Health IT Standards Committee

A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT

Clinical Quality Workgroup

Comments on the ONC Voluntary 2015 Edition Proposed Rule

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Clinical Quality WG Assignments

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Description	Unchanged in 2015 Edition	2015 Edition	2017 Edition	Status
CDS – Health eDecisions Proposal		X		Discussion Item
CQM – Import and Calculate	X			Did not Discuss
CQM – Electronic submission	X			Did not Discuss
CQM – Patient Population Data Filtering		X		Discussion Item
CQM - Electronic Processing			X	Discussion Item
CQM – Functions and Standards for CQM Certification			X	Discussion Item
CQM – Capture and Export	X		X	Discussion Item

Clinical Decision Support: Health eDecisions Proposal (I)

ONC proposes to adopt the HL7 Implementation Guide: **Clinical Decision Support Knowledge Artifact Implementation Guide, Release 1 (January 2013) ("HeD standard") as a standard at § 170.204(d**) and to require that EHR technology be able to electronically process a CDS artifact formatted in the HeD standard. We also propose to adopt the **HL7 Decision Support Service Implementation Guide, Release 1, Version 1 (December 2013) as a standard at § 170.204(e**) and to require that EHR technology demonstrate the ability to make an information request, send patient data, and receive CDS guidance according to the interface requirements defined in the Decision Support Service IG.

CQ Workgroup Comment:

a) The ease with which EHR technology could be developed to consume CDS Knowledge Artifacts

Response: Can be done BUT standards immature and likely to be technically challenging because no shared data model or standard data elements/value sets.

Suggestion: Constrain to a few ECA rules only and link to specific eCQMs. Need to provide a CDS artifact repository and implementation guidance.

Clinical Decision Support: Health eDecisions Proposal (II)

b) 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.

Response: Yes—should apply a tiered system to CDS KA (and CQM). More simple initially . Focus on common areas 80% labs, drugs, core patient demographics, vital signs and get those aligned in consumable way so can be exchanged and reused for many purposes.

c) The ability to map the CDS Knowledge Artifact standard to data within the EHR technology (including medications, laboratory, and allergies information).

Response: Ability –yes. Made easier by addressing the recommendations in a) and b).

Clinical Decision Support: Health eDecisions Proposal (III)

d) The ability to store and auto-configure a CDS Knowledge Artifact in EHR technology.
Response: WG not clear on the ask and what is meant by "auto-configure". But, if means consume/ share then would need a standard data model, logic, implementation guidance to configure systems.

e) 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

Response: Feasible--but again challenging so WG suggests likelihood of success with this requirement could be increased if it were narrowed to just 2 or perhaps 3 of the 7 "interaction" types listed in the NPRM.

Clinical Quality Measures:
§ 170.315(c)(4) Patient Population Filtering (I)

ONC proposes to adopt a new 2015 Edition certification criterion to require filtering of CQMs by patient population characteristics and propose to require that EHR technology be able to record structured data for the purposes of being able to filter CQM results to create different patient population groupings by one or a combination of the following patient characteristics:

- Practice site and address;
- Tax Identification Number (TIN), National Provider Identifier (NPI), and TIN/NPI combination;
- Diagnosis (e.g., by SNOMED CT code);
- Primary and secondary health insurance, including identification of Medicare and
- Medicaid dual eligibles;
- Demographics including age, sex, preferred language, education level, and socioeconomic status.

Clinical Quality Measures:
§ 170.315(c)(4) Patient Population Filtering (II)

ONC solicits comment on:

- 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.
  - For some, not all for QRDA I. For instance no established standards to collect/exchange education level or socioeconomic status.
  - This type of data "lives" in different systems so hard to certify against this. Insurance may be in an administrative/billing system, whereas clinical data in the EHR, and not all providers can bring the two data sets together easily.
  - Should not be required of the EHR—rather a data warehouse, data intermediary, etc.
- Are there vocabulary standards that could be used to record the characteristics proposed above
  - For some (demographics, diagnosis), not all (SES, education).
  - Would need more than just the vocabulary but the whole data element, metadata, value set.

Clinical Quality Measures: § 170.315(c)(1) Capture and Export

ONC proposes to adopt a 2015 Edition certification criterion that is the same as the 2014 Edition version. Response: Standards haven't been evaluated well enough to know that we can import. Not mature enough of a process to really say it's ready to capture directly from HQMF and report out.

ONC solicits comment on upcoming 2017 Edition Rulemaking

- ONC solicits 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.
  - 2017 should focus on improving what goes in to CAT I and improving utilization of CAT I on the receiving end.
  - QRDA Category II was considered at a conceptual level when QRDA was first developed but it has never been detailed or balloted in HL7. Category II has not been defined so it is not yet a "standard."
  - QRDA Categories I and III have been balloted and are DSTUs. However, no action has been taken on reported errata since at least September 2013. CMS also has separate program-specific QRDA implementation guides that have caused confusion for implementers.
  - No one using QRDA III. Shouldn't have providers submit QRDA III data –which is a summary of QRDA I data. Too burdensome---those receiving the data should aggregate.

Clinical Quality Measures: Electronic Processing eMeasures (I)

For 2017 Edition rulemaking, ONC hopes to propose for adoption a certification criterion focused on EHR technology's ability to **electronically process CQMs**.

ONC solicits comment on:

- Industry readiness to adopt the HL7 Health Quality Measures Format (HQMF) R2 standard for representing a clinical quality measure as an electronic document.
  - Not ready—and has not been tested to determine if it can enable processing of eCQMs; limited evidence could be done broadly in an automated fashion.
  - Much of the data required in the measure remains unstructured (if it exists at all).
  - QM value sets not ready to support. If the issues with value sets aren't addressed, then requiring a "plug and play" approach to electronic CQM specifications will likely result in a material decrease in the accuracy of the quality measurements yielded. One way to address this issue would be to establish a centralized authority to create and manage value sets.

Clinical Quality Measures: Electronic Processing eMeasures (II)

For 2017 Edition rulemaking, ONC hopes to propose for adoption a certification criterion focused on EHR technology's ability to **electronically process CQMs**.

ONC solicits comment on:

- Industry support for unified, modularized CDS and CQM standards for the 2017 Edition.
  - Support for harmonized standards for QI to better enable CDS and eCQM consumption and exchange. Promising but early. Underlying standards have not been sufficiently tested and implemented, nor has a repository been identified to make modular CDS components (CDEs) available similar to the work currently under development for S&I's Structured Data Capture.
- What should ONC 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).
  - Until standards harmonized, tested, and widely used, certification should be outcome-based, i.e., assure the measures are reported without being prescriptive as to how (i.e., with which emerging standards) the EHR processes the measures.
- Recommended testing and certification processes for the electronic processing of eCQMs
  - Require minimal levels of processing capability while not requiring full adherence to all aspects of existing eMeasure complexity

Clinical Quality Measures: Electronic Processing eMeasures (III)

For 2017 Edition rulemaking, ONC hopes to propose for adoption a certification criterion focused on EHR technology's ability to **electronically process CQMs**.

ONC solicits comment on:

- 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;

Response: WG agreed it would be good to have a tiered system of measures. Measures designed for EHRs should address basic, outcome-based data that are **routinely structured in EHRs** to help drive the process and encourage appropriate measurement. The design currently in used to capture every nuance that might impact performance is severely limiting the ability to drive EHRs to participate in the process. Rather the current measure designs encourage the hard wiring that persists from MU stage 1 through 2014 measures. A new approach to defining measures for EHRs should start with basics and determine from the output what are **reliable and valid data for use in measures** that lead to the type of rigorous endorsement process such as required by NQF. The MU measures should take a step back and evaluate the process of measurement to identify the appropriate data to use for subsequent value based purchasing measure requirements. That process will more directly drive the type of measures, over time, that CMS needs to evaluate care.

Clinical Quality Measures: Electronic Processing eMeasures (IV)

For 2017 Edition rulemaking, ONC hopes to propose for adoption a certification criterion focused on EHR technology's ability to **electronically process CQMs**.

ONC solicits comment on:

- The ability/readiness of EHR technology to store and incorporate an eCQM in HQMF R2; WG felt this question did not appear to differ from the first. They are not ready and have not been given the opportunity to absorb the standards in a meaningful way.

- The ability/readiness of EHR technology to map the HQMF R2 standard to data within the EHR technology (including medications, laboratory, allergies information). Again the lack of common data elements and value sets are the challenge. EHRs don't have a standard way to assure accurate capture of clinical conditions that drive most measures. Potential solution map/bind to the data elements (CDEs) rather than the value set; separate these out to be modular. It would be a much better approach to define the type of data desired and measure that it is appropriately documented for reuse - a basic infrastructure component for eCQMs and CDS. The infrastructure needs to be assured before complex use of the data can lead to valuable information.

For 2017 Edition Rulemaking**, ONC solicits comment on:**

- 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: Supplemental data are useful only if the measures define how to use them. Such data may be reported in QRDA Category I if CDA has defined it. However, Category III QRDA requires aggregate analysis - such analysis requires that the measure provide the instruction about how the analysis should be performed. In a sense, supplemental data can be useful if it is feasible to collect and if all QRDA Category I submissions are extracted to allow a central site to perform statistical analysis. But if they are to be evaluated at the practice or hospital site, the measure needs to define their use - and then, by definition, they are no longer supplemental, but measure criteria.