**2016 Hospital Inpatient Prospective Payment System Proposed Rule**

**Excerpts for Quality Measures Task Force Review**

The full proposed rule can be accessed at: <https://www.federalregister.gov/articles/2015/04/30/2015-09245/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the>

Note that key proposals and questions for comment are highlighted in the below text excerpts.

From the Executive Summary:

We are proposing to align the reporting and submission timelines for the

electronic submission of clinical quality measures for the Medicare EHR Incentive

Program for eligible hospitals and critical access hospitals (CAHs) with the reporting and

submission timelines for the Hospital IQR Program. Lastly, ONC is proposing a 2015

Edition certification criterion for “CQMs – report” as part of the proposed 2015 Edition

of certification criteria that would require a certified Health IT Module to enable a user to

electronically create a data file for transmission of clinical quality measurement data.

This proposed certification criterion would apply to eligible professionals, eligible

hospitals, and CAHs.

**Key Sections of the Rule for Task Force Review**

* “CQMs – Report” Certification Criterion in ONC’s 2015 Edition Proposed Rule

As described previously in section VIII.D.3.a. of the preamble of this proposed

rule, ONC reserved the 2015 Edition certification criterion for “CQMs - report” (at

proposed new § 170.315(c)(3)) to be proposed in conjunction with IPPS and/or PFS

rulemaking. The 2014 Edition certification criterion for CQMs – electronic submission

(at § 170.314(c)(3)) requires CEHRT to enable a user to electronically create a data file

for transmission of clinical quality measurement data using the Quality Reporting

Document Architecture (QRDA) Category I and Category III standards, and which can

be electronically accepted by CMS. The QRDA standard provides a document format

and standard structure to electronically report clinical quality measure data.221 The

QRDA Category I standard enables an individual patient-level quality report that contains

quality data for one patient for one or more quality measures. The QRDA Category III

standard enables an aggregate quality report containing calculated summary data for one

or more measures for a specified population of patients within a particular health system

over a specific period of time.222

Building off of the 2014 Edition criterion for submission of CQMs, ONC is

proposing a 2015 Edition certification criterion for “CQMs – report”223 at proposed new

§ 170.315(c)(3) as part of the proposed 2015 Edition of certification criteria that would

require a certified Health IT Module to enable a user to electronically create a data file

for transmission of clinical quality measurement data using the “base” HL7 (that is,

industry-wide, non-program-specific) Quality Reporting Data Architecture (QRDA)

Category I and Category III standards, at a minimum. ONC also is proposing to allow

optional certification for EHRs according to the CMS “form and manner” requirements

defined in CMS’ QRDA Implementation Guide224 as part of this proposed criterion. We

reiterate that this proposed certification criterion would apply to EPs, eligible hospitals,

and CAHs.

CMS anticipates proposing to require EPs, eligible hospitals, and CAHs seeking

to report CQMs electronically (if using proposed new § 170.315(c)(3)) as part of

meaningful use under the EHR Incentive Programs for 2016 to adhere to the additional

standards and constraints on the QRDA standards for electronic reporting as described in

the CMS QRDA Implementation Guide. CMS anticipates proposing to revise the

definition of “certified electronic health record technology (CEHRT)” at 42 CFR 495.4 to

require certification to the optional portion of the 2015 Edition CQM reporting criterion

(proposed at § 170.315(c)(3)) in the CY 2016 Medicare Physician Fee Schedule proposed

rule later this year.

As noted previously, ONC proposed standards for proposed new § 170.315(c)(1)

and § 170.315(c)(2) in the 2015 Edition proposed rule (80 FR 16844), but retained a

placeholder for proposed new § 170.315(c)(3) so that this certification criterion for

reporting could be proposed in conjunction with the proposals for CMS quality reporting

programs in the IPPS and PFS rules. Therefore, in this proposed rule, for the

requirements for the 2015 Edition certification criteria, ONC is proposing the following

at proposed new § 170.315(c)(3) for clinical quality measurement to state that technology

certified to the 2015 Edition must enable a user to electronically create a data file for

transmission of clinical quality measurement data which is:

● At a minimum, in accordance with the standards specified in § 170.205(h) and

§ 170.205(k); and

● Optionally, can be electronically accepted by CMS.

The standard specified in § 170.205(h) is the HL7 Implementation Guide (IG) for

CDA Release 2: Quality Reporting Document Architecture – Category I, Draft Standard

for Trial Use (DSTU) Release 2 (July 2012).225 The standard specified in § 170.205(k) is

the HL7 Implementation Guide for CDA Release 2: Quality Reporting Document

Architecture – Category III, DSTU Release 2 (November 2012).226

ONC previously adopted the July 2012 version of the QRDA Category I IG and

the November 2012 version of the QRDA Category III IG in its 2014 Edition

(77 FR 54232). Given the timing of this proposed rule and the expected deliverables for

harmonized CQM and clinical decision support (CDS) standards (described further in the

2015 Edition proposed rule at 80 FR 16842 through 16843), ONC is soliciting comment

on a series of three options to determine if the version of QRDA Category I or the

QRDA-like standards it should adopt for the certification criterion should be a more

recent update to the standard. Specifically, ONC is soliciting comment on the following

options for individual patient-level quality reports (QRDA Category I):

(1) The July 2012 QRDA Category I IG;

(2) The July 2012 QRDA Category I IG with the September 2014 Errata;227 and

(3) QRDA-like standards for individual patient-level quality reports based on the

anticipated Quality Improvement and Clinical Knowledge (QUICK)228 Fast Health

Interoperability Resources (FHIR)-based Draft Standard for Trial Use CQM standards.

Option 1 includes the same version of the QRDA Category I standard ONC

adopted in the 2014 Edition. Option 2 includes this same version with the

September 2014 Errata, which provides guidance on implementing QRDA Category I

based on a new version of the underlying information model for representing quality

measures (that is, the Quality Data Model based-Health Quality Measures Format

Release 2.1229). Option 3 would include standards based on the harmonized CQM and

CDS standards on which the industry is currently developing.

ONC is also soliciting comment on a fourth option of QRDA Category I standard

it could consider adopting for this proposed certification criterion:

(4) The next release of the QRDA Category I IG (Release 3).230

While this option was not discussed in the 2015 Edition proposed rule,

stakeholders have recently made ONC aware that the industry is in the process of

updating the QRDA Category I to the next Release 3. ONC understands that Release 3 is

expected to be balloted in May 2015. Release 3 would include major updates to align

with the Quality Data Model, address comments from Release 2, and better align with the

Consolidated CDA Release 2 used for transitions of care/summary care records.

While not discussed in the 2015 Edition proposed rule, ONC in this proposed rule

is also soliciting comment on three options for aggregate-level quality reports (QRDA

Category III) it could adopt for this certification criterion:

(1) The November 2012 QRDA Category III IG;

(2) The November 2012 QRDA Category III IG with the September 2014

Errata;231 and

(3) QRDA-like standards for aggregate-level quality reports based on the

anticipated Quality Improvement and Clinical Knowledge (QUICK)232 Fast Health

Interoperability Resources (FHIR)-based Draft Standard for Trial Use CQM standards.

Option 1 includes the same version of the QRDA Category III standard which

ONC adopted in the 2014 Edition. Option 2 includes this same version with the

September 2014 Errata, which provides guidance on implementing QRDA Category III

based on a new version of the underlying information model for representing quality

measures (that is, the Quality Data Model based-Health Quality Measures Format

Release 2.1233). Option 3 would include standards based on the harmonized CQM and

CDS standards on which the industry is currently developing.

In connection with ONC, we are inviting public comment on these options and

this proposal.

221Available at: http://www.hl7.org/implement/standards/product\_brief.cfm?product\_id=35.

222Available at: http://www.hl7.org/implement/standards/product\_brief.cfm?product\_id=286.

223 As noted in the 2015 Edition proposed rule, ONC proposed to title proposed new § 170.315(c)(3)

“CQMs - report” to better align with the use of the term “report” throughout the 2015 Edition. Also, ONC

is proposing to discontinue to reference “electronic” in the title of certification criteria as it is assumes that

all functions performed by certified health IT are done electronically. See 80 FR 16844.

224 The CMS QRDA Implementation Guide can be accessed at http://www.cms.gov/Regulations-and-

Guidance/Legislation/EHRIncentivePrograms/eCQM\_Library.html.

225Available at: http://www.hl7.org/implement/standards/product\_brief.cfm?product\_id=35.

226Available at: http://www.hl7.org/implement/standards/product\_brief.cfm?product\_id=286.

227Available at: http://www.hl7.org/implement/standards/product\_brief.cfm?product\_id=35. Note that in

order to access the errata, the user should download the “HL7 Implementation Guide for CDA Release 2:

Quality Reporting Document Architecture – Category I, DSTU Release 2 (US Realm)” package.

228Available at:

http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumber

=1045.

229Available at: http://www.hl7.org/implement/standards/product\_brief.cfm?product\_id=97.

230http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumb

er=210.

231 http://www.hl7.org/implement/standards/product\_brief.cfm?product\_id=286. Note that in order to

access the errata, the user should download the “HL7 Implementation Guide for CDA Release 2: Quality

Reporting Document Architecture – Category III, DSTU Release 1 (US Realm)” package.

232Available at:

http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumber

=1045.

233Available at: http://www.hl7.org/implement/standards/product\_brief.cfm?product\_id=97.

* (Hospital Inpatient Quality Reporting Program) Future Considerations for Electronically Specified Measures: Consideration to Implement a New Type of Measure that Utilizes Core Clinical Data Elements

a. Background

We have implemented several claims-based measures comparing hospital

performance on 30-day mortality, 30-day readmission, and complications following

hospitalization for several conditions and procedures in the Hospital IQR, Hospital

Readmissions Reductions, and Hospital VBP Programs. Although these measures have

been shown to provide valid information about hospital performance, the clinical

community continues to express the opinion that data gathered directly from patients and

used by clinicians to guide diagnostic decisions and treatment are preferable for risk

adjustment of hospital outcome measures. In response to clinicians and providers’

feedback in public comment periods during measure development, and keeping with our

goal to move toward the use of electronic health records (EHRs) for electronic quality

measure reporting throughout CMS programs, where feasible, we are considering:

(1) the use of core clinical data elements derived from EHRs for use in future quality

measures (for example, risk adjustment of outcome measures); (2) the collection of

additional administrative linkage variables to link a patient’s episode of care from EHR

data with his administrative claim data, and (3) use of content exchange standards.

During a July 2014 public comment period on the CMS Call for Public Comment

Web site146 for the hybrid hospital-wide readmission measure with administrative claims

and electronic health record data, we received supportive feedback on the importance of

the use of clinical data in hospital outcome measures. Commenters supported our efforts

in examining new approaches to provide a more accurate assessment and portrayal of

services provided by clinicians and hospitals, and the feedback also indicated their belief

that it is very important that enriched clinical data from an EHR be used to supplement

the clinically limited datasets available from administrative claims data. We note that

reviewers can find the public comment summary report within the Hybrid Hospital-Wide

Readmission Measure with Electronic Health Record Extracted Risk Factors

(Version 1.1), in the “Downloads” section of our Measure Methodology Web page. We

refer readers to the Core Clinical Data Elements and Hybrid Measures zip file found on

our Web site at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-

Instruments/HospitalQualityInits/Measure-Methodology.html.

In response to this public feedback, as well as CMS policy goals, we have

identified a set of 21 clinical variables, or core clinical data elements, which we note are

routinely collected on hospitalized adults and feasibly extracted from hospital EHRs. We

believe that these core clinical data elements can be adapted for future use as part of

specific quality measures. During our testing, we found that these 21 core clinical data

elements can be used to risk adjust 30-day mortality and 30-day readmission outcome

measures. Although we have thus far only tested the core clinical data elements for use

in the risk adjustment models of hospital-level outcome measures, they could be utilized

in other ways in the future. We anticipate that EHRs will continue to improve capturing

of relevant clinical data and we also anticipate future expansion of the list of core clinical

data elements.

In the future, one way in which we envision using core clinical data elements in

conjunction with other sources of data, such as administrative claims, is to calculate

“hybrid” outcome measures, which are quality measures that utilize more than one source

of data. We believe that these types of hybrid measures could enhance the current CMS

administrative claims-based outcome measures by utilizing patient clinical data captured

in the EHR. We have shown that core clinical data elements captured in EHRs and used

to risk adjust hospital outcome measures improve the discrimination of the measures, or

the ability to distinguish good and poor performers, as assessed by the c-statistic, which

evaluates the measure’s ability to discriminate or differentiate among high and low

performing hospitals.147, 148, 149 Finally, hybrid measure results would need to be

calculated by CMS to determine hospitals’ risk-adjusted rates relative to national rates

used in public reporting. With hybrid measures, hospitals would forward data extracted

from the EHR, and CMS would perform the measure calculations.

To illustrate one way in which the 21 core clinical data elements can be used, we

developed two hybrid measures: (1) Hospital 30-Day Risk-Standardized Acute

Myocardial Infarction (AMI) Mortality eMeasure (NQF #2473); and (2) a hybrid

hospital-wide 30-day readmission measure, which has not yet undergone NQF

endorsement proceedings. However, the latter measure’s development was encouraged

by the MAP.150 We note that the 2013 Core Clinical Data Elements Technical Report

Version 1.1 (a methodology report) provides a more detailed review of the clinical core

data elements. This document is posted on our Measure Methodology Web page, under

the “Downloads” section in Core Clinical Data Elements and Hybrid Measures zip file,

available on our Web site at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-

Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

b. Overview of Core Clinical Data Elements

Core clinical data elements are a set of clinical variables derived from EHRs that

can be used to risk adjust hospital outcome measures. We have currently identified a set

of 21 core clinical data elements that: (1) can be feasibly extracted from current EHR

systems; (2) are available on most adult patients; and (3) are relevant to patient outcomes

following hospitalization. These core clinical data elements are listed in the table below.

| **Currently Identified Core Clinical Data Elements Considered for Risk-Adjustment of Hybrid Outcome Measures used in the Hospital setting** |
| --- |
| **Data Elements** | **Units of Measurement** | **Time Window for First Captured Values** |
| **Patient Characteristics** |
| Age at admission | Years | --- |
| Gender  | Male or female | --- |
| **First-Captured Vital Signs** |
| Heart Rate | Beats per minute | 0-2 hours |
| Systolic Blood Pressure | mmHg | 0-2 hours |
| Diastolic Blood Pressure | mmHg | 0-2 hours |
| Respiratory Rate | Breath per minute | 0-2 hours |
| Temperature | Degrees Fahrenheit | 0-2 hours |
| Oxygen Saturation | Percent | 0-2 hours |
| Weight | Pounds | 0-24 hours |
| **First-Captured Laboratory Results** |
| Hemoglobin | g/dL | 0-24 hours |
| Hematocrit | % red blood cells | 0-24 hours |
| Platelet | Count | 0-24 hours |
| WBC Count | Cells/mL | 0-24 hours |
| Potassium | mEq/L | 0-24 hours |
| Sodium | mEq/L | 0-24 hours |
| Chloride | mEq/L | 0-24 hours |
| Bicarbonate | mmol/L | 0-24 hours |
| BUN | mg/dL | 0-24 hours |
| Creatinine | mg/dL | 0-24 hours |
| Glucose | mg/dL | 0-24 hours |
| Troponin | ng/mL | 0-24 hours |

This set of core clinical data elements consists of the first captured vital signs, and

the results of a complete blood count and basic chemistry panel. These core clinical data

elements were selected because they were empirically shown to be captured during

routine clinical practice on most adult hospitalized patients.151 Among other ways, one

way in which we envision using these core clinical data elements is to risk adjust

outcomes measures, since the elements improve the discrimination of hospital outcome

measures as assessed by c-statistic and enhances the face validity of measures for the

clinical community, which continue to express a preference for these types of data to

account for patients’ severity of illness.152

In the context of risk-adjustment, future hybrid measures would utilize some or all

of the 21 core clinical data elements listed above, as well as any future feasible core

clinical data elements. For example, the Hospital 30-day Risk-Standardized Acute

Myocardial Infarction (AMI) Mortality eMeasure (NQF #2473) uses five core clinical

data elements: age; heart rate; systolic blood pressure; troponin; and creatinine.153 In

contrast, the hybrid hospital-wide measure uses 14 of the 21 core clinical data elements

(age, heart rate, respiratory rate, temperature, systolic blood pressure, oxygen saturation,

weight, hematocrit, white blood cell count, sodium, potassium, bicarbonate, creatinine

and glucose).154 These two hybrid measures illustrate how specific core clinical data

elements used in a given hybrid measure will vary depending on the core clinical data

elements identified as relevant for and predictive of that measure outcome in the target

cohort.

We note that the 21 core clinical data elements included are already routinely

recorded in the EHR by clinical staff at the beginning of an inpatient encounter to

diagnose and treat patients. Collection of these core clinical data elements are in

response to stakeholder preference, and in particular, for the use of clinical information in

risk models, but is not meant to guide or alter the care patients receive. We believe

clinical staff should continue to only perform measurements or tests that are appropriate

for diagnostic assessment or treatment of patients.

We assessed the feasibility of extraction of the 21 core clinical data elements in

models of readmission and mortality outcome measures (Core Clinical Data Elements

Development is discussed below). For additional detail on testing and the measure

methodologies, we refer readers to the 2013 Core Clinical Data Elements Technical

Report Version 1.1 methodology report posted on our Measure Methodology Web page,

under the “Downloads” section in Core Clinical Data Elements and Hybrid Measures zip

file, on our Web site at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-

Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

c. Core Clinical Data Elements Development

To identify this set of core clinical data elements, we first focused on those data

elements that can be used to risk adjust hospital outcome measures. We developed a

systematic five-step approach in which we: (1) established a set of criteria to assess the

feasibility of consistently identifying and extracting EHR data elements, and convened a

diverse group of health information technology experts and end users to apply these

criteria to EHR data; (2) conducted a systematic review of the literature to identify

clinical data that has been shown to predict patient outcomes following acute care

hospital admissions; (3) assessed the frequency and timing of capture of candidate data

elements using a dataset from an active EHR data warehouse of a large healthcare system

serving over 3.3 million beneficiaries;155 (4) tested the utility of feasible data elements in

risk-adjusted hierarchical models of 30-day mortality following hospitalization for a

variety of common and costly medical conditions (for example, heart failure, pneumonia,

and stroke); and (5) tested the core clinical data elements as risk-adjustment variables in

the previously adopted Hospital IQR Program measure, CMS 30-Day Hospital-Wide

All-Cause Unplanned Readmission Outcome measure (NQF #1789) finalized in the

FY 2013 IPPS/LTCH PPS final rule (77 FR 53521 through 53528), creating the hybrid

hospital-wide readmission measure. These steps are discussed in more detail below.

To identify and test the core clinical data elements, a TEP was convened. TEP

members applied feasibility criteria to each data type in the Quality Data Model (QDM)

considering the context of adult hospitalized patients only. The QDM is an information

model that provides a standardized description of the clinical information captured in

EHRs, and provides a uniform framework to support quality measurement that utilizes

EHR data. TEP members were asked to indicate whether at least one data element within

each data type was: (1) consistently obtained in the target population (patients 18 years

and older) based on current clinical practice; (2) captured with a standard definition and

recorded in a standard format within the EHR; and (3) entered in structured fields that are

feasibly retrieved from current EHR systems.

Next, we conducted a systematic review of the literature to identify clinical data

shown to be predictive of mortality and readmission in statistical models. A thorough

review of studies revealed that several categories of clinical information from patient

medical records captured during diagnostic assessment and treatment were commonly

used to predict mortality and readmission. These included, but were not limited to, basic

demographic information, laboratory test results, and vital sign findings. The results are

described in the 2013 Core Clinical Data Elements Technical Report (Version 1.1) and is

available on our Measure Methodology Web page, under the “Downloads” section in

Core Clinical Data Elements and Hybrid Measures zip file found on our Web site at:

http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-

Instruments/HospitalQualityInits/Measure-Methodology.html.

In order to empirically establish the feasibility of potential clinical data elements

identified by the TEP, we used a large multi-site database from a healthcare system

serving over 3.3 million beneficiaries. We examined the format of the clinical data

elements, the consistency and timing of capture, and the distribution of these extracted

clinical data values across conditions, hospitals, and point of hospital entry. From the

results of that analysis, we identified a list of clinical data elements that were consistently

captured for more than 90 percent of adults admitted for common medical conditions. In

addition, only the first clinical data elements captured close to the time a patient arrived

at the facility were considered in order to reflect patients’ clinical status when they

presented, and not the results of treatment received at the facility. Analyses showed that

vital signs (heart rate, systolic blood pressure, diastolic blood pressure, respiratory rate,

temperature, and oxygen saturation) were captured within 2 hours of arrival to the

hospital for most patients who were subsequently admitted to the same facility. In

addition, analyses showed that weight and laboratory tests (hemoglobin, hematocrit,

platelet, white blood cell (WBC) count, potassium, sodium, chloride, bicarbonate, blood

urea nitrogen (BUN), creatinine, glucose, and troponin) were captured within 24 hours of

arrival to the hospital for most patients who were subsequently admitted to the same

facility. This was true whether patients were first assessed in the emergency department,

or an inpatient unit. From these analyses, we specified the units of measurement and

time window for first captured values for each of the 21 feasible and relevant core

clinical data elements.

d. Core Clinical Data Elements Feasibility Testing Using Readmission and Mortality

Models

In order to demonstrate that the core clinical data elements improved hospital

outcome measures, we tested them in models of 30-day mortality and 30-day readmission

following hospitalization from a variety of conditions. The 21 core clinical data elements

shown in the table above were statistically significant predictors in at least one measure

of 30-day mortality after admission for eight common medical conditions: AMI;

congestive heart failure; pneumonia; acute cerebrovascular disease; septicemia (except

during labor); diabetes mellitus with complications; coronary atherosclerosis; and cardiac

dysrhythmias.156 All of the core clinical data elements listed above were also statistically

significant predictors of readmission in the risk-adjusted models of 30-day readmission in

a hospital-wide cohort.157 The testing results demonstrate that the core clinical data

elements enhanced the discrimination (assessed using the c-statistic) when used either in

combination with or in place of administrative claims data for risk adjustment of

currently reported CMS 30-day mortality and readmission outcome measures. For more

detailed information on testing, we refer readers to the methodology reports posted on our

Measure Methodology Web page, under the “Downloads” section in Core Clinical Data

Elements and Hybrid Measures zip file, found on our Web site at:

http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-

Instruments/HospitalQualityInits/Measure-Methodology.html.

e. Use of Core Clinical Data Elements in Hospital Quality Measures for the Hospital

IQR Program

In the future, we are considering requiring hospitals to electronically submit core

clinical data elements in several contexts. One use considered would be to risk-adjust

claims-based hybrid quality measures similar to what is described in our discussion

above. In addition, we are also considering using core clinical data elements for quality

measures that apply more generally to an all-payer population (that is, a population

greater than or equal to 18 years of age). As we learn more about this method of data

collection, we will be able to give more information. As it stands, we envision that use of

core clinical data elements for an all payer population would not be limited to merely

risk-adjustment or in claims-based hybrid measures. However, should we require

reporting of core clinical data elements, it would be in the context of specific measures

proposed through rulemaking for the Hospital IQR Program and potentially other CMS

quality programs. Specific electronically submitted core clinical data elements required

would depend on the individual measure adopted.

For claims-based hybrid measures, linking variables would be required to ensure

that the datasets containing administrative claims data are correctly linked with EHR

datasets containing the core clinical data elements for proper risk adjustment. The

linkage variables would come from an additional requirement for hospitals to submit

these variables. Such linkage variables, for example, might include admission and

discharge dates, CMS certification number, and date of birth. Some of these linkage

variables are already routinely collected by EHRs; however, actual linkage variables

required for a specific hybrid measure would depend on empirical testing of approaches

to linkage for individual measure cohorts.

f. Content Exchange Standard Considerations for Core Clinical Data Elements

Data can be collected in EHRs and health information technology (IT) systems

using standardized formats to promote consistent representation and interpretation, as

well as to allow for systems to compute data without needing human interpretation.

These standards are referred to as content exchange standards, because the standard

details how data should be represented and the relationships between data elements. This

allows the data to be exchanged across EHRs and health IT systems while retaining their

meaning. Commonly used content exchange standards include the Consolidated Clinical

Data Architecture (C-CDA) and the Quality Reporting Data Architecture (QRDA). The

C-CDA standard is frequently used for the representation of summary care records and

provides a format for electronically representing data within document templates and

sections.158 The QRDA standard provides a document format and standard structure to

electronically report quality measure data.159 QRDA allows for the use of CDA

templates (the same underlying standard used in C-CDA) to represent quality measures

using the QDM information model described above. Thus, QRDA could be considered a

related standard to C-CDA for the specific quality reporting use case.

The core clinical data elements we are considering could be electronically

reported to CMS formatted according to either the C-CDA or QRDA standard to promote

consistent representation and more efficient calculation of hybrid measure results. These

standards are also currently required for participation in the Medicare and Medicaid EHR

Incentive Programs. Sections 1886(n) and 1814(l) of the Act, as added by the HITECH

Act, authorize incentive payments under Medicare for eligible hospitals and critical

access hospitals that successfully demonstrate the meaningful use of Certified EHR

Technology (CEHRT). Section 1903(t)(6)(C) of the Act also requires that Medicaid

providers adopt, implement, upgrade, or meaningfully use CEHRT if they are to receive

incentives. We refer readers to the CEHRT definition adopted by the Office of the

National Coordinator for Health IT (ONC) in its 2014 Edition standards and certification

criteria final rule (77 FR 53972). ONC’s CEHRT definition is adopted in § 170.102 and

includes the capabilities defined for the Base EHR, including certification to create

transitions of care documents using the C-CDA standard and to successfully report

clinical quality measures using the QRDA standard (we refer readers to Table 6 of the

ONC 2014 Edition standards and certification criteria final rule at 77 FR 54265).

We are specifically considering the use of QRDA Category I (QRDA-I) as the

transmission standard for core clinical data elements to CMS, because the core clinical

data elements specified for risk adjustment need to be captured in relation to the start of

an inpatient encounter, to be certain the data has been appropriately connected to the

encounter. The QRDA-I standard enables an individual patient-level quality report that

contains quality data for one patient for one or more quality measures. For further detail

on QRDA-I, the most recently available QRDA-I specifications can be found at:

http://www.hl7.org/implement/standards/product\_brief.cfm?product\_id=35.

Regardless of whether C-CDA or QRDA-I was used for the reporting of core

clinical data elements, we note that these data exchange standards would enhance

alignment across CMS programs, as well as reduce EHR developer and provider burden

by adopting standards that are already in place for the exchange of electronically

specified clinical and quality data.

As part of this comment solicitation, we are inviting comment on whether EHR

technology should be required to be certified under the ONC Health IT Certification

Program160 for the submission of the core clinical data elements for participation in the

Hospital IQR Program using the most appropriate content exchange standard (such as,

and not limited to, QRDA-1 or C-CDA). We believe that certification could test and

certify that EHR technology can properly collect the core clinical data elements formatted

to the appropriate content exchange standard (such as, and not limited to QRDA-1 or

C-CDA), promoting more standardized and consistently represented data that can be

submitted to CMS to risk-adjust hybrid measures.

In summary, we are seeking public comment on the concept of collecting core

clinical data elements, and in particular, we are interested in feedback specifically

regarding: (1) the use of the core clinical data elements derived from EHRs for use in

risk adjustment of outcome measures as well as other types of measures; (2) the

collection of additional administrative linkage variables to link a patient’s episode of care

from EHR data with his/her administrative claim data; and (3) the use of content

exchange standards for reporting these data elements. Regarding the use of content

exchange standards, we welcome input on the benefits and implementation

considerations if CMS were to require QRDA-I, as well as the tradeoffs to requiring

QRDA-I instead of C-CDA or other content exchange standards.

146 CMS.gov. Measure Management System, Public Comment. Hybrid Hospital-Wide Readmission

Measure with Claims and Electronic Health Record Data. Available at:

http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-

Instruments/MMS/CallforPublicComment.html.

147 Hybrid 30-Day Risk-standardized Acute Myocardial Infarction Mortality Measure with Electronic

Health Record Extracted Risk Factors (Version 1.1).

148 Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors

(Version 1.1).

149 2013 Core Clinical Data Elements Technical Report (Version 1.1).

150 National Quality Forum. Measure Application Partnership. Available at:

https://share.cms.gov/center/CCSQ/QMHAG/DHMM/Measures%20Development%20and%20Maintenanc

e/map/MAP%202014/MAP%202015/map\_pre-rulemaking\_final\_report\_2015.pdf. Accessed on

February 5, 2015.

151 2013 Core Clinical Data Elements Technical Report (Version 1.1). Available at:

http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-

Instruments/HospitalQualityInits/Measure-Methodology.html.

152 Hybrid 30-day Risk-standardized Acute Myocardial Infarction Mortality Measure with Electronic

Health Record Extracted Risk Factors (Version 1.1) and Hybrid Hospital-Wide Readmission Measure with

Electronic Health Record Extracted Risk Factors (Version 1.1). Available at:

http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-

Instruments/HospitalQualityInits/Measure-Methodology.html.

153 Hybrid 30-day Risk-standardized Acute Myocardial Infarction Mortality Measure with Electronic

Health Record Extracted Risk Factors (Version 1.1). Available at: http://www.cms.gov/Medicare/Quality-

Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

154 Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors

(Version 1.1). Available at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-

Instruments/HospitalQualityInits/Measure-Methodology.html.

155 2013 Core Clinical Data Elements Technical Report Version 1.1. Available at:

http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-

Instruments/HospitalQualityInits/Measure-Methodology.html.

156 Hybrid 30-Day Risk-standardized Acute Myocardial Infarction Mortality Measure with Electronic

Health Record Extracted Risk Factors (Version 1.1). Available at: http://www.cms.gov/Medicare/Quality-

Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

157 Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors

(Version 1.1). Available at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-

Instruments/HospitalQualityInits/Measure-Methodology.html.

158 Health Level 7 International. Product Brief. Available at:

http://www.hl7.org/implement/standards/product\_brief.cfm?product\_id=379.

159 Health Level 7 International. Product Brief. Available at:

http://www.hl7.org/implement/standards/product\_brief.cfm?product\_id=35.

160 Health IT.gov. Certification Programs and Policy. Available at: http://healthit.gov/policy-researchersimplementers/

about-onc-hit-certification-program.

**Summaries of Standards (descriptions of standards are also contained within the rule preamble language)**

* HL7 Implementation Guide for CDA® R2: Quality Reporting Document Architecture – Category I, DSTU Release 2 (US Realm) and Errata (September 2014).

URL: <http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35>. Access requires a “user account” and a license agreement. There is no monetary cost for a user account and license agreement. The DSTU package must be downloaded in order to access the errata.

Summary: The Quality Reporting Document Architecture (QRDA) is an electronic document format that provides a standard structure with which to report quality measure data to organizations that will analyze and interpret the data. The Implementation Guide is consistent with CDA, and Category I is an individual-patient-level quality report. The September 2014 Errata reflects updates for the implementation of QRDA Category I consistent with the Quality Data Model-based Health Quality Measures Format Release 2.1, an incremental version of harmonized clinical quality measure and CDS standards.

* HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.0.

URL: <http://www.hl7.org/implement/standards/product_brief.cfm?product_id=379>. Access requires a “user account” and a license agreement. There is no monetary cost for a user account and license agreement.

Summary: The Consolidated CDA (C-CDA) implementation guide contains a library of CDA templates, incorporating and harmonizing previous efforts from HL7, IHE, and Health Information Technology Standards Panel (HITSP). It represents harmonization of the HL7 Health Story guides, HITSP C32, related components of IHE Patient Care Coordination (IHE PCC), and Continuity of Care (CCD). The C-CDA Release 2 implementation guide, in conjunction with the HL7 CDA Release 2 (CDA R2) standard, is to be used for implementing the following CDA documents and header constraints for clinical notes: Care Plan including Home Health Plan of Care, Consultation Note, CCD, Diagnostic Imaging Reports, Discharge Summary, History and Physical, Operative Note, Procedure Note, Progress Note, Referral Note, Transfer Summary, Unstructured Document, and Patient Generated Document (US Realm Header).

Clinical Quality Framework (pulled from 2015 Edition proposed rule)

In the 2014 Edition “CQM – capture and export” certification criterion, we require that technology must be able to export a data file formatted in accordance with the HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture (QRDA), DSTU Release 2 (July 2012) standard. We understand that the industry is working to harmonize both clinical quality measurement and CDS standards through initiatives such as the Clinical Quality Framework (CQF) S&I initiative. CDS guides a clinician to follow a standard plan of care, while CQMs measure adherence to a standard plan of care. Thus, these two areas are closely related and would benefit from standard ways to reference patient data within health IT as well as common logic to define a sub-population. The CQF S&I initiative is working to define a shared format, terminology, and logic between CQMs and CDS for improved efficiency, cost, and quality of care.

In order to harmonize CQM and CDS standards, the industry is using pieces of existing

CQM standards (e.g., Health Quality Measures Format (HQMF), QRDA Categories I and III, and the Quality Data Model (QDM)) and CDS standards (e.g., Clinical Decision Support Knowledge Artifact Specification (also known as HeD Schema) and the Virtual Medical Record). HL7 issued an errata (September 2014)[[1]](#footnote-1) that reflects updates based on an incremental version of the harmonized CQM and CDS standards (i.e., QDM-based HQMF Release 2.1[[2]](#footnote-2)). This errata is meant to be used in conjunction with the July 2012 QRDA IG we adopted in the 2014 Edition. Our understanding is that the fully harmonized CQM and CDS standards will be based on the Quality Improvement and Clinical Knowledge (QUICK) data model[[3]](#footnote-3), and that the industry expects to ballot a QUICK FHIR-based DSTU serving the same function as the HQMF standard at the May 2015 HL7 meeting. Subsequent standards for electronically processing and reporting CQMs and CDS would then be expected to be built on the QUICK data model, including a QRDA-like standard based on the anticipated QUICK FHIR-based DSTU.

…

We anticipate that the QUICK data model will not be available to review during the public comment period of this NPRM, and welcome stakeholder input on the usefulness of adopting the current (July 2012) QRDA standard alone or in conjunction with the September 2014 errata given that we anticipate there will be harmonized CQM and CDS standards available in mid-2015. We also seek to understand the tradeoffs stakeholders perceive in adopting each standard provided that the EHR Incentive Programs Stage 3 proposed rule is proposing that technology certified to the 2015 Edition would not be required until January 1, 2018, but that technology certified to the 2015 Edition “CQM – record and export” certification criterion would be needed for EPs, eligible hospitals, and CAHs participating in the EHR Incentive Programs Stage 3 objectives and measures in 2017. Thus, we welcome input on recommended QRDA standards for the “CQM – record and export” certification criterion factoring in where the industry may be with adoption of CQM and CDS standards over the next few years.

**Other Sections of the Rule the Task Force May Want to Review if Time Permits**

d. Alignment of the Medicare EHR Incentive Program Reporting for Eligible Hospitals

and CAHs with the Hospital IQR Program

(1) Background

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50256

through 50259) for our policies to align electronic clinical quality measures data

reporting and submission periods on a calendar year basis for the FY 2017 payment

determination for both the Medicare EHR Incentive Program for eligible hospitals and

CAHs, and the Hospital IQR Program. In this proposed rule, we are proposing to:

(1) continue to require Certified Electronic Health Record Technology (CEHRT) 2014

Edition and (2) update reporting periods and submission deadlines, for the FY 2018

payment determination for the Hospital IQR Program.

(2) Proposed Electronic Clinical Quality Measure Certification for the FY 2018 Payment

Determination

As described in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50251), for the

Hospital IQR Program, hospitals that submit electronic clinical quality measures data for

the FY 2017 payment determination are required to submit data using CEHRT 2014

Edition, which is an Electronic Health Record certification. Although we required

CEHRT, eligible hospitals were not required to ensure that their CEHRT products were

recertified to the most recent version of the electronic specifications for the clinical

quality measures. We also stated in the FY 2015 IPPS/LTCH PPS final rule

(79 FR 50251), that for the FY 2017 payment determination, a hospital could submit

electronic clinical quality measures for the Hospital IQR Program during CY 2015 even

if they attest their aggregate measure numerators and denominators through the Medicare

EHR Incentive Program. The hospital could submit as test data or production data. Test

data submissions are submissions that do not count as submissions; they are practice

submissions. Production data submissions are considered final submissions meant to

We are proposing to continue the requirement for hospitals to use CEHRT 2014

Edition161 when submitting electronic clinical quality measures for the CY 2016/FY 2018

payment determination. We note that the Office of the National Coordinator for Health

Information Technology (ONC) has proposed a new Edition of EHR technology which

may be available for some providers as early as 2016 in its “2015 Edition Health

Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic

Health Record (EHR) Definition, and ONC Health IT Certification Program

Modifications” (hereafter known as the “2015 Edition proposed rule”) (80 FR 16804

through 16921). However, we will require hospitals to continue to submit data for

Hospital IQR Program purposes using the 2014 Edition for the FY 2018 payment

determination. Any changes for the Hospital IQR Program because of ONC’s update will

be proposed in future rule making.

We are inviting public comments on this proposal.

161 Meaningful Use in 2014. Retrieved from: http://www.cms.gov/Regulations-and-

Guidance/Legislation/EHRIncentivePrograms/EducationalMaterials.html.

D. Clinical Quality Measurement for Eligible Hospitals and Critical Access Hospitals

Participating in the EHR Incentive Programs in 2016

1. Background

The HITECH Act (Title IV of Division B of the ARRA, together with Title XIII

of Division A of the ARRA) authorizes incentive payments under Medicare and

Medicaid for the adoption and meaningful use of certified electronic health record (EHR)

technology (CEHRT). Eligible hospitals and CAHs may qualify for these incentive

payments under Medicare (as authorized under sections 1886(n) and 1814(l) of the Act,

respectively) if they successfully demonstrate meaningful use of CEHRT, which includes

reporting on clinical quality measures (CQMs) using CEHRT.

Sections 1886(b)(3)(B) and 1814(l) of the Act also establish downward payment

adjustments under Medicare, beginning with FY 2015, for eligible hospitals and CAHs

that are not meaningful users of CEHRT for certain associated reporting periods.

Section 1903(a)(3)(F)(i) of the Act establishes 100 percent Federal financial participation

(FFP) to States for providing incentive payments to eligible Medicaid providers

(described in section 1903(t)(2) of the Act) to adopt, implement, upgrade and

meaningfully use CEHRT.

Under sections 1886(n)(3)(A) and 1814(l)(3)(A) of the Act and the definition of

“meaningful EHR user” under 42 CFR 495.4, eligible hospitals and CAHs must report on

CQMs selected by CMS using CEHRT, as part of being a meaningful EHR user under

the Medicare EHR Incentive Program. The set of CQMs from which eligible hospitals

and CAHs will report under the EHR Incentive Program beginning in FY 2014 is listed in

Table 10 of the EHR Incentive Program Stage 2 final rule (77 FR 54083).

Section 1886(n)(3)(B)(iii) of the Act requires that, in selecting measures for eligible

hospitals and CAHs for the Medicare EHR Incentive Program, and establishing the form

and manner for reporting measures, the Secretary shall seek to avoid redundant or

duplicative reporting with reporting otherwise required, including reporting under

section 1886(b)(3)(B)(viii) of the Act, the Hospital IQR Program.

In the EHR Incentive Program Stage 3 proposed rule219 (80 FR 16769), to further

our alignment goal among CMS quality reporting programs for eligible hospitals and

CAHs and avoid redundant or duplicative reporting among hospital programs, we stated

our intent to address CQM reporting requirements for the Medicare and Medicaid EHR

Incentive Program for eligible hospitals and CAHs for 2016, 2017, and future years in the

IPPS rulemaking. We further stated our belief that receiving and reviewing public

comments for various CMS quality programs at one time and finalizing the requirements

for these programs simultaneously would allow us to better align these programs for

eligible hospitals and CAHs, allow more flexibility into the Medicare and Medicaid EHR

Incentive Programs, and add overall value and consistency by providing us the

opportunity to address public comments that affect multiple programs at one time.

ONC, in its 2015 Edition proposed rule (80 FR 16844), also indicated that it

intends to propose certification policy for the reporting of CQMs for eligible hospitals

and CAHs in or with annual IPPS rulemaking to better align with the reporting goals of

other CMS programs.

219 Medicare and Medicaid Programs: Electronic Health Record Incentive Program – Stage 3; proposed

rule (80 FR 16731 through 16804) (“EHR Incentive Program Stage 3 proposed rule”).

2. CQM Reporting for the Medicare and Medicaid EHR Incentive Programs in 2016

a. Background

In the EHR Incentive Program Stage 2 final rule, we outlined the CQMs available

for use in the EHR Incentive Programs beginning in 2014 for eligible hospitals and CAHs

in Table 10 at 77 FR 54083 through 54087, as well as the form and method for

submission at 77 FR 54087 through 54089. In this proposed rule, for CQM reporting for

the EHR Incentive Programs in 2016, we are proposing to maintain the existing

requirements established in earlier rulemaking for the reporting of CQMs, unless

indicated otherwise in this proposed rule. These requirements include reporting on

16 CQMs covering at least 3 NQS domains for eligible hospitals and CAHs

(77 FR 54079).

As we expand the current measures to align with the National Quality Strategy

and the CMS Quality Strategy220 and incorporate updated standards and terminologies in

current CQMs, including updating the electronic specifications for these CQMs, and

creating de novo CQMs, we plan to expand the set of CQMs available for reporting under

the EHR Incentive Programs in CY 2017 and subsequent years. We will continue to

engage stakeholders to provide input on future proposals for CQMs as well as requesting

comment on future electronic specifications for new and updated CQMs.

220Available at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-

Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html.

b. Proposed CQM Reporting Period for the Medicare and Medicaid EHR Incentive

Programs in CY 2016

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50319 through 50321), we

began to shift CQM reporting to a calendar year basis for eligible hospitals and CAHs for

the Medicare EHR Incentive Program. We established that for eligible hospitals and

CAHs that submit CQMs electronically in 2015, the reporting period is one calendar

quarter from Q1, Q2, or Q3 of CY 2015 (79 FR 50321).

In the EHR Incentive Program Stage 3 proposed rule, beginning in 2015, we

proposed to change the definition of “EHR reporting period” in § 495.4 for EPs, eligible

hospitals, and CAHs such that the EHR reporting period would begin and end in relation

to a calendar year. In connection with that proposal, we are proposing that the reporting

period for CQMs in 2016 for eligible hospitals and CAHs for the Medicare and Medicaid

EHR Incentive Programs would also be based on the calendar year. We believe it is

important to continue our goal of aligning the EHR Incentive Program with the Hospital

IQR Program because alignment of these programs will serve to reduce hospital reporting

burden and encourage the adoption and meaningful use of CEHRT by eligible hospitals

and CAHs.

For 2016 (FY 2018 payment determination), the Hospital IQR Program is

proposing to require quarterly reporting and submission periods for eCQMs for the 3rd

and 4th CY quarters. We refer readers to section VIII.A.8.b. of the preamble of this

proposed rule for further discussion of the proposals for the Hospital IQR Program. We

believe it is important for us to maintain our goal of alignment between the Hospital IQR

and EHR Incentive Programs. Therefore, we are proposing to align the reporting period

in CY 2016 for eligible hospitals and CAHs that report CQMs electronically for the

Medicare EHR Incentive Program with that of the Hospital IQR Program and require

quarterly reporting and submission periods for eCQMs in the 3rd and 4th CY quarters.

In addition, in this proposed rule, the Hospital IQR Program is proposing to

change its submission period for eCQMs from annual to quarterly submission, and

proposing to change the submission deadline from November 30, 2015 to ending

2 calendar months after the close of the reporting CY quarter (for CY 2016/FY 2018

payment determination, the proposed deadlines are November 30, 2016 for Q3 and

February 28, 2017 for Q4). We refer readers to the Hospital IQR Program discussion in

section VIII.A.10.d.(3) of the preamble of this proposed rule for more information about

these proposals. Therefore, to coincide with the submission period in the Hospital IQR

Program, we also are proposing to align the Medicare EHR Incentive Program

submission period for CY 2016 with the submission period proposed for the Hospital

IQR Program.

We are proposing the following CQM reporting periods and submission deadlines

for eligible hospitals and CAHs participating in the Medicare EHR Incentive Program in

CY 2016:

● Eligible hospitals and CAHs Reporting CQMs by Attestation

++ For eligible hospitals and CAHs demonstrating meaningful use for the first

time in 2016, any continuous 90-day reporting period within CY 2016; or one full

calendar year reporting period for CY 2016. Attestation by February 28, 2017.

++ For eligible hospitals and CAHs that demonstrated meaningful use in any year

prior to 2016, one full calendar year reporting period for CY 2016. Attestation by

February 28, 2017.

● Eligible hospitals and CAHs Reporting CQMs Electronically --Two full

quarters of data (Q3 and Q4 of CY 2016) submitted via electronic reporting within

2 months after the close of each quarter (Q3 by November 30, 2016; Q4 by

February 28, 2017).

We also are proposing that the CQM reporting period for eligible hospitals and

CAHs participating in the Medicaid EHR Incentive Program would be any continuous

90-day reporting period within CY 2016 for eligible hospitals and CAHs demonstrating

meaningful use for the first time; and one full calendar year reporting period of CY 2016

for eligible hospitals and CAHs that demonstrated meaningful use in any year prior to

2016. Providers should refer to their State Medicaid program for requirements on

submission methods and deadlines.

We note that, beginning in CY 2017 and in subsequent years, we proposed in the

Stage 3 proposed rule (80 FR 16739 through 16740) to require a reporting period of one

full calendar year for CQM reporting for all providers participating in the EHR Incentive

Programs, with a limited exception for Medicaid providers demonstrating meaningful use

for the first time.

We are inviting public comment on these proposals.

c. CQM Reporting Form and Method for the Medicare EHR Incentive Program in 2016

In the EHR Incentive Program Stage 2 final rule (77 FR 54087 through 54089),

we finalized the reporting methods for eligible hospitals and CAHs for the Medicare

EHR Incentive Program, which included reporting electronically or by attestation. We

finalized that eligible hospitals and CAHs that are beyond their first year of meaningful

use will be required to electronically submit the selected 16 CQMs. Subsequent to the

Stage 2 final rule, we determined that electronic submission of aggregate-level data using

QRDA–III would not be feasible in 2014 and 2015, and thus, eligible hospitals and CAHs

would have the option to continue to report aggregate CQM results through attestation for

the reporting periods in 2014 and 2015 (78 FR 50904 through 50905; 79 FR 50321

through 50322).

We are proposing to continue our existing policy that eligible hospitals and CAHs

in any year of participation in the Medicare EHR Incentive Program in 2016 may report

CQMs by attestation or electronically using the options previously outlined for electronic

reporting either for single program participation in the Medicare EHR Incentive Program,

or for participation in multiple programs if the requirements of the aligned quality

program are met. The options for CQM submission for eligible hospitals and CAHs in

the Medicare EHR Incentive Program are as follows:

● Eligible hospital and CAH options for Medicare EHR Incentive Program

participation *(single program participation)*

++ Option 1: Attest to CQMs through the EHR Registration & Attestation

System.

++ Option 2: Electronically report CQMs through QualityNet Portal.

● Eligible hospital and CAH options for electronic reporting for multiple

programs *(for example: EHR Incentive Program plus Hospital IQR Program*

*participation* --Electronically report through QualityNet Portal.

For the Medicaid EHR Incentive Program, States will continue to be responsible

for determining whether and how electronic reporting of CQMs would occur, or if they

wish to allow reporting through attestation. Any changes that States make to their CQM

reporting methods must be submitted through the State Medicaid Health IT Plan (SMHP)

process for CMS review and approval prior to being implemented.

We are proposing to continue our policy that electronic submission of CQMs

would require the use of the most recent release of the CQM version for each CQM to

which the EHR is certified. For electronic reporting in 2016, this means eligible hospitals

and CAHs would be required to use the Spring 2015 release of the CQMs available at the

CMS eCQM Library (http://cms.gov/Regulations-and-

Guidance/Legislation/EHRIncentivePrograms/eCQM\_Library.html). We note that an

EHR certified for CQMs under the 2014 Edition certification criteria does not need to be

recertified each time it is updated to a more recent version of the CQMs. (For further

information on CQM reporting, we direct readers to the EHR Incentive Program Web site

where guides and tip sheets are available for each reporting option

(www.CMS.gov/ehrincentiveprograms).) However, we encourage EHR developers to

test any updates, including any changes to the CQMs and changes to the CMS reporting

requirements based on the CMS QRDA implementation guide, on an annual basis.

The form and method of electronic submission is further explained in

subregulatory guidance and the certification process. For example, the following

documents are updated annually to reflect the most recent CQM electronic specifications:

the CMS QRDA Implementation Guide; program specific performance calculation

guidance; and CQM electronic specifications and guidance documents. These documents

are located on the CMS eCQM Library (http://cms.gov/Regulations-and-

Guidance/Legislation/EHRIncentivePrograms/eCQM\_Library.html).

We are inviting public comments on this proposal.

3. Certified EHR Technology for CQMs for the EHR Incentive Programs in 2016

a. Edition of Certified EHR Technology Requirements in 2016

As previously stated in the Medicare and Medicaid EHR Incentive Programs

Stage 2 final rule (77 FR 54051 through 54053), CQM data submitted by eligible

hospitals and CAHs are required to be captured, calculated, and reported using CEHRT.

In accordance with this policy, for CQM reporting for the Medicare and Medicaid EHR

Incentive Programs in 2016, eligible hospitals and CAHs must use EHR technology

certified to at least the 2014 Edition certification criteria for CQMs, which are defined at

45 CFR 170.314(c)(1) for the capture of data elements, 45 CFR 170.314(c)(2) for the

calculation of CQMs, and 45 CFR 170.314(c)(3) for the submission of CQM data

electronically.

However, in the 2015 Edition proposed rule (80 FR 16810 through 16872,

16900), ONC has proposed a new Edition of certification criteria for EHR technology,

which may be available for some providers as early as 2016. The 2015 Edition proposed

rule (80 FR 16842 through 16846) would establish three certification criteria for CQMs

and set a placeholder for a fourth certification criterion. These three criteria are:

● Proposed new § 170.315(c)(1) “CQMs – record and export” - to record and

export data which aligns with the prior capture criteria.

● Proposed new § 170.315(c)(2) “CQMs – import and calculate” - to import and

calculate data which aligns with the prior calculate criteria.

● Proposed new § 170.315(c)(4) “CQMs – filter” - to filter data which is a new

function for CQM criteria in the 2015 Edition and is not currently proposed to be

required by the EHR Incentive Programs.

ONC proposed (80 FR 16844) to reserve § 170.315(c)(3) “CQMs – report” – to

report data electronically, including submission testing, to be proposed in or with annual

IPPS and/or PFS rulemaking. ONC believes that, going forward, proposing a 2015 Edition certification criterion for CQM reporting with CMS’ annual payment rules would

allow better alignment of ONC’s certification policy and standards for electronically

specified CQM, known as eCQMs, with reporting with other CMS programs that include

eCQMs, such as the PQRS and Hospital IQR Programs, which update their measure

specifications on an annual basis through rulemaking. Therefore, ONC is proposing a

2015 Edition certification criterion for “CQMs - report” in section VIII.D.3.b. of the

preamble of this proposed rule.

4. CQM Development and Certification Cycle

We stated in the Stage 2 final rule (77 FR 54055) that we do not intend to use

notice and comment rulemaking as the means to update or modify CQM specifications.

Given the necessity to update CQM specifications after they have been published to

ensure their continued clinical relevance, accuracy, and validity, we publish annual

updates to the electronic specifications for EHR submission. Although we require

eligible hospitals and CAHs to submit the most updated versions of CQMs when

reporting electronically, CEHRT is not required to be recertified on annual basis. CMS

and ONC understand that standards for electronically representing CQMs continue to

evolve, and believe there may be value in retesting certified Health IT Modules

(including CEHRT) periodically to ensure that CQMs are being accurately calculated and

represented, and that they can be reported to CMS in the “form and manner” required for

the Hospital IQR Program and EHR Incentive Program. As mentioned previously, CMS

and ONC encourage health IT developers to retest their certified technology annually,

and are soliciting comment on the appropriate frequency for requiring retesting and

recertification to the most updated versions of CQMs and most recent “form and manner”

reporting requirements.

However, given the continuing evolution of technology and clinical standards, as

well as the need for a predictable cycle from measure development to provider data

submission, CMS intends to publish a request for information (RFI) on the establishment

of an ongoing cycle for the introduction and certification of new measures, the testing of

updated measures, and the testing and certification of submission capabilities. We

encourage readers to submit their insights and recommendations for our consideration

upon publication of that RFI.

1. <http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35>. Please note that in order to access the errata, the user should download the “HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture – Category I, DSTU Release 2 (US Realm)” package. [↑](#footnote-ref-1)
2. <http://www.hl7.org/implement/standards/product_brief.cfm?product_id=97> [↑](#footnote-ref-2)
3. <http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumber=1045> [↑](#footnote-ref-3)