2016 Electronic Clinical Quality Measures (eCQM) Pre-Publication Information

February 2016

This document describes important standards, terminology, and measure changes slated for the 2016 measure specification update, which corresponds to the 2017 reporting period for the Centers for Medicare & Medicaid Services (CMS) electronic Clinical Quality Measure (eCQM) programs. It is designed to help developers, Eligible Professionals (EP), and Eligible Hospitals (EH) prepare for the 2017 reporting period through transparent pre-release of expected changes and requirements.

Where and when to obtain the 2016 eCQM specifications for the CMS eCQM programs:

- **Electronic Clinical Quality Improvement (eCQI) Resource Center**
  - **Eligible Professional Quality Reporting Programs**
  - **Eligible Hospital/Hospital Inpatient Quality Reporting Program**
- **eCQM Library Page**

The 2016 eCQMs are expected to be available in Spring 2016. Please follow the eCQI Resource Center, CMS, and ONC listservs to receive live updates and announcements on the measure specification publication and related content.

Note: A preview package of 2016 eCQMs is available on the JIRA site for testing and development purposes. CMS is providing vendors an opportunity to review draft measures that include value set, logic, and header changes. Draft measure packages are available on the JIRA clinical quality measurement (CQM) project for EH (at (https://jira.oncprojectracking.org/browse/CQM-1865) and for EP measures at (https://jira.oncprojectracking.org/browse/CQM-1866).

This is an opportunity for CMS to receive feedback from electronic health record (EHR) vendors who have the technical capability to test Health Quality Measures Format (HQMF) code by directly consuming machine-readable XML files for eCQMs. Testing will help to identify instances where XML code produces errors to better resolve issues before posting the updated measures in Spring 2016. The measures in both HTML and XML formats will be available through March 3, 2016. Questions and comments on the draft sample measures can be posted directly on JIRA. These files should **not** be used to implement the final measures, because additional changes are possible.

Standards used in the 2016 eCQM specifications:

- CDA R2
- HQMF R2.1
- QDM-based HQMF Implementation Guide R1.2
- QRDA-I R3.1 (publication expected April 2016)
- QRDA-III R1.1 (publication expected April 2016)
- QDM v4.2
- CMS QRDA IG (publication expected July 2016)

Code system versions used in the 2016 eCQM specifications:

The following have been updated:

- RxNorm 2016-01
- SNOMED CT 2015-09
- LOINC 2.54
- CPT 2016
- CDT 2016
- CVX 2016
- HCPCS 2016
- ICD-10-CM 2016
- ICD-10-PCS 2016
- AdministrativeGender HL7V3.0_2014-08

The following remain the same:

- CDCREC 1.0
- HSLOC 2010
- ICD-9-CM 2013
- SOP 5.0

Guidance on the use of ICD-9 in the 2016 eCQM updated specifications:

In October 2015, CMS formally retired the use of International Classification of Diseases, Ninth Revision (ICD-9) code systems for billing and reporting purposes. CMS designated a one-year period of transition to complete the phasing out of the ICD-9 content, which will end on October 1, 2016. The eCQMs, however, use ICD-9 codes in multiple ways, including look back periods or to reference historical data. Therefore, CMS and ONC provided the following guidance to developers:

- For ICD-9 codes in the 2016 measure update, measure developers were directed to review all ICD-9 codes in measure value sets as with any measure update. For ICD-9 value sets, the expectation is they will be removed if they only pull patients into the measure based on timing starting from the end of CMS's transition period to ICD-10. Therefore, it is expected that many ICD-9 value sets will remain to represent historical data and that is permitted per a consensus-based decision across the eCQM stakeholder federal agencies and partners. It is not expected that any new ICD-9 value sets will be added, and moving forward, we expect the gradual phasing out of ICD-9 codes in the value sets.

Binding Parameter Specification and the Data Element Catalog

Beginning with the 2016 Annual Update, the National Library of Medicine (NLM) will provide a file that contains a complete listing of all the information necessary to determine the value set expansions to be used for each value set referenced by the measures included in the Annual Update. The parameters necessary to determine this are the value set definition version used and the code system version used. This new document—the Binding Parameter Specification (BPS) document—will contain all the information currently in the Data Element Catalogue (DEC) but significantly expand upon the specificity and detail of that document. The new BPS document contains all the value sets plus identifiers used for each eCQM. Each value set version and code system version used to define the value set expansion is noted. The Value Set Authority Center (VSAC) Expansion Profile used will also be included.

Given that the content of the BPS includes but supersedes the content of the current DEC, the current DEC will no longer be produced after this annual update and only the new BPS will be produced. Future instructions will describe how to filter the BPS to generate content consistent with the current DEC for those that wish to use the old content view.

Specifying Patient Death and Birthdate in eCQMs

In 2014, the QDM made updates to define the events of patient death and birthdate as a single code locked into these datatypes. As a result, these codes are the only reportable option for identifying each datatype but do not appear in the Health Quality Measures Format (HQMF).

Male and Female Value Sets in the eCQMs

To comply with federal regulation, the eCQMs must use the HL7 V3 value set for AdministrativeGender (not AdministrativeSex) when specifying birth sex. ONC has created a new definition version of these value sets, changing the code system from AdministrativeSex to

AdministrativeGender. The value set object identifiers (OID) of the two affected value sets remain the same.

The text of the regulation states, "The standard specified in section 170.207(n)(1) – Birth sex must be coded in accordance with HL7 Version 3 (V3) Standard, Value Sets for AdministrativeGender and NullFlavor attributed as follows: (1) Male, M (2) Female, F (3) Unknown, nullFlavor UNK" – from Table 8 Common Clinical Data Set, 45 CFR Part 170, p. 339.

ONC and CMS indicated that the code system to be used when representing the gender of the patient is to be the AdminstrativeGender (OID: .16.840.1.113883.5.1) code system. This code system is already used for the ONC Administrative Sex value set required for recording the patient gender in a Quality Reporting Data Architecture (QRDA) type 1. With the 2016 Annual Update, the gender-specific value sets used within eCQM logic to identify gender-specific patient populations will also use the AdministrativeGender code system to define the included code in the value set. These value sets previously used the older "AdministrativeSex" code system. Because the actual codes—"M" and "F"—are the same in both code systems, the codes included in each gender-specific value set remain the same. With this change, the version of the value set will also change. The two value sets affected are:

1. "Female" (OID: 2.16.840.1.113883.3.560.100.2)
2. "Male" (OID: 2.16.840.1.113883.3.560.100.1)

The following table shows the measures affected by the removal of the "Female" and "Male" value sets.

Data Element	CMS eMeasure ID	Previous Element Vocabulary	New Element Vocabulary	Value Set OID (does not change)
Female	CMS124	AdministrativeSex	AdministrativeGender	2.16.840.1.113883.3.560.100.2
Female	CMS125	AdministrativeSex	AdministrativeGender	2.16.840.1.113883.3.560.100.2
Male	CMS129	AdministrativeSex	AdministrativeGender	2.16.840.1.113883.3.560.100.1
Female	CMS140	AdministrativeSex	AdministrativeGender	2.16.840.1.113883.3.560.100.2
Female	CMS153	AdministrativeSex	AdministrativeGender	2.16.840.1.113883.3.560.100.2
Female	CMS158	AdministrativeSex	AdministrativeGender	2.16.840.1.113883.3.560.100.2
Female	CMS61	AdministrativeSex	AdministrativeGender	2.16.840.1.113883.3.560.100.2
Male	CMS61	AdministrativeSex	AdministrativeGender	2.16.840.1.113883.3.560.100.1
Female	CMS64	AdministrativeSex	AdministrativeGender	2.16.840.1.113883.3.560.100.2
Male	CMS64	AdministrativeSex	AdministrativeGender	2.16.840.1.113883.3.560.100.1

Activities That Were "Not Done"

For the Spring 2016 release, the QRDA-I R3.1 and CMS Implementation Guide utilize null values to replace a specific code associated with a value set when describing activities that were negated or "not done." This approach is intended for use with all datatypes that use negation to describe activities "not done," with the exception of "Device, not done." This approach is aligned with the expression of negation in the HQMF and QRDA and uses an HL7 nullFlavor code instead of one specific code from the value set that is associated with these activities in the QRDA-I file.

The intent of the null flavor in this context is to specify that ALL the activities in the value set were intentionally not done. Indicating that only one of the items in the value set was not performed could suggest that one of the other items in that value set should have been performed instead. The purpose of the null flavor is to specify than NONE of the items in the value set are appropriate (i.e., ALL are not done). To certify such negation, the provider should also document the justification for intentionally not ordering or performing the activity in question.

An example of a negation instance being "not done" in a QRDA-I file:

```
<entry>
        <!--Medication administered not done,
          patient refusal: Drug declined by patient - reason unknown.
          No "Antibiotic Medications for Pharyngitis" were administered -->
        <act classCode="ACT" moodCode="EVN" negationInd="true">
          ...
          <consumable>
            <manufacturedProduct classCode="MANU">
              ...
              <manufacturedMaterial>
                <code nullFlavor="NA" sdtc:valueSet="2.16.840.1.113883.3.464.1003.196.12.1001">
                  <originalText>None of value set: Antibiotic Medications for
Pharyngitis</originalText>
                </code>
              </manufacturedMaterial>
            </manufacturedProduct>
          </consumable>
          ...
        </act>
      </entry>
```

Vendors/providers using these concepts are expected to have a documented reason for these exclusions and could be expected to demonstrate the relevant justification if audited. The QRDA-I and –III standards and the CMS QRDA Implementation Guide provide more detailed technical guidance on how to use null values to describe activities that were "not done."

For the datatype, "Device (supply), not done" and "Encounter, not done" negation must be performed creating an act instance and then negating the instance. Specifically, one would use Act with supply (or encounter) as the subject of the Act and apply negation for the Act. This is due to prior removal of device (supply) and encounter as a negatable datatypes in the Consolidated Document Architecture (CDA). We anticipate that the device (supply) and encounter datatypes will be added back to CDA at the next update; until that time this approach is needed.

See Draft Standard for Trial Use (DSTU) comment:
http://www.hl7.org/dstucomments/showdetail_comment.cfm?commentid=696

This content will be updated and clarified in QRDA-I R3.1.

NLM VSAC Collaboration Tool:

On December 16, 2015, NLM VSAC launched VSAC Collaboration—a tool that supports communication, knowledge management, and document management by value set authors and stewards. VSAC Collaboration provides a central site where value set authors can post value sets for collaborative discussion. In that site, teams can share threaded discussions about the value sets, view recent value set expansions posted by site members, organize their value sets by usage and the team's workflow needs, and receive activity and change notifications from VSAC.

The VSAC Collaboration Tool can be accessed through the VSAC Authoring Tool (https://vsac.nlm.nih.gov Authoring Tab), and the VSAC Collaboration Tool directly at https://vsaccollab.nlm.nih.gov. The VSAC Collaboration Tool training webinars and slides are available at https://www.nlm.nih.gov/vsac/support/userforum/userforum.html.

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