Guidance for
2016 CMS QRDA I Schematron v2.3
HQR and EP Programs

Fixes

Major Issue

Description:
When submitting a Quality Reporting Document Architecture (QRDA) Category I file with a code other than a Logical Observations Identifiers Names and Codes (LOINC) in the Diagnostic Study Performed and Laboratory Test Performed data element fields, an “error” message is received preventing successful submission of QRDA Category I files. The CMS Implementation Guide (IG) states that codes from the electronic clinical quality measures (eCQM) specified value sets must be used, which could contain codes other than LOINC, such as SNOMED CT, ICD-9, ICD-10, etc., depending on the value set definition. This issue pertains to the Result Observation, which the Diagnostic Study Performed and Laboratory Test Performed data elements make use of. Several eCQMs use these Quality Data Model (QDM) data types in their measure definition. This means that users submitting for any measures with these templates could potentially be unable to successfully submit their QRDA Category I files if an appropriate LOINC code is not used.

This issue affects the following conformance numbers in the Eligible Professional (EP) Programs and Hospital Quality Reporting (HQR) Schematrons:
- CONF. #:1098-7133
- CONF. #:1140-28026
- CONF. #:1098-30784

Correction:
To correct this issue, the following updated versions of the 2016 CMS QRDA I Schematron have been published. The 2016 CMS QRDA III Schematron v2.2 files are not affected.
- 2016 CMS QRDA-I Schematrons and Sample Files version 2.3 for Hospital Quality Reporting
- 2016 CMS QRDA-I Schematrons and Sample Files version 2.3 for Eligible Professional Programs
Minor Known Issues

Issue #1

**Description:**
The structure of the data type rule for Concept Descriptor (CD) and Coded with Equivalents (CE) does not coincide with the guidance in the 2016 CMS QRDA IG for Category-I and III. The 2016 CMS QRDA IG states that @nullFlavor="NA" SHALL be submitted in both QRDA-I and QRDA-III for both HQR and Physician Quality Reporting System (PQRS). If both @codeSystem and @nullFlavor attributes are present for the CD or CE data types, the Schematron rule requires the value of @nullFlavor to use the nullFlavor code “OTH” only. If @nullFlavor is present without @codeSystem, the value of @nullFlavor can be any nullFlavor codes, such as “NA” and “NI”.

**Correction:**

The example below shows how data for “Not Done with a reason” should be submitted:

**Examples:**

```xml
<value xsi:type="CD" @nullFlavor="NA" @sdtc:valueSet="2.16.840.1.113883.3.464.1003.104.12.1001"/>
```

The example below is not permitted since it will fail the Schematron validation:

```xml
<value xsi:type="CD" @nullFlavor="NA" @codeSystem="2.16.840.1.113883.6.90" @sdtc:valueSet="2.16.840.1.113883.3.464.1003.104.12.1001"/>
```
Issue #2

**Description:**
CMS Schematron for RY 2016, **CONF:1098-7508** currently cannot be met with @value because @xsi:type="IVL_TS" is required by the Schematron, Pre-Submission Validation Application (PSVA), and QualityNet. While the HL7 R3 QRDA-I specifications state data Type IVL_TS in Table 132, there is no mention of IVL_TS in the main body and the IG does specifically states that @value or low should be acceptable. According to the specifications, @value should be used for a single-administration timestamp whereas low and high should be used for medication start and stop times.

**Correction:**
As a workaround, all single administrations should be sent with IVL_TS data type and a low timestamp to satisfy the CMS Schematron.

**Example:**

```xml
<effectiveTime>
<low value="20160809163000-0600"/>
</effectiveTime>
```

Trivial Known Issues

Issue #1

**Description:**
The base QRDA-I and QRDA-III HL7 IGs used for 2016 reporting has **CONF:23-3277** defined differently than the way it is implemented in version 2.2 of the CMS PQRS Schematron rules. Specifically, the Schematron checks for the typeCode='DRIV' on a Reporting Parameters Act as a separate conformance statement.

**Correction:**
This best practice has been noted by Schematron developers to implement the typeCode='DRIV' check along with the relevant conformance statement for future development. Submitters will not be hindered from submitting QRDA files due to the separate checks currently implemented in the Schematron.
Issue #2

Description:
The base QRDA-I HL7 IG the Patient Data Section is defined with both an @root and an @extension, but the constraint (CONF:1140-28405) within the 2016 CMS QRDA IG section only identifies the @root attribute.

Correction:
Please note that CMS Schematron rules *do* check for the @extension.

Issue #3

Description:
Typo Corrections: CMS Schematron rule constraints: 1140-27994 and 1140-27980, are in the reverse order than they appear in the base HL7 QRDA-I IG. This also appears with: CONF: 1140-27972, 1140-27976, 1140-27973.

Correction:
The IG has the typeCode message first and the participantRole last. The check is fine; however, please note that the message does not match the base HL7 QRDA-I IG exactly.

Examples:

The text of the conformance statement in the CMS Schematron is:

```
SHALL contain exactly one [1..1] participant (CONF:1140-27980) such that it SHALL contain exactly one [1..1] participantRole (CONF:1140-27981). SHALL contain exactly one [1..1] @typeCode="CSM" Consumable (CodeSystem: HL7ParticipationType urn:oid:2.16.840.1.113883.5.90) (CONF:1140-27984)
```

The text of the conformance statement in the Base IG is:

```
SHALL contain exactly one [1..1] participant (CONF:1140-27980) such that it SHALL contain exactly one [1..1] @typeCode="CSM" Consumable (CodeSystem: HL7ParticipationType urn:oid:2.16.840.1.113883.5.90) (CONF:1140-27984). SHALL contain exactly one [1..1] participantRole (CONF:1140-27981)
```