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Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-3323-NC
P.O. Box 80133
Baltimore, MD 21244-8013

[File Code CMS-3323-NC Submitted electronically via http://www.regulations.gov]

Dear Mr. Slavitt:

HL7 appreciates the opportunity to provide feedback on the CMS RFI relating to the Certification Frequency and Requirements for the Reporting of Quality Measures. Health Level Seven International (HL7) -- the global authority on interoperability for healthcare information technology (IT) -- is a not-for-profit, ANSI-accredited standards developing organization (SDO) dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. HL7's members represent approximately 500 organizations that comprise more than 90% of the information systems vendors serving healthcare in the U.S.

In summary, HL7 offers the following general observations and suggestions:

1) There are many sources of required yearly changes to eCQM processes. Some of these are permanent yearly changes, such as updates to the measure specifications and value sets, while others such as refinement of the HL7 standards and ONC/CMS tooling should, over-time, become a less frequent driver of the yearly changes.
2) Nevertheless, a predictable annual cycle is not currently possible. There are too many groups (i.e., standards developers, measure developers, government tool developers, vendors, providers, CMS data warehouse) that need time to perform their responsibilities and none of the groups is satisfied with the time available to them.
3) There are many data problems, such as date/time inconsistencies, which cannot be corrected through certification or yearly testing.
4) Certification is a "heavy weight" process that should be reserved for major changes. A simpler, cheaper, lighter process is needed for confirming measure-reporting accuracy.
5) The current CMS/ONC testing tools are not sufficiently robust and do not provide sufficiently detailed feedback to meet requirements.

HL7 is suggesting improvements to address some of these issues.

HL7's Clinical Quality Information (CQI) Work Group and Policy Advisory Committee have contributed notable time and effort to these comments. We would be happy to answer questions or provide further information to you. Please e-mail HL7's Ticia Gerber at tgerber@hl7.org if you or your staff have questions or need further information.

Sincerely,

Charles Jaffe, MD, PhD
Chief Executive Officer
Health Level Seven International

Patricia Van Dyke
Board of Directors, Chair
Health Level Seven International

Detailed Comments

The following detailed comments respond to those questions that involve the use of HL7 standards.

A. Frequency of Certification:

(81825-81826) To ensure accuracy of the implementation of these updates, we have considered requiring recertification of already certified EHR products with these annual updates. We 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 as required

What are the benefits of requiring additional testing and recertification?

HL7 is continuously working to improve the standards used to specify the eCQMs (HQMF) and transport the quality measure data (QRDA). The measure developers assisting HL7 with these improvements believe that the eCQM specifications will continue to change every year until the standards are mature and stabilized. Therefore, the benefits of requiring additional testing and recertification include:

- Full re-certification of Health IT modules whenever health information technology (HIT) standards are newly adopted would help ensure the vendors have properly implemented relevant HIT standards, such as the impending adoption of HL7's Clinical Quality Language (CQL) standard.

  To reduce burden, HL7 suggests that CMS adopts new standards only at the beginning of a mandatory Certification cycle and not in the middle.

- Providers and hospitals would benefit from the assurance that their Health IT Module is calculating CMS required measures consistently based on the most recent version of eCQM specifications.

  HL7 therefore suggests:

  - Existing measures undergo annual testing based upon the changes that are occurring in the next version of the specifications.
  - New, mandatory measures adopted via HHS regulations undergo full certification.

- It is important that a timely process be in place to identify developers not meeting the testing and certification requirements, to support provider's ongoing evaluation and understanding of their HIT vendor's capabilities.

How will it affect the timeline for CQM and standard updates?

Certification adds several months to the release time of Health IT modules. It is anticipated that even a smaller, yearly testing process would also add several months to the release time. HL7 believes there is currently a high-level twelve-step process required for CMS to receive quality measure data. By adding a yearly testing requirement, the steps will be: (1) Quality Data Model (QDM) is updated; (2) HL7 standards are updated; (3) Measure Authoring Tool (MAT) is updated; (4) measure developers update the measures; (5) measures are released to the public (spring of the preceding year); (6) vendors implement the new / updated measures; (7) vendors are tested / certified; (8) hospitals implement the updated software, modify workflow(s) as

needed, and train providers; (9) hospital go-live occurs; (10) data capture occurs; (11) data submission occurs; (12) CMS and other data receives evaluate the data.

Due to the tight timeframe between measure specification release and provider implementation, HL7 is concerned that a yearly testing process will mean that providers have less time to implement new and updated measures and associated workflows. To mitigate this concern at least in part HL7 suggests to:

- Primarily focus certification on new measures and less on updated measures.
- Focus certification against what CMS accepts as input, rather than a separate specification.

B. Changes to Minimum CQM Certification Requirements

(81826) We believe EHRs should be certified to more than the minimum number of CQMs as required by the ONC 2014 Edition Base EHR definition of a minimum of 9 CQMs for EPs or 16 for eligible hospitals and CAHs (80 FR 16771, see also 45 CFR 170.102).

CMS seeks comment on the feasibility of health IT developers complying with the requirements of each policy option in the first year in which the requirements would become effective; the impact of each option (1,2,3) on EP, EH/CAHs and health IT developers; and what to consider when assessing each option.

HL7 believes that health IT developers currently drive which eCQMs eligible professionals (EPs), eligible hospitals (EHs), and critical access hospitals (CAHs) have available to them. As a result, providers may not be able to report on CQMs that are most applicable to their patient population, or scope of practice, or aligned with their improvement objectives.

Experience shows that there are specialty quality developers within the hospital space. Typically, these are software developers who provide services to specific units within the hospital, such as perinatal / maternal care, pediatric, and psychiatric care. In addition, there are health systems that are their own vendor and HL7 does not believe they should be required to certify on measures that they know they will not use within any of their hospitals based on the services they provide. Our preferred position would be to provide 'specialty developer' and 'internal developer' categories for hospitals so that market forces and hospital needs will continue to determine the best combination of health IT quality modules needing to be certified . Consequently, developers should not be required to support all eCQMs at all times and, while none of the options presented addresses this need fully, we would prefer option 3B or option 3C over the others.

C. CQM Testing and Certification

(81827) ONC has adopted a new edition of certification criteria in the 2015 Edition final rule (80 FR 62601). One objective of testing for the 2015 Edition CQM criteria (80 FR 62651) is to increase testing robustness (for example, increasing number of test records, robustly testing pathways by which a patient can enter the numerator or denominator of a measure), thereby ensuring that all certified products have capabilities commensurate to the increased requirements enumerated in the 2015 Edition final rule.

CMS requests information on the following:

(1) What changes to testing are recommended (or are not recommended) to increase testing robustness?

(2) How can the CQM certification process be made more efficient and how can the certification tools and resources be augmented or made more usable?

HL7 requests that the eCQM testing tools provider more information than just the end measure results for each patient. These tools need to produce better, more robust results that show the path each patient took through the HQMF. Knowing the end results is a first step towards understanding if a vendor's quality software is functioning correctly; however, the vendors need as much information as possible in order to understand where their implementation of the HQMF is different from what the testing tool was expecting.

For vendors providing software to EPs, HL7 requests that the testing tools are enhanced to allow QRDA Category III files to be submitted based upon a given set of patient-level records. This would help ensure not only are the same measure results being identified, but also that the software is aggregating the data correctly.

HL7 suggests that CMS investigate the possibility of providing on-going evaluation of both the submitter's software and CMS' data warehouse. This evaluation would require vendor software that generates a QRDA Category I file, to include the software result (i.e., not in population, in denominator, in numerator, excluded/exclusion) for each measure for each episode of care. This functionality already exists in the QRDA Category I file for proportion measures and could be enhanced for other types of measures. CMS' data warehouse would compare the vendor's measure results to their own measure results and provide a report showing the differences. This on-going evaluation could be used to reduce the time required to test / certify eCQMs by providing ONC the ability to determine which vendors are routinely having measure calculation issues. In addition, vendors could utilize this feedback for their own internal software evaluation.

HL7 would like to re-iterate that certification and testing activities must focus on the specifications that are actually to be used during submission. HL7 is ready to help harmonize any variances to allow the industry to arrive at one specification.

How could CMS and ONC determine how many test cases are needed for adequate test coverage?

The number of test cases required for adequate test coverage will be different for every measure. To ensure vendors have implemented a given measure accurately, there needs to be enough test cases to cover the entire measure logic (i.e., IPP, denominator, numerator, exceptions/exclusions). This does not mean testing every member of all value sets, but testing every path that a quality-processing engine might take based upon the logic within the HQMF. This should include all reasonable combinations of data elements for each eCQM's population criteria, while using malformed or inaccurately defined data as well to reflect real world settings. HL7 believes that once the Clinical Quality Language (CQL) standard has been adopted for use within the measure specifications, it will be much easier to determine all of the test cases required to provide adequate test coverage.

Are there recommendations for the format of test cases that could be entered both manually and electronically?

- Since C-CDA R2 is unable to contain all of the data required for quality measures, HL7 recommends that ONC continue to utilize QRDA Category I files for the testing of quality processing engines. HL7 suggests that the usage of QRDA Category I files is re-examined once CMS has adopted the FHIR standard for quality measurement.
- Not all health IT quality modules are developed in conjunction with health IT software that provides the data capture capability (i.e., a "complete" EHR). These vendors would

be unable to test a complete process starting with manually entering a patient to submitting the patient's data in a QRDA file.

What, if any, adverse implications could the increased certification standards have on providers?

Due to the tight timeframe between measure specification release and provider implementation, HL7 is concerned that increased certification standards will mean that providers have less time to implement new and updated measures and associated workflows. Compressing the timeframe could lead to the hospitals not being able to perform robust testing and training for new releases of eCQMs and this could inadvertently create patient safety issues.

Would flexibility on the vocabulary codes allowed for test files reduce burden on health IT developers?

If flexibility refers to allowing the use of multiple codes, such as ICD and SNOMED-CT, or multiple versions of the codes, we would agree that such flexibility on test files would reduce burden on health IT developers. However, if each developer is expected to support multiple vocabulary codes, then the burden is actually increased.