CDAR2_QRDA_I_R1_STU_R5.1_2018DEC_Vol1

HL7 CDA® R2 Implementation Guide:
Quality Reporting Document Architecture Category I (QRDA I),
Release 1, STU Release 5.1 - US Realm

HL7 Standard for Trial Use

December 2018

Volume 1 — Introductory Material

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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)

.Structure of This Guide

Two volumes comprise this *HL7 Standard for CDA® Release 2: Quality Reporting Document Architecture Category I (QRDA I), Release 1, STU Release 5.1 - US Realm.*

Volume 1 provides narrative introductory and background material pertinent to this implementation guide, including information on how to understand and use the templates in Volume 2. Volume 2 contains the normative Clinical Document Architecture (CDA) templates for this guide along with lists of all templates, code systems, value sets, and changes from the previous version.

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Release 1 of this guide was produced and developed through the efforts of the Quality Reporting Document Architecture (QRDA) Project supported by the Child Health Corporation of America (CHCA) to develop and support a standard for quality reporting. The QRDA committee was comprised of representatives from the American Health Information Management Association (AHIMA), Integrating the Healthcare Enterprise (IHE), CHCA, the Collaborative for Performance Measure Integration with EHR Systems, MedAllies, and the Nationwide Health Information Network (NHIN).

This specification is a set of constraints on existing work, and the extent to which it can accommodate the expressive requirements of quality reporting over time is a function of the richness of the model on which it is built, the Health Level Seven (HL7) Reference Information Model (RIM) and the RIM document standard, and the Clinical Document Architecture Release 2 (CDA R2). We thank all those who have worked for over a decade to produce these fundamental specifications; we especially thank the HL7 Clinical Quality Information Work Group for their support of this project.

Table of Contents

Table of Figures

Table of Tables

1 INTRODUCTION

1.1 Purpose

This two-volume implementation guide (IG) describes constraints on the Clinical Document Architecture Release 2 (CDA R2) header and body elements for Quality Reporting Document Architecture (QRDA) documents. The National Academy of Medicine, formerly called the Institute of Medicine (IOM), definition of quality is: "The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."[1] For care quality to be evaluated, it must be standardized and communicated to the appropriate organizations.

QRDA is a document format that provides a standard structure with which to report quality measure data to organizations that will analyze and interpret the data. Quality measurement in health care is complex. Accurate, interpretable data efficiently gathered and communicated is key in correctly assessing that quality care is delivered.

1.2 Audience

The audience for this implementation guide includes software developers and implementers with reporting capabilities within their electronic health record (EHR) systems; developers and analysts in receiving institutions; and local, regional, and national health information exchange networks who wish to create and/or process CDA reporting documents created according to this specification.

1.3 Approach

The approach taken here is consistent with balloted implementation guides for CDA. These publications view the ultimate implementation specification as a series of layered constraints. CDA itself is a set of constraints on the Health Level Seven (HL7) Reference Information Model (RIM) defined in the CDA R2 Refined Message Information Model (RMIM). Implementation guides such as this add constraints to CDA through conformance statements that further define and restrict the sequence and cardinality of CDA objects and the vocabulary sets for coded elements.

This implementation guide is the QRDA I Release 1 Standard for Trial Use (STU) Release 5.1 (QRDA I R1 STU5.1). The QRDA Background and Current Project sections describe the development of the STU.

1.4 Organization of the Guide

This implementation guide is organized into two volumes. Volume 1 contains primarily narrative text describing CDA and QRDA, whereas Volume 2 contains normative CDA template definitions for the QRDA Category I (individual patient) report framework and

[1] "Crossing the Quality Chasm". http://www.nationalacademies.org/hmd/Global/News%20Announcements/Crossing-the-Quality-Chasm-The-IOM-Health-Care-Quality-Initiative.aspx

the QDM-Based QRDA in which the patient data entry-level templates are derived from the Quality Data Model (QDM).[2]

1.4.1 Volume 1 Introductory Material

This document, Volume 1, provides an overview of CDA, summaries of recent changes to the standard, and information on how to understand and use the CDA templates provided in Volume 2.

- **Chapter 1—Introduction**
- **Chapter 2—CDA and QRDA** contains background material on the CDA R2 base standard, a description of the "templated CDA" approach to implementation guide development, and background on QRDA.
- **Chapter 3—Design Considerations** includes descriptions of overarching principles that have been developed and applied across the CDA templates in this guide. Material in this section can be thought of as "heuristics", as opposed to the formal and testable constraints found in Volume 2 of this guide.
- **Chapter 4—Using This Implementation Guide** describes the rules and formalisms used to constrain the CDA R2 standard. It describes the formal representation of CDA templates, the mechanism by which templates are bound to vocabulary, and additional information necessary to understand and correctly implement the normative content found in Volume 2 of this guide.
- **Chapter 5—QRDA Category I Framework** describes the QRDA Framework and recent changes.
- **Chapter 6—Quality Data Model-Based QRDA** describes the relationship between the QDM, Health Quality Measures Format (HQMF), and QRDA. It also describes the concept of dynamic generation of QDM QRDA documents.
- **Appendices**. The Appendices include a high-level change log, a summary of extensions to CDA R2, a summary of Unique Device Identification (UDI) issuing agency formats, and the HQMF QDM Datatype to CDA Mapping Tables.

1.4.2 Volume 2 CDA Templates and Supporting Material

Volume 2 includes CDA templates and prescribes their use for a set of specific document types. The main chapters are:

- **Chapter 1—Document-Level Templates** defines the US Realm Header (V3) template that applies to the QRDA Document Category I Framework and the QDM-Based QRDA (V6). It defines each of the document types and header constraints specific to each as well as the section-level templates (required and optional) for each.
- **Chapter 2—Section-Level Templates** defines the section templates referenced within the document types. Sections are atomic units and can be reused by future specifications.

[2] Quality Data Model. https://ecqi.healthit.gov/qdm

- **Chapter 3—Entry-Level Templates** defines entry-level templates, called clinical statements. Machine processable data are sent in the entry templates. The entry templates are referenced by one or more section templates. Entry-level templates are always contained in section-level templates, and section-level templates are always contained in a document. Entries are atomic units and can be reused by future specifications.
- **Chapter 4—Subentry Templates** defines templates for recording facility and transfer location information.
- **Chapter 5—Participation and Other Templates** defines templates for the CDA author participant and other fielded items (e.g., address, name) that cannot stand on their own without being nested in another template.
- **Chapters 6 - 10**—Provide lists of template Ids, value sets, and code systems used in this guide as well as a list of retired templates and a detailed change log.

1.5 Contents of the Package

The following files comprise this implementation guide package.

Table 1: Contents of the Package

Filename or folder	Description	Standards Applicability
QRDA-I_CDAR2_QRDA_I_R1_S5.1_2018DEC_Vol1.pdf	Implementation Guide Introductory Material	Normative
QRDA-I_CDAR2_QRDA_I_R1_S5.1_2018DEC_Vol2.pdf	Implementation Guide Template Library and Supporting Material	Normative
CDAR2_QRDA_I_R1_STU_R5_1_2018OCT_Sample.xml	Sample QRDA category I	Informative
QRDA.xsl	Stylesheet for rendering	Informative
schema	Folder containing updated CDA XML schemas	Informative

2 CDA AND QRDA

2.1 CDA R2 Background

CDA R2 is "… a document markup standard that specifies the structure and semantics of 'clinical documents' for the purpose of exchange" [CDA R2, Section 1.1].[3] Clinical documents, according to CDA, have the following characteristics:

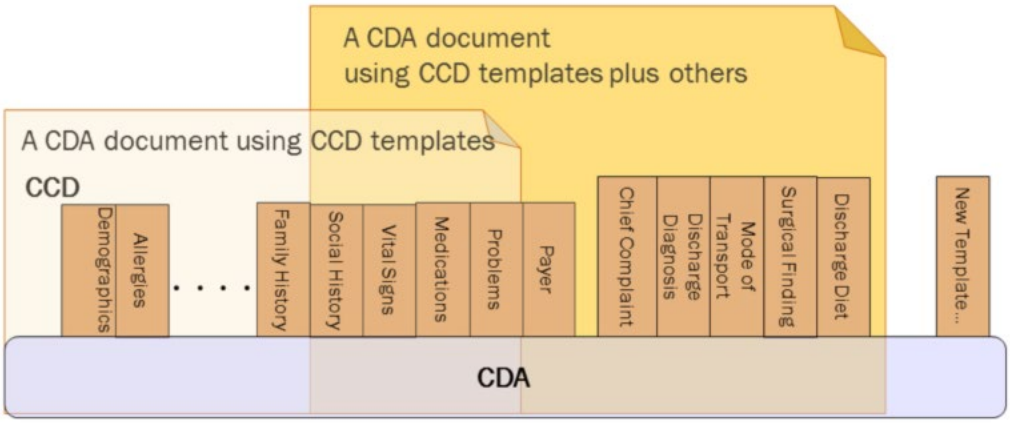
- Persistence
- Stewardship
- Potential for authentication
- Context
- Wholeness
- Human readability

CDA defines a header for classification and management and a document body that carries the clinical record. While the header metadata are prescriptive and designed for consistency across all instances, the body is highly generic, leaving the designation of semantic requirements to implementation.

2.2 Templated CDA

CDA R2 can be constrained by mechanisms defined in the "Refinement and Localization"[4] section of the *HL7 Version 3 Interoperability Standards*. The mechanism most commonly used to constrain CDA is referred to as "templated CDA." In this approach, a library is created containing modular CDA templates such that the templates can be reused across any number of CDA document types, as shown in the following figure.

Figure 1: Templated CDA



[3] *HL7 CDA Release 2.* http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7
[4] *HL7 V3: Refinement, Constraint and Localization.* http://www.hl7.org/v3ballot/html/infrastructure/conformance/conformance.htm

There are many different kinds of templates that might be created. Among them, the most common are:

- **Document-level templates:** These templates constrain fields in the CDA header and define containment relationships to CDA sections. For example, a History and Physical document-level template might require that the patient's name be present, and that the document contain a Physical Exam section.
- **Section-level templates:** These templates constrain fields in the CDA section and define containment relationships to CDA entries. For example, a Physical Exam section-level template might require that the section/code be fixed to a particular LOINC code, and that the section contain a Systolic Blood Pressure observation.
- **Entry-level templates:** These templates constrain the CDA clinical statement model in accordance with real world observations and acts. For example, a Systolic Blood Pressure entry-level template defines how the CDA Observation class is constrained (how to populate observation/code, how to populate observation/value, etc.) to represent the notion of a systolic blood pressure.
- **Participation and other templates:** These templates group a common set of constraints for reuse in CDA documents. For example, US Realm Date and Time (DTM.US.FIELDED) includes a set of common constraints for recording time. This template is referenced several times throughout the implementation guide in place of repeating constraints.

A CDA implementation guide (such as this one) includes references to those templates that are applicable. On the implementation side, a CDA instance populates the template identifier (`templateId`) field where it wants to assert conformance to a given template. On the receiving side, the recipient can not only test the instance for conformance against the CDA Extensible Markup Language (XML) schema, but also test the instance for conformance against asserted templates.

2.3 QRDA Background

In early pilots of the QRDA initiative, participating organizations confirmed the feasibility of using the HL7 CDA as the foundation for the QRDA specification. The participants concluded that CDA provided the technical underpinnings for communicating pediatric and adult quality measures for both inpatient and ambulatory care settings.

In later pilots, the HL7 Child Health Work Group and the Structured Documents Work Group developed a QRDA DSTU, Release 1 (R1), first published in September 2008.

The QRDA DSTU R1 defined three categories of quality reporting: A QRDA Category I – Single Patient Report, a QRDA Category II – Patient List Report, and a QRDA Category III – Calculated Report. The concepts of the report types are described below.

2.3.1 QRDA Category I – Single Patient Report

A QRDA Category I report is an individual-patient-level quality report. Each report contains quality data for one patient for one or more quality measures, where the data elements in the report are defined by the particular measure(s) being reported on. A QRDA Category I report contains raw applicable patient data. When pooled and

analyzed, each report contributes the quality data necessary to calculate population measure metrics.

2.3.2 QRDA Category II – Patient List Report (retired)

A QRDA Category II report is a multi-patient-level quality report. Each report contains quality data for a set of patients for one or more quality measures, where the data elements in the report are defined by the particular measure(s) being reported on.

Whereas a QRDA Category I report contains only raw applicable patient data, a QRDA Category II report includes flags for each patient indicating whether the patient qualifies for a measure's numerator, denominator, exclusion, or other aggregate data element. These qualifications can be pooled and counted to create the QRDA Category III report.

QRDA Category II was only a ballot for comment and was never taken through a ballot cycle.

2.3.3 QRDA Category III – Calculated Report

A QRDA Category III report is an aggregate quality report. Each report contains calculated summary data for one or more measures for a specified population of patients within a particular health system over a specific period of time.

Data needed to generate QRDA Category II and QRDA Category III reports need to be included in the collected QRDA Category I reports, as the processing entity will not have access to additional data sources.

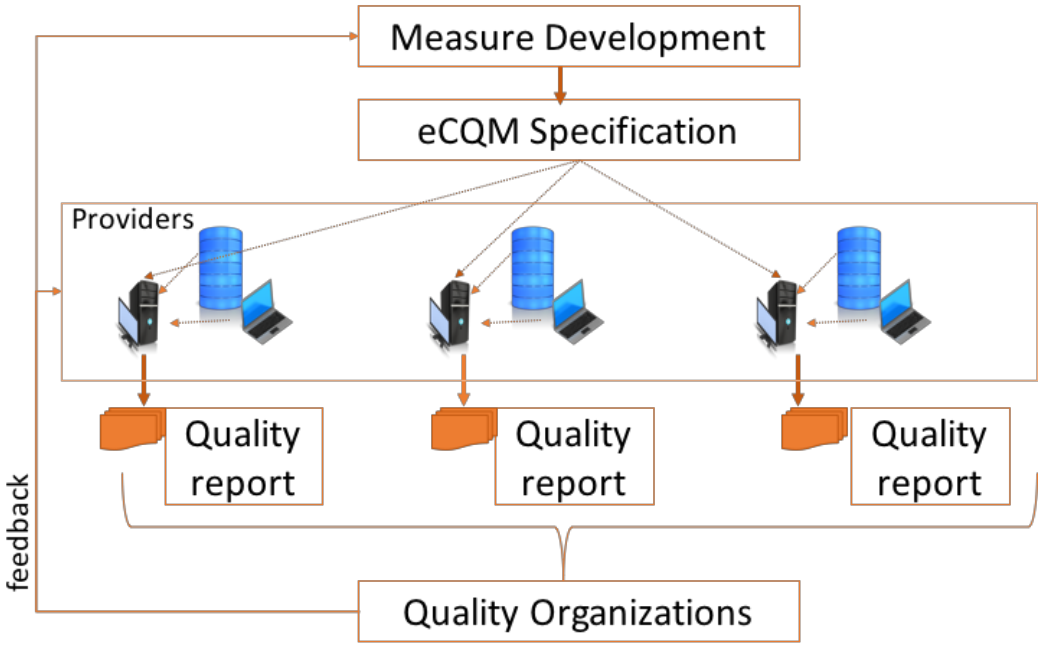
2.4 Relationship to Health Quality Measures Format: eMeasure

The HL7 Health Quality Measures Format (HQMF) is a standard for representing a health quality measure as an electronic document. A quality measure is a quantitative tool that provides an indication of the performance of an individual or organization in relation to a specified process or outcome via the measurement of an action, process, or outcome of clinical care. Quality measures are often derived from clinical guidelines and are designed to determine whether the appropriate care has been provided given a set of clinical criteria and an evidence base. Quality measures are also often referred to as performance measures or quality indicators. A quality measure expressed in HQMF format is referred to as an electronic clinical quality measure, or "eCQM".

Measure developers, drawing upon available evidence, devise measurable parameters to gauge the quality of care in a particular area. These measurable parameters are assembled into quality measures, which are then expressible as eCQMs. The eCQMs define the information to be retrieved from the EHR data and other data, which are then assembled into QRDA quality reports and submitted to quality or other organizations. This relationship is summarized in the Overview of Quality Framework figure.

While there is no prerequisite that a QRDA document must be generated based on an eCQM, the QRDA standard is written to tightly align with HQMF.

Figure 2: Overview of Quality Framework



2.5 Current Project

Since the creation of QRDA Category I R1[5], understanding of the end-to-end electronic quality reporting process has increased. HL7 created a standard for the Health Quality Measures Format (HQMF), also known as "eMeasure."[6] Using this standard, quality measures are redefined using HL7 RIM semantics, thus expressing the measures using a well-vetted model. The measure fully expressed in HQMF is known as an eCQM. The goal is to enable formally expressed criteria within an eCQM to be converted into queries expressed to retrieve EHR data.

QRDA Category I R2[7] was published in 2012. It simplified the QRDA framework and correlated the QRDA with the HQMF standard.[8] In addition to updating the QRDA Category I DSTU, the QRDA Category I R2 included a specific QRDA Category I DSTU designed to carry data based on Meaningful Use Stage 2 quality measures expressed in HQMF format. The QRDA Category I R2 recommended use of defined CDA templates based on the QDM, the same model used in the construction of Meaningful Use Stage 2 eCQMs. Since the publication of QRDA Category I R2 in 2012, the standard has experienced very rapid adoption. The Meaningful Use Stage 2 rulemaking specifies it as the standard for reporting patient level data for clinical quality measures.[9]

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[5] HL7's naming conventions have been changed since these early releases - under today's naming conventions this would have been QRDA Category I Release 1, STU 1
[6] *HL7 HQMF R1,* http://www.hl7.org/implement/standards/product_brief.cfm?product_id=97
[7] Similar to footnote 5, this would have today been called QRDA Category I Release 1, DSTU 2
[8] *HL7 HQMF R2.1,* http://www.hl7.org/implement/standards/product_brief.cfm?product_id=97
[9] *HIT: Standards, Implementation Specifications, and Certification Criteria for EHR Technology, 2014 Edition.* http://www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-20982.pdf

In June 2015, QRDA Category I R1 DSTU 3[10] was published. QRDA Category I R1 DSTU 3 incorporated errata changes approved June 2014 and took that work further. QRDA I R1 DSTU 3 re-used the US Realm Header (V2) from the *HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2* (C-CDA R2).[11] The updates of the QRDA Category I R1 DSTU 3 included: updates of templates to align with the Quality Data Model (QDM) version 4.1.2, incorporation of appropriate QRDA Category I Release 2 (R2) DSTU comments that were considered as New Feature Requests, and updates of the QRDA I R1 DSTU3 templates to align with the published C-CDA R2 templates, where applicable.

In April 2016, QRDA Category I R1 DSTU 3.1 was released. QRDA Category I R1 DSTU 3.1 incorporated errata and new feature requests approved since the publication of QRDA Category I R1 DSTU 3. The updates of the QRDA Category I R1 STU 3.1 include updates of templates to align with QDM version 4.2. QDM version 4.2 was published in August 2015. There are many changes between QDM version 4.2 and its predecessor 4.1.2. As a result of these changes QRDA templates were updated and new QRDA templates were created. Shortly after the publication of QRDA Category I DSTU 3, the *HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1* (C-CDA R2.1)[12] was published to support "on-the-wire" compatibility with C-CDA R1.1 systems and to include approved errata to C-CDA R2. QRDA I R1 DSTU 3.1 was also updated to reuse the US Realm Header (V3) and C-CDA R2.1 templates where applicable. QRDA Category I R1 STU 4[13], incorporated errata approved since the publication of QRDA Category I R1 DSTU 3.1. The updates of the QRDA Category I R1 STU 4 also include updates of templates to align with QDM version 4.3.

QRDA Category I R1 STU 5 was released in December 2017 and incorporateed errata approved since the publication of QRDA Category I R1 STU 4. The updates of the QRDA Category I R1 STU 5 also include template updates to align with QDM version 5.3. QDM 5.3 represents a significant change because the previous QDM logic and mathematical operators were replaced with a new HL7 standard for logic expression, Clinical Quality Language (CQL).[14] QDM 5.3 contains only the conceptual data model used to express the individual data elements. The QDM data model is also modified to more explicitly define the information desired including cardinality and timing details.

This current project, QRDA Category 1 R1 STU 5.1 supports QDM 5.4 and addresses the errata approved since the publication of QRDA Category I R1 STU 5. The QDM 5.4 specification is used in conjunction with CQL which provides the ability to express logic that is human-readable yet structured enough to electronically processing a query.[15] QDM 5.4 update details can be found in the Change Log of the QDM 5.4 specification.

This specific guide is considered as a "Quality Data Model-Based QRDA implementation guide". Rather than a specific implementation guide for each measure or set of

[10] Due to the changes to the HL7's naming conventions, this release is named QRDA Category R1 DSTU 3 instead of QRDA Category I R3.
[11] HL7 C-CDA R2. http://www.hl7.org/implement/standards/product_brief.cfm?product_id=379
[12] HL7 C-CDA R2.1. http://www.hl7.org/implement/standards/product_brief.cfm?product_id=379
[13] Note – The term "Standard for Trial Use" (STU) has replaced Draft Standard for Trial Use (DSTU) at the time of publication of QRDA Category I R1 STU 4.
[14] Clinical Quality Language. https://ecqi.healthit.gov/cql.
[15] Quality Data Model, Version 5.4, August 2018. https://ecqi.healthit.gov/qdm-quality-data-model

measures, reporting organizations will be able to dynamically generate QRDA instances based on the corresponding eCQM(s). This is described in detail in the Quality Data Model-Based QRDA chapter.

The QRDA framework provides guidance such that conformant measure-specific QRDA implementation guides can be developed through the HL7 process, by quality organizations, provider organization, and other quality stakeholder.

2.6 Scope

This implementation guide is a conformance profile, as described in the "Refinement and Localization" section of the *HL7 Version 3 Interoperability Standards*. The base standard for this implementation guide is the *HL7 Clinical Document Architecture, Release 2.0.* This implementation guide does not describe every aspect of CDA. Rather, it defines constraints on the base CDA used in a QRDA document in the US realm. Additional optional CDA elements, not included here, can be included and the result will be compliant with the specifications in this guide.

3 DESIGN CONSIDERATIONS

Design considerations describe overarching principles that have been developed and applied across the CDA templates in this guide. Material in this section can be thought of as "heuristics", as opposed to the formal and testable constraints found in Volume 2 of this guide.

3.1 Determining a Clinical Statement's Status

A general recipient requirement is to be able to determine the status of an entry—whether it (a problem, a medication administration, etc.) is active, completed, or in some other state. Often complicating the determination is the interplay between an act's various components (such as `statusCode` and `effectiveTime`), and inconsistent modeling between different objects.

This guide uses general rules for formalizing the representation of an object's status.

This IG follows the following principles of C-CDA's approach to status:

- **`Act.statusCode` specifies the state of the entry**: Per the RIM, the `statusCode` "reflects the state of the activity. In the case of an Observation, this is the status of the activity of observing, not the status of what is being observed".
- **`Act.moodCode` and `Act.statusCode` are inter-related**: Generally, an Observation in EVN (event) mood is a discrete event (you look, listen, measure; you record what you see; you're done), so generally an Observation in EVN mood will have a `statusCode` of "completed". An exception is a prolonged period of observation, where potentially you'd have an observation in EVN mood that is "active". For an Observation in RQO (request) mood, the `statusCode` generally remains "active" until the request is complete, at which time the `statusCode` changes to "completed". For an Observation in GOL (goal) mood, the `statusCode` generally remains "active" as long as the observation in question is still an active goal for the patient.
- **`Act.effectiveTime` and `Act.statusCode` are inter-related**: Per the RIM, the `effectiveTime`, also referred to as the "biologically relevant time", is the time at which the observation holds for the patient. So, whereas the `effectiveTime` is the biologically relevant time, the `statusCode` is the state of the activity. For a provider seeing a patient in the clinic today, observing a history of heart attack that occurred five years ago, the status of the observation is completed, and the `effectiveTime` is five years ago.

3.2 Rendering Header Information for Human Presentation

Metadata carried in the header may already be available for rendering from EHRs or other sources external to the document. An example of this would be a doctor using an EHR that already contains the patient's name, date of birth, current address, and phone number. When a CDA document is rendered within that EHR, those pieces of information may not need to be displayed since they are already known and displayed within the EHR's user interface.

Good practice recommends that the following be present whenever the document is viewed:

- Document title and document dates
- Service and encounter types, and date ranges as appropriate
- Names of all persons along with their roles, participations, participation date ranges, identifiers, address, and telecommunications information
- Names of selected organizations along with their roles, participations, participation date ranges, identifiers, address, and telecommunications information
- Date of birth for `recordTarget`(s)
- Patient identifying information

3.3 Unknown and No Known Information

Information technology solutions store and manage data, but sometimes data are not available. An item may be unknown, not relevant, or not computable or measureable, such as where a patient arrives at an emergency department unconscious and with no identification.

In many cases, the C-CDA standard will stipulate that a piece of information is required (e.g., via a SHALL conformance verb). However, in most of these cases, the standard provides an "out", allowing the sender to indicate that the information isn't known.

Here, we provide guidance on representing unknown information. Further details can be found in the HL7 V3 Data Types Release 1 specification that accompanies the CDA R2 normative standard. However, it should be noted that the focus of C-CDA R2 is on the unambiguous representation of known data, and that in general, the often subtle nuances of unknown information representation are less relevant to the recipient.

Many fields in C-CDA contain a "@nullFlavor" attribute, used to indicate an exceptional value. Some flavors of Null are used to indicate that the known information falls outside of value set binding constraints. Not all uses of the @nullFlavor attribute are associated with a case in which information is unknown. Allowable values for populating the attribute give details about the reason the information is unknown, as shown in the following example.

Figure 3: nullFlavor Example

```
<birthTime nullFlavor="UNK"/>   <!--Sender does not know the birthTime, but a
proper value is applicable -->
```

Use null flavors for unknown, required, or optional attributes:

NI	No information. This is the most general and default null flavor.
NA	Not applicable. Known to have no proper value (e.g., last menstrual period for a male).
UNK	Unknown. A proper value is applicable, but is not known.

ASKU Asked, but not known. Information was sought, but not found (e.g., the patient was asked but did not know).

NAV Temporarily unavailable. The information is not available, but is expected to be available later.

NASK Not asked. The patient was not asked.

MSK There is information on this item available but it has not been provided by the sender due to security, privacy, or other reasons. There may be an alternate mechanism for gaining access to this information.

OTH The actual value is not an element in the value domain of a variable. (e.g., concept not provided by required code system).

The list above contains those null flavors that are commonly used in clinical documents. For the full list and descriptions, see the `nullFlavor` vocabulary domain in the CDA R2 normative edition.

Any **SHALL**, **SHOULD** or **MAY** conformance statement may use `nullFlavor`, unless the `nullFlavor` is explicitly disallowed (e.g., through another conformance statement which includes a **SHALL** conformance for a vocabulary binding to the @code attribute, or through an explicit **SHALL NOT** allow use of `nullFlavor` conformance).

Figure 4: Attribute Required (nullFlavor not allowed)

1. **SHALL** contain exactly one [1..1] `code` (CONF:15407).
   a. This `code` **SHALL** contain exactly one [1..1] **`@code`**="`11450-4`" Problem List (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:15408).

   or

2. **SHALL** contain exactly one [1..1] **`effectiveTime/@value`** (CONF:5256).

Figure 5: Allowed nullFlavors When Element is Required (with xml examples)

1. **SHALL** contain at least one `[1..*] id`
2. **SHALL** contain exactly one `[1..1] code`
3. **SHALL** contain exactly one `[1..1] effectiveTime`

```
<entry>
  <observation classCode="OBS" moodCode="EVN">
    <id nullFlavor="NI"/>
    <code nullFlavor="OTH">
      <originalText>New Grading system</originalText>
    </code>
    <statusCode code="completed"/>
    <effectiveTime nullFlavor="UNK"/>
    <value xsi:type="CD" nullFlavor="OTH">
      <originalText>Spiculated mass grade 5</originalText>
    </value>
  </observation>
</entry>
```


If a sender wants to state that a piece of information is unknown, the following principles apply:

1. If the sender doesn't know an attribute of an act, that attribute can be null.

Figure 6: Unknown Medication Example

1. **SHALL** contain exactly one `[1..1] code`

```
<entry>
  <text>patient was given a medication but I do not know what it was</text>
  <substanceAdministration moodCode="EVN" classCode="SBADM">
    <consumable>
      <manufacturedProduct>
        <manufacturedLabeledDrug>
          <code nullFlavor="NI"/>
        </manufacturedLabeledDrug>
      </manufacturedProduct>
    </consumable>
  </substanceAdministration>
</entry>
```

2. If the sender doesn't know if an act occurred, the `nullFlavor` is on the act (detail could include specific allergy, drug, etc.).

Figure 7: Unknown Medication Use of Anticoagulant Drug Example

```
<entry>
  <substanceAdministration moodCode="EVN" classCode="SBADM" nullFlavor="NI">
    <text>I do not know whether or not patient received an anticoagulant
          drug</text>
    <consumable>
      <manufacturedProduct>
        <manufacturedLabeledDrug>
          <code code="81839001" displayName="anticoagulant drug"
                codeSystem="2.16.840.1.113883.6.96"
                codeSystemName="SNOMED CT"/>
        </manufacturedLabeledDrug>
      </manufacturedProduct>
    </consumable>
  </substanceAdministration>
</entry>
```


3. If the sender wants to state "no known", a `negationInd` can be used on the corresponding act (`substanceAdministration`, `Procedure`, etc.)

   Previously, Continuity of Care Document (CCD[16]), IHE, and Health Information Technology Standards Panel (HITSP[17]) recommended using specific codes to assert no known content, for example `160244002 No known allergies` or `160245001 No current problems or disability`. Specific codes are still allowed; however, use of these codes is not recommended.

   These next examples illustrate nuances of representing information in coded fields when information is a negative assertion, for example it is not the case that the patient has an allergy or it is not the case that a patient takes a medication. The phrases "no known allergies" or "no known medications" are typically associated with this type of negative assertion.

Figure 8: No Known Medications Example

```
<entry>
  <substanceAdministration moodCode="EVN" classCode="SBADM" negationInd=”true”>
    <text>No known medications</text>
    <consumable>
      <manufacturedProduct>
        <manufacturedLabeledDrug>
          <code code="410942007" displayName="drug or medication"
                codeSystem="2.16.840.1.113883.6.96"
                codeSystemName="SNOMED CT"/>
         </manufacturedLabeledDrug>
       </manufacturedProduct>
     </consumable>
  </substanceAdministration>
</entry>
```

Figure 9: Value Known, Code for Value Not Known

```
<entry>
  <observation classCode="OBS" moodCode="EVN">
    …
    <value xsi:type="CD" nullFlavor="OTH">
      <originalText>Spiculated mass grade 5</originalText>
    </value>
  </observation>
</entry>
```

Figure 10: Value Completely Unknown

```
<entry>
  <observation classCode="OBS" moodCode="EVN">
    …
    <value xsi:type="CD" nullFlavor="UNK"/>
  </observation>
</entry>
```

[16] *HL7 Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD), Release 1.* http://www.hl7.org/implement/standards/product_brief.cfm?product_id=6

[17] *HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component (HITSP/C32)* .http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=4&PrefixNumeric=32

Figure 11: Value Known, Code in Required Code System Not Known But Code from Another Code System is Known

```
<entry>
  <observation classCode="OBS" moodCode="EVN">
    …
    <value xsi:type="CD" nullFlavor="OTH">
      <originalText>Spiculated mass grade 5</originalText>
      <translation code="129742005" displayName="spiculated lesion"
                codeSystem="2.16.840.1.113883.6.96"
                codeSystemName="SNOMED CT"/>/>
    </value>
  </observation>
</entry>
```

3.4 Asserting an Act Did Not Occur with a Reason

The `negationInd` attribute, if true, specifies that the act indicated was observed to not have occurred (which is subtly but importantly different from having not been observed). `negationInd='true'` is an acceptable way to make a clinical assertion that something did not occur, for example, "no gestational diabetes".

A nested reason for the act not being done can be represented through the use of an `entryRelationship` clinical statement with an `actRelationship` type of "RSON".

The QDM attribute Negation Rationale is represented by setting `negationInd='true'` and stating the reason (rationale) in a contained Reason (V3) template. Although Reason (V3) is not explicitly contained in every template, it is available for use in any template.

Since QDM Version 5.3, QDM elements can now be specified by either binding to value sets or direct referenced codes. Figure 12 shows a "not done" example for reporting a QDM element that is defined with a direct referenced code. The `negationInd='true'` and the code is the direct referenced code.

When the QDM elements are defined with value sets, reporting "not done" follows the same approach that was specified in the previous QRDA Category I release (e.g., STU R4). Figure 13 shows an example of "not done" for reporting a QDM element that is defined with a value set.

Some cases need to exclude all possibilities, not just that of a single formulation or specific procedure. One example is the general "no Antibiotic Medications for Pharyngitis" compared to the specific "no Amoxicillin 60 MG/ML Oral Suspension." Another example is the general "no Hepatitis A Antigen Test" compared to the specific "no Hepatitis A virus Ab [Units/volume] in Serum by Immunoassay."

In such cases, where no code exists in the Value Set Authority Center (VSAC) value set to represent the general concept, use all of the following steps:

- Use `code/[@nullFlavor="NA"]`
- Set code attribute `code/sdtc:valueset="[VSAC value set OID]"`
- Use `code/originalText` for the text description of the concept in the pattern `"None of value set: [value set name]"`

Figure 12: Not Done Example for QDM Element Defined with Direct Referenced Code

```
<!-- QDM Data Type: Intervention, Performed (Intervention not performed,
     with Negation Rationale (negationInd="true" and Reason given) -->
<act classCode="ACT" moodCode="EVN" negationInd="true">
  <!-- Conforms to C-CDA R2.1 Procedure Activity Act (V2) -->
  <templateId root="2.16.840.1.113883.10.20.22.4.12"
    extension="2014-06-09" />
  <!-- Intervention Performed (V4) -->
  <templateId root="2.16.840.1.113883.10.20.24.3.32"
    extension="2017-08-01" />
  <id root="db734647-fc99-424c-a864-7e3cda82e703" />
  <code code="419553002"
    codeSystem="2.16.840.1.113883.6.96"
    codeSystemName="SNOMED CT"
    displayName="diet education"/>
  <statusCode code="completed" />
  <effectiveTime>
    <!-- QDM Attibute: Relevant Period - Start dateTime -->
    <low value="20170301" />
    <!-- QDM Attibute: Relevant Period - Stop dateTime -->
    <high value="20170301" />
  </effectiveTime>
  <!-- QDM Attribute: Reason (V3) -->
  <entryRelationship typeCode="RSON">
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.24.3.88"
        extension="2017-08-01" />
      <code code="77301-0"
        codeSystem="2.16.840.1.113883.6.1"
        displayName="Reason care action performed or not"
        codeSystemName="LOINC" />
      <value xsi:type="CD" code="105480006"
        codeSystem="2.16.840.1.113883.6.96"
        displayName="refusal of treatment by patient"
        codeSystemName="SNOMED CT"/>
    </observation>
  </entryRelationship>
</act>
```


Figure 13: Not Done Example for QDM Element Defined with Value Set

```
<!--Medication administered not done,
    patient refusal: Drug declined by patient - reason unknown.
    No "Antibiotic Medications for Pharyngitis" were administered -->
    <substanceAdministration classCode="SBADM" moodCode="EVN" negationInd=”true”>
      <templateId root="2.16.840.1.113883.10.20.22.4.16" extension="2014-06-09" />
      <templateId root="2.16.840.1.113883.10.20.24.3.42" extension="2017-08-01" />
      <id root="9a5f4d94-ccad-4d57-80ea-27737545c7ed" />
      <statusCode code="completed" />
      <effectiveTime xsi:type="IVL_TS">
        <low nullFlavor="NA" />
      </effectiveTime>
      <doseQuantity nullFlavor="NA" />
      <consumable>
        <manufacturedProduct classCode="MANU">
          <!-- Conforms to C-CDA R2.1 Medication Information (V2) -->
          <templateId root="2.16.840.1.113883.10.20.22.4.23"
            extension="2014-06-09" />
          <id root="37bfe02a-3e97-4bd6-9197-bbd0ed0de79e" />
          <manufacturedMaterial>
            <code nullFlavor="NA"
                  sdtc:valueSet="2.16.840.1.113883.3.464.1003.196.12.1001">
             <originalText>
              None of value set: Antibiotic Medications for Pharyngitis
             </originalText>
            </code>
          </manufacturedMaterial>
        </manufacturedProduct>
      </consumable>
    </substanceAdministration>
  </entryRelationship>
  ...
</act>
```

Several QDM data types, including Device Order, Device Recommended, Encounter Order, Encounter Performed, and Encounter Recommended, are modeled using the Supply or Encounter act. However, both the Supply and Encounter act classes in CDA R2 do not support negationInd attribute, hence not supporting the Negation Rationale QDM attribute for these QDM data types. New templates such as Device Order Act were introduced in QRDA R1 STU 3.1 to serve as act wrapper that wrap the templates for these QDM data types to allow the use of negationInd attribute. Figure 14 shows an example of Device Order not done.

Figure 14: Not Done Example – Device Order Not Done (with Value Set)

```
<act classCode="ACT" moodCode="RQO" negationInd=”true”>
    <templateId root="2.16.840.1.113883.10.20.24.3.130" extension=”2017-08-01"/>
    <id root="ec8a6ff8-ed4b-4f7e-82c3-e98e58b45de7"/>
    <code code="SPLY" codeSystem="2.16.840.1.113883.5.6" displayName="Supply"
codeSystemName="ActClass"/>
    <entryRelationship typeCode="SUBJ">
      <supply classCode="SPLY" moodCode="RQO">
         <templateId root="2.16.840.1.113883.10.20.22.4.43" extension="2014-06-09"/>
         <!-- Device Order (V4) TemplateId -->
         <templateId root="2.16.840.1.113883.10.20.24.3.9" extension="2017-08-01"/>
         <id root="6a8d037d-f144-4071-9d1f-8a92a11dedc6"/>
         <statusCode code="active"/>
         <author>
           <time value="201702101030"/>
           <assignedAuthor>
              <id nullFlavor=”NA”/>
           </assignedAuthor>
         </author>
         <participant typeCode="DEV">
           <participantRole classCode="MANU">
              <playingDevice classCode="DEV">
                 <code nullFlavor=”NA”
                       sdtc:valueSet="2.16.840.1.113883.3.117.1.7.1.230">
                   <originalText>
                    None of value set: Venous foot pumps (VFP) SNOMEDCT Value Set
                   </originalText>
                 </code>
              </playingDevice>
           </participantRole>
         </participant>
         <!-- QDM Attribute: Reason -->
         <entryRelationship typeCode="RSON">
            <observation classCode="OBS" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.20.24.3.88" extension="2017-
08-01"/>
                 <code code="77301-0" codeSystem="2.16.840.1.113883.6.1"
         displayName="Reason care action performed or not" codeSystemName="LOINC"/>
                 <value xsi:type="CD" code="105480006"
codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" displayName="Refusal
of treatment by patient (situation)" />
            </observation>
         </entryRelationship>
        </supply>
    </entryRelationship>
</act>
```

3.5 Use of UTC Time Zone Offset in Datetimes

If no UTC offset is provided in a datetime, then the provided datetime will be utilized as it is given with no modification (for example, with regards to location). A UTC time zone offset should not be reported in a QRDA Category I document, even if the datetime value is more precise than day, unless one or more of the datetime fields are from different time zones or any datetimes overlap with Daylight Savings time adjustments. In such cases, a UTC offset must be specified everywhere a time component in a datetime field is provided, with the

following two exceptions: the effectiveTime element of the Reporting Parameter Act template and birthTime/value.

This IG assumes that datetime fields are reported in accordance with the rules regulating Daylight Savings Time. Certain areas of the United States do not adjust their local time to Daylight Savings Time. Datetimes reported from these areas without a UTC time zone offset while Daylight Savings is in effect in other areas may be inconsistent with what is expected. If no UTC time zone offset is provided, then no offset or daylight saving will be assumed and/or applied and the given datetime is used.

For example, Daylight Savings took effect in 2018 on March 11 at 2 AM, when the time moved from 1:59 AM to 3 AM. A datetime of March 11, 2018, at 2:15 AM can be valid as a reported local time in locations that do not observe Daylight Savings.

In other instances, when the time is moved back an hour during the return to Standard time, the report could erroneously indicate that an event's starting time is after its ending time. Daylight Savings ceased in 2018 on November 4 at 2 AM, when the time moved from 1:59 AM back to 1 AM. An event could have begun at 1:50 AM in Daylight Savings Time and ended 40 minutes later at 1:30 AM in Standard Time.

In order to provide accurate data a QRDA report must contain the UTC offset for situations in which no UTC offset would lead to a datetime or sequence of events. Failure to include the offset could lead to inaccurate reports.

4 USING THIS IMPLEMENTATION GUIDE

This chapter describes the rules and formalisms used to constrain the CDA R2.1 standard. It describes the formal representation of CDA templates, the mechanism by which templates are bound to vocabulary, and additional information necessary to understand and correctly implement the normative content found in Volume 2 of this guide. This guide further constrains templates in the C-CDA R2.1 standard.

4.1 Conformance Conventions Used in This Guide

4.1.1 Errata or Enhancements

Comments regarding errata or enhancements may be noted on the HL7 STU Comments page (http://www.hl7.org/dstucomments/) for this guide.

4.1.2 Templates and Conformance Statements

Conformance statements within this implementation guide are presented as constraints from Trifolia Workbench, a template repository.[18] An algorithm converts constraints recorded in Trifolia to a printable presentation. Each constraint is uniquely identified by an identifier at or near the end of the constraint (e.g., CONF:86-7345). The digits in the conformance number before the hyphen identify which implementation guide the template belongs to and the number after the hyphen is unique to the owning implementation guide. Together, these two numbers uniquely identify each constraint. These identifiers are persistent but not sequential. Conformance numbers in this guide associated with a conformance statement that is carried forward from a previous version of this guide will carry the same conformance number from the previous version. This is true even if the previous conformance statement has been edited. If a conformance statement is entirely new it will have a new conformance number.

Bracketed information following each template title indicates the template type (section, observation, act, procedure, etc.), the object `identifier (OID)` or `uniform resource name (URN)`, and whether the template is open or closed. The `identifier OID` is the `templateId/@root` value; all `templateIds` have an `@root` value. Versioned templates also have an `@extension` value, which is a date identifying the version of this template; such templates are identified by `URN` and the HL7 version (`urn:hl7ii`). The `URN` identifier includes both the `@root` and `@extension` value for the `templateId` (for example, `identifier` urn:hl7ii:2.16.840.1.113883.10.20.24.3.1:2017-08-01).

Each section and entry template in Volume 2 of this guide includes a context table. The "Contained By" column indicates which templates use this template, and if the template is optional or required in the containing template. The "Contains" column indicates any templates that the template uses.

[18] Trifolia Workbench. https://trifolia.lantanagroup.com/

Table 2: Contexts Table Example—Care Goal (V4)

Contained By:	Contains:
Patient Data Section QDM (V6) (optional)	Related To Target Outcome (V2)

Each entry template also includes a constraints overview table to summarize the constraints in the template.

Table 3: Constraints Overview Example— Care Goal (V4)

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.3.1:2017-08-01)					
@classCode	1..1	SHALL		3343-11245	urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = OBS
@moodCode	1..1	SHALL		3343-11246	urn:oid:2.16.840.1.113883.5.1001 (HL7ActMood) = GOL
@negationInd	0..0	SHALL NOT		3343-28040	
templateId	1..1	SHALL		3343-11247	
@root	1..1	SHALL		3343-11248	2.16.840.1.113883.10.20.24.3.1
@extension	1..1	SHALL		3343-27067	2017-08-01
…					

The expression “such that it” at the end of one conformance statement links that conformance statement to the following subordinate conformance statement to further constrain the first conformance statement. To understand the full effect of this conformance construct, the two conformances must be considered as a single compound requirement. The subordinate conformance statement functions as a subordinate clause (like a "where" clause), which is being applied on the first conformance statement.

The following example shows a compound conformance statement made up of two conformance statements joined by a "such that it" clause. The effect of this syntax can be interpreted as a "where" clause. Thus...

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:81-7899) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.31" (CONF:81-10487).

...is understood as:

This template **SHALL** contain exactly one [1..1] **templateId** where it contains exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.31".

This means that you must have a template id with **@root**="2.16.840.1.113883.10.20.22.4.31", but you can also have other template ids with different valued attributes.

The following figure shows a typical template's set of constraints presented in this guide. The next chapters describe specific aspects of conformance statements—open vs. closed templates, conformance verbs, cardinality, vocabulary conformance, containment relationships, and null flavors.

Figure 15: Constraint Conformance Including "such that it" Syntax Example

Age Observation

[observation: identifier urn:oid:2.16.840.1.113883.10.20.22.4.31 (open)]

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:81-7613).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:81-7614).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:81-7899) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.31" (CONF:81-10487).

...

4.1.3 Template Versioning

A new version of an existing implementation guide reuses templates from the previous version. During the ballot phase or update phase, templates carry the designation "Published" to indicate the template is unchanged from the previous version or "Draft" to indicate a new or revised template. Substantial revisions to previously published templates are indicated by the version number (V2, V3, etc.) in all phases: ballot, update, and published guides.

If there are no substantive changes to a template that has been successfully published, the template will carry the same templateId/@root (identifier oid) and templateId/@extension as in the previous implementation guide. (In the case of older templates, the @extension attribute will not be present.) During a new ballot or update phase, "Published" is appended to the main heading for the template to indicate that the template cannot be commented on in the ballot or update. The "Published" designation is removed in the final publication versions.

A revised version of a previously published template keeps the same templateId/@root as the previous version but is assigned a new templateId/@extension. The notation "(Vn)" (V2, V3, etc.) is also added to the template name. Versions are not necessarily forward or backward compatible. A versioning may be due to substantive changes in the template or because a contained template has changed. The "(Vn)" designation is persistent; it appears with that template when it is used in subsequent guides. During a new ballot or update phase, "Draft" is appended to the main heading for the template to indicate that it may be

voted on in the ballot or commented on in the update; the "Draft" designation is removed in the final publication versions.

A new version of a template is explicitly linked to the prior version, enabling the automatic generation of the detailed change log found in Volume 2, Chapter 9 "Changes From Previous Version".

An example of the change log for a versioned template is shown in the following figure. In this example, Care Goal (V3) (2.16.840.1.113883.10.20.24.3.1:2016-02-01) has versioned to Care Goal (V4) (2.16.840.1.113883.10.20.24.3.1:2017-08-01).

Figure 16: Versioned Template Change Log Example

Change	Old	New
Name	Care Goal (V3)	Care Goal (V4)
Oid	urn:hl7ii:2.16.840.1.113883.10.20.24.3.1: 2016-02-01	urn:hl7ii:2.16.840.1.113883.10.20.24.3.1:2017-08-01
…		
CONF #: 2228-27577 Removed	This code SHALL contain exactly one [1..1] `@sdtc:valueSet` (CONF:2228-27577).	
…		

4.1.4 Open and Closed Templates

In open templates, all of the features of the CDA R2 base specification are allowed except as constrained by the templates. By contrast, a closed template specifies everything that is allowed and nothing further may be included.

There are no closed templates in this guide.

Open templates allow HL7 implementers to develop additional structured content not constrained within this guide. HL7 encourages implementers to bring their use cases forward as candidate requirements to be formalized in a subsequent version of the standard to maximize the use of shared semantics.

4.1.5 Conformance Verbs (Keywords)

The keywords **SHALL, SHOULD, MAY, NEED NOT, SHOULD NOT,** and **SHALL NOT** in this document are to be interpreted as described in the HL7 Version 3 Publishing Facilitator's Guide.[19]

- **SHALL**: an absolute requirement
- **SHALL NOT**: an absolute prohibition against inclusion
- **SHOULD/SHOULD NOT**: best practice or recommendation. There may be valid reasons to ignore an item, but the full implications must be understood and carefully weighed before choosing a different course

[19] HL7, *Version 3 Publishing Facilitator's Guide.* http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm

- **MAY/NEED NOT**: truly optional; can be included or omitted as the author decides with no implications

The keyword "**SHALL**" allows the use of `nullFlavor` unless the requirement is on an attribute or the use of `nullFlavor` is explicitly precluded.

When conformance statements are nested (or have subordinate clauses) the conformance statements are to be read and interpreted in hierarchical order. These hierarchical clauses can be interpreted as "if then, else" clauses. Thus...

a. This structuredBody **SHOULD** contain zero or one [0..1] **component** (CONF:1098-29066) such that it
   i. **SHALL** contain exactly one [1..1] **Plan of Treatment Section (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.2.10:2014-06-09) (CONF:1098-29067).

...is understood as:

a. It is recommended (**SHOULD**) that the structuredBody contains a component.
   i. **If** the component exists, **then** it must contain a Plan of Treatment Section (V2),
   ii. **Else if** the component does not exist, the conformance statement about the Plan of Treatment Section (V2) should be skipped.

In the case where the higher level conformance statement is a **SHALL,** there is no conditional clause. Thus...

a. This structuredBody **SHALL** contain exactly one [1..1] **component** (CONF:1098-29086) such that it
   i. **SHALL** contain exactly one [1..1] **Problem Section (entries required) (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.2.5.1:2014-06-09) (CONF:1098-29087).

...means that the structuredBody is always required to have a component.

4.1.6 Cardinality

The cardinality indicator (0..1, 1..1, 1..*, etc.) specifies the allowable occurrences within a document instance. The cardinality indicators are interpreted with the following format “m...n” where m represents the least and n the most:

- 0..1 zero or one
- 1..1 exactly one
- 1..* at least one
- 0..* zero or more
- 1..n at least one and not more than n

When a constraint has subordinate clauses, the scope of the cardinality of the parent constraint must be clear. In the next figure, the constraint says exactly one participant is to be present. The subordinate constraint specifies some additional characteristics of that participant.

Figure 17: Constraints Format – only one allowed

1. **SHALL** contain exactly one [1..1] **participant** (CONF:2777).
    a. This participant **SHALL** contain exactly one [1..1] **@typeCode**="LOC" (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) (CONF:2230).

In the next figure, the constraint says only one participant "like this" is to be present. Other participant elements are not precluded by this constraint.

Figure 18: Constraints Format – only one like this allowed

1. **SHALL** contain exactly one [1..1] **participant** (CONF:2777) such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="LOC" (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) (CONF:2230).

4.1.7 Optional and Required with Cardinality

The terms *optional* and *required* describe the *lower* bound of cardinality as follows:

Optional means that the number of allowable occurrences of an element may be 0; the cardinality will be expressed as [0..1] or [0..*] or similar. In these cases, the element may not be present in the instance. Conformances formulated with **MAY** or **SHOULD** are both considered "optional" conformances.

Required means that the number of allowable occurrences of an element must be at least 1; the cardinality will be expressed as [m..n], where m >=1 and n >=m (for example, [1..1] or [1..*]). In these cases, the element must be present in the instance. Conformance statements formulated with SHALL are required conformances. If an element is required but it is not known, the @nullFlavor attribute must be used. See Unknown and No Known Information.

4.1.8 Vocabulary Conformance

The templates in this document use terms from several code systems. These vocabularies are defined in various supporting specifications and may be maintained by other bodies, as is the case for the LOINC® and SNOMED CT® vocabularies.

Note that value set identifiers (e.g., ValueSet 2.16.840.1.113883.1.11.78 Observation Interpretation (HL7) **DYNAMIC**) used in the binding definitions of template conformance statements do not appear in the XML instance of a CDA document. The definition of the template must be referenced to determine or validate the vocabulary conformance requirements of the template.

Value set bindings adhere to HL7 Vocabulary Working Group best practices, and include both an indication of stability and of coding strength for the binding. Value set bindings can be **STATIC**, meaning that they bind to a specified version of a value set, or **DYNAMIC**, meaning that they bind to the most current version of the value set. If a **STATIC** binding is specified, a date **SHALL** be included to indicate the value set version. If a **DYNAMIC** binding is specified, the value set authority and link to the base definition of the value set **SHALL** be included, if available, so implementers can access the current version of the value set. When a vocabulary binding binds to a single code, the stability of the binding is implicitly **STATIC**.

Figure 19: Binding to a Single Code

2. **SHALL** contain exactly one [1..1] **code** (CONF:15403).
   a) This code **SHALL** contain exactly one [1..1] **@code**="11450-4" Problem List (CONF:15408).
   b) This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC 2.16.840.1.113883.6.1 **STATIC**) (CONF: 31141).

The notation conveys the actual code (`11450-4`), the code's `displayName` (Problem List), the OID of the `codeSystem` from which the code is drawn (2.16.840.1.113883.6.1), and the `codeSystemName` (LOINC).

HL7 Data Types Release 1 requires the `codeSystem` attribute unless the underlying data type is "Coded Simple" or "CS", in which case it is prohibited. The `displayName` and the `codeSystemName` are optional, but recommended, in all cases.

The above example would be properly expressed as follows.

Figure 20: XML Expression of a Single-Code Binding

```
<code code="11450-4" codeSystem="2.16.840.1.113883.6.1"/>

<!-- or -->

<code code="11450-4" codeSystem="2.16.840.1.113883.6.1"
      displayName="Problem List"
      codeSystemName="LOINC"/>
```

A full discussion of the representation of vocabulary is outside the scope of this document; for more information, see the *HL7 V3 Normative Edition 2010*[20] sections on Abstract Data Types and XML Data Types R1.

When a template uses value set bindings, value set tables are presented below the template or are referenced if they occur elsewhere in the specification. The value set table provides the value set identifier, a description, and a link to the source of the value set when possible. Ellipses in the last row indicate the value set members shown are examples and the true source must be accessed to see all members.

If a value set binding has a **DYNAMIC** stability, implementers creating a CDA document must go to the location in the URL to check for the most current version of the value set expansion.

[20] *HL7 Version 3 Interoperability Standards.* http://www.hl7.org/memonly/downloads/v3edition.cfm - V32010

Table 4: Example Value Set Table (Referral Types)

Value Set: Referral Types 2.16.840.1.113883.11.20.9.56 A value set of SNOMED-CT codes descending from "3457005" patient referral (procedure). Value Set Source: http://vtsl.vetmed.vt.edu/TerminologyMgt/RF2Browser/ISA.cfm?SCT_ConceptID=3457005			
Code	**Code System**	**Code System OID**	**Print Name**
44383000	SNOMED CT	2.16.840.1.113883.6.96	Patient referral for consultation
391034007	SNOMED CT	2.16.840.1.113883.6.96	Refer for falls assessment (procedure)
86395003	SNOMED CT	2.16.840.1.113883.6.96	Patient referral for family planning (procedure)
306106002	SNOMED CT	2.16.840.1.113883.6.96	Referral to intensive care service (procedure)
306140002	SNOMED CT	2.16.840.1.113883.6.96	Referral to clinical oncology service (procedure)
396150002	SNOMED CT	2.16.840.1.113883.6.96	Referral for substance abuse (procedure)
…			

4.1.9 Containment Relationships

Containment constraints between a section and its entry are indirect in this guide, meaning that where a section asserts containment of an entry, that entry can either be a direct child or a further descendent of that section.

For example, in the following constraint:

1. **SHALL** contain at least one [1..*] **entry** (CONF:8647) such that it
    a. **SHALL** contain exactly one [1..1] **Advance Directive Observation** (templateId:2.16.840.1.113883.10.20.22.4.48) (CONF:8801).

the Advance Directive Observation can be a direct child of the section (i.e., `section/entry/AdvanceDirectiveObservation`) or a further descendent of that section (i.e., `section/entry/…/AdvanceDirectiveObservation`). Either of these are conformant.

All other containment relationships are direct, for example:

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.21" (CONF:7928).

The `templateId` must be a direct child of the section (i.e., section/templateId).

4.1.10 Data Types

All data types used in a CDA document are described in the CDA R2 normative edition. All attributes of a data type are allowed unless explicitly prohibited by this specification.

4.1.11 Document-Level Templates "Properties" Heading

In Volume 2 of this implementation guide, each document-level template has a "Properties" heading for ease of navigation. The Properties heading is an organizational construct, underneath which relevant CDA act-relationships and roles are called out as headings in the document.

4.2 XML Conventions Used in This Guide

4.2.1 XPath Notation

Instead of the traditional dotted notation used by HL7 to represent RIM classes, this document uses XML Path Language (XPath) notation[21] in conformance statements and elsewhere to identify the XML elements and attributes within the CDA document instance to which various constraints are applied. The implicit context of these expressions is the root of the document. This notation provides a mechanism that will be familiar to developers for identifying parts of an XML document.

XPath statements appear in this document in a `monospace font`.

XPath syntax selects nodes from an XML document using a path containing the context of the node(s). The path is constructed from node names and attribute names (prefixed by a '@') and catenated with a '/' symbol.

Figure 21: XML Document Example

```
<author>
  <assignedAuthor>
  ...
    <code codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'
          code='17561000' displayName='Cardiologist' />
  ...
  </assignedAuthor>
</author>
```

In the above example, the `code` attribute of the code could be selected with the XPath expression in the next figure.

Figure 22: XPath Expression Example

```
author/assignedAuthor/code/@code
```

4.2.2 XML Examples and Sample Documents

Extensible Mark-up Language (XML) examples appear in figures in this document in this `monospace font`. XML elements (`code, assignedAuthor`, etc.) and attribute names (`SNOMED CT, 17561000`, etc.) also appear in this `monospace font`. Portions of the XML content may be omitted from the content for brevity, marked by an ellipsis (…) as shown in the example below.

[21] W3C, XML Path Language. http://www.w3.org/TR/xpath/

Figure 23: ClinicalDocument Example

```
<ClinicalDocument xmls="urn:h17-org:v3">
  ...
</ClinicalDocument>
```


5 QRDA CATEGORY I FRAMEWORK

A QRDA Category I report is an individual-patient-level quality report. Each report contains quality data for one patient for one or more quality measures, where the data elements in the report are defined by the particular measure(s) being reported. A QRDA Category I report contains raw applicable patient data. When pooled and analyzed, each report contributes the quality data necessary to calculate population measure metrics.

5.1 Measure Section

A Measure Section template contains explicit reference to the measure or measures being reported. The standard allows a QRDA Category I report instance to contain data for any number of measures.

5.2 Reporting Parameters Section

The Reporting Parameters Section provides information about the reporting time interval and may contain other information that provides context for the patient data being reported. The receiving organization may tell the reporting organizations what information is needed in this section.

5.3 Patient Data Section

The Patient Data Section conveys all the patient data elements expected in the measure(s) stated in the Measure Section. A patient data element is information about a particular person (as opposed to a population). Examples include: individual's test results, individual's encounter location, and an individual's date of birth.

In the Quality Data Model-Based QRDA, corresponding template patterns exist for the majority of the QDM Quality Datatypes and Attributes. Where possible, data elements in a QRDA framework instance should be communicated with entry-level templates from the C-CDA R2.1. In many cases these templates will require further constraint to convey the exact data elements required by a measure or set of measures. Data elements should always be sent with a date/time stamp.

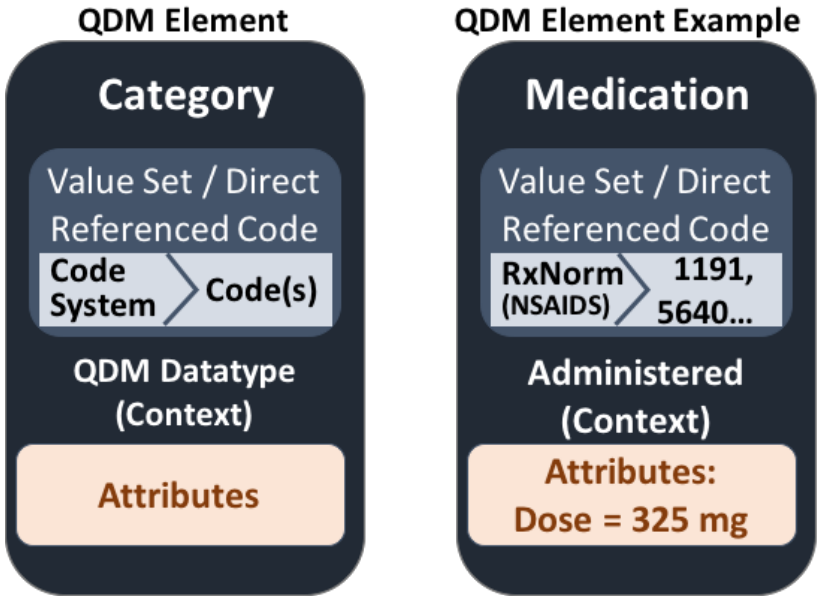
6 QUALITY DATA MODEL-BASED QRDA

6.1 Introduction

This section introduces the Quality Data Model (QDM), and describes how it is used to construct both QDM-based eCQMs and corresponding QDM-based QRDA documents as defined in this guide.

From HL7's perspective, the QDM is a domain analysis model that defines concepts recurring across quality measures. The figure below illustrates components of the QDM relevant to understanding how that model guides the construction of CDA templates in QRDA documents.

Figure 24: QDM Element Structure



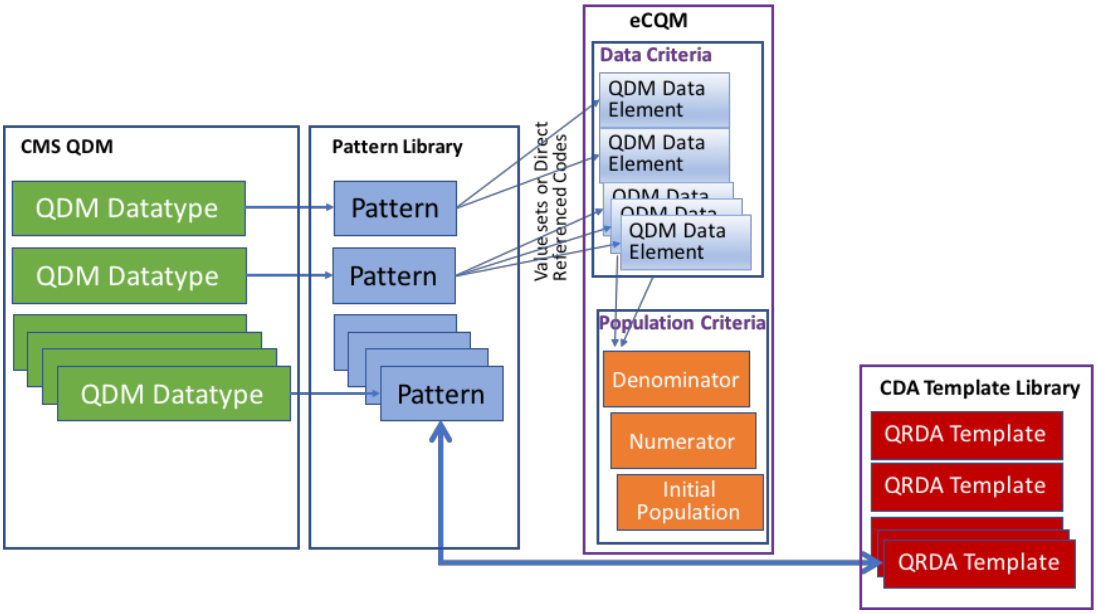
The QDM breaks a concept down into a "QDM Datatype" based on the category (or class) of information and the context (or state) of expected used (Figure 24 shows the example of Medication, Administered), and "QDM Attributes." The category defines which code system(s) should be used to express the data element (e.g., RxNorm for medications, LOINC for Laboratory Tests). A "QDM Data Element" is the combination of a QDM datatype, the associated value set or direct referenced code, and the desired attributes[22]. QDM Attributes represent various metadata associated with the QDM Datatype, such as timing, or category-specific characteristics, as shown above in the Medication, Administered example. Previous versions of QDM required a value set to define every data element. Some value sets contained only a single code. This practice provided an alternate identifier (the value set name) for the code system concept.

[22] For the purposes of this document, we make reference to QDM Datatypes, and make no further reference to clinical categories or states.

Beginning with QDM version 5.3, QDM data elements can use either a value set or a single code. The term used for the single code is *direct referenced code*. eCQMs use such direct referenced codes when only one code system concept meets the definition of the QDM data element.

Figure 25 illustrates the relationship between QDM and QRDA (and eCQMs).

Figure 25: Relationship Between QDM, eCQM, and QRDA



QDM datatypes have been manually converted into HL7 Reference Information Model (RIM)-derived XML patterns that, when coupled with value sets or direct referenced codes, become QDM Data Elements that can be used as data criteria within a QDM-based eCQM.

Each QDM datatype pattern is assigned a unique ID, which is present in the eCQM, and which is mapped to a corresponding CDA template.

A QDM data element further constrains a QDM datatype pattern via vocabulary binding to either a value set or a direct referenced code. The linked CDA template can be further constrained through a corresponding value set or a direct referenced code.

The further constraint on a CDA template through value set or direct referenced code provides the ability to define new QDM-based eCQMs (e.g., assign new value sets or direct referenced codes to existing QDM datatypes thereby creating new QDM data elements) without the need to update this guide. In essence, this guide has predefined CDA templates corresponding to QDM datatypes, and it provides a mechanism for referencing arbitrary value sets or direct referenced codes, thereby allowing a QRDA instance to conform to a QDM data element.

The previous releases of the QRDA Category I IG (QRDA I STU R4 and prior) required the value set OID that the code is drawn from (as specified in an eCQM for QDM data elements or QDM attributes) must be reported. This was done by requiring the `sdtc:valueSet` attribute where the value set binding occurs when creating QRDA templates for QDM data elements. As a result, if the same code is contained by multiple value sets, the same Quality datatype may have to be reported multiple times,

each associated with a different value set by assigning `sdtc:valueset` attribute's value a different OID.

For example, the eCQM specification (CMS104v6) for the Discharged on Antithrombotic Therapy measure (STK-10) defines "Encounter, Performed: Non-Elective Inpatient Encounter" using "Non-Elective Inpatient Encounter SNOMEDCT Value Set (2.16.840.1.113883.3.117.1.7.1.424)", and the eCQM specification (CMS111v6) for the Median Admit Decision Time to ED Departure Time for Admitted Patient (ED-2) defines "Encounter, Performed: Encounter Inpatient" using "Encounter Inpatient SNOMEDCT Value Set (2.16.840.1.113883.3.666.5.307)". The SNOMED CT code 32485007 "Hospital admission (procedure)" is contained in both of these two value sets. As shown in Table 5, this same hospital admission encounter data (the same encounter code, data stamp) from EHR had to be reported twice, each with a different value set. In some cases, this could potentially lead to a large duplication of data in a QRDA Category I report and adds burden to the receiving system for downstream processing.

Table 5: Example of Duplicate Entries (Same Code in Multiple Value Sets)

QDM data type	Instance Identifier	Admission Time	Discharge Time	Encounter Code	Encounter Code Display Name	Value Set OID
Encounter Performed	49741bcc-496d-4b20-bcb6-619e0335342c	2016-07-24 03:40	2016-07-31 12:40	32485007	Hospital admission (procedure)	2.16.840.1.113883.3.117.1.7.1.424
Encounter Performed	49741bcc-496d-4b20-bcb6-619e0335342c	2016-07-24 03:40	2016-07-31 12:40	32485007	Hospital admission (procedure)	2.16.840.1.113883.3.666.5.307

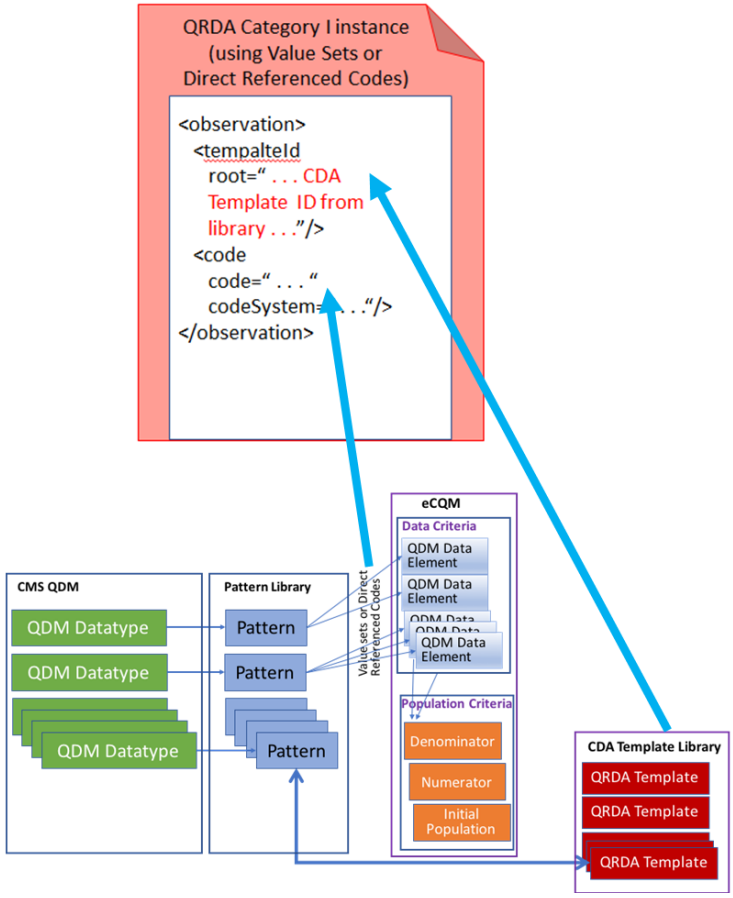
Feedback received from the implementation communities is to submit patient data as it exists in the medical record and not duplicated due to eCQM value sets used in the same or different measures within a topic or across topics. Each QDM data element needs to contain all of the attributes required by each measure (e.g., principal diagnosis, discharge status, etc.) that are reported in the same QRDA Category I file. The receiving system will be able to use terminology look up to match which value sets the code belongs to.

Beginning with QDM 5.3, direct referenced codes can be used to describe QDM elements instead of having to create a value set that contains only a single code. For example, eCQM logics can directly reference the SNOMED CT code 4525004 "Emergency department patient visit (procedure)", and it does not have to create a value set to contain the code 4525005 only. Requiring the `sdtc:valueSet` be submitted does not support the direct referenced codes use case.

Therefore, this IG removes the value set OID requirement for reporting QDM data elements and QDM attributes. The constraints that specifies SHALL requirement for `sdtc:valueSet` are removed from the affected templates specified in the Volume 2 of this IG.

Since `sdtc:valueSet` is no longer required, both value sets or direct referenced codes are referenced the same way as depicted in Figure 26.

Figure 26: QDM Data Element Representation in a QRDA Category I Instance



This guide describes how to construct a QDM-based QRDA document for any QDM-based eCQM rather than give prescriptive rules for QRDA construction on an eCQM-by-eCQM basis.

6.2 QDM-Based QRDA Category I Construction Rules

This section provides guidelines on when to create QRDA documents and what data to include.

6.2.1 How Many QRDA Documents Should be Created?

A QDM-based QRDA Category I instance contains data on a single patient for one or more QDM-based eCQMs. Each eCQM for which data is included shall be referenced in a QRDA Measure Section that adheres to the Measure Section QDM template.

As a result of this rule, a QRDA Category I instance may contain data elements for multiple measures, thus it is very important to include date/time stamps for the various objects (e.g., to know that a particular medication was administered during a

particular encounter). This guide, therefore, further constrains those CDA templates used elsewhere, such as in C-CDA R2.1, e.g., to require date/time stamps.

6.2.2 Generate a QRDA for Which Patients?

As noted above, a QDM-based QRDA Category I instance will reference one or more eCQMs in the QRDA Measure Section. Some quality programs may require that a QDM-based QRDA Category I instance reference only those eCQMs for which the corresponding Initial Population (IPOP) criteria have been met. Other quality programs may require that a QDM-based QRDA Category I instance reference a pre-negotiated set of measures.

A QRDA document should be created for each patient meeting the IPOP criteria of at least one of the referenced eCQM(s). No QRDA document should be created for patients that fail to meet any of the IPOP criteria.

Where a QRDA document references multiple measures, the patient should have met at least one of the referenced IPOP criteria. For instance, at a hospital reporting on three acute myocardial infarction measures (AMI-1, AMI-2, AMI-3), where the quality program requires that all three eCQMs be referenced in the QRDA Category I instance, if a patient meets the IPOP for AMI-1, AMI-2, or AMI-3, then a QRDA for that patient will be generated. As described below, that QRDA would contain data for all referenced eCQMs.

Often times, a quality program implementing QRDA will provide prescriptive guidelines that define the exact rules for which eCQMs to reference in a QDM-based QRDA Category I instance or the exact triggers for sending a QRDA document. Where such prescriptive guidelines exist, they take precedence over the more general guidance provided here.

6.2.3 How Much Data Should be Sent?

QDM-based QRDA adheres to a "scoop and filter" philosophy, whereby data from an EHR are scooped up and filtered, and the remaining content is packaged into the instance.

When the recipient of the instance has access to no other EHR data, it is important that the instance include data elements relevant to computing eCQM criteria, as well as the other data elements defined in an eCQM —for stratification, for risk adjustment, etc. Every data element present in the EHR that is required by the referenced eCQM(s), not just those needed to compute criteria, shall be included in the QRDA document.

The EHR may have more data than are relevant to the referenced eCQM(s) and more data than are needed to compute the criteria. For instance, a patient who has been in the Intensive Care Unit undergoing continuous blood pressure monitoring will have reams of blood pressure observations. QDM-based QRDA adheres to a "smoking gun" philosophy where, at a minimum, the conclusive evidence needed to confirm that a criterion was met shall be included in the instance.

At the very least, the QRDA document should include:

- For each data element in each referenced eCQM, smoking gun data that offer confirmatory proof, where a patient has met the criterion—For disjunctive criteria

(i.e., where a criterion can be satisfied by one of multiple data elements) include minimal smoking gun data for at least one data element.

- Stratification variables, supplemental data elements, risk adjustment variables, and any other data element specified in the referenced eCQM(s)

A quality program implementing QRDA will often provide prescriptive guidelines that define additional data, outside the smoking gun, that may or must be sent (such as the complete problem or medication list). Where such prescriptive guidelines exist, those take precedence over the more general guidance provided here. In other words, the "smoking gun" heuristic ensures that the minimum is present in the QRDA, and does not preclude inclusion of additional data.

6.2.4 What if There are No Data in the EHR?

Not all data elements defined within the referenced eCQM will be present in the EHR for each patient for which a QDM-based QRDA Category I instance is to be sent. Following from the scoop and filter philosophy, a QDM-based QRDA document will not contain data elements that aren't present in the source system. For instance, if an eCQM has a criterion "patient is in the Numerator if they have blue eyes" and the patient doesn't have eye color captured in the source system, then the corresponding QRDA document will not contain an eye color observation for that patient.

Whereas a QDM-based QRDA defines this consistent approach to missing data, the QDM-based eCQM defines the logical processing of missing data (e.g., how to classify a patient into various populations in the absence of an eye color observation). In other words, the eCQM addresses how it factors in missing data when calculating criteria, and it is the job of the QDM-based QRDA to include relevant data that was present in the EHR, and to not include data that was missing from the EHR.

6.3 Generating a QDM-Based QRDA Category I Instance from a QDM-Based eCQM

This guide does not give prescriptive rules for QRDA construction on an eCQM-by-eCQM basis, but rather, describes how to construct a QDM-based QRDA instance for any QDM-based eCQM (eCQMs that are specified using QDM as data models). This section walks through an illustrative QRDA generation process, to illustrate how to construct a QDM-based QRDA for one or more QDM-based eCQMs. Detailed mapping tables, that allow an implementer to figure out which templates to include in a QDM-based QRDA Category I instance based on the criteria and other data elements in a QDM-based eCQM are included in the appendix "HQMF QDM Datatype to CDA Mapping Tables".

Illustrative steps to construct a QDM-based QRDA for a given patient in this scenario:

1. Identify those eCQMs to be included in the QRDA document. List each of these eCQMs in the "Measure Section QDM" section template (identifier urn:oid:2.16.840.1.113883.10.20.24.2.3).
2. For all eCQMs in the "Measure Section QDM" section template, take the union of QDM data elements. Include all data elements, including those needed to

calculate population criteria, those needed for stratification, those needed for risk adjustment, etc. You'll wind up with a table, looking something like this:

Table 6: Union of Quality Datatypes from eCQM of Interest

QDM Element	QDM Datatype Pattern ID	Value Set Name / Direct Referenced Code Description	Value Set ID	Direct Referenced Code – Code System	Direct Referenced Code
Diagnosis: Pregnancy	2.16.840.1.113883.10.20.28.3.110	Pregnancy Grouping Value Set	2.16.840.1.113883.3.526.3.378	NA	NA
Medication, Administered: Aspirin	2.16.840.1.113883.10.20.28.3.45:2015-09-30	Aspirin RxNorm Value Set	2.16.840.1.113883.3.666.5.626	NA	NA
Medication, Administered: Beta Blocker	2.16.840.1.113883.10.20.28.4.45:2017-05-01	Beta Blocker Therapy RxNorm Value Set	2.16.840.1.113883.3.526.3.1174	NA	NA
Assessment, Performed: Patient Health Questionnaire 9	urn:hl7ii:2.16.840.1.113883.10.20.28.4.117:2017-05-01	PHQ-9 Direct Referenced Code	NA	LOINC	70271-2

3. For each QDM datatype identified, identify the corresponding CDA template from this guide. The HQMF QDM Pattern to CDA Template Mapping Table in the appendix maps from HQMF QDM datatype Pattern ID to the corresponding CDA template ID. You'll wind up with a table, looking something like this:

Table 7: QDM HQMF Pattern to CDA Mapping Table

QDM Element	QDM Datatype Pattern ID	Value Set Name	Value Set ID	CDA Template Name	CDA Template Library ID
Diagnosis: Pregnancy	2.16.840.1.113883.10.20.28.3.110:2017-08-01	Pregnancy Grouping Value Set	2.16.840.1.113883.3.526.3.378	Diagnosis	urn:hl7ii:2.16.840.1.113883.10.20.24.3.137:2017-08-01 2.16.840.1.113883.10.20.24.3.135:2017-08-01
Medication, Administered: Aspirin	2.16.840.1.113883.10.20.28.3.45:2018-05-01	Aspirin RxNorm Value Set	2.16.840.1.113883.3.666.5.626	Medication Administered	2.16.840.1.113883.10.20.24.3.42:2017-08-01
Medication, Administered: Beta Blocker	2.16.840.1.113883.10.20.28.3.45:2018-05-01	Beta Blocker Therapy RxNorm Value Set	2.16.840.1.113883.3.526.3.1174	Medication Administered	2.16.840.1.113883.10.20.24.3.42:2017-08-01
…					
QDM Data Element	**QDM datatype Pattern ID**	**Direct Referenced Code Description**	**Direct Referenced Code**	**CDA Template Name**	**CDA Template Library ID**
Assessment, Performed: Patient Health Questionnaire 9	urn:hl7ii:2.16.840.1.113883.10.20.28.4.117:2017-08-01	PHQ-9 Depression Scale	70271-2	Assessment, Performed	urn:hl7ii:2.16.840.1.113883.10.20.24.3.144:2017-08-01
…					

Given this, an implementer can figure out which CDA templates to include in a QDM-based QRDA Category I instance, given one or more QDM-based eCQMs.

4. Not all QDM HQMF patterns correspond to CDA templates. QDM Attributes for instance, map to fields within CDA templates, as shown in the HQMF QDM Attribute Patterns to CDA Elements in Specific Templates Mapping Table and the HQMF QDM Attribute Patterns to CDA Elements Mapping Table. For example, eCQM "Statin Prescribed at Discharge" has a criterion "Diagnosis: AMI," where the "Diagnosis" QDM datatype maps to the CDA "Diagnosis" template, there is a value set for "AMI" (acute myocardial infarction). The resulting instance is illustrated in the following figure.

Figure 27: Fully Formed Template in a QRDA Category I Instance

```
<!-- Diagnosis: AMI-->
<act classCode=”ACT” moodCode=”EVN”>
  <!-- Problem Concern Act (V3) -->
  <templateId root="2.16.840.1.113883.10.20.22.4.3" extension="2015-08-01"/>
  <!—Diagnosis Concern Act (V3) -->
  <templateId root="2.16.840.1.113883.10.20.24.3.137” extension=”2017-08-01”/>
    ...
  <entryRelationship typeCode=”SUBJ”>
    <observation classCode="OBS" moodCode="EVN">
    <!--  Problem observation (V3) template -->
      <templateId root="2.16.840.1.113883.10.20.22.4.4" extension="2015-08-
01"/>
      <!-- Diagnosis template -->
      <templateId root="2.16.840.1.113883.10.20.24.3.135" extension=”2017-08-
01”/>
      <id root="2a620155-9d11-439e-92b3-5d9815ff4de8"/>
      <code code="282291009" codeSystem="2.16.840.1.113883.6.96"
        codeSystemName="SNOMED CT"
        displayName="diagnosis"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <!-- Onset Datetime -->
        <low value="20150329090000+0500"/>
      </effectiveTime>
      <value xsi:type="CD" code="410.41"
        codeSystem=" 2.16.840.1.113883.6.103"
        codeSystemName="ICD9"
        displayName="Acute myocardial infarction of other inferior wall,
initial episode of care"
    </observation>
  </entryRelationship>
</act>
```

6.4 QDM-Based QRDA Category I Instance Validation

The dynamic approach to QDM-based QRDA Category I instance generation, coupled with the construction rules, has implications for instance validation. While the typical Schematron-based validation used in many CDA implementation guides will be applicable here (e.g., if an entry asserts a templateId, then validate that the instance conforms to that template), other types of validation are also made possible by the fact that the QRDA references relevant eCQMs.

Types of validation that can be performed on a QDM-based QRDA Category I instance include:

- Test that where a `templateId` is asserted, the instance conforms to that template.
- Test that where a code is referenced, the supplied code is a member of the value sets or a direct referenced code specified by the eCQMs.
    - Data elements for referenced eCQMs may or may not be present. Absence of data elements from referenced eCQMs does not constitute an error. It would be possible for a validation report to issue warnings, showing which of the data elements from referenced eCQMs are not present in the QRDA.

- Test whether the QRDA contains more data than is required by the referenced eCQMs. This type of test might be necessary, for instance, by federal agencies precluded from receiving data above and beyond that which is absolutely required by an eCQM. It would be possible for a validation report to issue warnings, showing that there are templates (or extensions to open templates) present that aren't specifically called for by the referenced eCQMs.

A quality program implementing QRDA may provide prescriptive guidelines that define validation criteria. Where such prescriptive guidelines exist, they take precedence over the more general guidance provided here.

7 REFERENCES

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APPENDIX A — ACRONYMS AND ABBREVIATIONS

AHIMA	American Health Information Management Association
AMA	American Medical Association
BCG	Bacillus Calmette–Guérin
CCD	Continuity of Care Document
C-CDA R1, R1.1, R2, R2.1	Consolidated CDA (Release 1, 1.1, 2, and 2.1)
CCN	CMS Certification Number
CCR	Continuity of Care Record
CDA, CDA R2	Clinical Document Architecture (Release 2)
CDC	Centers for Disease Control and Prevention
CDS	clinical decision support
CFR	Code of Federal Regulations
CHCA	The Child Health Corporation of America
CMS	Centers for Medicare and Medicaid Services
CPT	Current Procedural Terminology
CQL	Clinical Quality Language
CQM	clinical quality measure
CVX	Codes for Vaccine Administered
DI	device identifier
DICOM	Digital Imaging and Communications in Medicine
DRIV	is derived from
DSTU	Draft Standard for Trial Use
ECOG	Eastern Cooperative Oncology Group
eCQM	electronic clinical quality measure
EEG	electroencephalogram
EHR	electronic health record
EMR	electronic medical record
EVN	event
FDA	Food and Drug Administration
FIPS	Federal Information Processing Standards
GOL	goal
HCO	health care organization
HCT/P	Human Cell & Tissue Products

HIBCC	Health Industry Business Communications Council
HIE	health information exchange
HIPAA	Health Insurance Portability and Accountability Act of 1996
HIT	healthcare information technology
HITSP	Health Information Technology Standards Panel
HL7	Health Level Seven
HQMF	Health Quality Measures Format
HTML	Hypertext Markup Language
ICCBBA	International Council for Commonality in Blood Banking Automation, Inc.
ICD	International Classification of Diseases
IG	implementation guide
IHE	Integrating the Healthcare Enterprise
IHTSDO	International Health Terminology Standard Development Organization
IOM	Institute of Medicine
IPOP	Initial Population
LOINC	Logical Observation Identifiers Names and Codes
MAR	Medication Administration Record
MPHO	Medical Products of Human Origin
NA	not applicable
NCQA	National Committee for Quality Assurance
NDC	National Drug Code
NDFRT	National Drug File Reference Terminology
NHIN	Nationwide Health Information Network
NHSN	National Healthcare Safety Network
NI	no information
NLM	National Library of Medicine
NPI	National Provider Identifier
NQF	National Quality Forum
NUBC	National Uniform Billing Committee
NUCC	National Uniform Claim Committee
OID	object identifier
ONC	Office of National Coordinator
OTH	not an element in the value domain

PDF	Portable Document Format
PGP	Pretty Good Privacy
PHIN VADS	Public Health Information Network Vocabulary Access and Distribution System
PHR	personal health record
PI	production identifier
PKCS#7	public-key cryptography standard seven (Cryptographic Message Syntax Standard
PQ	physical quantity
QDM	Quality Data Model
QRDA	Quality Reporting Document Architecture
RFC	Request for Comments
RIM	Reference Information Model
RMIM	Refined Message Information Model
RQO	request
RSNA	Radiological Society of North America
S&I	Standards and Interoperability
sdtc	Structured Documents Technical Committee
SDWG	Structured Documents Working Group
SNOMED CT	Systematized Nomenclature of Medicine, Clinical Terms
SPL	Structured Product Labeling
STU	Standard for Trial Use
UCUM	Unified Code for Units of Measure
UDI	Unique Device Identification
UNII	Unique Ingredient identifier
UNK	unknown
URL	uniform resource locator
URN	uniform resource name
UUID	universally unique identifier
VIS	Vaccine Information Statement
vMR	Virtual Medical Record
VSAC	Value Set Authority Center
XML	Extensible Markup language
XML-DSIG	XML digital signature
XPath	XML Path Language

APPENDIX B — HIGH-LEVEL CHANGE LOG

This implementation guide builds on the *HL7 CDA R2 Implementation Guide: Quality Reporting Document Architecture Category I (QRDA I); Release 1, STU Release 5 - US Realm*, Standard for Trial Use, December 2017.

Volume 1 Summary of Changes

- Chapter 3 Design Considerations
  - Added 3.5 Use of UTC Time Zone Offset in Datetimes
- Appendix E HQMF QDM Datatype to CDA Mapping Tables
  - Updated to reflect the HQMF template ids from the HL7 Version 3 Implementation Guide: Clinical Quality Language (CQL) – based Health Quality Measure Format (HQMF) Release 1 – US Realm, STU 3, August 2018, Volume 3 – QDM Templates for CQL-based HQMF (and its Errata Change List 2018-08-31),[23] and the QRDA template ids in this guide (both guides are based on the QDM Version 5.4).

[23] HL7 CQL-based HQMF IG, STU R3 Volume 3 – QDM Templates for CQL-based HQMF, August 2018 (and its Errata Change List 2018-08-31)
http://www.hl7.org/implement/standards/product_brief.cfm?product_id=405

Volume 2 Summary of Changes

General Changes (not specifically stated in tables below)

1) Aligned with QDM Version 5.4 – published August 2018. Summary of the changes made in QDM Version 5.4 can be found in the Appendix B. Change Log of the QDM Version 5.4 specification.[24]
    a) Removed (retired) QRDA templates where corresponding QDM datatypes or QDM attributes have been removed.
    b) Added QRDA templates where new QDM data types and attributes have been introduced.
    c) Versioned templates and make required modifications to existing QRDA templates.
2) Included approved STU comments (from http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=220) that were considered "New Feature Requests", “Errata Report”, and “Clarification” and are appropriate for inclusion.
    3) Reasons for templates are versioned include:
        a) Where a modification has been made to the template
        b) Where the implied template has been versioned
        c) Where contained templates have been versioned (Versioning a template at the bottom of a hierarchy causes a bubble-up effect and all the way up the tree, each containing template will need to be versioned.)
    4) Where a template has been versioned for this specific STU, a new version number has been suffixed to the name of that template (e.g., Medication Order (V5)), and the extension "2018-10-01" has been added to the template identifier. To reflect the change to the template identifier, a constraint for templateId/extension="2018-10-01" has been added.
    5) Where contained templates have been versioned, references to those templates have been updated.

Summary Tables

For detailed template changes, please reference the Chapter 10. Changes from Previous Version in the Volume 2 of this IG. The tables below describe the high-level changes to the templates.

[24] Quality Data Model, Version 5.4, August 2018. https://ecqi.healthit.gov/qdm-quality-data-model

Table 8: High-Level Change Log

Type of Template	Template	Summary of New Content or Update to Template
Document	QDM-Based QRDA (V6) (urn:hl7ii:2.16.840.1.113883.10.20.24.1.2:2018-10-01)	• Template has been versioned (template was modified, contained template was versioned). • Updated the contained Patient Data Section QDM (V5) to new version (V6).
Section	Patient Data Section QDM (V6) (urn:hl7ii:2.16.840.1.113883.10.20.24.2.1:2018-10-01)	• Template has been versioned (template was modified, implied template was versioned, contained template was versioned). • Added references to the following new template: o Assessment Order o Communication Performed • Removed references to the following templates (the QDM data types were retired in QDM 5.4) o Communication from Patient to Provider o Communication from Provider to Patient o Communication from Provider to Provider o
Entry	Device Applied (V5) (urn:hl7ii: urn:hl7ii:2.16.840.1.113883.10.20.24.3.7.105:2018-10-01)	• Template has been versioned (template was modified). • Removed the anatomicalApproachSite attribute
Entry	Discharge Medication (V4) (urn:hl7ii:2.16.840.1.113883.10.20.24.3.105:2018-10-01)	• Template has been versioned (template was modified). • Added the Days Supplied attribute
Entry	Medication Dispensed (V5) (urn:hl7ii:2.16.840.1.113883.10.20.24.3.45.105:2018-10-01)	• Template has been versioned (template was modified). • Added the daysSupplied attribute • Added the dispensedId attribute • Added the prescriberId attribute

Type of Template	Template	Summary of New Content or Update to Template
Entry	Medication Order (V5) (urn:hl7ii:2.16.840.1.113883.10.20.24.3.47.105:2018-10-01)	• Template has been versioned (template was modified). • Added the daysSupplied attribute • Added the prescriberId attribute • Added the setting attribute • Added the MAY entreyRelationship to a Medication Supply Request template to address errata (commend id 1568)
Entry	Procedure Order (V5) (urn:hl7ii: urn:hl7ii:2.16.840.1.113883.10.20.24.3.63.105:2018-10-01)	• Template has been versioned (template was modified). • Removed the method attribute • Removed the anatomicalApproachSite attribute
Entry	Procedure Order (V5) (urn:hl7ii: urn:hl7ii:2.16.840.1.113883.10.20.24.3.65.105:2018-10-01)	• Template has been versioned (template was modified). • Removed the method attribute • Removed the anatomicalApproachSite attribute
Entry	Procedure Performed (V5) (urn:hl7ii: urn:hl7ii:2.16.840.1.113883.10.20.24.3.64.105:2018-10-01)	• Template has been versioned (template was modified). • Removed the anatomicalApproachSite attribute

Table 9: New Templates

Type of Template	Template	Reason for new template
Entry	Assessment Order (urn:hl7ii:2.16.840.1.113883.10.20.24.3.158:2018-10-01)	New QDM data type in QDM Version 5.4.
Entry	Communication Performed (urn:hl7ii:2.16.840.1.113883.10.20.24.3.156:2018-10-01)	New QDM data type in QDM Version 5.4.
Entry	Days Supplied (urn:hl7ii:2.16.840.1.113883.10.20.24.3.157:2018-10-01)	New QDM attribute in QDM Version 5.4.

Table 10: Retired Templates

Type of Template	Template	Reason for retirement
Entry	Communication from Patient to Provider (V4) (urn:hl7ii:2.16.840.1.113883.10.20.24.3.2:2017-08-01)	The QDM data type was removed in QDM Version 5.4
Entry	Communication from Provider to Patient (V4) (urn:hl7ii:2.16.840.1.113883.10.20.24.3.3:2017-08-01)	The QDM data type was removed in QDM Version 5.3
Entry	Communication from Provider to Provider (V4) (urn:hl7ii:2.16.840.1.113883.10.20.24.3.4:2017-08-01)	The QDM data type was removed in QDM Version 5.3

APPENDIX C — EXTENSIONS TO CDA R2

Where there is a need to communicate information for which there is no suitable representation in CDA R2, extensions to CDA R2 have been developed. These extensions are described above in the context of the section where they are used. This section serves to summarize the extensions and provide implementation guidance.

Extensions created for this guide include:

- `sdtc:raceCode` - The `raceCode` extension allows for multiple races to be reported for a patient.
- `sdtc:id` - The id extension in the family history organizer on the related subject allows for unique identification of the family member(s).
- `sdtc:deceasedInd` - The `deceasedIndextension` (= "true" or "false") in the family history organizer on the related subject is used inside to indicate if a family member is deceased.
- `sdtc:deceasedTime` - The `deceasedTime` extension in the family history organizer on the related subject allows for reporting the date and time a family member died.
- `sdtc:birthTime` - The `sdtc:birthTime` element allows for the birth date of any person to be recorded. The purpose of this extension is to allow the recording of the subscriber or member of a health plan in cases where the health plan eligibility system has different information on file than the provider does for the patient.
- `sdtc:dischargeDispositionCode` - The `sdtc:dischargeDispositionCode` element allows the provider to record a discharge disposition in an encounter activity.
- `sdtc:signatureText` - The `sdtc:signatureText` element provides a location in CDA for a textual or multimedia depiction of the signature by which the participant endorses and accepts responsibility for his or her participation in the Act as specified in the `Participation.typeCode`. Details of what goes in the field are described in the *HL7 Implementation Guide for CDA® Release 2: Digital Signatures and Delegation of Rights, Release 1.*[25]

To resolve issues that need to be addressed by extension, the developers of this guide chose to approach extensions as follows:

- An extension is a collection of element or attribute declarations and rules for their application to the CDA Release 2.0.
- All extensions are optional. An extension may be used, but need not be under this guide.
- A single namespace for all extension elements or attributes that may be used by this guide will be defined.
- The namespace for extensions created by the HL7 Structured Documents Working Group (formerly Structured Documents Technical Committee) shall be urn:hl7-org:sdtc.

[25] *HL7 Digital Signatures.* http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=131

- This namespace shall be used as the namespace for any extension elements or attributes that are defined by this implementation guide.
- Each extension element shall use the same HL7 vocabularies and data types used by CDA Release 2.0.
- Each extension element shall use the same conventions for order and naming as is used by the current HL7 tooling.
- An extension element shall appear in the XML where the expected RIM element of the same name would have appeared had that element not been otherwise constrained from appearing in the CDA XML schema.

APPENDIX D — UNIQUE DEVICE IDENTIFICATION (UDI) ISSUING AGENCY FORMATS

Each issuing agency has its own specified format for representing the two main components of a UDI – the Device Identifier (DI) and Production Identifiers (PI). The device identifier is a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device. The production identifier is the conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device and include: lot or batch within which a device was manufactured; serial number of a specific device; expiration date of a specific device; date a specific device was manufactured; and for an HCT/P regulated as a device, the distinct identification code required by 21 CFR 1271.290(c). The format of each issuing agency's UDI is outlined in the tables below. These issuing agencies maintain responsibility for the uniqueness of their device identifiers.

Table 11: GS1 UDI Format[26]

Issuing Agency	Data Delimiters	Identifier	Data type	Human Readable Field Size	Database Field Size
GS1	(01)	DI	numeric	16	14
GS1	(11)	Manufacturing/ Production Date	numeric [YYMMDD]	8	6
GS1	(17)	Expiration Date	numeric [YYMMDD]	8	6
GS1	(10)	Batch/Lot Number	alphanumeric	22	20
GS1	(21)	Serial Number	alphanumeric	22	20
GS1		**Maximum Base UDI**	**alphanumeric**	**76**	**66**
ex: (01) 51022222233336(11)141231(17)150707(10)A213B1(21)1234					

[26] GS1 website. http://www.gs1.org/

Table 12: Health Industry Business Communications Council (HIBCC) UDI Format[27]

Issuing Agency	Data Delimiters	Identifier	Data Type	Human Readable Field Size	Database Field Size
HIBCC	+	DI	alphanumeric	7 to 24	6 to 23
HIBCC	$	Lot Number Only	alphanumeric	19	18
HIBCC	$$7	Lot Number Only (alternative option)	alphanumeric	21	18
HIBCC	$$	Expiration Date followed by Lot Number	Expiration Date: numeric [MMYY]	6	4
			Lot Number: alphanumeric	18	18
HIBCC	$$2	Expiration Date followed by Lot Number	Expiration Date: numeric [MMDDYY]	9	6
			Lot Number: alphanumeric	18	18
HIBCC	$$3	Expiration Date followed by Lot Number	Expiration Date: numeric [YYMMDD]	9	6
			Lot Number: alphanumeric	18	18
HIBCC	$$4	Expiration Date followed by Lot Number	Expiration Date: numeric [YYMMDDHH]	11	8
			Lot Number: alphanumeric	18	18
HIBCC	$$5	Expiration Date followed by Lot Number	Expiration Date: numeric [YYJJJ] – Julian Date format	8	5
			Lot Number: alphanumeric	18	18
HIBCC	$$6	Expiration Date followed by Lot Number	Expiration Date: numeric [YYJJJHH] – Julian Date format with Hour option	10	7
			Lot Number: alphanumeric	18	18
HIBCC	$+	Serial Number only	alphanumeric	20	18
HIBCC	$$+7	Serial Number only (alternative option)	alphanumeric	22	18
HIBCC	$$+	Expiration Date followed by Serial Number	Expiration Date: numeric [MMYY]	7	4
			Serial Number: alphanumeric	18	18
HIBCC	$$+2	Expiration Date followed by Serial	Expiration Date: numeric [MMDDYY]	10	6

[27] HIBCC website. http://www.hibcc.org/

Issuing Agency	Data Delimiters	Identifier	Data Type	Human Readable Field Size	Database Field Size
		Number	Serial Number: alphanumeric	18	18
HIBCC	$$+3	Expiration Date followed by Serial Number	Expiration Date: numeric [YYMMDD]	10	6
			Serial Number: alphanumeric	18	18
HIBCC	$$+4	Expiration Date followed by Serial Number	Expiration Date: numeric [YYMMDDHH]	12	8
			Serial Number: alphanumeric	18	18
HIBCC	$$+5	Expiration Date followed by Serial Number	Expiration Date: numeric [YYJJJ]	9	5
			Serial Number: alphanumeric	18	18
HIBCC	$$+6	Expiration Date followed by Serial Number	Expiration Date: numeric [YYJJJHH]	11	7
			Serial Number: alphanumeric	18	18
HIBCC	/S	Supplemental Serial Number, where lot number also required and included in main secondary data string	alphanumeric	20	18
HIBCC	/16D	Manufacturing Date (supplemental to secondary barcode)	numeric [YYYYMMDD]	12	8
HIBCC		Maximum Base UDI	alphanumeric	70 to 87	58 to 75
Ex of Human Readable Barcode: +H123PARTNO1234567890120/$$420020216LOT123456789012345/SXYZ456789012345678/16D20130202C					

Table 13: International Council for Commonality in Blood Banking Automation, Inc. (ICCBBA) UDI Format[28]

Issuing Agency	Data Delimiters	Identifier	Data type	Human Readable Barcode Field Size	Database Field Size
ICCBBA	=/	DI	alphanumeric	18	16
ICCBBA	=,	Serial Number	alphanumeric	8	6
ICCBBA	=	Donation Identification Number	alphanumeric	16	15
ICCBBA	=>	Expiration Date	numeric [YYYJJJ]	8	6
ICCBBA	=}	Manufacturing Date	numeric [YYYJJJ]	8	6
ICCBBA	&,1	MPHO Lot Number	alphanumeric	21	18
ICCBBA		**Maximum Base UDI for HCT/Ps**	**alphanumeric**	**79**	**67**
Ex of Human Readable Barcode:=/A9999XYZ100T0944=,000025=A99971312345600=>014032=}013032&,1000000000000XYZ123					

Table 14: ICCBBA UDI Format for Blood Bags Only

Issuing Agency	Identifying Symbol	Identifier	Data type	Eye Readable Barcode Field Size	Database Field Size
ICCBBA	=)	DI for blood containers (bags)	alphanumeric	12	10
ICCBBA	&)	Lot Number for blood containers (bags)	alphanumeric	12	10
ICCBBA		**Maximum Base UDI for Blood Bags**	**alphanumeric**	**24**	**20**
Ex of Human Readable Barcode: =)1TE123456A&)RZ12345678					

[28] ICCBBA website http://iccbba.org/

APPENDIX E — HQMF QDM DATATYPE TO CDA MAPPING TABLES

The HQMF QDM Pattern to CDA Template Mapping Table provides the name of the QDM quality datatype and its HQMF pattern ID and maps it to its corresponding CDA template name and its template ID.

The HQMF QDM Attribute Patterns to CDA Elements in Specific Templates Mapping Table provides the name of the QDM quality datatype and its HQMF pattern ID and maps it to the corresponding CDA element within particular templates using XPath notation.

The HQMF QDM Attribute Patterns to CDA Elements Mapping Table provides the name of the QDM quality datatype and its HQMF pattern ID and maps it to the corresponding CDA element wherever it may be needed using XPath notation.

The HQMF QDM Datatype Patterns Not Mappable table lists those datatypes that cannot be mapped.

The QDM allows for an attribute "Negation Rationale" to be used with Quality Datatype Patterns to assert that the act did not occur or was not observed. Please refer to Asserting an Act Did Not Occur with a Reason for information on how to represent this concept in CDA.

Table 15: HQMF QDM Pattern to CDA Template Mapping Table

Quality Datatype or Attribute Name	Quality Datatype Pattern ID	CDA Template Name	CDA Template ID
Admission Source	urn:hl7ii:2.16.840.1.113883.10.20.28.4.123:2017-05-01	Admission Source	urn:hl7ii:2.16.840.1.113883.10.20.24.3.151:2017-08-01
Adverse Event	urn:hl7ii:2.16.840.1.113883.10.20.28.4.120:2017-08-01	Adverse Event	urn:hl7ii:2.16.840.1.113883.10.20.24.3.146:2017-08-01
Allergy / Intolerance	urn:hl7ii:2.16.840.1.113883.10.20.28.4.119:2017-08-01	Allergy Intolerance	urn:hl7ii:2.16.840.1.113883.10.20.24.3.147:2017-08-01
Assessment Order	urn:hl7ii:2.16.840.1.113883.10.20.28.4.131:2018-05-01	Assessment Order	urn:hl7ii:2.16.840.1.113883.10.20.24.3.158:2018-10-01
Assessment, Performed	urn:hl7ii:2.16.840.1.113883.10.20.28.4.117:2017-08-01	Assessment Performed (V2)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.144:2017-08-01
Assessment, Recommended	urn:hl7ii:2.16.840.1.113883.10.20.28.4.118:2018-05-01	Assessment Recommended (V2)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.145:2017-08-01
Care Goal	urn:hl7ii:2.16.840.1.113883.10.20.28.4.7:2017-08-01	Care Goal (V4)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.1:2017-08-01
Communication Performed	urn:hl7ii:2.16.840.1.113883.10.20.28.4.132:2018-05-01	Communication Performed	urn:hl7ii:2.16.840.1.113883.10.20.24.3.156:2018-10-01
Component (attribute)	Component urn:hl7ii:2.16.840.1.113883.10.20.28.4.121:2017-05-01 Laboratory Test Component urn:hl7ii:2.16.840.1.113883.10.20.28.4.126:2017-05-01	Component	urn:hl7ii:2.16.840.1.113883.10.20.24.3.149:2017-08-01
Days Supplied (attribute)	urn:hl7ii:2.16.840.1.113883.10.20.28.4.133:2018-05-01 (Errata Change List 2018-08-31)	Days Supplied	urn:hl7ii:2.16.840.1.113883.10.20.24.3.157:2018-10-01
Device, Applied	urn:hl7ii:2.16.840.1.113883.10.20.28.4.13:2018-05-01	Device Applied (V5)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.7:2018-10-01
Device, Order	urn:hl7ii:2.16.840.1.113883.10.20.28.4.15:2017-05-01	Device Order Act (V2)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.130:2017-08-01
Device, Recommended	urn:hl7ii:2.16.840.1.113883.10.20.28.4.16:2017-05-01	Device Recommended Act (V2)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.131:2017-08-01
Diagnosis	urn:hl7ii:2.16.840.1.113883.10.20.28.4.110:2017-08-01	Diagnosis Concern Act (V3)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.137:2017-08-01

Quality Datatype or Attribute Name	Quality Datatype Pattern ID	CDA Template Name	CDA Template ID
Diagnostic Study, Order	urn:hl7ii:2.16.840.1.113883.10.20.28.4.22:2018-05-01	Diagnostic Study, Order (V4)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.17:2017-08-01
Diagnostic Study, Performed	urn:hl7ii:2.16.840.1.113883.10.20.28.4.23:2017-08-01	Diagnostic Study Performed (V4)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.18:2017-08-01
Diagnostic Study, Recommended	urn:hl7ii:2.16.840.1.113883.10.20.28.4.24:2018-05-01	Diagnostic Study Recommended (V4)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.19:2017-08-01
Encounter, Order	urn:hl7ii:2.16.840.1.113883.10.20.28.4.27:2017-05-01	Encounter Order Act (V2)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.132:2017-08-01
Encounter, Performed	urn:hl7ii:2.16.840.1.113883.10.20.28.4.5:2017-08-01	Encounter Performed Act (V2)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.133:2017-08-01
Encounter, Recommended	urn:hl7ii:2.16.840.1.113883.10.20.28.4.28:2017-05-01	Encounter Recommended Act (V2)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.134:2017-08-01
Facility Location (attribute)	urn:hl7ii:2.16.840.1.113883.10.20.28.4.92:2017-05-01	Facility Location (V2)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.100:2017-08-01
Family History	urn:hl7ii:2.16.840.1.113883. 0.20.28.4.111:2017-05-01	Family History Organizer QDM (V4)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.12:2017-08-01
Immunization, Administered	urn:hl7ii:2.16.840.1.113883.10.20.28.4.112:2018-05-01	Immunization Administered (V2)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.140:2017-08-01
Immunization, Order	urn:hl7ii:2.16.840.1.113883.10.20.28.4.113:2017-08-01	Immunization, Order (V2)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.143:2017-08-01
Incision dateTime (attribute)	urn:hl7ii:2.16.840.1.113883.10.20.28.4.89:2017-05-01	Incision Datetime	urn:oid:2.16.840.1.113883.10.20.24.3.89
Intervention, Order	urn:hl7ii:2.16.840.1.113883.10.20.28.4.35:2017-05-01	Intervention Order (V4)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.31:2017-08-01
Intervention, Performed	urn:hl7ii:2.16.840.1.113883.10.20.28.4.36:2017-08-01	Intervention Performed (V4)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.32:2017-08-01
Intervention, Recommended	urn:hl7ii:2.16.840.1.113883.10.20.28.4.37:2017-05-01	Intervention Recommended (V4)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.33:2017-08-01
Laboratory Test, Order	urn:hl7ii:2.16.840.1.113883.10.20.28.4.41:2018-05-	Laboratory Test Order (V4)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.37:2017-08-

Quality Datatype or Attribute Name	Quality Datatype Pattern ID	CDA Template Name	CDA Template ID
	01		01
Laboratory Test, Performed	urn:hl7ii:2.16.840.1.113883.10.20.28.4.42:2017-08-01	Laboratory Test Performed (V4)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.38:2017-08-01
Laboratory Test, Recommended	urn:hl7ii:2.16.840.1.113883.10.20.28.4.43:2018-05-01	Laboratory Test Recommended (V4)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.39:2017-08-01
Medication, Active	urn:hl7ii:2.16.840.1.113883.10.20.28.4.44:2018-05-01	Medication Active (V4)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.41:2017-08-01
Medication, Administered	urn:hl7ii:2.16.840.1.113883.10.20.28.4.45:2018-05-01	Medication Administered (V4)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.42:2017-08-01
Medication, Discharge	urn:hl7ii:2.16.840.1.113883.10.20.28.4.48:2017-08-01	Discharge Medication (V4)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.105:2018-10-01
Medication, Dispensed	urn:hl7ii:2.16.840.1.113883.10.20.28.4.49:2017-08-01 (Errata Change List 2018-08-31)	Medication Dispensed (V5)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.45:2018-10-01
Medication, Order	urn:hl7ii:2.16.840.1.113883.10.20.28.4.51:2018-05-01 (Errata Change List 2018-08-31)	Medication Order (V5)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.47:2018-10-01
Patient Care Experience	urn:hl7ii:2.16.840.1.113883.10.20.28.4.52:2017-05-01	Patient Care Experience (V4)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.48:2017-08-01
Patient Characteristic Clinical Trial Participant	urn:hl7ii:2.16.840.1.113883.10.20.28.4.6:2017-05-01	Patient Characteristic Clinical Trial Participant (V4)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.51:2017-08-01
Patient Characteristic Payer	urn:hl7ii:2.16.840.1.113883.10.20.28.4.58:2017-05-01	Patient Characteristic Payer	urn:oid:2.16.840.1.113883.10.20.24.3.55
Physical Exam, Order	urn:hl7ii:2.16.840.1.113883.10.20.28.4.61:2018-05-01	Physical Exam Order (V4)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.58:2017-08-01
Physical Exam, Performed	urn:hl7ii:2.16.840.1.113883.10.20.28.4.62:2017-08-01	Physical Exam Performed (V4)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.59:2017-08-01
Physical Exam, Recommended	urn:hl7ii:2.16.840.1.113883.10.20.28.4.63:2018-05-01	Physical Exam Recommended (V4)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.60:2017-08-01
Principal Diagnosis (attribute)	urn:hl7ii:2.16.840.1.113883.10.20.28.4.122:2017-05-01	Principal Diagnosis	urn:hl7ii:2.16.840.1.113883.10.20.24.3.152:2017-08-01
Procedure, Order	urn:hl7ii:2.16.840.1.113883.10.20.28.4.66:2018-05-	Procedure Order (V5)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.63:2018-10-

Quality Datatype or Attribute Name	Quality Datatype Pattern ID	CDA Template Name	CDA Template ID
	01		01
Procedure, Performed	urn:hl7ii:2.16.840.1.113883.10.20.28.4.67:2018-05-01	Procedure Performed (V5)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.64:2018-10-01
Procedure, Recommended	urn:hl7ii:2.16.840.1.113883.10.20.28.4.68:2018-05-01	Procedure Recommended (V5)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.65:2018-10-01
Program Participation	urn:hl7ii:2.16.840.1.113883.10.20.28.4.130:2017-08-01	Program Participation	urn:hl7ii:2.16.840.1.113883.10.20.24.3.154:2017-08-01
Provider Care Experience	urn:hl7ii:2.16.840.1.113883.10.20.28.4.70:2017-05-01	Provider Care Experience (V4)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.67:2017-08-01
Provider Characteristic	urn:hl7ii:2.16.840.1.113883.10.20.28.4.71:2017-08-01	Provider Characteristic Observation Assertion (V3)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.114:2017-08-01
Reason (attribute)	urn:hl7ii:2.16.840.1.113883.10.20.28.4.88:2017-05-01	Reason (V3)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.88:2017-08-01
Related To (attribute)	urn:hl7ii:2.16.840.1.113883.10.20.28.4.127:2017-08-01	Related To	urn:hl7ii:2.16.840.1.113883.10.20.24.3.150:2017-08-01
Severity (attribute)	urn:hl7ii:2.16.840.1.113883.10.20.28.4.93:2017-08-01	Severity Observation (V2)	urn:hl7ii:2.16.840.1.113883.10.20.22.4.8:2014-06-09
Status (attribute)	urn:hl7ii:2.16.840.1.113883.10.20.28.4.94:2017-08-01	Status	urn:oid:2.16.840.1.113883.10.20.24.3.93
Substance, Administered	urn:hl7ii:2.16.840.1.113883.10.20.28.4.73:2018-05-01	Medication Administered (V4)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.42:2017-08-01
Substance, Order	urn:hl7ii:2.16.840.1.113883.10.20.28.4.77:2018-05-01	Medication Order (V5)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.47:2018-10-01
Substance, Recommended	urn:hl7ii:2.16.840.1.113883.10.20.28.4.78:2018-05-01	Substance Recommended (V4)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.75:2017-08-01
Symptom	urn:hl7ii:2.16.840.1.113883.10.20.28.4.116:2017-08-01	Symptom Concern Act (V3)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.138:2017-08-01
Target Outcome (attribute)	urn:hl7ii:2.16.840.1.113883.10.20.28.4.128:2017-08-01	Target Outcome (V2)	urn:hl7ii:2.16.840.1.113883.10.20.24.3.119:2017-08-01

Table 16: HQMF QDM Attribute Patterns to CDA Elements in Specific Templates Mapping Table

Quality Attribute Name	Quality Datatype Pattern ID	CDA Template Name and CDA Element XPath	CDA Template ID
Active dateTime	N/A	Immunization Order|Medication Order /../substanceAdministration/effectiveTime/low	Immunization Order (V2) urn:hl7ii:2.16.840.1.113883.10.20.24.3.143:2017-08-01 Medication Order (V5) urn:hl7ii:2.16.840.1.113883.10.20.24.3.47:2018-10-01
Prevalence Period (attribute)	N/A	Allergy Intolerance Diagnosis|Symptom /../observation/effectiveTime	Allergy Intolerance urn:hl7ii:2.16.840.1.113883.10.20.24.3.147:2017-08-01 Diagnosis (V2) urn:hl7ii:2.16.840.1.113883.10.20.24.3.135:2017-08-01 Symptom (V2) urn:hl7ii:2.16.840.1.113883.10.20.24.3.136:2017-08-01
Diagnosis (attribute)	urn:hl7ii:2.16.840.1.113883.10.20.28.4.110:2017-08-01	Encounter Diagnosis (V3) urn:hl7ii:2.16.840.1.113883.10.20.22.4.80:2015-08-01 /…/act/entryRelationship/observation/code	Encounter Performed (V4) urn:hl7ii:2.16.840.1.113883.10.20.24.3.23:2017-08-01
Discharge Disposition (attribute)	N/A	Encounter Activity /…/encounter/sdtc:dischargeDispositionCode	Encounter Activity (V3) urn:hl7ii:2.16.840.1.113883.10.20.22.4.49:2015-08-01
Dispenser Id (attribute)	N/A	Medicastion Dispensed (V5) /../author/assignedAuthor/id	Medicastion Dispensed (V5) urn:hl7ii:2.16.840.1.113883.10.20.24.3.45:2018-10-01
Expiration Time (attribute)	N/A	Patient Characteristic Expired /…/observation/effectiveTime/low	Patient Characteristic Expired (V3) urn:hl7ii:2.16.840.1.113883.10.20.24.3.54:2016-02-01
Location Period (attribute)	N/A	Facility Location /…/participant/time/low /…/participant/time/high	Facility Location (V2) urn:hl7ii:2.16.840.1.113883.10.20.24.3.100:2017-08-01

Quality Attribute Name	Quality Datatype Pattern ID	CDA Template Name and CDA Element XPath	CDA Template ID
Prescriber Id (attribute)	N/A	Medication Dispensed (V5) /../participant[@typeCode="PRF"]/particpantRole/id Medication Order (V5) /../author/assignedAuthor/id	Medication Dispensed (V5) urn:hl7ii:2.16.840.1.113883.10.20.24.3.45:2018-10-01 Medication Order (V5) urn:hl7ii:2.16.840.1.113883.10.20.24.3.47:2018-10-01
Principal Diagnosis (attribute)	urn:hl7ii:2.16.840.1.113883.10.20.28.4.122:2017-05-01	Encounter Performed (V4) /…/encounter/entryRelationship/observation/value	Principal Diagnosis urn:hl7ii:2.16.840.1.113883.10.20.24.3.152:2017-08-01
Reference Range High (attribute)	urn:hl7ii:2.16.840.1.113883.10.20.28.4.124:2017-05-01	Laboratory Test Performed /../observation[@templateId="2.16.840.1.113883.10.20.22.4.2"][@extension="2015-08-01"]/referenceRange/value	Laboratory Test Performed (V4) urn:hl7ii:2.16.840.1.113883.10.20.24.3.38:2017-08-01 Result Observation urn:hl7ii:2.16.840.1.113883.10.20.22.4.2:2015-08-01
Reference Range Low (attribute)	urn:hl7ii:2.16.840.1.113883.10.20.28.4.124:2017-05-01	Laboratory Test Performed /…/observation[@templateId="2.16.840.1.113883.10.20.22.4.2"][@extension="2015-08-01"]/referenceRange/value	Laboratory Test Performed (V4) urn:hl7ii:2.16.840.1.113883.10.20.24.3.38:2017-08-01 Result Observation urn:hl7ii:2.16.840.1.113883.10.20.22.4.2:2015-08-01
Relationships (attribute)	N/A	Family History /…/organizer/subject/relatedSubject/code	urn:hl7ii:2.16.840.1.113883.10.20.22.4.45:2015-08-01
Result (attribute)	N/A	Assessment Performed Physical Exam Performed /../observation/value	Assessment Performed (V2) urn:hl7ii:2.16.840.1.113883.10.20.24.3.144:2017-08-01 Physical Exam Performed (V4) urn:hl7ii:2.16.840.1.113883.10.20.24.3.59:2017-08-01 Procedure Activity Observation (V2) urn:hl7ii:2.16.840.1.113883.10.20.22.4.13:2014-06-09

Quality Attribute Name	Quality Datatype Pattern ID	CDA Template Name and CDA Element XPath	CDA Template ID
Result (attribute)	N/A	Intervention Performed|Procedure Performed| /../observation[@templateId="2.16.840.1.113883.10.20.22.4.2"][@extension="2015-08-01"]/value	Result Observation (V3) urn:hl7ii:2.16.840.1.113883.10.20.22.4.2:2015-08-01
Result (attribute) Result dateTime (attribute)	N/A	Laboratory Test Performed|Diagnostic Study Performed /../observation/value /../observation/effectiveTime	Result Observation (V3) urn:hl7ii:2.16.840.1.113883.10.20.22.4.2:2015-08-01
Setting (attribute)	N/A	Medication Order /../participant[@typeCode="LOC"] /particpantRole/code	Medication Order (V5) urn:hl7ii:2.16.840.1.113883.10.20.24.3.47:2018-10-01

Table 17: HQMF QDM Attribute Patterns to CDA Elements Mapping Table

Quality Attribute Name	Quality Datatype Pattern ID	CDA Element XPath
Relevant Period (attribute)	N/A	/…/**effectiveTime**
Anatomical Location Site (attribute)	N/A	targetSiteCode. /…/[observation|procedure]/**targetSiteCode**
Dosage (attribute)	N/A	substanceAdministration/doseQuantity. /…/substanceAdministration/**doseQuantity**
Frequency (attribute)	N/A	substanceAdministration/effectiveTime. /…/substanceAdministration/**effectiveTime/period**
Method (attribute)	N/A	methodCode. /…/[observation|procedure]/**methodCode**
Ordinality (attribute)	N/A	priorityCode. /…/[observation|procedure|act]/**priorityCode**
Patient Characteristic Birthdate	urn:hl7ii:2.16.840.1.113883.10.20.28.4.54:2017-05-01	/ClinicalDocument/recordTarget/patientRole/patient/**birthTime**
Patient Characteristic Ethnicity	urn:hl7ii:2.16.840.1.113883.10.20.28.4.56:2017-05-01	/ClinicalDocument/recordTarget/patientRole/patient/**ethnicGroupCode**
Patient Characteristic Sex	urn:hl7ii:2.16.840.1.113883.10.20.28.4.55:2017-05-01	/ClinicalDocument/recordTarget/patientRole/patient/**administrativeGenderCode**
Patient Characteristic	urn:hl7ii:2.16.840.1.113883.10.2	/ClinicalDocument/recordTarget/patientRole/patient/**raceCode**

Quality Attribute Name	Quality Datatype Pattern ID	CDA Element XPath
Race	0.28.4.59:2017-05-01	
Refills (attribute)	N/A	repeatNumber. /…/[substanceAdministration|supply]/**repeatNumber**
Route (attribute)	N/A	routeCode. /…/substanceAdministration/**routeCode**
Author dateTime (attribute)	N/A	/…/author/time
Negation Rationale	N/A	/…/@negationInd

Table 18: HQMF QDM Datatype Patterns Not Mappable

Quality Attribute Name	Quality Datatype Pattern ID	Comment
Patient Characteristic	urn: hl7ii:2.16.840.1.113883.10.20.28.4.53:2017-08-01	A generic patient characteristic is not mappable See specific Patient Characteristic concepts in the tables above.
Provider Characteristic	urn:hl7ii:2.16.840.1.113883.10.20.28.4.71:2017-08-01	A generic provider characteristic is not mappable