QTS Basic requirements AND Successfully submit test reports under QTS Basic for a **minimum of 6 months** with no issues before being considered by eHealth Exchange staff in consultation with the vendor, CC, and vendor's customers.	Has satisfied all QTS Basic and Intermediate requirements. AND **ALL** Production Participants utilizing the vendor's approved QTS-Intermediate solution have successfully demonstrated Content Testing Validation, with no errors
Scope	• Transport • Security • Content • PKI Certs	• Transport • Content • PKI Certs	• Transport • Content • PKI Certs	• Content • PKI Certs	• PKI Certs
Cost	• Participant : $19,000	• Vendor: $34,000 • Participant: $11,000 + content	• Vendor: $0 • Participant: content	• Vendor: $0 • Participant: content	• Vendor: $0 • Participant: $0

Content Testing is required for all levels EXCEPT QTS Advanced, and will be bundled with Participant fees based on revenue tiers. PKI Cert Testing is required for ALL levels.

Tooling Demo

Sequoia/Gazelle Content Testing Tools
Hosted and Developed in Partnership with IHE Services

http://www.ihe-services.net/about-us/Why-IHE-Services

Questions?

testing@ehealthexchange.org

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