CQI Workgroup’s Comments on 2015 Voluntary Certification NPRM

## Overall

The CQI workgroup appreciates the notion of a voluntary certification and wishes to clarify that while we believe such voluntary certifications can be useful, we don’t believe that they should be the only place used to test emerging standards. We note that requiring standards which are not yet finalized goes against the third “R” of the goals for this NPRM (“rational” – i.e. having fewer errors) and additionally wish to point out that there will probably not be enough time between when the 2015 certification is finalized and when the 2017 rule comes out for feedback to make it into the rulemaking process. Additionally, we remark that EHR vendors may consider the certification requirements “holistically”, and therefore may choose not to do any of the certification if even one objective proves too onerous.

The CQI workgroup also wishes to emphasize that our comments are based on the assumption that the proposed certification criteria are voluntary, and may not apply if the certification is, for example, made mandatory by another program.

# *10890-10891* – Clinical Decision Support

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| ***Criterion*** | ***Standard*** |
| ***§ 170.315(a)(10)*** - Clinical decision support. (i) Evidence-based decision support interventions. Enable a limited set of identified users to select (i.e., activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on each one and at least one combination of the following data: (A) Problem list; (B) Medication list; (C) Medication allergy list; (D) At least one demographic specified in paragraph (a)(5)(i) of this section; (E) Laboratory tests ~~and values/results~~; and (F) Vital signs.(ii) Linked referential clinical decision support.  (A) EHR technology must be able to: (1) Electronically identify for a user diagnostic and therapeutic reference information; or (2) Electronically identify for a user diagnostic and therapeutic reference information in accordance with the standard specified at ***§ 170.204(b)*** and the implementation specifications at ***§ 170.204(b)(1) or (3)***. (B) For paragraph (a)(10)(ii)(A) of this section, EHR technology must be able to electronically identify for a user diagnostic or therapeutic reference information based on each one and at least one combination of the data referenced in paragraphs (a)(10)(i)(A), (B), and (D) of this section.(iii) Clinical decision support configuration.  (A) Enable interventions and reference resources specified in paragraphs (a)(10)(i) and (ii) of this section to be configured by a limited set of identified users (e.g., system administrator) based on a user's role. (B) EHR technology must enable interventions to be electronically triggered: (1) Based on the data referenced in paragraphs (a)(10)(i)(A) through (F) of this section. (2) When a patient's medications, medication allergies, and problems are incorporated from a transition of care/referral summary received pursuant to paragraph (b)(1)(i)(B) of this section. (3) Ambulatory setting only. When a patient's laboratory tests and values/results are incorporated pursuant to paragraph (b)(4)(i)(A)(1) of this section.(iv) Automatically and electronically interact. Interventions triggered in accordance with paragraphs (a)(10)(i) through (iii) of this section must automatically and electronically occur when a user is interacting with EHR technology.(v) Source attributes. Enable a user to review the attributes as indicated for all clinical decision support resources: (A) For evidence-based decision support interventions under paragraph (a)(10)(i) of this section: (1) Bibliographic citation of the intervention (clinical research/guideline); (2) Developer of the intervention (translation from clinical research/guideline); (3) Funding source of the intervention development technical implementation; and (4) Release and, if applicable, revision date(s) of the intervention or reference source. (B) For linked referential clinical decision support in paragraph (a)(10)(ii) of this section and drug-drug, drug-allergy interaction checks in paragraph(a)(4) of this section, the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research/guideline).(vi) Decision support – knowledge artifact. Electronically process clinical decision support knowledge artifacts in accordance with the standard specified at ***§ 170.204(d)***.(vii) Decision support – service. Enable a user to electronically make an information request with patient data and receive in return electronic clinical guidance in accordance with the standard specified at ***§ 170.204(e)***. | ***§ 170.204(b)*** - HL7 Context-Aware Retrieval Application (“Infobutton”), Release 1, July 2010***§ 170.204(b)(1)*** - URL-Based Implementations of the Context-Aware Information Retrieval (Infobutton) Domain, Release 3, December 2010***§ 170.204(b)(2)*** - HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Draft Standard for Trial Use, Release 1.***§ 170.204(b)(3)*** - HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1.***§ 170.204(d)*** - Decision Support. Standard. HL7 Implementation Guide: Clinical Decision Support Knowledge Artifact Implementation Guide.***§ 170.204(e)*** - Decision Support. Standard. HL7 Decision Support Service Implementation Guide. |

* + What specifically ONC should focus on when it comes to testing and certification for acceptance and incorporation of CDS Knowledge Artifacts;
	+ The feasibility of implementing the interface requirements defined in the Decision Support Service IG to make an information request, send patient data, and receive CDS guidance in near real-time;
	+ The ease with which EHR technology could be developed to consume CDS Knowledge Artifacts;
	+ Whether we should work to distinguish between complex CDS Knowledge Artifacts and simple Knowledge Artifacts and to require only acceptance and incorporation of simple Knowledge Artifacts in the 2015 Edition, with increasing expectations of more complex capabilities in future editions;
	+ The ability to store and auto-configure a CDS Knowledge Artifact in EHR technology;
	+ The ability to map the CDS Knowledge Artifact standard to data within the EHR technology (including medications, laboratory, and allergies information).

## Response

We appreciate the NPRM’s requirements for CDS and have the following comments on their feasibility:

* The CDS Knowledge Artifact is still early in its development and validation phase. We are concerned that the standard is not ready for wide consumption at this point.
* As the proposed standards are not yet aligned with HQMF, we are concerned that this proposal will be a step away from unification of CDS and CQM.
* We request more clarity on the distinction between “simple” and “complex” knowledge artifacts but comment that such a distinction may prove beneficial, especially if we can identify the simple artifacts which represent the most “bang for the buck.”
* We believe that the DSS standard is robust enough to be considered for inclusion in the rule. However, we are concerned that the use of vMR will be a step away from unified CDS/CQM standards, and reiterate our concern about implementing these standards before they are unified.
* We remark that many EHRs currently use the same infrastructure to calculate their quality measures as to provide decision support. If this infrastructure is required to shift to the vMR it may represent a step backwards in alignment between CDS and CQM. Therefore, we reiterate our concern about implementing these standards before they are unified.

Further, the CQI workgroup notes than many EHR developers may not be aware of the harmonization projects between CQM and CDS, and suggests the rule more clearly indicate that the relevant standards may change between the 2015 and 2017 certifications.

# *10902-10903* - Clinical Quality Measures

* + We solicit comment on industry readiness to adopt the HL7 Health Quality Measures Format (HQMF) standard for representing a clinical quality measure as an electronic document.
	+ We solicit comment on industry support for unified, modularized CDS and CQM standards for the 2017 Edition.
	+ We solicit comment on what we should require EHR technology to be able to demonstrate for certification (e.g., to require that EHR technology be able to electronically process any eCQM formatted in a unified, modularized CQM standard such as a new HQMF standard).
	+ Recommended testing and certification processes for the electronic processing of eCQMs;
	+ A way in which to classify measures so as to select a subset of measures that would be easier and simpler to be electronically processed by EHR technology in testing and certification;
	+ The ability/readiness of EHR technology to store and incorporate an eCQM in HQMF R2;
	+ The ability/readiness of EHR technology to map the HQMF R2 standard to data within the EHR technology (including medications, laboratory, allergies information).
	+ What requirements for supplemental data and reporting should be included as part of CQM certification criteria
	+ What specific capabilities, reporting requirements, standards, and data elements ONC should consider for CQM certification going forward.

## Response

The CQI workgroup supports the idea of unified CDS and CQM standards, and reiterates our wish that standards not be required before such alignment occurs.

Additionally, we seek clarification on what the intent of classifying measures as “easier and simpler” is. However the following may be some starting points for classifying measures that may be similar to each other in terms of how difficult they are to implement:

* + Rating measures in terms of cyclomatic complexity, although keep in mind cyclomatic complexity is not necessarily the same as implementation complexity. For more info on MITRE’s cyclomatic complexity analysis of measures, see [www.projectkamira.org](http://www.projectkamira.org)
* Rating measures based on feasibility or the ability to matching internal EHR system data model to QDM
* Rating measures based on how frequently the data elements are captured as standardized, discrete elements in EHRs. For example, procedures which are not ordered (such as foot examinations for diabetic patients) are often not captured in the EHR as a discrete data element (instead being part of the free-text note) and as a result measures using these elements are difficult to implement.

The CQI workgroup appreciates the request for input on EHR requirements and has the following comments:

* We have given several areas in which we are concerned that the existing standards do not have the capabilities required to meet the desired requirements (e.g. the proposed §170.315(c)(4) criterion). We note that if such criteria are put in place, it will be impossible for EHRs to simultaneously satisfy these standards while still electronically processing the standardized file, since these additional criteria must come in the form of free-text guidance.
	1. As the proposed rule notes in §170.315(c)(4), programs such as PQRS GPRO already have similar requirements which may not be standards-compliant. We remark that EHRs who support such programs may have a difficult time supporting such programs while still having an eCQM engine based on the electronic processing of HQMF, even if the MU requirements are standards-compliant.
* We request clarification on the criterion that EHRs “store and incorporate an eCQM in HQMF R2.” We are unclear what the intent of requiring EHRs to store eCQMs is.
* We request clarification on the intent of the requirement that EHRs “map the HQMF R2 standard to data within the EHR technology (including medications, laboratory, allergies information)” and are uncertain how such an ability would be demonstrated beyond the ability to process and evaluate eCQMs written in HQMF R2 standard. We further consider that the Quality Data Model (QDM) is the recommended standard for requirements regarding the data model used in quality measurement, and suggest that data model requirements be based on the QDM instead of HQMF.

Lastly, the CQI workgroup wishes to draw attention to our recent comment-only ballot “FHIR as a Potential Common Logical Model for Clinical Quality Measures and Decision Support” which is an initial investigation into the use of FHIR to align CQM and CDS standards. We point readers to the ballot itself for full details, but wish to quote the concluding paragraph:

In terms of moving towards convergence, if the path forward involves FHIR, a considerable amount of work to harmonize FHIR with QIDAM will be required. Because the requirements of QIDAM have been validated (albeit indirectly) through the use of vMR and QDM, FHIR is likely to benefit from this analysis in terms of completeness and maturity. Ultimately, adoption of FHIR in this area will require reworking on several levels, authoring tools, artifact formats, and execution engines. Whether this investment is worthwhile remains to be seen.

# *10903* - Clinical Quality Measures – Capture and Export

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| ***Criterion*** | ***Standard*** |
| ***§ 170.315(c)(1)*** - Clinical quality measures—capture and export. (i) Capture. For each and every CQM for which the EHR technology is presented for certification, EHR technology must be able to electronically record all of the data identified in the standard specified at ***§ 170.204(c)*** that would be necessary to calculate each CQM. Data required for CQM exclusions or exceptions must be codified entries, which may include specific terms as defined by each CQM, or may include codified expressions of “patient reason,” “system reason,” or “medical reason.”(ii) Export. EHR technology must be able to electronically export a data file formatted in accordance with the standards specified at ***§ 170.205(h)*** that includes all of the data captured for each and every CQM to which EHR technology was certified under paragraph (c)(1)(i) of this section. | ***§ 170.204(c)*** - NLMData Element Catalog, Version: August 2012***§ 170.205(h)*** - HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture, DSTU, July 2012 |

* + We solicit public comment on the potential usefulness of broadening the export requirement to also include reference to a QRDA Category II formatted data file, which would address the bulk reporting of quality data that includes the patient level data as outlined in the QRDA Category I report.

## Response

The CQI work group appreciates that the NPRM provides requirements for a possible QRDA Category 2 standard, however the work group requests clarification on the proposed requirements and has the following concerns:

* The QRDA Category II standard has only been passed on a “for comment” ballot as part of the original QRDA DSTU. We are concerned that the standard has not been fleshed out enough yet for commenters to give constructive feedback
	+ - * Category 2 reports will be more difficult for document generators to create than either the Category I or III reports as they combine all the elements from both formats
			* QRDA Category 2 reports may be more trouble than its worth; simply collecting multiple QRDA Category 1 reports may be easier since it wouldn’t force implementers to learn and adopt yet another QRDA specification. Many widely-used formats such as zip already exist and are capable of combining multiple reports into one file.
			* Some implementers of QRDA, such as CMS, are already creating a “wrapper” for QRDA Category 1. If various implementers are creating similar “wrappers”, that may make the case for supporting a standardized approach to wrapping the QRDA Category 1 with a potential QRDA Category 2 specification.
				+ If QRDA category 2 is intended as an interim step between taking QRDA category 1 reports and aggregating up to a QRDA category 3 report, it should account for the fact that the aggregation is not always simple once reporting stratification is factored in.
				+ Based on the experience of the Cypress project, the most difficult part of CQMs for implementers currently is the QRDA standards and adding a new standard will only exacerbate that.

# 10903-10904 – Clinical Quality Measures – Patient Population Filtering

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| ***Criterion*** | ***Standard*** |
| ***§ 170.315(c)(4)*** - Clinical quality measures – patient population filtering. EHR technology must be able to record structured data for the purposes of being able to filter CQM results to create different patient population grouping by one or a combination of the following patient characteristics:(i) practice site and address;(ii) Tax Identification Number (TIN), National Provider Identifier (NPI), and TIN/PIN combination;(iii) Diagnosis;(iv) Primary and secondary health insurance, including identification of Medicare and Medicaid dual eligibles; and(v) Demographics including age, sex, preferred language, education level, and socioeconomic status. |  |

* + Whether current CQM standards (e.g., QRDA Category I and Category III) can collect metadata for the characteristics listed above to filter and create a CQM report for a particular characteristic or combination of characteristics.
	+ We also solicit comment on vocabulary standards that could be used to record the characteristics proposed above.

## ResponseThe CQI workgroup requests clarification on what it means to “filter” a report. As an example, consider measure CMS 138: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention. For this measure a patient must have 2 office visits with the EP to be included.

## Scenario 1: A patient is seen by Provider A during the measurement period for one office visit. Later, and also during the measurement period, the patient is seen by Provider B for one office visit. Both encounters are billed under the same TIN.

## Option A: We would evaluate the measures at the provider level (following the MU specifications). Because of this, the patient would not be included in the measure’s initial patient population because they had neither 2 office visits with Provider A nor 2 office visits with Provider B.

## Option B: We would evaluate the measures at the TIN level. Because of this, the patient would be included in the initial patient population for the group because they had 2 office visits with providers within the TIN.

## Scenario 2: A patient is seen by Provider A during the measurement period for two office visits. The patient is also seen during the measurement period for two office visits with Provider B.

## Option A: We would evaluate the measures at the provider level and summarize at the group level. This would mean the patient would be in the initial patient population for Provider A and also in the initial patient population for Provider B. When summarizing the data at the group level, the patient would only be included once because both providers are part of the TIN.

## Option B: We would evaluate the measures at the TIN level. This would mean the patient would be in the initial patient population for the TIN because they were seen for 4 office visits by providers within the TIN, which is greater than the requirement of 2.

## We request clarification on which of these options EHRs would be required to support. We believe that current standards are able to support options (A) in the above two scenarios, but not options (B).

## Additionally, we have the following comments on the ability of current standards to support these requirements:

## HQMF supports some patient characteristics, such as diagnosis, via supplemental data elements, but it does not, in general, support provider characteristics.

## QRDA-I and III support many patient and provider characteristics (the latter through program-specific Implementation Guides)

## We have several concerns with filtering by socioeconomic status:

## It is unclear what data would be used to indicate socioeconomic status. Is this measured by income? Education level? Occupation? The CQI workgroup requests clarification on which specific data elements would be used.

## We do not believe that indicators such as income are currently recorded in EHRs and would often not be provided by patients, even if they were asked.

## Furthermore, we don’t believe that standardized terminologies for these indicators exist, and for example in the case of income it is even unclear whether we should have “categories” of income levels or if this should be a numeric value.

* We also believe that education level is not regularly captured in EHRs today. However, there is a possible value set 2.16.840.1.113883.5.1077 which could be used to standardize these values, if captured. The granularity of this value set may or may not be appropriate for the goals of the program.

The CQI workgroup also requests clarification on how Continuous Variable Measures will function under these filtering requirements.

# *10909-10910* - Transmission to Public Health Agencies – Syndromic Surveillance

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| ***Criterion*** | ***Standard*** |
| ***§ 170.315(f)(3)*** - Transmission to public health agencies—syndromic surveillance. EHR technology must be able to electronically create syndrome-based public health surveillance information for electronic transmission in accordance with:(i) Ambulatory setting only.  (A) The standard specified in ***§ 170.205(d)(2), (d)(5), or (k)***. (B) Optional. The standard (and applicable implementation specifications) specified in ***§ 170.205(d)(4)***.(ii) Inpatient setting only. The standard (and applicable implementation specifications) specified in ***§ 170.205(d)(4)***. | ***§ 170.205(d)(2)*** - HL7 V2.5.1***§ 170.205(d)(4) -*** HL7 2.5.1. Implementation specifications. PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, and Inpatient Settings, Release 1.9.***§ 170.205(d)(5)*** - HL7 Clinical Document Architecture (CDA), Release 2.0, Normative Edition***§ 170.205(k)*** – MISSING QRDA III?? |

* + We solicit comment on whether public health agencies are using the QRDA Category I standard to receive query-based syndromic surveillance data, and whether ONC should consider adopting the QRDA Category I standard for the ambulatory setting.

## Response

The CQI workgroup appreciates consideration of the QRDA Category I standard, and has the following comments on the feasibility of the requirements:

* While the QRDA standard has received use in the CQM domain, we are concerned that the standard has had limited implementations in the syndromic surveillance domain, and is too immature to be implemented as a requirement.
* We are unclear why the Category I standard was chosen for this requirement, and request clarification why alternative standards were not considered.
* We request clarification on which data elements will be required in the submitted files, the submission mechanism, and whether a standard like HQMF will be used to provide guidance to implementers.

In answer to the question asked in the NPRM: the CQI workgroup is not aware of any public health agencies using the QRDA-I standard to receive query-based syndromic surveillance data.