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1. Introduction

This guide is a CMS Eligible Professional Quality Reporting Document Architecture Category I (QRDA-I) supplementary implementation guide to the *HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture, Category I, DSTU Release 2, (US Realm), Draft Standard for Trial Use - July 2012*, with errata updates included to make it current to December 21, 2012 (referred to as *QRDA-I Implementation Guide* in this guide). This guide describes additional conformance statements and constraints for Electronic Health Record (EHR) data submissions that are required for reporting information to the Centers for Medicare and Medicaid Services (CMS) EHR Incentive Program 2014 Reporting Year.

The purpose of this supplemental guide is to serve as a companion to the original *QRDA-I Implementation Guide* for entities such as Eligible Professional (EP), Group Practice Reporting Option (GPRO), Accountable Care Organizations (ACO), and Data Submission Vendors (DSV) to submit QRDA-I data for consumption by CMS systems including the Physician Quality Reporting System (PQRS).

2. Conformance Conventions Used in This Guide

2.1 Conformance Verbs (Keywords)

The keywords **SHALL**, **SHOULD**, **MAY**, **NEED NOT**, **SHOULD NOT**, and **SHALL NOT** in this guide are to be interpreted as follows:

- **SHALL**: an absolute requirement for the particular element. Where a **SHALL** constraint is applied to an Extensible Markup Language (XML) element, that element must be present in an instance, but may have an exceptional value (i.e., may have a `nullFlavor`), unless explicitly precluded. Where a **SHALL** constraint is applied to an XML attribute, that attribute must be present, and must contain a conformant value.
- **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.
- **MAY/NEED NOT**: truly optional; can be included or omitted as the author decides with no implications.

2.2 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

2.3 Null Flavor

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. In HL7, a flavor of null, or `nullFlavor`, describes the reason for missing data.

Examples of `nullFlavor` for `raceCode`

```
<raceCode nullFlavor="ASKU" />
<!--coding a raceCode when the patient declined to specify his/her
race-->

<raceCode nullFlavor="UNK" />
<!--coding a raceCode when the patient's race is unknown-->
```

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 and will not be assigned a standard coded value. An example is the name or identifier of a clinical trial.

This above list contains those null flavors that are commonly used in clinical documents. For the full list and descriptions, see the `nullFlavor` vocabulary domain in the in the HL7 standard, *Clinical Document Architecture, Release 2.0*.

Any **SHALL** conformance statement may use `nullFlavor`, unless the attribute is required or the `nullFlavor` is explicitly disallowed. **SHOULD** and **MAY** conformance statements may also use `nullFlavor`.

3. Overview

CMS will process Clinical Quality Measure (CQM) QRDA-I documents originating from EHR systems. Submitted QRDA-I documents for EHR Incentive Program 2014 must meet the conformance statements specified in this guide in addition to the conformance statements specified in the *QRDA-I Implementation Guide*. Only documents that are valid against the Clinical Document Architecture (CDA) Release 2 schema enhanced to support the sdtc namespace (CDA_SDTC.xsd) will be accepted for processing. Documents that are invalid against this rule will be rejected.

This guide is based on following rules:

1. The *QRDA-I Implementation Guide* provides information about QRDA data elements with conformance numbers and constraints. Some of these existing conformance restrictions have been modified in accordance with CMS system requirements. In such cases, the existing conformance number will have a "_Pxx" appended to it (e.g., CONF:12345 becomes CONF:12345_P01). When a new conformance number has been defined, it contains the prefix "DECC" to the conformance number as in "DECC_Pxxxx".
2. The original **SHALL/SHOULD/MAY** keywords along with conformance numbers from the *QRDA-I Implementation Guide* for relevant data elements and attributes have been included in this guide for ease of reference. For brevity, the hierarchy of enclosing elements has not been shown.
3. In some cases, a constraint on a data element has been made more restrictive (e.g., a '**SHOULD**' has been changed to a '**SHALL**'). This potentially impacts all the data elements above it in the hierarchy. These higher-level changes have not been shown in this guide and must be inferred from the identified change.

4. QRDA Category I Requirements

4.1 QRDA Category I Group Practice and Individual Provider Reporting

A QRDA-I document should be submitted for each patient who meets the Initial Patient Population criteria of an eCQM. The QRDA-I base standard allows either one or multiple measures to be reported in a QRDA-I document. For group practice reporting, CMS requires only one QRDA-I report to be submitted per patient aggregated for the group's Tax Identification Number (TIN) for a reporting period. For individual provider reporting, there should be one QRDA-I report per patient for the eligible professional's unique National Provider Identification (NPI) and Tax Identification Number (TIN) combination.

4.2 Succession Management

This section describes the succession management for QRDA-I. (For example, a submitter notices an error in the submission and wants to replace it with a corrected version.) The document that replaces a previous document will have a replacement relationship and will have a new unique QRDA-I document/id. The document/id of the previous QRDA-I will be referenced in the current document's /ClinicalDocument/relatedDocument/parentDocument/id.

Currently, references to the 'id' of a parentDocument are not consistently used. A more reliable means of determining the current version of a QRDA-I document is used by the receiving system at CMS. For group practice reporting, it is the submission timestamp, the EHR Patient ID, and the TIN number combination. For individual provider reporting, it is the submission timestamp, the EHR Patient ID, and the combination of NPI and TIN.

4.3 Value Sets

There are some cases where the value sets specified in electronic Clinical Quality Measures (eCQMs) contradict the value sets specified in the QRDA-I standard. In these cases, the value sets that are specified in eCQMs take precedence. For example, the Tobacco Use (2.16.840.1.113883.10.20.22.4.85) QRDA-I template requires "Tobacco Use (2.16.840.1.113883.11.20.9.41)" value set, but an eCQM criterion uses "Tobacco User Grouping Value Set (2.16.840.1.113883.3.526.3.1170)", the "Tobacco User Grouping Value Set (2.16.840.1.113883.3.526.3.1170)" shall take precedence over the "Tobacco Use (2.16.840.1.113883.11.20.9.41)" value set in constructing a QRDA-I document. This precedence rule also applies to cases where a value set specified in an eCQM is a subset of the value set that is specified in the QRDA-I standard.

5. QRDA Category I Validation

The CMS QRDA-I documents are identified based on the root element ClinicalDocument[templateId/@root='2.16.840.1.113883.10.20.24.1.3'] being present in the QRDA file. This chapter describes:

- Document Templates: This section defines the top-level structure of the document as well as the header constraints that apply to QRDA-I documents.
- Section-Level Templates: This section defines the section templates, which are defined in the QRDA-I document.
- Entry-Level Templates: This section defines the entry templates in the QRDA-I document.

5.1 Document Templates

This section defines the document-level templates in a QRDA-I document. All of the templates in the *QRDA-I Implementation Guide* are Clinical Document Architecture (CDA) templates.

5.1.1 General Header

This template describes header constraints that apply to the CMS Quality Reporting Document Architecture (QRDA) Category I document.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Clinical Document Template Id: /ClinicalDocument/templateId/	@root	1..1	SHALL	DECC_P0039 DECC_P0001	2.16.840.1.1 13883.10.20 .24.1.3
Globally Unique Identifier (GUID): /ClinicalDocument/id/	@root	1..1	SHALL	5363 9991	n/a
Version Number: /ClinicalDocument/	version Number	0..1	MAY	5264 6387	n/a
Document Created Date: /ClinicalDocument/effectiveTime/	@value	1..1	SHALL	5256 16865	n/a
CMS EHR Certification ID: /ClinicalDocument/participant/associatedEntity/id [@root='2.16.840.1.113883.3.2074.1']/	@extension	0..1	MAY	10003_P01 DECC_P0040 DECC_P0003 DECC_P0004	n/a

1. Conforms to QDM-Based QRDA template (2.16.840.1.113883.10.20.24.1.2).
2. **SHALL** contain exactly one [1..1] templateId (CONF:DECC_P0039) such that it
 - a. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.24.1.3" (CONF:DECC_P0001).
3. **SHALL** contain exactly one [1..1] id (CONF:5363).

- a. This id **SHALL** be a globally unique identifier for the document (CONF:9991).
- 4. **MAY** contain zero or one [0..1] **versionNumber** (CONF:5264).
 - a. If versionNumber is present setId **SHALL** be present (CONF:6387).
- 5. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:5256).
 - a. The content **SHALL** be a conformant US Realm Date and Time (DTM.US.FIELDED) (2.16.840.1.113883.10.20.22.5.4) (CONF:16865).
- 6. **MAY** contain zero or more [0..*] **participant** (CONF:10003_P01) such that it
 - a. **SHALL** contain exactly one [1..1] **associatedEntity** (CONF:DECC_P0040)
 - b. This **associatedEntity** **MAY** contain zero or one [0..1] **id** (CONF:DECC_P0003) such that it
 - i. **SHALL** contain exactly one [1..1]
 $\text{@root} = '2.16.840.1.113883.3.2074.1'$ CMS EHR Certification Number (formerly known as Office of the National Coordinator Certification Number) and the value of **@extension** is the Certification Number (CONF: DECC_P0004).

5.1.2 Record Target

The **recordTarget** records the patient whose health information is described by the clinical document; it must contain at least one **patientRole** element.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
First Name: /ClinicalDocument/recordTarget/patientRole/patient/name/	given	1..1	SHALL	5283 5284 10411 7157 _P01	n/a
Last Name: /ClinicalDocument/recordTarget/patientRole/patient/name/	family	1..1	SHALL	5284 10411 7159	n/a
Birth Date: /ClinicalDocument/recordTarget/patientRole/patient/birthTime/	@value	1..1	SHALL	5298 5300 _P01	n/a
Ethnicity: /ClinicalDocument/recordTarget/patientRole/patient/ethnicGroupCode/	@code	1..1	SHALL	5323 _P01	2.16.840.1.1142 22.4.11.837 (Ethnicity Value Set)
Race: /ClinicalDocument/recordTarget/patientRole/patient/raceCode/	@code	1..1	SHALL	5322 _P01	2.16.840.1.1142 22.4.11.836 (Race Value Set)
Race (if multiple race): /ClinicalDocument/recordTarget/patientRole/patient/sdtc:raceCode/	@code	0..*	MAY	7263_P01	2.16.840.1.1142 22.4.11.836 (Race Value Set)

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Gender: /ClinicalDocument/record Target/patientRole/patient/ administrativeGenderCode/	@code	1..1	SHALL	6394_P 01	2.16.840.1.1137 62.1.4.1 (ONC Administrative Sex Value Set) or 2.16.840.1.1138 83.1.11.1 (Administrative Gender Value Set)
Medicare HIC Number: /ClinicalDocument/record Target/patientRole/id[@root= '2.16.840.1.113883.4.572']/	@extension	0..1	SHOULD	16858	n/a
EHR Patient ID Root (Medical Record Number Root): /ClinicalDocument/record Target/patientRole/id/	@root	1..1	SHALL	DECC _P0002	n/a
EHR Patient ID Extension (Medical Record Number Extension): /ClinicalDocument/record Target/patientRole/id/	@extension	1..1	SHALL	DECC _P0002	n/a
Address: /ClinicalDocument/record Target/patientRole/addr/	street Address Line	1..4	SHALL	5271 10412 7291	n/a
City: /ClinicalDocument/record Target/patientRole/addr/	city	1..1	SHALL	7292 10412	n/a
State: /ClinicalDocument/record Target/patientRole/addr/	state	0..1	SHOULD	7293 10024	2.16.840.1.1138 83.3.88.12.80.1 (State Value Set)
Patient Postal Code: /ClinicalDocument/record Target/patientRole/addr/	postalCode	0..1	SHOULD	5271 7294_P 01 10025	n/a
Country: /ClinicalDocument/record Target/patientRole/addr/	country	0..1	SHOULD	7295_P 01	n/a

1. SHALL contain exactly one [1..1] recordTarget (CONF:12913).
 - a. This recordTarget SHALL contain exactly one [1..1] patientRole (CONF:16856).
 - i. This patientRole SHALL contain exactly one [1..1] id (CONF:16857) such that it

1. **SHOULD** contain zero or one [0..1] @root='2.16.840.1.113883.4.572' Medicare HIC number¹) (CONF:16858)
 - ii. This patientRole **SHALL** contain exactly one [1..1] id such that it
 1. **SHALL** contain exactly one [1..1] Medical Record Number (CONF:DECC_P0002)
 - iii. This patientRole **SHALL** contain at least one [1..*] addr (CONF:5271).
 1. The content of addr **SHALL** be a conformant US Realm Address (AD.US.FIELDED) (2.16.840.1.113883.10.20.22.5.2) (CONF:10412).
 - a. The content of addr **SHALL** contain exactly one [1..1] city (CONF:7292).
 - b. **SHOULD** contain zero or one [0..1] state (ValueSet: StateValueSet 2.16.840.1.113883.3.88.12.80.1 DYNAMIC) (CONF:7293).
 - i. State is required if the country is US. If country is not specified, it is assumed to be the US. If country is something other than US, the state **MAY** be present but **MAY** be bound to different vocabularies (CONF:10024).
 - c. **SHOULD** contain zero or one [0..1] postalCode (CONF:7294_P01).
 - i. PostalCode is required if the country is US. If country is not specified, it is assumed to be the US. If country is something other than US, the postalCode **MAY** be present but **MAY** be bound to different vocabularies (CONF:10025).
 - d. **SHOULD** contain zero or one [0..1] country (CONF:7295_P01).
 - e. contain at least one and not more than 4 streetAddressLine (CONF:7291).
 2. This patientRole **SHALL** contain exactly one [1..1] patient (CONF:5283).
 - a. This patient **SHALL** contain exactly one [1..1] name (CONF:5284).
 - i. The content of name **SHALL** be a conformant US Realm Patient Name (PTN.US.FIELDED) (2.16.840.1.113883.10.20.22.5.1) (CONF:10411).
 1. **SHALL** contain exactly one [1..1] given (CONF:7157_P01).
 2. **SHALL** contain exactly one [1..1] family (CONF:7159).
 - b. This patient **SHALL** contain exactly one [1..1] administrativeGenderCode, which **SHALL** be selected from either ValueSet ONC Administrative Sex 2.16.840.1.113762.1.4.1 or ValueSet Administrative Gender (HL7 V3) 2.16.840.1.113883.1.11.1 DYNAMIC (CONF:6394_P01).
 - c. This patient **SHALL** contain exactly one [1..1] birthTime (CONF:5298).
 - i. **SHALL** be precise to day (CONF:5300_P01).
 - d. This patient **SHALL** contain exactly one [1..1] raceCode, which **SHALL** be selected from ValueSet Race 2.16.840.1.114222.4.11.836 DYNAMIC (CONF:5322_P01).
 - e. This patient **MAY** contain zero or more [0..*] sdtc:raceCode, where the @code **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.836 DYNAMIC (CONF:7263_P01).

¹ See Appendix 7.3 for Medicare HIC number validation rule.

- f. This patient **SHALL** contain exactly one [1..1] **ethnicGroupCode**, which **SHALL** be selected from ValueSet **Ethnicity Value 2.16.840.1.114222.4.11.837 DYNAMIC (CONF:5323_P01)**.

5.1.3 documentationOf/serviceEvent

A serviceEvent represents the main act, such as a colonoscopy or a cardiac stress study, being documented.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
National Provider Identification (NPI) Number: /ClinicalDocument[templateId/@root='2.16.840.1.113883.10.20.24.1.2']/documentationOf/serviceEvent[@classCode="PCPR"]/performer[@typeCode="PRF"]/assignedEntity/id[@root='2.16.840.1.113883.4.6']/	@extension	1..1	SHALL	16857 16588 _P01	n/a
Tax Identification Number (TIN): /ClinicalDocument[templateId/@root='2.16.840.1.113883.10.20.24.1.2']/documentationOf/serviceEvent[@classCode="PCPR"]/performer[@typeCode="PRF"]/assignedEntity/representedOrganization/id[@root='2.16.840.1.113883.4.2']/	@extension	1..1	SHALL	16591 16592 _P01 16593 16594	n/a
Provider Given Name: /ClinicalDocument[templateId/@root='2.16.840.1.113883.10.20.24.1.2']/documentationOf/serviceEvent[@classCode="PCPR"]/performer[@typeCode="PRF"]/assignedEntity/assignedPerson/name/	given	0..1	MAY	DECC _P0036 DECC _P0037	n/a
Provider Family Name: /ClinicalDocument[templateId/@root='2.16.840.1.113883.10.20.24.1.2']/documentationOf/serviceEvent[@classCode="PCPR"]/performer[@typeCode="PRF"]/assignedEntity/assignedPerson/name/	family	0..1	MAY	DECC _P0036 DECC _P0037	n/a
Clinic Name: /ClinicalDocument[templateId/@root='2.16.840.1.113883.10.20.24.1.2']/documentationOf/serviceEvent[@classCode="PCPR"]/performer[@typeCode="PRF"]/assignedEntity/representedOrganization/name/	name	0..1	MAY	DECC _P0038	n/a

1. **SHALL** contain exactly one [1..1] **documentationOf** (CONF:16579_P01) such that it
 - a. **SHALL** contain exactly one [1..1] **serviceEvent** (CONF:16580).
 - i. This serviceEvent **SHALL** contain exactly one [1..1] **@classCode="PCPR"** Care Provision (CONF:16581).

- ii. This serviceEvent **SHALL** contain at least one [1..*] **performer** (CONF:16583).
 - 1. Such performers **SHALL** contain exactly one [1..1] **@typeCode="PRF"** Performer (CONF:16584).
 - 2. Such performers **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:16586).

This assignedEntity id/@root='2.16.840.1.113883.4.6' coupled with the id/@extension represents the individual provider's National Provider Identification number (NPI).

NPI is required except for the Group Practice Reporting Option (GPRO). For GPRO, id/@root='2.16.840.1.113883.4.6' is coupled with @nullFlavor="NA", and @extension shall be omitted.

- 3. This assignedEntity **SHALL** contain exactly one [1..1] **id** (CONF:16587) such that it
 - a. **SHALL** contain exactly one [1..1] **@root='2.16.840.1.113883.4.6'** National Provider ID (CONF:16588_P01).
- 4. This assignedEntity **MAY** contain zero or one [0..1] **assignedPerson** (DECC_P0036)
 - a. This assignedPerson **MAY** contain zero or one [0..1] **name** (DECC_P0037)

This representedOrganization id/@root='2.16.840.1.113883.4.2' coupled with the id/@extension represents the organization's Tax Identification Number (TIN).

- 5. This assignedEntity **SHALL** contain exactly one [1..1] **representedOrganization** (CONF:16591).
 - a. This representedOrganization **SHALL** contain exactly one [1..1] **id** (CONF:16592_P01) such that it
 - i. **SHALL** contain exactly one [1..1] **@root='2.16.840.1.113883.4.2'** Tax ID Number (CONF:16593).
 - ii. **SHALL** contain exactly one [1..1] **@extension** (CONF:16594).
 - b. This representedOrganization **MAY** contain zero or one [0..1] **name** (DECC_P0038)

5.1.4 informationRecipient

The informationRecipient element records the intended recipient of the information at the time the document is created.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
CMS Program Name: /ClinicalDocument/information Recipient/intendedRecipient/id[root= '2.16.840.1.113883.3.249.7']/	@extension	1..1	SHALL	16703_P01 16704 16705_P01 DECC_P0010 DECC_P0009	n/a

1. **SHALL** contain exactly one [1..1] **informationRecipient** (CONF:16703_P01).
 - a. The informationRecipient, if present, **SHALL** contain exactly one [1..1] **intendedRecipient** (CONF:16704).

- b. This intendedRecipient **SHALL** contain exactly one [1..1] **id** (CONF:16705_P01)
 - i. It **SHALL** contain exactly one [1..1] **@root='2.16.840.1.113883.3.249.7'** (CONF:DECC_P0010)
- c. It **SHALL** contain exactly one [1..1] **@extension**, the value of **@extension** is CMS Program Name (CONF:DECC_P0009).

CMS Program Name	Description
PQRS_MU_INDIVIDUAL	PQRS Meaningful Use Individual
PQRS_MU_GROUP	PQRS Meaningful Use Group
PIONEER_ACO	Pioneer ACO

5.2 Section Level

5.2.1 Measure Section

This section contains information about the eMeasure or eMeasures being reported. (An eMeasure is called an "eCQM" in the Meaningful Use program.) It must contain entries with the identifiers of all the eMeasures so that corresponding QRDA Quality Data Model (QDM) data element entry templates to be instantiated in the Patient Data Section are identified. Each eMeasure for which QRDA QDM data elements are being sent must reference the eMeasures **act/id** (eMeasure version specific identifier). Other eMeasure identifiers that could be referenced are the eMeasure Identifier (Measure Authoring Tool), eMeasure Version Number, eMeasure Title, and the National Quality Forum (NQF) Number.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Measure Version specific identifier: <code>//section[templateId/@root='2.16.840.1.113883.10.20.24.2.3']/entry/organizer[templateId/@root='2.16.840.1.113883.10.20.24.3.97']/reference[@typeCode="REFR"]/externalDocument[@classCode="DOC"][@moodCode="EVN"]/id/</code>	@root	1..1	SHALL	12808 12809 12810 12811 12812 12813	n/a

1. **SHALL** contain exactly one [1..1] **reference** (CONF:12808) such that it
 - a. **SHALL** contain exactly one [1..1] **@typeCode="REFR"** refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:12809).
 - b. **SHALL** contain exactly one [1..1] **externalDocument="DOC"** Document (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:12810).
 - i. This externalDocument **SHALL** contain exactly one [1..1] **id** (CONF:12811) such that it
 1. **SHALL** contain exactly one [1..1] **@root** (CONF:12812).
 - a. This ID **SHALL** equal the version specific identifier for eMeasure (i.e., QualityMeasureDocument/id) (CONF:12813).

5.2.2 Reporting Parameter 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.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Reporting Period Effective Start Date: //act[templateId/@root='2.16.840.1.113883.1.20.17.3.8']/effectiveTime/low/	@value	1..1	SHALL	3273 3274	n/a
Reporting Period Effective End Date: //act[templateId/@root='2.16.840.1.113883.1.20.17.3.8']/effectiveTime/high/	@value	1..1	SHALL	3273 3275	n/a

1. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:3273).
 - a. This effectiveTime **SHALL** contain exactly one [1..1] **low** (CONF:3274).
 - b. This effectiveTime **SHALL** contain exactly one [1..1] **high** (CONF:3275).

5.2.3 Patient Data Section

The Patient Data Section QDM contains entries that conform to the QDM approach to QRDA.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
QDM-based QRDA Entries: //section[templateId/@root='2.16.840.1.113883.10.20.24.2.1']/	entry	1..*	SHALL	12833_P01 16573	n/a

1. **SHALL** contain at least one [1..*] **entry** (CONF:12833_P01)
 - a. Where the clinical statement codes **SHALL** contain the @sdtc:valueSet extension to reference the value set from which the supplied code was drawn (CONF:16573).
Note: For PQRS program, validation for the generic constraint CONF:16573 is applied at an individual data element constraint level where applicable.

5.3 Entry Level

This section defines the entry templates in a QDM approach to a QRDA-I document.

5.3.1 Communication

5.3.1.1 Communication: From Patient to Provider

This template represents a communication initiated by the patient and received by the provider.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Communication Code: //act[templateId/@root='2.16.840.1.1 13883.10.20.24.3.2']/	code	1..1	SHALL	DECC_P0007	n/a
Communication Status Code: //act[templateId/@root='2.16.840.1.1 13883.10.20.24.3.2']/statusCode/	@code	1..1	SHALL	11620	2.16.840.1.11 3883.5.14 (ActStatus) = completed
Communication Effective Date Time: //act[templateId/@root='2.16.840.1.1 13883.10.20.24.3.2']/	effectiveTime	1..1	SHALL	11622	n/a

1. **SHALL** contain exactly one [1..1] **code** (CONF:DECC_P0007).
2. **SHALL** contain exactly one [1..1] **statusCode= "completed"**, which **SHALL** be selected from CodeSystem ActStatus (2.16.840.1.113883.5.14) **STATIC** (CONF:11620).
3. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:11622).

5.3.1.2 Communication: From Provider to Provider

This template represents the provision of any communication from one clinician to another regarding findings, assessments, plans of care, consultative advice, instructions, educational resources, etc.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Communication Code: //act[templateId/@root='2.16.840.1.113 883.10.20.24.3.4']/	code	1..1	SHALL	DECC_P0008	n/a
Communication Status Code: //act[templateId/@root='2.16.840.1.113 883.10.20.24.3.4']/statusCode/	@code	1..1	SHALL	11822	2.16.840.1.1 13883.5.14 (ActStatus) = completed
Communication Effective Date Time: //act[templateId/@root='2.16.840.1.113 883.10.20.24.3.4']/	effectiveTime	1..1	SHALL	11823	n/a

1. **SHALL** contain exactly one [1..1] **code** (CONF:DECC_P0008).
2. **SHALL** contain exactly one [1..1] **statusCode= "completed"** (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:11822).
3. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:11823).

5.3.1.2.1 Communication: From Provider to Provider Not Done (Negation)

This template indicates a Communications from Provider to Provider that was not performed. This information is collected only when `negationInd="true"`.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Negation Reason Code: <code>//act[templateId/@root='2.16.840.1.113883.10.20.24.3.4']/entryRelationship[@typeCode="RSON"]/observation[templateId/@root='2.16.840.1.113883.10.20.24.3.88']/</code>	<code>value[xsi:type="CD"]</code>	1..1	SHALL	DECC_P0012 DECC_P0013 11367	n/a

1. **SHALL** contain exactly one [1..1] **entryRelationship** (CONF:DECC_P0012) such that it
 - a. **SHALL** contain exactly one [1..1] **Reason** (`templateId:2.16.840.1.113883.10.20.24.3.88`) (CONF:DECC_P0013).
2. **SHALL** contain exactly one [1..1] **value** with `@xsi:type="CD"` (CONF:11367).

5.3.1.3 Communication: From Provider to Patient

This template represents the provision of any communication to the patient (e.g., results, findings, plans for care, medical advice, instructions, educational resources, appointments, result).

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Communication Code: <code>//act[templateId/@root='2.16.840.1.113883.10.20.24.3.3']/</code>	<code>code</code>	1..1	SHALL	DECC_P0005	n/a
Communication Status Code: <code>//act[templateId/@root='2.16.840.1.113883.10.20.24.3.3']/StatusCode/</code>	<code>@code</code>	1..1	SHALL	11846	2.16.840.1.113883.5.14 (ActStatus) = completed
Communication Effective Date Time: <code>//act[templateId/@root='2.16.840.1.113883.10.20.24.3.3']/</code>	<code>effectiveTime</code>	1..1	SHALL	11847	n/a

1. **SHALL** contain exactly one [1..1] **code** (CONF:DECC_P0005).
2. **SHALL** contain exactly one [1..1] **statusCode= "completed"** (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:11846).
3. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:11847).

5.3.2 Device

5.3.2.1 Device Applied

This template indicates that equipment designed to treat, monitor, or diagnose a patient's status is in use.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Device Applied Code: //procedure[templateId/@root='2.16.8 40.1.113883.10.20.24.3.7']/participant/participantRole/playingDevice[@classCode="DEV"]/	code	1..1	SHALL	12402	n/a
Device Applied Status Code: //procedure[templateId/@root='2.16.8 40.1.113883.10.20.24.3.7']/statusCode/	@code	1..1	SHALL	12394	2.16.840.1.13883.5.14 (ActStatus) = completed
Device Applied Effective Date Time: //procedure[templateId/@root='2.16.8 40.1.113883.10.20.24.3.7']	effectiveTime	1..1	SHALL	12395	n/a

1. This playingDevice **SHALL** contain exactly one [1..1] **code** (CONF:12402).
2. **SHALL** contain exactly one [1..1] **statusCode** = "completed", which **SHALL** be selected from CodeSystem ActStatus (2.16.840.1.113883.5.14) **STATIC** (CONF:12394).
3. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:12395).

5.3.3 Diagnosis

5.3.3.1 Diagnosis Active

An active diagnosis is a problem, diagnosis, or condition that is currently monitored, tracked, or is a factor that must be considered as part of the treatment plan in progress.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Diagnosis Code: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.11']/	value[@xsi:type="CD"]	1..1	SHALL	12008	n/a

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Diagnosis Active Status Code: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.11']/entryRelationship/observation[templateId/@root='2.16.840.1.113883.10.20.24.3.94']/value[@xsi:type="CD"]/	@code	1..1	SHALL	11975 11979 12253 12207 12214	2.16.840.1.13883.6.96 (SNOMED-CT) = 55561003
Diagnosis Active Effective Start Date Time: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.11']/effectiveTime/low/	@value	1..1	SHALL	11983 11984	n/a
Diagnosis Active Effective End Date Time: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.11']/effectiveTime/high/	@value	1..1	SHALL	11983 11985	n/a

1. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:11983).
 - a. This **effectiveTime** **SHALL** contain exactly one [1..1] **low** (CONF:11984).
 - b. This **effectiveTime** **SHALL** contain exactly one [1..1] **high** (CONF:11985).
2. **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD" (CONF:12008).
3. **SHALL** contain exactly one [1..1] **entryRelationship** (CONF:11975) such that it
 - a. **SHALL** contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:11979).
 - b. **SHALL** contain exactly one [1..1] Problem Status Active (templateId:2.16.840.1.113883.10.20.24.3.94) (CONF:12253).
 - i. **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD" (CONF:12207).
 1. This value **SHALL** contain exactly one [1..1] @code="55561003" active (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96 STATIC) (CONF:12214).

5.3.3.2 Diagnosis Family History

Family History Observations related to a particular family member are contained within a Family History Organizer. The effectiveTime in the Family History Observation is the biologically or clinically relevant time of the observation. The biologically or clinically relevant time is the time at which the observation holds (is effective) for the family member (the subject of the observation).

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Originator Code: //organizer[templateId/@root='2.1 6.840.1.113883.10.20.24.3.12']/subject/relatedSubject/	code	1..1	SHALL	15246 15247	2.16.840.1.113 883.1.11.1957 9 (Family Member Value Set)
Administrative Gender: //organizer[templateId/@root='2.1 6.840.1.113883.10.20.24.3.12']/subject/relatedSubject/subject/administrativeGenderCode/	@code	1..1	SHALL	15248 15974 15975_P01	2.16.840.1.113 762.1.4.1 (ONC Administrative Sex Value Set) or 2.16.840.1.113 883.1.11.1 (Administrative Gender Value Set)
Originator Birth Date: //organizer[templateId/@root='2.1 6.840.1.113883.10.20.24.3.12']/subject/relatedSubject/subject/birthTime/	@value	0..1	SHOULD	15976	n/a
Diagnosis Family History Observation Code: //organizer[templateId/@root='2.1 6.840.1.113883.10.20.24.3.12']/component/observation[templateId/@root='2.16.840.1.113883.10.20.22.4.46']/	value[@ xsi:type="CD"]	1..1	SHALL	8607 16888	n/a
History Observation Date: //organizer[templateId/@root='2.1 6.840.1.113883.10.20.24.3.12'] /	effectiveTime	1..1	SHALL	14178	n/a

1. SHALL contain exactly one [1..1] **subject** (CONF:8609).
 - a. This subject SHALL contain exactly one [1..1] **relatedSubject** (CONF:15244).
 - i. This relatedSubject SHALL contain exactly one [1..1] **code** (CONF:15246).
 1. This code SHALL contain exactly one [1..1] @code, which SHOULD be selected from ValueSet Family Member Value Set 2.16.840.1.113883.1.11.19579 **DYNAMIC** (CONF:15247).
 - ii. This relatedSubject SHOULD contain zero or one [0..1] **subject** (CONF:15248).

1. The subject, if present, **SHALL** contain exactly one [1..1] **administrativeGenderCode** (CONF:15974).
 - a. This administrativeGenderCode **SHALL** contain exactly one [1..1] @code, which **SHALL** be selected from either ValueSet ONC Administrative Sex 2.16.840.1.113762.1.4.1 or ValueSet Administrative Gender (HL7 V3) 2.16.840.1.113883.1.11.1 **DYNAMIC**(CONF:15975_P01).
2. The subject, if present, **SHOULD** contain zero or one [0..1] **birthTime** (CONF:15976).
2. **SHALL** contain at least one [1..*] **component** (CONF:8607).
 - a. Such components **SHALL** contain exactly one [1..1] Family History Observation (templateId:2.16.840.1.113883.10.20.22.4.46) (CONF:16888).
3. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:14178).

5.3.3.3 Diagnosis Inactive

An inactive diagnosis is a problem, diagnosis, or condition that has been present in the past and is currently not under active treatment or causing clinical manifestations, but may require treatment or monitoring in the future (e.g., a cancer diagnosis in remission). A time/date stamp is required.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Diagnosis Code: //observation[templateId/@root='2.1 6.840.1.113883.10.20.24.3.13']/	value[xsi:type="CD"]	1..1	SHALL	9058	n/a
Diagnosis Inactive Status Code: //observation[templateId/@root='2.1 6.840.1.113883.10.20.24.3.13']/entryRelationship/observation/[templateId/@root='2.16.840.1.113883.10.20.24.3.95']/value[@xsi:type="CD"]/	@code	1..1	SHALL	12019 12023 12219 12208 12211	2.16.840.1.113883.6.96 (SNOMED-CT) = 73425007
Diagnosis Inactive Effective Start Date Time: //observation[templateId/@root='2.1 6.840.1.113883.10.20.24.3.13']/effectiveTime/low/	@value	1..1	SHALL	12028 12029	n/a
Diagnosis Inactive Effective End Date Time: //observation[templateId/@root='2.1 6.840.1.113883.10.20.24.3.13']/effectiveTime/high/	@value	1..1	SHALL	12028 12030	n/a

1. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:12028).
 - a. This effectiveTime **SHALL** contain exactly one [1..1] **low** (CONF:12029).
 - b. This effectiveTime **SHALL** contain exactly one [1..1] **high** (CONF:12030).

2. **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD", where the @code **SHOULD** be selected from ValueSet Problem Value Set 2.16.840.1.113883.3.88.12.3221.7.4 **DYNAMIC** (CONF:9058).
Note: The @code SHALL be selected from the value set specified in the eCQMs.
3. **SHALL** contain exactly one [1..1] **entryRelationship** (CONF:12019) such that it
 - a. **SHALL** contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:12023).
 - b. **SHALL** contain exactly one [1..1] Problem Status Inactive (templateId:2.16.840.1.113883.10.20.24.3.95) (CONF:12219).
 - i. **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD" (CONF:12208).
 1. This value **SHALL** contain exactly one [1..1] @code="73425007" inactive (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96 **STATIC**) (CONF:12211).

5.3.3.4 Diagnosis Resolved

A resolved diagnosis is a diagnosis that no longer requires treatment and, by its nature, is unlikely to recur. A time/date stamp is required.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Diagnosis Code: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.14']/	value[@xsi:type="CD"]	1..1	SHALL	9058	n/a
Diagnosis Resolved Status Code: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.14']/entryRelationship/observation/[templateId @root='2.16.840.1.113883.10.20.24.3.96']/value[@xsi:type="CD"]/	@code	1..1	SHALL	12054 12058 12313 12215 12216	2.16.840.1.113883.6.96 (SNOMED-CT) = 413322009
Effective Start Date Time: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.14']/effectiveTime/low/	@value	1..1	SHALL	12061 12062	n/a
Effective End Date Time: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.14']/effectiveTime/high/	@value	1..1	SHALL	12061 12063	n/a

1. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:12061).
 - a. This effectiveTime **SHALL** contain exactly one [1..1] **low** (CONF:12062).
 - b. This effectiveTime **SHALL** contain exactly one [1..1] **high** (CONF:12063).
2. **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD", where the @code **SHOULD** be selected from ValueSet Problem Value Set 2.16.840.1.113883.3.88.12.3221.7.4 **DYNAMIC** (CONF:9058).
Note: The @code SHALL be selected from the value set specified in the eCQMs.
3. **SHALL** contain exactly one [1..1] **entryRelationship** (CONF:12054) such that it

- a. **SHALL** contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:12058).
- b. **SHALL** contain exactly one [1..1] Problem Status Resolved (templateId:2.16.840.1.113883.10.20.24.3.96) (CONF:12313).
- c. **SHALL** contain exactly one [1..1] value with @xsi:type="CD" (CONF:12215).
 - i. This value **SHALL** contain exactly one [1..1] @code="413322009" resolved (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96 **STATIC**) (CONF:12216).

5.3.4 Diagnostic Study

5.3.4.1 Diagnostic Study Order

This template represents that a diagnostic study has been ordered. Diagnostic studies are those that are not performed in the clinical laboratory. Such studies include but are not limited to imaging studies, cardiology studies (electrocardiogram, treadmill stress testing), pulmonary function testing, vascular laboratory testing, and others.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Diagnostic Study Order Code: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.17']	code	1..1	SHALL	13415	n/a
Diagnostic Study Order Status Code: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.17']/statusCode/	@code	1..1	SHALL	13416 13417	2.16.840.1.13883.5.14 (ActStatus) = new
Diagnostic Study Order Date Time: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.17']/author/time/	@value	1..1	SHALL	13419 13420	n/a

1. **SHALL** contain exactly one [1..1] code (CONF:13415).
2. **SHALL** contain exactly one [1..1] statusCode (CONF:13416).
 - a. This statusCode **SHALL** contain exactly one [1..1] @code="new" (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:13417).
3. **SHALL** contain exactly one [1..1] author (CONF:13419) such that it
 - a. **SHALL** contain exactly one [1..1] time (CONF:13420).

5.3.4.2 Diagnostic Study Performed

This template indicates that diagnostic study has been completed. Diagnostic studies are those that are not performed in the clinical laboratory. Such studies include but are not limited to imaging studies, cardiology studies (electrocardiogram, treadmill stress testing), pulmonary function testing, vascular laboratory testing, and others. A time/date stamp is required, moodCode is constrained to "EVN" and statusCode is constrained to "completed".

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Diagnostic Study Performed Code: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.18']	code	1..1	SHALL	19197	n/a
Diagnostic Study Performed Status Code: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.18']/statusCode/	@code	1..1	SHALL	12956 12957	2.16.840.1.113883.5.14 (ActStatus) = completed
Diagnostic Study Performed Effective Start Date Time: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.18']/effectiveTime/low/	@value	1..1	SHALL	12958 12959	n/a
Diagnostic Study Performed Effective End Date Time: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.18']/effectiveTime/high/	@value	1..1	SHALL	12958 12960	n/a

1. SHALL contain exactly one [1..1] code (CONF:19197).
2. SHALL contain exactly one [1..1] statusCode (CONF:12956).
 - a. This statusCode SHALL contain exactly one [1..1] @code = "completed" (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:12957).
3. SHALL contain exactly one [1..1] effectiveTime (CONF:12958).
 - a. This effectiveTime SHALL contain exactly one [1..1] low (CONF:12959).
 - b. This effectiveTime SHALL contain exactly one [1..1] high (CONF:12960).

5.3.4.2.1 Diagnostic Study Performed Not Done (Negation)

This template indicates that a Diagnostic Study was not performed in the clinical laboratory. This information is collected only when negationInd="true" for Diagnostic Study Performed.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Negation Reason Code: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.18']/entryRelationship[@typeCode="RSON"]/ observation[templateId/@root='2.16.840.1.113883.10.20.24.3.88']/value [xsi:type="CD"]/	value	1..1	SHALL	12963_P01 12964 12965 11367	n/a

1. SHALL contain exactly one [1..1] entryRelationship (CONF:12963_P01) such that it
 - a. SHALL contain exactly one [1..1] @typeCode = "RSON" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:12964).

- b. **SHALL** contain exactly one [1..1] Reason
(templateId:2.16.840.1.113883.10.20.24.3.88) (CONF:12965).
 - i. **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD"
(CONF:11367).

5.3.4.3 Diagnostic Study Result

This template describes a result of a diagnostic study on a patient in concepts or numerical values. Diagnostic studies are those that are not performed in the clinical laboratory. Such studies include but are not limited to imaging studies, cardiology studies (electrocardiogram, treadmill stress testing), pulmonary function testing, vascular laboratory testing, and others. A time/date stamp is required.

Parameter Name: XPath	Attribute/ Element	Card.	Verb	CONF#	Fixed Value
Diagnostic Study Result Value: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.20']/	value	1..1	SHALL	16695	n/a
Diagnostic Study Result Status Code: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.20']/statusCode/	@code	1..1	SHALL	7134 14849	2.16.840.1.13883.11.20.9.39 (Result Status)
Diagnostic Study Result Effective Date Time: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.20']/	effectiveTime	1..1	SHALL	7140	n/a

1. **SHALL** contain exactly one [1..1] **value** (CONF:16695)
2. **SHALL** contain exactly one [1..1] **statusCode** (CONF:7134).
 - a. This **statusCode** **SHALL** contain exactly one [1..1] **@code**, which **SHALL** be selected from ValueSet Result Status 2.16.840.1.113883.11.20.9.39 **STATIC** (CONF:14849).
3. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:7140).

5.3.4.3.1 Diagnostic Study Result Not Done (Negation)

This template describes when a result of a diagnostic study in the clinical laboratory on a patient was not performed. This information is collected only when `negationInd="true"`.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Negation Reason Code: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.20']/entryRelationship[@typeCode="RSON"]/observation[templateId/@root='2.16.840.1.113883.10.20.24.3.88']/	value[@xsi:type="CD"]/	1..1	SHALL	13804_P01 13805 13806 11367	n/a

1. **SHALL** contain exactly one [1..1] `entryRelationship` (CONF:13804_P01) such that it
 - a. **SHALL** contain exactly one [1..1] `@typeCode="RSON"` (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:13805).
 - b. **SHALL** contain exactly one [1..1] `Reason` (`templateId:2.16.840.1.113883.10.20.24.3.88`) (CONF:13806).
 - i. **SHALL** contain exactly one [1..1] `value` with `@xsi:type="CD"` (CONF:11367).

5.3.5 Encounter

5.3.5.1 Encounter Order

This clinical statement describes the ordered interactions between the patient and clinicians. Interactions include in-person encounters, telephone conversations, and email exchanges.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Patient Encounter Code: //encounter[templateId/@root='2.16.840.1.113883.10.20.24.3.22']/	code	1..1	SHALL	11936	n/a
Patient Encounter Status Code: //encounter[templateId/@root='2.16.840.1.113883.10.20.24.3.22']/statusCode/	@code	1..1	SHALL	11937 11938	2.16.840.1.13883.5.14 (ActStatus) = new
Patient Encounter Order Date Time: //encounter[templateId/@root='2.16.840.1.113883.10.20.24.3.22']/author/time/	@value	1..1	SHALL	11939 11940	n/a

1. **SHALL** contain exactly one [1..1] `code` (CONF:11936)
2. **SHALL** contain exactly one [1..1] `statusCode` (CONF:11937).
 - a. This `statusCode` **SHALL** contain exactly one [1..1] `@code="new"` (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:11938).
3. **SHALL** contain exactly one [1..1] `author` (CONF:11939).

- a. This author **SHALL** contain exactly one [1..1] **time** (CONF:11940).

5.3.5.2 Encounter Performed

This clinical statement describes the interactions between the patient and clinicians that have been completed. Interactions include in-person encounters, telephone conversations, and email exchanges. The **ActStatus** is constrained to "completed" and both a low and high **effectiveTime** are required.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Patient Encounter Code: //encounter[templateId/@root='2.16.840.1.11 3883.10.20.24.3.23']/	code	1..1	SHALL	11864	n/a
Patient Encounter Status Code: //encounter[templateId/@root='2.16.840.1.11 3883.10.20.24.3.23']/statusCode/	@code	1..1	SHALL	11874 11875	n/a
Patient Encounter Effective Start Date Time: //encounter[templateId/@root='2.16.840.1.11 3883.10.20.24.3.23']/effectiveTime/low/	@value	1..1	SHALL	11876 11877	n/a
Patient Encounter Effective End Date Time: //encounter[templateId/@root='2.16.840.1.11 3883.10.20.24.3.23']/effectiveTime/high/	@value	1..1	SHALL	11876 11878	n/a

1. **SHALL** contain exactly one [1..1] **code** (CONF:11864)**SHALL** contain exactly one [1..1] **statusCode** (CONF:11874).
 - a. This **statusCode** **SHALL** contain exactly one [1..1] **@code="completed"** (**CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC**) (CONF:11875).
2. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:11876).
 - a. This **effectiveTime** **SHALL** contain exactly one [1..1] **low** (CONF:11877).
 - b. This **effectiveTime** **SHALL** contain exactly one [1..1] **high** (CONF:11878).

5.3.6 Functional Status Result

This clinical statement represents the results of a functional status assessment. This template uses the Result Observation template to represent physical or behavioral performance.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Functional Status Result Code: //observation[templateId/@root='2.16.8 40.1.113883.10.20.24.3.28']/	code	1..1	SHALL	13908 26448	n/a
Functional Status Result Status Code: //observation[templateId/@root='2.16.8 40.1.113883.10.20.24.3.28']/statusCode	@code	1..1	SHALL	13929 19101	2.16.840.1.13883.5.14 (ActStatus) = completed
Functional Status Result Effective Date Time: //observation[templateId/@root='2.16.8 40.1.113883.10.20.24.3.28']/	effectiveTime	1..1	SHALL	13930	n/a
Functional Status Result Value: //observation[templateId/@root='2.16.8 40.1.113883.10.20.24.3.28']/	value	1..1	SHALL	13932 14234	n/a

1. **SHALL** contain exactly one [1..1] **code** (CONF:13908).
 - a. This code **SHALL** contain exactly one [1..1] **@code**, which **SHOULD** be selected from CodeSystem LOINC (2.16.840.1.113883.6.1) **STATIC** (CONF:26448).
Note: The **@code** SHALL be selected from the value set specified in the eCQMs.
2. **SHALL** contain exactly one [1..1] **statusCode** (CONF:13929).
 - a. This statusCode **SHALL** contain exactly one [1..1] **@code="completed"** Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:19101).
3. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:13930).
4. **SHALL** contain exactly one [1..1] **value** (CONF:13932).
 - a. If xsi:type="CD", **SHOULD** contain a code from SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96) (CONF:14234).

5.3.7 Intervention

5.3.7.1 Intervention Order

An intervention order is a request by a physician or appropriately licensed care provider to an appropriate provider or facility to perform a service and/or other type of action necessary for care. An example of this is an order for smoking cessation counseling or physical therapy. The moodCode is constrained to "RQO" and actStatus is constrained to "new". An author/time is required to represent the intervention ordering date time.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Intervention Order Code: //act[templateId/@root='2.16.840.1.113 883.10.20.24.3.31']/	code	1..1	SHALL	13746	n/a
Intervention Order Status Code: //act[templateId/@root='2.16.840.1.113 883.10.20.24.3.31']/statusCode/	@code	1..1	SHALL	DECC_P0006 DECC_P0016	2.16.840.1.1 13883.5.14 (ActStatus) = new
Intervention Order Date Time: //act[templateId/@root='2.16.840.1.113 883.10.20.24.3.31']/author/time/	@value	1..1	SHALL	13747 13748	n/a

1. SHALL contain exactly one [1..1] code (CONF:13746)
2. SHALL contain exactly one [1..1] statusCode (CONF:DECC_P0006).
 - a. This statusCode SHALL contain exactly one [1..1] @code= "new" (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:DECC_P0016).
3. SHALL contain exactly one [1..1] author (CONF:13747).
 - a. This author SHALL contain exactly one [1..1] time (CONF:13748).

5.3.7.2 Intervention Performed

This clinical statement template represents an intervention has been completed. An intervention is an influencing force or act that occurs in order to modify a given state of affairs. An intervention is any action carried out (by a healthcare provider or a consumer) to improve or maintain the health of a subject of care with the expectation of producing an outcome. A time/date stamp is required and moodCode is constrained to "EVN".

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Intervention Performed Code: //act[templateId/@root='2.16.840.1.1 13883.10.20.24.3.32']/	code	1..1	SHALL	13594	n/a
Intervention Performed Status Code: //act[templateId/@root='2.16.840.1.1 13883.10.20.24.3.32']/statusCode/	@code	1..1	SHALL	8298	2.16.840.1.11 13883.11.20.9. 22 (ProcedureAct statusCode)
Intervention Performed Effective Start Date Time: //act[templateId/@root='2.16.840.1.1 13883.10.20.24.3.32']/effectiveTime/ low/	@value	1..1	SHALL	13611 13612	n/a
Intervention Performed Effective End Date Time: //act[templateId/@root='2.16.840.1.1 13883.10.20.24.3.32']/effectiveTime/ high/	@value	1..1	SHALL	13611 13613	n/a

1. **SHALL** contain exactly one [1..1] **code** (CONF:13594)
2. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:13611).
 - a. This effectiveTime **SHALL** contain exactly one [1..1] **low** (CONF:13612).
 - b. This effectiveTime **SHALL** contain exactly one [1..1] **high** (CONF:13613).
3. **SHALL** contain exactly one [1..1] **statusCode**, which **SHALL** be selected from ValueSet ProcedureAct statusCode 2.16.840.1.113883.11.20.9.22 DYNAMIC (CONF:8298)

5.3.7.2.1 Intervention Performed Not Done (Negation)

This template describes an Intervention that was not performed. This information is collected only when negationInd="true".

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Negation Reason Code: //act[templateId/@root='2.16.840.1.113883.10.20.24.3.32']/entryRelationship[@typeCode="RSON"]/observation[templateId/@root='2.16.840.1.113883.10.20.24.3.88']/	value[@xsi:type="CD"]	1..1	SHALL	13604_P01 13605 13606 11367	n/a

1. **SHALL** contain exactly one [1..1] **entryRelationship** (CONF:13604_P01) such that it
 - a. **SHALL** contain exactly one [1..1] @typeCode="RSON" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:13605).
 - b. **SHALL** contain exactly one [1..1] Reason (templateId:2.16.840.1.113883.10.20.24.3.88) (CONF:13606).
 - i. **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD" (CONF:11367).

5.3.8 Laboratory Test

5.3.8.1 Laboratory Test Order

This template represents an order for a laboratory test. A laboratory test is a medical procedure that involves testing a sample of blood, urine, or other substance from the body. Tests can help determine a diagnosis, plan treatment, check if treatment is working, or monitor the disease over time. The moodCode is constrained to "RQO" and actStatus is constrained to "new". An author/time is required to represent the laboratory test ordering date time. This represents the order only and does not include a result.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Laboratory Test Order Code: //observation[templateId/@root='2.16.8 40.1.113883.10.20.24.3.37']/	code	1..1	SHALL	11957	n/a
Laboratory Test Order Status Code: //observation[templateId/@root='2.16.8 40.1.113883.10.20.24.3.37']/statusCode/	@code	1..1	SHALL	11958 11959	2.16.840.1.1 13883.5.14 (ActStatus) = new
Laboratory Test Order Date Time: //observation[templateId/@root='2.16.8 40.1.113883.10.20.24.3.37']/author/time/	@value	1..1	SHALL	11961 11962	n/a

1. SHALL contain exactly one [1..1] code (CONF:11957)
2. SHALL contain exactly one [1..1] statusCode (CONF:11958).
 - a. This statusCode SHALL contain exactly one [1..1] @code="new" (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:11959).
3. SHALL contain exactly one [1..1] author (CONF:11961) such that it
 - a. SHALL contain exactly one [1..1] time (CONF:11962).

5.3.8.2 Laboratory Test Performed

The Laboratory Test Performed template represents the medical procedure of obtaining a sample of blood, urine, or other substance from the body. This template may not contain any information about the result of a lab test. The focus is on the procedure itself.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Laboratory Test Performed Code: //observation[templateId/@root='2.16.8 40.1.113883.10.20.24.3.38']/	code	1..1	SHALL	11708	n/a
Laboratory Test Performed Status Code: //observation[templateId/@root='2.16.8 40.1.113883.10.20.24.3.38']/statusCode/	@code	1..1	SHALL	11709 11710	2.16.840.1.1 13883.5.14 (ActStatus) = completed
Laboratory Test Performed Effective Start Date Time: //observation[templateId/@root='2.16.8 40.1.113883.10.20.24.3.38']/effectiveTime/low/	@value	1..1	SHALL	11711 11712	n/a
Laboratory Test Performed Effective End Date Time: //observation[templateId/@root='2.16.8 40.1.113883.10.20.24.3.38']/effectiveTime/high/	@value	1..1	SHALL	11711 11713	n/a

1. **SHALL** contain exactly one [1..1] code (CONF:11708)
2. **SHALL** contain exactly one [1..1] statusCode (CONF:11709).
 - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:11710).
3. **SHALL** contain exactly one [1..1] effectiveTime (CONF:11711).
 - a. This effectiveTime **SHALL** contain exactly one [1..1] low (CONF:11712).
 - b. This effectiveTime **SHALL** contain exactly one [1..1] high (CONF:11713).

5.3.8.2.1 Laboratory Test Performed Not Done (Negation)

This template describes a Laboratory Test that was not performed. This information is collected only when negationInd="true".

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Negation Reason Code: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.38']/entryRelationship[@typeCode="RSON"]/observation[templateId/@root='2.16.840.1.113883.10.20.24.3.88']/value[@xsi:type="CD"]/	value	1..1	SHALL	11727_P01 11728 11729 11367	n/a

1. **SHALL** contain exactly one [1..1] entryRelationship (CONF:11727_P01) such that it
 - a. **SHALL** contain exactly one [1..1] @typeCode="RSON" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:11728).
 - b. **SHALL** contain exactly one [1..1] Reason (templateId:2.16.840.1.113883.10.20.24.3.88) (CONF:11729).
 - i. **SHALL** contain exactly one [1..1] value with @xsi:type="CD" (CONF:11367).

5.3.8.3 Laboratory Test Result

The result of a study in the clinical laboratory (traditionally chemistry, hematology, microbiology, serology, urinalysis, blood bank). A time/date stamp is required.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Laboratory Test Result Code: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.40']/	code	1..1	SHALL	7133	n/a
Laboratory Test Result Value: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.40']/	value	1..1	SHALL	16697 16698	n/a
Laboratory Test Result Status Code: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.40']/statusCode/	@code	1..1	SHALL	7134 14849	2.16.840.1.113883.11.20.9.39 (Result Status)

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Laboratory Test Result Start Date: //observation[templateId/@root='2.1.6.840.1.113883.10.20.24.3.40']/	effective Time	1..1	SHALL	7140	n/a

1. SHALL contain exactly one [1..1] code (CONF:7133)
2. SHALL contain exactly one [1..1] statusCode (CONF:7134).
 - a. This statusCode SHALL contain exactly one [1..1] @code, which SHALL be selected from ValueSet Result Status 2.16.840.1.113883.11.20.9.39 STATIC (CONF:14849).
3. SHALL contain exactly one [1..1] effectiveTime (CONF:7140).
4. SHALL contain exactly one [1..1] value (CONF:16697).
 - a. If xsi:type=PQ, then @units SHALL be drawn from Unified Code for Units of Measure (UCUM) 2.16.840.1.113883.6.8 code system. Additional constraint is dependent on criteria in the corresponding eMeasure (CONF:16698).

5.3.9 Medication

5.3.9.1 Medication Active

This template represents medications currently taken by a patient. A time/date stamp is required. ActStatus is constrained to "active" and moodCode is constrained to "EVN". Quality Measures are sometimes interested in the total time a patient has been on medication over time. This section conforms to the Medication Activity template.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Medication Active Code: //substanceAdministration[templateId/@root='2.16.840.1.113883.10.20.24.3.41']/consumable/manufacturedProduct[templateId/@root='2.16.840.1.113883.10.20.22.4.23']/manufacturedMaterial/	code	1..1	SHALL	7520 16085 7412	n/a
Medication Active Status Code: //substanceAdministration[templateId/@root='2.16.840.1.113883.10.20.24.3.41']/statusCode/	@code	1..1	SHALL	12412 12413	2.16.840.1.13883.5.14 (ActStatus) = active
Medication Dose Quantity: //substanceAdministration[templateId/@root='2.16.840.1.113883.10.20.24.3.41'][templateId/@root='2.16.840.1.113883.10.20.22.4.16']/	dose Quantity	0..1	SHOULD	7516 7526	n/a
Medication Effective Start Date Time: //substanceAdministration[templateId/@root='2.16.840.1.113883.10.20.24.3.41']/effectiveTime/low/	@value	1..1	SHALL	7508 7511	n/a

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Medication Effective End Date Time: <code>//substanceAdministration[templateId/@root='2.16.840.1.113883.10.20.24.3.41']/effectiveTime/high/</code>	@value	1..1	SHALL	7508 7512	n/a

1. **SHALL** contain exactly one [1..1] **consumable** (CONF:7520).
 - a. This consumable **SHALL** contain exactly one [1..1] **Medication Information** (templateId:2.16.840.1.113883.10.20.22.4.23) (CONF:16085).
 - i. This manufacturedMaterial **SHALL** contain exactly one [1..1] **code**, which **SHALL** be selected from ValueSet Medication Clinical Drug Name Value Set 2.16.840.1.113883.3.88.12.80.17 **DYNAMIC** (CONF:7412). Note: The code SHALL be selected from the value set specified in the eCQMs.
2. **SHALL** contain exactly one [1..1] **statusCode** (CONF:12412).
 - a. This statusCode **SHALL** contain exactly one [1..1] @code="active" (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:12413).
3. **SHOULD** contain zero or one [0..1] **doseQuantity** (CONF:7516).
 - a. The doseQuantity, if present, **SHOULD** contain zero or one [0..1] @unit, which **SHALL** be selected from ValueSet UCUM Units of Measure (case sensitive) 2.16.840.1.113883.1.11.12839 **DYNAMIC** (CONF:7526).
4. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:7508) such that it
 - a. **SHALL** contain exactly one [1..1] **low** (CONF:7511).
 - b. **SHALL** contain exactly one [1..1] **high** (CONF:7512).

5.3.9.2 Medication Administered

This template represents a record by the care provider that a medication actually was administered. A time/date stamp for medication administration is required.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Medication Administered Code: //act[templateId/@root='2.16.840.1.13883.10.20.24.3.42']/entryRelationship[@typeCode="COMP"]/substanceAdministration[templateId/@root='2.16.840.1.113883.10.20.22.4.16']/consumable/manufacturedProduct[templateId/@root='2.16.840.1.113883.10.20.22.4.23']/manufacturedMaterial/	code	1..1	SHALL	12454 12455 12456 12457 7520 16085 7411 7412	n/a
Medication Administered Status Code: //act[templateId/@root='2.16.840.1.13883.10.20.24.3.42']/statusCode/	@code	1..1	SHALL	12452 13241	2.16.840.1.13883.5.14 (ActStatus) = completed
Medication Administered Effective Date Time: //act[templateId/@root='2.16.840.1.13883.10.20.24.3.42']/	effectiveTime	1..1	SHALL	26714	n/a
Medication Dose Quantity: //act[templateId/@root='2.16.840.1.13883.10.20.24.3.42']/entryRelationship[@typeCode="COMP"]/substanceAdministration[templateId/@root='2.16.840.1.113883.10.20.22.4.16']/	doseQuantity	0..1	SHOULD	7516 7526	n/a

1. **SHALL** contain exactly one [1..1] **statusCode** (CONF:12452).
 - a. This **statusCode** **SHALL** contain exactly one [1..1] **@code="completed"** (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:13241).
2. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:26714).
3. **SHALL** contain exactly one [1..1] **entryRelationship** (CONF:12454) such that it
 - a. **SHALL** contain exactly one [1..1] **@typeCode="COMP"** (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:12455).
 - b. **SHALL** contain exactly one [1..1] Medication Activity (templateId:2.16.840.1.113883.10.20.22.4.16) (CONF:12456).
 - i. This **substanceAdministration** **SHALL** contain exactly one [1..1] **@moodCode="EVN"** (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:12457).
 - ii. **SHALL** contain exactly one [1..1] **consumable** (CONF:7520).
 1. This **consumable** **SHALL** contain exactly one [1..1] Medication Information (templateId:2.16.840.1.113883.10.20.22.4.23) (CONF:16085).
 - a. **SHALL** contain exactly one [1..1] **manufacturedMaterial** (CONF:7411).
 - i. This **manufacturedMaterial** **SHALL** contain exactly one [1..1] **code**, which **SHALL** be selected from ValueSet Medication

Clinical Drug Name Value Set
2.16.840.1.113883.3.88.12.80.17
DYNAMIC (CONF:7412).

Note: The code SHALL be selected from the value set specified in the eCQMs.

4. **SHOULD** contain zero or one [0..1] **doseQuantity** (CONF:7516).
 - a. The doseQuantity, if present, **SHOULD** contain zero or one [0..1] @unit, which **SHALL** be selected from ValueSet UCUM Units of Measure (case sensitive) 2.16.840.1.113883.1.11.12839 **DYNAMIC** (CONF:7526).

5.3.9.2.1 Medication Administered Not Done (Negation)

This template describes a medication that was actually not administered. This information is collected only when negationInd="true".

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Negation Reason Code: //act[templateId/@root='2.16.840.1.113883.10.20.24.3.42']/entryRelationship[@typeCode="RSON"]/observation[templateId/@root='2.16.840.1.113883.10.20.24.3.88']/	code[xsi:type="CD"]	1..1	SHALL	DECC_P0020 DECC_P0021 DECC_P0022 11367	n/a

1. **SHALL** contain exactly one [1..1] **entryRelationship** (CONF:DECC_P0020) such that it
 - a. **SHALL** contain exactly one [1..1] @typeCode="RSON" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:DECC_P0021).
 - b. **SHALL** contain exactly one [1..1] Reason (templateId:2.16.840.1.113883.10.20.24.3.88) (CONF:DECC_P0022).
 - i. **SHALL** contain exactly one [1..1] value with @xsi:type="CD" (CONF:11367).

5.3.9.3 Medication Allergy

A medication allergy is an immunologically mediated reaction that exhibits specificity and recurs on re-exposure to the offending drug. This template may contain patient or provider preferences or thoughts about the allergy.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Medication Allergy Code: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.44']/participant/participantRole/playingEntity/	code	1..1	SHALL	14143 14144 14145 14146 14147 14148	n/a

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Medication Allergy Status Code: //observation[templateId/@root='2.16.84 0.1.113883.10.20.24.3.44']/statusCode/	@code	1..1	SHALL	14164	n/a
Medication Allergy Effective Date Time: //observation[templateId/@root='2.16.84 0.1.113883.10.20.24.3.44']/	effectiveTime	1..1	SHALL	14142	n/a
Medication Allergy Reaction Code: //observation[templateId/@root='2.16.84 0.1.113883.10.20.24.3.44'] /entryRelationship[@typeCode="MFST"] [@inversionInd="true"]/br/> observation[templateId/@root='2.16.840 .1.113883.10.20.24.3.85']/	code	0..1	SHOULD	11661 11662 14155 14156 14157 14158	n/a

1. **SHALL** contain exactly one [1..1] **participant** (CONF:14143).
 - a. This participant **SHALL** contain exactly one [1..1] **@typeCode="CSM"** (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90 **STATIC**) (CONF:14144).
 - b. This participant **SHALL** contain exactly one [1..1] **participantRole** (CONF:14145).
 - i. This participantRole **SHALL** contain exactly one [1..1] **@classCode="MANU"** (CodeSystem: RoleClass 2.16.840.1.113883.5.110 **STATIC**) (CONF:14146).
 - ii. This participantRole **SHALL** contain exactly one [1..1] **playingEntity** (CONF:14147).
 1. This playingEntity **SHALL** contain exactly one [1..1] **code** (CONF:14148)
2. **SHALL** contain exactly one [1..1] **statusCode** (CONF:14164).
3. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:14142).
4. **SHOULD** contain zero or one [0..1] **entryRelationship** (CONF:14155) such that it
 - a. **SHALL** contain exactly one [1..1] **@typeCode="MFST"** (CONF:14156).
 - b. **SHALL** contain exactly one [1..1] **@inversionInd="true"** (CONF:14157).
5. **SHALL** contain exactly one [1..1] Reaction (templateId:2.16.840.1.113883.10.20.24.3.85) (CONF:14158).
 - a. **SHALL** contain exactly one [1..1] **code** (CONF:11661).
 - i. This code **SHALL** contain exactly one [1..1] **@code="263851003"** reaction (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96 **STATIC**) (CONF:11662).

5.3.9.4 Medication Dispensed

This template represents that a medication prescription has been filled by a pharmacy and the medication has been provided to the patient or patient proxy. In the ambulatory setting, medications are primarily taken directly by patients and not directly observed by a clinician. Hence, "dispensed" is the closest health provider documentation of medication compliance. In settings where patients attest to taking medications in electronic format (perhaps a Personal

Health Record), patient attestation of "medication taken" may be available. A time/date stamp is required and `actStatus` is constrained to "completed".

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Medication Dispensed Code: //supply[templateId/@root='2.16.840.1.113883.10.20.24.3.45']/product/manufacturedProduct[templateId/@root='2.16.840.1.113883.10.20.22.4.23']/manufacturedMaterial/	code	1..1	SHALL	15607 7411 7412	n/a
Medication Quantity Dispensed: //supply[templateId/@root='2.16.840.1.113883.10.20.24.3.45'][templateId/@root='2.16.840.1.113883.10.20.22.4.18']/	quantity	0..1	SHOULD	7458	n/a
Medication Dispensed Status Code: //supply[templateId/@root='2.16.840.1.113883.10.20.24.3.45']/statusCode/	@code	1..1	SHALL	19440 19441	2.16.840.1.13883.5.14 (ActStatus) = completed
Medication Dispensed Effective Date Time: //supply[templateId/@root='2.16.840.1.113883.10.20.24.3.45']/	effectiveTime	1..1	SHALL	13856	n/a

1. **SHALL** contain exactly one [1..1] Medication Information (templateId:2.16.840.1.113883.10.20.22.4.23) (CONF:15607).
 - a. **SHALL** contain exactly one [1..1] `manufacturedMaterial` (CONF:7411).
 - i. This `manufacturedMaterial` **SHALL** contain exactly one [1..1] `code`, which **SHALL** be selected from ValueSet Medication Clinical Drug 2.16.840.1.113883.3.88.12.80.17 **DYNAMIC** (CONF:7412).
Note: The code SHALL be selected from the value set specified in the eCQMs.
2. **SHOULD** contain zero or one [0..1] `quantity` (CONF:7458).
3. **SHALL** contain exactly one [1..1] `statusCode` (CONF:19440).
 - a. This `statusCode` **SHALL** contain exactly one [1..1] `@code="completed"` (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:19441).
4. **SHALL** contain exactly one [1..1] `effectiveTime` (CONF:13856).

5.3.9.5 Medication Intolerance

This clinical statement template represents medication intolerance. Medication intolerance is a reaction in specific patients representing a low threshold to the normal pharmacological action of a drug. Intolerance is generally based on patient report and perception of his or her ability to tolerate proper administration of a medication. Medication intolerance is distinct from medication allergy and medication adverse effects.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Medication Intolerance Code: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.46']/participant/participantRole/playingEntity/	code	1..1	SHALL	14094 14095 14097 14098 14099	n/a
Medication Intolerance Status Code: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.46']/statusCode/	@code	1..1	SHALL	19084 19085	2.16.840.1.13883.5.14 (ActStatus) = completed
Medication Intolerance Effective Date Time: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.46']/	effectiveTime	1..1	SHALL	14092	n/a
Medication Intolerance Reaction Code: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.46']/entryRelationship[@typeCode="MFST"][@inversionInd="true"]/observation[templateId/@root='2.16.840.1.113883.10.20.24.3.85']/observation/	code	0..1	SHOULD	14106 14107 14108 14109 11661	n/a

1. **SHALL** contain exactly one [1..1] **participant** (CONF:14094).
 - a. This participant **SHALL** contain exactly one [1..1] @typeCode="CSM" (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90 **STATIC**) (CONF:14095).
 - b. This participant **SHALL** contain exactly one [1..1] **participantRole** (CONF:14096).
 - i. This participantRole **SHALL** contain exactly one [1..1] @classCode="MANU" (CodeSystem: RoleClass 2.16.840.1.113883.5.110 **STATIC**) (CONF:14097).
 - ii. This participantRole **SHALL** contain exactly one [1..1] **playingEntity** (CONF:14098).
 1. This playingEntity **SHALL** contain exactly one [1..1] **code** (CONF:14099)
2. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:14092).
3. **SHOULD** contain zero or one [0..1] **entryRelationship** (CONF:14106) such that it
 - a. **SHALL** contain exactly one [1..1] @typeCode="MFST" (CONF:14107).
 - b. **SHALL** contain exactly one [1..1] @inversionInd="true" (CONF:14108).
 - c. **SHALL** contain exactly one [1..1] Reaction (templateId: 2.16.840.1.113883.10.20.24.3.85) (CONF:14109)
 - i. **SHALL** contain exactly one [1..1] **code** (CONF:11661).
4. **SHALL** contain exactly one [1..1] **statusCode** (CONF:19084).
 - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:19085).

5.3.9.6 Medication Order

This template represents an order by a clinician or appropriately licensed care provider to a pharmacy to provide medication to a patient. The request is in the form of prescriptions or other medication orders with detail adequate for correct filling and administration. An author/time is required to represent medication ordering date time. This template is broader than a pharmacy supply order and may include a supply order. The moodCode is constrained to "RQO".

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Medication Order Code: //substanceAdministration[templateId/@root='2.16.840.1.113883.10.20.24.3.47']/consumable/manufacturedProduct[templateId/@root='2.16.840.1.113883.10.20.24.3.23']/manufacturedMaterial/	code	1..1	SHALL	12610 12611 7411 7412	n/a
Medication Order Status Code: //substanceAdministration[templateId/@root='2.16.840.1.113883.10.20.24.3.47']/statusCode/	@code	1..1	SHALL	12592 12641	2.16.840.1.113883.5.14 (ActStatus) = new
Medication Order Date Time: //substanceAdministration[templateId/@root='2.16.840.1.113883.10.20.24.3.47']/author/time/	@value	1..1	SHALL	DECC_P0033 DECC_P0034	n/a
Medication Order Dose Quantity: //substanceAdministration[templateId/@root='2.16.840.1.113883.10.20.24.3.47']/	doseQuantity	0..1	SHOULD	12602 12603	n/a

1. **SHALL** contain exactly one [1..1] **consumable** (CONF:12610).
 - a. This consumable **SHALL** contain exactly one [1..1] Medication Information (templateId:2.16.840.1.113883.10.20.22.4.23) (CONF:12611).
 - i. **SHALL** contain exactly one [1..1] **manufacturedMaterial** (CONF:7411).
2. This manufacturedMaterial **SHALL** contain exactly one [1..1] **code**, which **SHALL** be selected from ValueSet Medication Clinical Drug Name Value Set 2.16.840.1.113883.3.88.12.80.17 **DYNAMIC** (CONF:7412).
Note: The code **SHALL** be selected from the value set specified in the eCQMs.
3. **SHALL** contain exactly one [1..1] **statusCode** (CONF:12592).
 - a. This statusCode **SHALL** contain exactly one [1..1] @code="new" (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:12641).
4. **SHALL** contain exactly one [1..1] **author** (DECC_P0033) such that it
 - a. **SHALL** contain exactly one [1..1] **time** (DECC_P0034).
5. **SHOULD** contain zero or one [0..1] **doseQuantity** (CONF:12602).
 - a. The doseQuantity, if present, **SHOULD** contain zero or one [0..1] @unit, which **SHALL** be selected from ValueSet UCUM Units of Measure (case sensitive) 2.16.840.1.113883.1.11.12839 **DYNAMIC**="1" (ValueSet: UCUM Units of Measure (case sensitive) 2.16.840.1.113883.1.11.12839) (CONF:12603).

5.3.9.6.1 Medication Order Not Done (Negation)

This template describes a Medication Order that was not performed. This information is collected only when `negationInd="true"`.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Negation Reason Code: <code>//substanceAdministration[templateId/@root='2.16.840.1.113883.10.20.24.3.47']/entryRelationship[@typeCode="RSON"]/observation[templateId/@root='2.16.840.1.113883.10.20.24.3.88']</code>	<code>value[xsi:type="CD"]</code>	1..1	SHALL	DECC_P0024 DECC_P0025 DECC_P0026 11367	n/a

1. **SHALL** contain exactly one [1..1] `entryRelationship` (CONF:DECC_P0024) such that it
 - a. **SHALL** contain exactly one [1..1] `@typeCode="RSON"` (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:DECC_P0025).
 - b. **SHALL** contain exactly one [1..1] `Reason` (`templateId:2.16.840.1.113883.10.20.24.3.88`) (CONF:DECC_P0026).
 - i. **SHALL** contain exactly one [1..1] `value` with `@xsi:type="CD"` (CONF:11367).

5.3.10 Patient Characteristic

5.3.10.1 Patient Characteristic Expired

This clinical statement represents the observation that a patient has expired.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Patient Characteristic Expired Code: <code>//observation[templateId/@root='2.16.840.1.113883.10.20.24.3.54']</code>	<code>value[xsi:type="CD"]</code>	1..1	SHALL	14857 15142	2.16.840.1.113883.6.96 (SNOMED-CT) = 419099009
Patient Characteristic Expired Status Code: <code>//observation[templateId/@root='2.16.840.1.113883.10.20.24.3.54']/statusCode/</code>	<code>@code</code>	1..1	SHALL	14854 19095	2.16.840.1.113883.5.14 (ActStatus) = completed
Patient Characteristic Expired Effective Date Time: <code>//observation[templateId/@root='2.16.840.1.113883.10.20.24.3.54']</code>	<code>effectiveTime</code>	1..1	SHALL	14855 14874	n/a

1. **SHALL** contain exactly one [1..1] `value` with `@xsi:type="CD"` (CONF:14857).

- a. This value **SHALL** contain exactly one [1..1] @code="419099009" Dead (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96 **STATIC**) (CONF:15142).
- 2. **SHALL** contain exactly one [1..1] **statusCode** (CONF:14854).
 - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:19095).
- 3. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:14855)
 - a. This effectiveTime **SHALL** contain exactly one [1..1] **low** (CONF:14874).

5.3.10.2 Patient Characteristic Clinical Trial Participant

This template represents that the patient is a clinical trial participant.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Patient Characteristic Clinical Trial Participant Code: //observation[templateId/@root='2.1 6.840.1.113883.10.20.24.3.51']/	value[xsi:type="CD"]	1..1	SHALL	16712	n/a
Patient Characteristic Clinical Trial Participant Status Code: //observation[templateId/@root='2.1 6.840.1.113883.10.20.24.3.51']/statusCode/	@code	1..1	SHALL	13042	2.16.840.1.1 13883.5.14 (ActStatus) = active
Patient Characteristic Clinical Trial Participant Effective Date Time: //observation[templateId/@root='2.1 6.840.1.113883.10.20.24.3.51']/	effectiveTime	1..1	SHALL	12536	n/a

- 1. **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD" (CONF:16712).
- 2. **SHALL** contain exactly one [1..1] **statusCode**="active" (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:13042).
- 3. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:12536).

5.3.10.3 Patient Characteristic Payer

This observation represents the policy or program providing the coverage for the patient.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Payer Code: //observation[templateId/@root='2.1 6.840.1.113883.10.20.24.3.55']/	value[@xsi:type='CD']	1..1	SHALL	16710_P01	2.16.840.1.1 14222.4.11. 3591 (Payer Source of Payment Typology)

- 1. **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD", where the @code **SHALL** be selected from ValueSet Payer Source of Payment Typology 2.16.840.1.114222.4.11.3591 **DYNAMIC** (CONF:16710_P01).

5.3.10.4 Patient Characteristic Observation Assertion

This clinical statement is a pattern that can be used for any simple assertion observation. A value/code binding, value/value set binding, or `sdtc:valueSet` association in the instance is required to provide meaning.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Patient Observation Assertion Code: <code>//observation[templateId/@root='2.1.6.840.1.113883.10.20.24.3.103']/</code>	<code>value[@xsi:type='CD']</code>	1..1	SHALL	16541	n/a
Patient Observation Assertion Status Code : <code>//observation[templateId/@root='2.1.6.840.1.113883.10.20.24.3.103']/statusCode/</code>	<code>@code</code>	1..1	SHALL	16539	2.16.840.1.13883.5.14 (ActStatus)=completed
Patient Observation Assertion Effective Date Time: <code>//observation[templateId/@root='2.1.6.840.1.113883.10.20.24.3.103']/</code>	<code>effectiveTime</code>	1..1	SHALL	16540	n/a

1. **SHALL** contain exactly one [1..1] `statusCode="completed"` Completed (CONF:16539).
2. **SHALL** contain exactly one [1..1] `effectiveTime` (CONF:16540).
3. **SHALL** contain exactly one [1..1] `value` with `@xsi:type="CD"` (CONF:16541).

5.3.11 Physical Exam

5.3.11.1 Physical Exam Finding

This template represents the result or finding of a physical exam. A time/date stamp is required.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Physical Exam Finding Code: //observation[templateId/@root='2.1.6.840.1.113883.10.20.24.3.57'][templateId/@root='2.16.840.1.113883.10.20.22.4.2']	value	1..1	SHALL	16699 16700	n/a
Physical Exam Finding Status Code: //observation[templateId/@root='2.1.6.840.1.113883.10.20.24.3.57'][templateId/@root='2.16.840.1.113883.10.20.22.4.2']/statusCode/	@code	1..1	SHALL	7134 14849	2.16.840.1.113883.11.20.9.39 (Result Status)
Physical Exam Finding Effective Date Time: //observation[templateId/@root='2.1.6.840.1.113883.10.20.24.3.57'][templateId/@root='2.16.840.1.113883.10.20.22.4.2']/	effectiveTime	1..1	SHALL	7140	n/a

1. **SHALL** contain exactly one [1..1] **value** (CONF:16699).
 - a. If xsi:type=PQ, then @units **SHALL** be drawn from Unified Code for Units of Measure (UCUM) 2.16.840.1.113883.6.8 code system. Additional constraint is dependent on criteria in the corresponding eMeasure (CONF:16700).
2. **SHALL** contain exactly one [1..1] **statusCode** (CONF:7134).
 - a. This statusCode **SHALL** contain exactly one [1..1] @code, which **SHALL** be selected from ValueSet Result Status 2.16.840.1.113883.11.20.9.39 **STATIC** (CONF:14849).
3. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:7140).

5.3.11.2 Physical Exam Performed

This template represents that a physical exam has been completed. A time/date stamp is required, moodCode has been constrained to "EVN", and statusCode has been constrained to "completed".

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Physical Exam Performed Code: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.59']	code	1..1	SHALL	19197	n/a
Physical Exam Performed Status Code: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.59']/statusCode	@code	1..1	SHALL	12649 12650	2.16.840.1.113883.5.14 (ActStatus) = completed
Physical Exam Performed Effective Start Date Time: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.59']/effectiveTime/low/	@value	1..1	SHALL	12651 12652	n/a
Physical Exam Performed Effective End Date Time: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.59']/effectiveTime/high/	@value	1..1	SHALL	12651 12653	n/a

1. **SHALL** contain exactly one [1..1] code (CONF:19197)
2. **SHALL** contain exactly one [1..1] statusCode (CONF:12649).
 - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:12650).
3. **SHALL** contain exactly one [1..1] effectiveTime (CONF:12651).
 - a. This effectiveTime **SHALL** contain exactly one [1..1] low (CONF:12652).
 - b. This effectiveTime **SHALL** contain exactly one [1..1] high (CONF:12653).

5.3.11.2.1 Physical Exam Performed Not Done (Negation)

This template describes a Physical Exam that was not performed on a patient. This information is collected only when negationInd="true".

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Negation Reason Code: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.59']/entryRelationship[@typeCode="RSON"]/observation[templateId/@root='2.16.840.1.113883.10.20.24.3.88']	value[xsi:type="CD"]	1..1	SHALL	12656_P01 12657 12658 11367	n/a

1. **SHALL** contain exactly one [1..1] entryRelationship (CONF:12656_P01) such that it
 - a. **SHALL** contain exactly one [1..1] @typeCode="RSON" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:12657).
 - b. **SHALL** contain exactly one [1..1] Reason (templateId:2.16.840.1.113883.10.20.24.3.88) (CONF:12658).

- i. **SHALL** contain exactly one [1..1] value with @xsi:type="CD"(CONF:11367).

5.3.12 Procedure

5.3.12.1 Procedure Intolerance

This clinical statement template represents intolerance to a procedure generally perceived and reported by the patient. For example, a patient may report that a certain physical therapy procedure causes too much pain to continue complying with the regime.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Procedure Intolerance Code: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.62']/entryRelationship[@typeCode="CAUS"][@inversionInd="true"]/procedure[templateId/@root='2.16.840.1.113883.10.20.24.3.64']/	code	1..1	SHALL	11601 11602 11603 13940 7656	n/a
Procedure Intolerance Status Code: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.62']/statusCode/	@code	1..1	SHALL	11441 11442	2.16.840.1.13883.5.14 (ActStatus) = completed
Procedure Intolerance Effective Start Date Time: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.62']/effectiveTime/low/	@value	1..1	SHALL	11443 11444	n/a
Procedure Intolerance Code Effective End Date: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.62']/effectiveTime/high/	@value	0..1	SHOULD	11443 11445	n/a

1. **SHALL** contain exactly one [1..1] entryRelationship (CONF:11601) such that it
 - a. **SHALL** contain exactly one [1..1] @typeCode="CAUS" (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90 STATIC) (CONF:11602).
 - b. **SHALL** contain exactly one [1..1] @inversionInd="true" (CONF:11603).
 - c. **SHALL** contain exactly one [1..1] Procedure Performed (templateId:2.16.840.1.113883.10.20.24.3.64) (CONF:13940).
 - i. **SHALL** contain exactly one [1..1] code (CONF:7656)
2. **SHALL** contain exactly one [1..1] statusCode (CONF:11441).
 - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC (CONF:11442)).
3. **SHALL** contain exactly one [1..1] effectiveTime (CONF:11443).
 - a. This effectiveTime **SHALL** contain exactly one [1..1] low (CONF:11444).
 - b. This effectiveTime **SHOULD** contain zero or one [0..1] high (CONF:11445).

5.3.12.2 Procedure Order

This clinical statement represents an order for a procedure. A procedure is a course of action intended to achieve a result in the care of persons with health problems. It is generally invasive and involves physical contact. A procedure may be a surgery or other type of physical manipulation of a person's body in whole or in part for purposes of making observations and diagnoses and/or providing treatment. Note that procedure is distinct from intervention. The moodCode is constrained to "RQO". ActStatus is constrained to "new" and author/time is required to represent the ordering date time.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Procedure Order Code: //procedure[templateId/@root='2.16.840.1.11 3883.10.20.24.3.63']/	code	1..1	SHALL	11101	n/a
Procedure Order Status Code: //procedure[templateId/@root='2.16.840.1.11 3883.10.20.24.3.63']/statusCode/	@code	1..1	SHALL	14576 14577	new
Procedure Order Date Time: //procedure[templateId/@root='2.16.840.1.11 3883.10.20.24.3.63']/author/time/	@value	1..1	SHALL	11595 11596	n/a

1. SHALL contain exactly one [1..1] code (CONF:11101)
2. SHALL contain exactly one [1..1] statusCode (CONF:14576).
 - a. This statusCode SHALL contain exactly one [1..1] @code="new" (CONF:14577).
3. SHALL contain exactly one [1..1] author (CONF:11595).
 - a. This author SHALL contain exactly one [1..1] time (CONF:11596).

5.3.12.3 Procedure Performed

This clinical statement represents a procedure that has been performed.

A procedure is a course of action intended to achieve a result in the care of persons with health problems. It is generally invasive and involves physical contact. A procedure may be a surgery or other type of physical manipulation of a person's body in whole or in part for purposes of making observations and diagnoses and/or providing treatment. Some of these procedures are not reimbursed. Note that procedure is distinct from intervention. The moodCode has been constrained to "EVN".

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Procedure Performed code: //procedure[templateId/@root='2.16.840.1.113883.10.20.24.3.64']/	code	1..1	SHALL	7656	n/a
Procedure Performed Status Code: //procedure[templateId/@root='2.16.840.1.113883.10.20.24.3.64']/statusCode/	@code	1..1	SHALL	7661	2.16.840.1.113883.11.20.9.22 (ProcedureAct statusCode)
Procedure Performed Start Date Time: //procedure[templateId/@root='2.16.840.1.113883.10.20.24.3.64']/effectiveTime/low/	@value	1..1	SHALL	11669 11670	n/a
Procedure Performed Stop Date Time: //procedure[templateId/@root='2.16.840.1.113883.10.20.24.3.64']/effectiveTime/high/	@value	1..1	SHALL	11669 11671	n/a

1. **SHALL** contain exactly one [1..1] code (CONF:7656)
2. **SHALL** contain exactly one [1..1] effectiveTime (CONF:11669).
 - a. This effectiveTime **SHALL** contain exactly one [1..1] low (CONF:11670).
 - b. This effectiveTime **SHALL** contain exactly one [1..1] high (CONF:11671).
3. **SHALL** contain exactly one [1..1] statusCode, which **SHALL** be selected from ValueSet ProcedureAct statusCode 2.16.840.1.113883.11.20.9.22 DYNAMIC (CONF:7661).

5.3.12.3.1 Procedure Performed Not Done (Negation)

This template describes a procedure that was not performed. This information is collected only when negationInd="true".

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Negation Reason Code: //procedure[templateId/@root='2.16.840.1.113883.10.20.24.3.64']/entryRelationship[@typeCode="RSON"]/observation[templateId/@root='2.16.840.1.113883.10.20.24.3.88']/	value[xsi:type="CD"]	1..1	SHALL	11371_P01 11372 11498 11367	n/a

1. **SHALL** contain exactly one [1..1] entryRelationship (CONF:11371_P01) such that it
 - a. **SHALL** contain exactly one [1..1] @typeCode="RSON" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:11372).
 - b. **SHALL** contain exactly one [1..1] Reason (templateId:2.16.840.1.113883.10.20.24.3.88) (CONF:11498).

- i. **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD" (CONF:11367).

5.3.12.4 Procedure Result

This template represents the findings identified as a result of the procedure. The moodCode has been constrained to "EVN" and statusCode has been constrained to "completed".

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Procedure Result Code: //procedure[templateId/@root='2.16.84 0.1.113883.10.20.24.3.66']	code	1..1	SHALL	11112	n/a
Procedure Result Status Code: //procedure[templateId/@root='2.16.84 0.1.113883.10.20.24.3.66']/statusCode/	@code	1..1	SHALL	14169 14170	2.16.840.1.13883.5.14 (ActStatus) = completed
Procedure Result Effective Start Date Time: //procedure[templateId/@root='2.16.84 0.1.113883.10.20.24.3.66']/effectiveTime/low/	@value	1..1	SHALL	11113 11696	n/a
Procedure Result Effective End Date Time: //procedure[templateId/@root='2.16.84 0.1.113883.10.20.24.3.66']/effectiveTime/high/	@value	1..1	SHALL	11113 11697	n/a
Procedure Result: //procedure[templateId/@root='2.16.84 0.1.113883.10.20.24.3.66']/entryRelationship[@typeCode="REFR"]/observation[templateId/@root='2.16.84 0.1.113883.10.20.24.3.87']	value	1..1	SHALL	16701 16702	n/a

1. **SHALL** contain exactly one [1..1] **code** (CONF:11112).
2. **SHALL** contain exactly one [1..1] **statusCode** (CONF:14169).
 - a. This **statusCode** **SHALL** contain exactly one [1..1] @code="completed" (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:14170).
3. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:11113).
 - a. This **effectiveTime** **SHALL** contain exactly one [1..1] **low** (CONF:11696).
 - b. This **effectiveTime** **SHALL** contain exactly one [1..1] **high** (CONF:11697).
4. **SHALL** contain exactly one [1..1] **value** (CONF:16701).
 - a. If xsi:type=PQ, then @units **SHALL** be drawn from Unified Code for Units of Measure (UCUM) 2.16.840.1.113883.6.8 code system. Additional constraint is dependent on criteria in the corresponding eMeasure (CONF:16702)

5.3.13 Risk Category

5.3.13.1 Risk Category Assessment

Risk category assessments include tools and calculators that suggest vulnerabilities for any given patient. Distinct from functional status, risk categorization uses findings, observations, results, and sometimes judgments and patient-generated information for use within clinical care algorithms, clinical decision support, and severity analysis. A time/date stamp is required.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Risk Category Assessment Code: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.69']	code	1..1	SHALL	14439	n/a
Risk Category Assessment Status Code: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.69']/statusCode	@code	1..1	SHALL	14444 19088	2.16.840.1.13883.5.14 (ActStatus) = completed
Risk Category Assessment Effective Date Time: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.69']	effectiveTime	1..1	SHALL	14445	n/a
Risk Category Assessment Value: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.69']	value	1..1	SHALL	14450	n/a

1. **SHALL** contain exactly one [1..1] **code** (CONF:14439)
2. **SHALL** contain exactly one [1..1] **statusCode** (CONF:14444).
 - a. This **statusCode** **SHALL** contain exactly one [1..1] **@code="completed"** Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:19088).
3. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:14445).
4. **SHALL** contain exactly one [1..1] **value** (CONF:14450).

5.3.13.1.1 Risk Category Assessment Not Done (Negation)

This template describes a Risk Category Assessments that was not performed on the patient. This information is collected only when negationInd="true".

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Negation Reason Code: //observation[templateId/@root='2.16.840.1.113883.10.20.24.3.69']/entryRelationship[@typeCode="RSON"]/observation[templateId/@root='2.16.840.1.113883.10.20.24.3.88']	value[xsi:type="CD"]	1..1	SHALL	DECC_P0030 DECC_P0031 DECC_P0032 11367	n/a

1. **SHALL** contain exactly one [1..1] **entryRelationship** (CONF:DECC_P0030) such that it

- a. **SHALL** contain exactly one [1..1] @typeCode="RSON" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:DECC_P0031).
- b. **SHALL** contain exactly one [1..1] Reason
(templateId:2.16.840.1.113883.10.20.24.3.88)
(CONF:DECC_P0032).
 - i. **SHALL** contain exactly one [1..1] value with @xsi:type="CD" (CONF:11367).

5.3.14 Tobacco Use

This clinical statement represents a patient's tobacco use.

Parameter Name: XPath	Attribute/ Element	Card.	Verb	CONF#	Fixed Value
Tobacco Use Code: <code>observation[templateId/@root='2.16.840.1.113883.10.20.22.4.85']/value[xsi:type="CD"]/</code>	code	1..1	SHALL	16562 16563	2.16.840.1.113883.11.20.9.41 (Tobacco Use)
Tobacco Use Status Code: <code>observation[templateId/@root='2.16.840.1.113883.10.20.22.4.85']/statusCode</code>	@statusCode	1..1	SHALL	16561 19118	2.16.840.1.113883.5.14 (ActStatus) = completed
Tobacco Use Effective Date Time: <code>observation[templateId/@root='2.16.840.1.113883.10.20.22.4.85']/</code>	effectiveTime	1..1	SHALL	16564 16565	n/a

1. **SHALL** contain exactly one [1..1] value with @xsi:type="CD" (CONF:16562).
 - a. This value **SHALL** contain exactly one [1..1] @code, which **SHALL** be selected from ValueSet Tobacco Use 2.16.840.1.113883.11.20.9.41 **DYNAMIC** (CONF:16563).
Note: The @code SHALL be selected from the value set specified in the eCQMs.
2. **SHALL** contain exactly one [1..1] statusCode (CONF:16561).
 - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:19118).
3. **SHALL** contain exactly one [1..1] effectiveTime (CONF:16564).
 - a. This effectiveTime **SHALL** contain exactly one [1..1] low (CONF:16565).

5.3.15 Attribute Facility Location

This clinical statement represents the location where an act, observation, or procedure took place.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Facility Location Code: //Participant[templateId/@root='2.16.840.1.113883.10.20.24.3.100']/ParticipantRole[@classCode="SDLOC"]	code	1..1	SHALL	13372 13373 13378	n/a
Facility Location Effective Start Date Time: //Participant[templateId/@root='2.16.840.1.113883.10.20.24.3.100'][@typeCode="LOC"]/time/low/	@value	1..1	SHALL	13371 13384	n/a
Facility Location Effective End Date Time: //Participant[templateId/@root='2.16.840.1.113883.10.20.24.3.100'][@typeCode="LOC"]/time/high/	@value	1..1	SHALL	13371 13385	n/a

1. SHALL contain exactly one [1..1] time (CONF:13371).
 - a. This time SHALL contain exactly one [1..1] low (CONF:13384).
 - b. This time SHALL contain exactly one [1..1] high (CONF:13385).
2. SHALL contain exactly one [1..1] participantRole (CONF:13372).
 - a. This participantRole SHALL contain exactly one [1..1] @classCode="SDLOC" service delivery location (CodeSystem: RoleClass 2.16.840.1.113883.5.110 STATIC) (CONF:13373).
 - b. This participantRole SHALL contain exactly one [1..1] code (CONF:13378)

5.3.16 Attribute Severity

This clinical statement represents the gravity of the problem.

Parameter Name: XPath	Attribute/Element	Card.	Verb	CONF#	Fixed Value
Diagnosis Severity Code: //observation[templateId/@root='2.16.840.1.113883.10.20.22.4.8']	value[@xsi:type='CD']	1..1	SHALL	7356	2.16.840.1.13883.3.88.12.3221.6.8 (Problem Severity)
Diagnosis Severity Status Code: //observation[templateId/@root='2.16.840.1.113883.10.20.22.4.8']/statusCode	@code	1..1	SHALL	7352 19115	2.16.840.1.13883.5.14 (ActStatus) = completed

1. SHALL contain exactly one [1..1] statusCode (CONF:7352).
 - a. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC) (CONF:19115).
2. SHALL contain exactly one [1..1] value with @xsi:type="CD", where the @code SHALL be selected from ValueSet Problem Severity 2.16.840.1.113883.3.88.12.3221.6.8 DYNAMIC (CONF:7356).

Note: The @code SHALL be selected from the value set specified in the eCQMs.

5.3.17 Attribute Result

This template represents the final consequences or data collected from a sequence of actions or events, or observable entities, including (but not limited to) procedures, laboratory tests, physical examinations, or diagnostic tests.

Parameter Name: XPath	Attribute/ Element	Card.	Verb	CONF#	Fixed Value
Result Code: <code>//observation[templateId/@root='2.16.840.1.13883.10.20.24.3.87'][templateId/@root='2.16.840.1.113883.10.20.22.4.2']</code>	code	1..1	SHALL	7133	n/a
Result Status Code: <code>//observation[templateId/@root='2.16.840.1.13883.10.20.24.3.87'][templateId/@root='2.16.840.1.113883.10.20.24.3.93']/value[xsi:type="CD"]</code>	@code	1..1	SHALL	11887	n/a
Result Effective Date Time: <code>//observation[templateId/@root='2.16.840.1.13883.10.20.24.3.87'][templateId/@root='2.16.840.1.113883.10.20.22.4.2']</code>	effective Time	1..1	SHALL	7140	n/a

1. SHALL contain exactly one [1..1] code (CONF:7133).
2. SHALL contain exactly one [1..1] effectiveTime (CONF:7140).
3. SHALL contain exactly one [1..1] value (CONF:11887).

5.3.18 Attribute Reason

This template represents the thought process or justification for an action or for not performing an action. Examples include patient, system, or medical-related reasons for declining to perform specific actions. Note that the parent template that calls this template can be asserted to have occurred or to not. Therefore, this template simply provides a reason to some other (possibly negated) act. As such, there is nothing in the template that says whether the parent act did or did not occur.

Parameter Name: XPath	Attribute/ Element	Card.	Verb	CONF#	Fixed Value
Reason Code: <code>//observation[templateId/@root='2.16.840.1.113883.10.20.24.3.88']</code>	value[xsi:type="CD"]	1..1	SHALL	11367	n/a
Reason Status Code: <code>//observation[templateId/@root='2.16.840.1.113883.10.20.24.3.88']/statusCode/</code>	@code	1..1	SHALL	11364 11365	2.16.840.1.13883.5.14 (ActStatus) = completed
Reason Effective Date Time: <code>//observation[templateId/@root='2.16.840.1.113883.10.20.24.3.88']</code>	effective Time	1..1	SHALL	11366	n/a

1. SHALL contain exactly one [1..1] statusCode (CONF:11364).

- a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:11365).
- 2. **SHALL** contain exactly one [1..1] effectiveTime (CONF:11366).
- 3. **SHALL** contain exactly one [1..1] value with @xsi:type="CD" (CONF:11367)

5.3.19 Attribute Ordinality

This template represents the scale in which objects are ordered in terms of their qualitative value, as opposed to a ranking performed strictly numerically or quantitatively. For ordinality of principal diagnosis, the ordinality maps to the priorityCode element in the Diagnosis Active template.

Parameter Name: XPath	Attribute/ Element	Card.	Verb	CONF#	Fixed Value
Ordinality Code: <code>//observation[templateId/@root='2.16.840.1.113883.10.20.24.3.11']/priorityCode/</code>	@code	0..1	MAY	14547	n/a

- 1. **MAY** contain zero or one [0..1] priorityCode (CONF:14547).

6. Troubleshooting and Support

6.1 Resources

The following are helpful resources for finding additional information:

- **eCQM Library** contains resources for eCQMs including Measure Logic Guidance: http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html
- **National Library of Medicine (NLM) Value Set Authority Center (VSAC)** contains the official versions of the value sets used for eCQMs: <https://vsac.nlm.nih.gov/>
- **Electronic Clinical Quality Measure specification feedback system** is a tool offered by CMS and ONC for implementers to submit issues and request guidance on eCQM logic, specifications, and certification: <http://oncprojecttracking.org/secure/Dashboard.jspa>

6.2 Support

Contact	Organization	Phone	Email	Role	Responsibility
CMS IT Service Desk	CMS	(410) 786-2580 (800) 562-1963	CMS_IT_Service_Desk@cms.hhs.gov	Help desk support	1 st level user support & problem reporting
QNet Help Desk	QualityNet	(866) 288-8912	qnetsupport@sdps.org	Help desk support	Troubleshooting assistance

7. Appendix

7.1 Supplemental Implementation Guide Changes to Base Standard

This table lists all changes made to QRDA-I in this supplemental guide. The "Base Standard" is the *HL7 Implementation Guide for CDA Release 2: Quality Report Document Architecture, Category I, DSTU Release 2, (US Realm), Draft Standard for Trial Use - July 2012* including updates to non-normative content for errata approved as of December 21, 2012.

CONF. #	Section	Base Standard	Changed To
10003_P01	5.1.1	MAY contain zero or more [0..*] participant (CONF:10003).	MAY contain zero or more [0..*] participant (CONF:10003_P01) such that it
7294_P01	5.1.2	SHOULD contain zero or one [0..1] postalCode (ValueSet: PostalCodeValueSet 2.16.840.1.113883.3.8 8.12.80.2 DYNAMIC) (CONF:7294).	SHOULD contain zero or one [0..1] postalCode (CONF:7294_P01).
7295_P01	5.1.2	SHOULD contain zero or one [0..1] country , where the @code SHALL be selected from ValueSet CountryValueSet 2.16.840.1.113883.3.8 8.12.80.63 DYNAMIC (CONF:7295).	SHOULD contain zero or one [0..1] country (CONF:7295_P01).
7157_P01	5.1.2	SHALL contain at least one [1..*] given (CONF:7157).	SHALL contain exactly one [1..1] given (CONF:7157_P01).
6394_P01	5.1.2	This patient SHALL contain exactly one [1..1] administrativeGenderCode , which SHALL be selected from ValueSet 2.16.840.1.113883.1.1 1.1 (Administrative Gender Value Set) DYNAMIC (CONF:6394).	This patient SHALL contain exactly one [1..1] administrativeGenderCode , which SHALL be selected from either ValueSet ONC Administrative Sex 2.16.840.1.113762.1.4.1 or ValueSet Administrative Gender (HL7 V3) 2.16.840.1.113883.1.11.1 DYNAMIC (CONF:6394_P01).
5300_P01	5.1.2	SHOULD be precise to day (CONF:5300)	SHALL be precise to day (CONF:5300_P01)
5322_P01	5.1.2	This patient MAY contain zero or one [0..1] raceCode , which SHALL be selected from ValueSet Race 2.16.840.1.113883.1.1 1.14914 DYNAMIC (CONF:5322).	This patient SHALL contain exactly one [1..1] raceCode , which SHALL be selected from ValueSet Race 2.16.840.1.114222.4.11.83 6 DYNAMIC (CONF:5322_P01)

CONF. #	Section	Base Standard	Changed To
7263_P01	5.1.2	This patient MAY contain zero or more [0..*] sdtc:raceCode , where the @code SHALL be selected from ValueSet Race Value Set 2.16.840.1.113883.1.1 1.14914 DYNAMIC (CONF:7263).	This patient MAY contain zero or more [0..*] sdtc:raceCode , where the @code SHALL be selected from ValueSet Race 2.16.840.1.114222.4.11.83 6 DYNAMIC (CONF:7263_P01).
5323_P01	5.1.2	This patient MAY contain zero or one [0..1] ethnicGroupCode , which SHALL be selected from ValueSet EthnicityGroup 2.16.840.1.114222.4.1 1.837 DYNAMIC (CONF:5323).	This patient SHALL contain exactly one [1..1] ethnicGroupCode , which SHALL be selected from ValueSet Ethnicity Group 2.16.840.1.114222.4.11.83 7 DYNAMIC (CONF:5323_P01).
16579_P01	5.1.3	MAY contain zero or one [0..1] documentationOf (CONF:16579)	SHALL contain exactly one [1..1] documentationOf (CONF:16579_P01)
16588_P01	5.1.3	SHOULD contain zero or one [0..1] @root='2.16.840.1.113883.4.6' National Provider ID (CONF:16588).	SHALL contain exactly one [1..1] @root='2.16.840.1.113883.4.6' • National Provider ID (CONF:16588_P01).
16592_P01	5.1.3	This representedOrganization SHOULD contain zero or one [0..1] id (CONF:16592) such that it	This representedOrganization SHALL contain exactly one [1..1] id (CONF:16592_P01) such that it
16703_P01	5.1.4	MAY contain zero or more [0..*] informationRecipient (CONF:16703).	SHALL contain exactly one [1..1] informationRecipient (CONF:16703_P01).
16705_P01	5.1.4	This intendedRecipient SHALL contain at least one [1..*] id (CONF:16705) such that	This intendedRecipient SHALL contain exactly one [1..1] id (CONF:16705_P01) such that
12833_P01	5.2.3	SHOULD contain zero or more [0..*] entry (CONF:12833)	SHALL contain at least one [1..*] entry (CONF:12833_P01)

CONF. #	Section	Base Standard	Changed To
15975_P01	5.3.3.2	This administrativeGenderCode SHALL contain exactly one [1..1] @code, which SHALL be selected from ValueSet Administrative Gender (HL7 V3) 2.16.840.1.113883.1.1 STATIC (CONF:15975).	This patient SHALL contain exactly one [1..1] administrativeGenderCode , which SHALL be selected from either ValueSet ONC Administrative Sex 2.16.840.1.113762.1.4.1 or ValueSet Administrative Gender (HL7 V3) 2.16.840.1.113883.1.11.1 DYNAMIC (CONF:15975_P01).
12963_P01	5.3.4.2.1	MAY contain zero or one [0..1] entryRelationship (CONF:12963)	SHALL contain exactly one [1..1] entryRelationship (CONF:12963_P01)
13804_P01	5.3.4.3.1	MAY contain zero or one [0..1] entryRelationship (CONF:13804)	SHALL contain exactly one [1..1] entryRelationship (CONF:13804_P01)
13604_P01	5.3.7.2.1	MAY contain zero or one [0..1] entryRelationship (CONF:13604)	SHALL contain exactly one [1..1] entryRelationship (CONF:13604_P01)
11727_P01	5.3.8.2.1	MAY contain zero or one [0..1] entryRelationship (CONF:11727)	SHALL contain exactly one [1..1] entryRelationship (CONF:11727_P01)
16710_P01	5.3.10.3	SHALL contain exactly one [1..1] value with @xsi:type="CD", where the @code SHALL be selected from ValueSet Source of Payment Typology Health Insurance Type Code List 2.16.840.1.113883.3.2 21.5 DYNAMIC (CONF:16710).	SHALL contain exactly one [1..1] value with @xsi:type="CD", where the @code SHALL be selected from ValueSet Payer Source of Payment Typology 2.16.840.1.114222.4.11.35 91(CONF:16710_P01).
12656_P01	5.3.11.2.1	MAY contain zero or one [0..1] entryRelationship (CONF:12656)	SHALL contain exactly one [1..1] entryRelationship (CONF:12656_P01)
11371_P01	5.3.12.3.1	MAY contain zero or one [0..1] entryRelationship (CONF:11371)	SHALL contain exactly one [1..1] entryRelationship (CONF:11371_P01)
DECC_P0039	5.1.1	n/a	Conforms to QDM-Based QRDA template (2.16.840.1.113883.10.20.24.1.2). SHALL contain exactly one [1..1] templateId (CONF:DECC_P0039) such that it
DECC_P0001	5.1.1	n/a	SHALL contain exactly one [1..1] @root="2.16.840.1.113883.1.0.20.24.1.3" (CONF:DECC_P0001).

CONF. #	Section	Base Standard	Changed To
DECC_P0040 DECC_P0003 DECC_P0004	5.1.1	n/a	<p>SHALL contain exactly one [1..1] associatedEntity (CONF:DECC_P0040)</p> <ul style="list-style-type: none"> • This associatedEntity MAY contain zero or one [1..1] id (CONF:DECC_P0003) such that it • SHALL contain exactly one [1..1] @root='2.16.840.1.11388 3.3.2074.1' CMS EHR Certification Number (formerly known as Office of the National Coordinator Certification Number) and the value of @extension is the Certification Number (CONF:DECC_P0004).
DECC_P0002	5.1.2	n/a	For Non-Medicare patients it SHALL contain exactly one [1..1] Medical Record Number (CONF:DECC_P0002)
DECC_P0036 DECC_P0037	5.1.3	n/a	<p>This assignedEntity MAY contain zero or one [0..1] assignedPerson (DECC_P0036)</p> <ul style="list-style-type: none"> • This assignedPerson MAY contain zero or one [0..1] name (DECC_P0037)
DECC_P0009 DECC_P0010	5.1.4	n/a	<p>This intendedRecipient SHALL contain exactly one [1..1] id (CONF:16705_P01) such that</p> <ul style="list-style-type: none"> • It SHALL contain exactly one [1..1] @root='2.16.840.1.113883.3.249.7' (CONF:DEC_C_P0010) <p>It SHALL contain exactly one [1..1] @extension, the value of @extension is CMS Program Name (CONF:DECC_P0009).</p>
DECC_P0038	5.1.4	n/a	This representedOrganization MAY contain zero or one [0..1] name (DECC_P0038)
DECC_P0007	5.3.1.1	n/a	SHALL contain exactly one [1..1] code (CONF:DECC_P0007).
DECC_P0008	5.3.1.2	n/a	SHALL contain exactly one [1..1] code (CONF:DECC_P0008).

CONF. #	Section	Base Standard	Changed To
DECC_P0012 DECC_P0013	5.3.1.2.1	n/a	<p>SHALL contain exactly one [1..1] entryRelationship (CONF:DECC_P0012) such that it</p> <ul style="list-style-type: none"> • SHALL contain exactly one [1..1] Reason (templateId: 2.16.840.1.113883.10.20.24.3.8 8) (CONF:DECC_P0013).
DECC_P0005	5.3.1.3	n/a	SHALL contain exactly one [1..1] code (CONF:DECC_P0005).
DECC_P0006 DECC_P0016	5.3.7.1	n/a	<p>SHALL contain exactly one [1..1] statusCode (CONF:DECC_P0006).</p> <ul style="list-style-type: none"> • This statusCode SHALL contain exactly one [1..1] @code = "new" (CodeSystem: ActStatus 2.16.840.1.113883.5.1 4 STATIC) (CONF:DECC_P0016).
DECC_P0020 DECC_P0021 DECC_P0022	5.3.9.2.1	n/a	<p>SHALL contain exactly one [1..1] entryRelationship (CONF:DECC_P0020) such that it</p> <ul style="list-style-type: none"> • SHALL contain exactly one [1..1] @typeCode = "RSON" (CodeSystem: HL7ActRelationship Type 2.16.840.1.113883.5.1 002 STATIC) (CONF:DECC_P0021). • SHALL contain exactly one [1..1] Reason (templateId: 2.16.840.1.113883.10.20.24.3.8 8) (CONF:DECC_P0022).
DECC_P0033 DECC_P0034	5.3.9.6	n/a	<p>SHALL contain exactly one [1..1] author (DECC_P0033) such that it</p> <ul style="list-style-type: none"> • SHALL contain exactly one [1..1] time (DECC_P0034).

CONF. #	Section	Base Standard	Changed To
DECC_P0024 DECC_P0025 DECC_P0026	5.3.9.6.1	n/a	<p>SHALL contain exactly one [1..1] entryRelationship (CONF:DECC_P0024) such that it</p> <ul style="list-style-type: none"> • SHALL contain exactly one [1..1] @typeCode= "RSON" (CodeSystem: HL7ActRelationship Type 2.16.840.1.113883.5.1 002 STATIC) (CONF:DECC_P0025). • SHALL contain exactly one [1..1] Reason (templateId: 2.16.840.1.113883.10.20.24.3.8 8) (CONF:DECC_P0026).
DECC_P0030 DECC_P0031 DECC_P0032	5.3.13.1.1	n/a	<p>SHALL contain exactly one [1..1] entryRelationship (CONF:DECC_P0030) such that it</p> <ul style="list-style-type: none"> • SHALL contain exactly one [1..1] @typeCode= "RSON" (CodeSystem: HL7ActRelationship Type 2.16.840.1.113883.5.1 002 STATIC) (CONF:DECC_P0031). • SHALL contain exactly one [1..1] Reason (templateId: 2.16.840.1.113883.10.20.24.3.8 8) (CONF:DECC_P0032).

7.2 Program Specific Constraints

This table lists program specific constraints made to QRDA-I in this supplemental guide.

CONF. #	Section	Data Element/ Section	Description
16858	5.1.2	Medicare HIC Number	<p>This data element is required for Pioneer ACO.</p> <p>This data element is required for PQRS, if the payer is Medicare.</p>
DECC_P0036 DECC_P0037	5.1.3	Provider Name (Given and Family)	This data element is optional for Pioneer ACO.
DECC_P0038	5.1.3	Clinic Name	This data element is optional for Pioneer ACO.
16588_P01	5.1.3	National Provider Identification (NPI) Number	This data element is optional for GPROs by setting <id @root='2.16.840.1.113883.4.6' @nullFlavor='NA'/>.

7.3 Validation Rules

Element	Validation Rule
Medicare HIC number	<p>The format of Medicare HIC numbers shall meet the following requirements.</p> <ul style="list-style-type: none">(a) No embedded dashes or spaces.(b) Must be alphanumeric.(c) Alpha characters must be upper case.(d) Length can't be > 12 or < 7.(e) If alphanumeric, all numbers cannot be 9s.(f) If length 7: must be 1 alpha + 6 numeric.(g) If length 8: must be 2 alpha + 6 numeric.(h) If length 9: must be 3 alpha + 6 numeric.(i) If length 10: can either be 1 alpha + 9 numeric, or 9 numeric + 1 alpha.(j) If length 11: must be 2 alpha + 9 numeric, or 9 numeric + 1 alpha + 1 numeric, or 9 numeric + 2 alpha.(k) If length 12: must be 3 alpha + 9 numeric.

Acronyms

This section describes the acronyms used in this guide.

Acronym	Literal Translation
ACO	Accountable Care Organizations
CDA	Clinical Document Architecture
CMS	Centers for Medicare & Medicaid Services
CQM	Clinical Quality Measure
DSTU	Draft Standard for Trial Use
DSV	Data Submission Vendor
eCQM	electronic Clinical Quality Measure
EHR	Electronic Health Record
EP	Eligible Professional
GPRO	Group Practice Reporting Option
GUID	Globally Unique Identifier
MU	Meaningful Use
n/a	not applicable
NPI	National Provider Identification Number
NQF	National Quality Forum
PQRS	Physician Quality Reporting System
QDM	Quality Data Model
QRDA	Quality Reporting Data Architecture
QRDA-I	Quality Reporting Data Architecture Category I
TIN	Tax Identification Number
XML	Extensible Markup Language

Glossary

Term	Definition
Electronic Health Record (EHR)	Electronic records of patient health information gathered and/or generated in any care delivery setting. This information includes patient demographics, progress notes, medications, vital signs, past medical history, immunizations, laboratory data, and radiology reports. This provides the ability to pass information from care point to care point providing the ability for quality health management by physicians.
eMeasure	A standardized performance measure in the Health Quality Measures Format (HQMF). CMS uses "eCQM" (electronic Clinical Quality Measure) for the eMeasures developed under the Meaningful Use program.
Physician Quality Reporting System (PQRS)	A quality reporting system that includes an incentive payment for eligible professionals who satisfactorily report data on quality measures for covered professional services provided during the specified program year.
XML Path Language (XPath)	This notation provides a mechanism that will be familiar to developers for identifying parts of an XML document. 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 an '@') and concatenated with a '/' symbol.

References

CMS eCQM Library, "2014 eCQM Specifications for EP Release June 2013 ". (The source of eMeasures used for analysis of QDM Data Elements in this guide.)

http://cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/2014_eCQM_EP_June2013.zip

HL7, *Clinical Document Architecture, Release 2.0.* (Normative Edition, May 2005.)

http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7

HL7 Implementation Guide for CDA Release 2: Quality Report Document Architecture, Category I (QRDA), DSTU Release 2, (US Realm), Draft Standard for Trial Use - July 2012 including updates to non-normative content for errata approved as of December 21, 2012.

http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35