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June 25, 2013

Ms. Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-1599-P
P.O. Box 8011
Baltimore, MD 21244-1850

Dear Ms. Tavenner:

Below are comments from Health Level Seven International (HL7) on file CMS-1599-P which is the CMS proposed rule entitled "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation" published in the May 10, 2013 *Federal Register*.

Health Level Seven International (HL7) 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 2,300+ members represent approximately 500 organizations that represent more than 90% of the information systems vendors serving healthcare in the US. As the global authority on standards for interoperability of health information technology, HL7 appreciates the opportunity to offer feedback to CMS on this proposed rule and would be happy to answer questions or provide further information on our comments.

Sincerely,

A handwritten signature in black ink that reads "Charles Jaffe MD, PhD".

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

A handwritten signature in black ink that reads "Donald T. Mon".

Donald T. Mon, PhD
Board of Directors, Chair
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Hospital Inpatient Quality (IQR) Program

1. Electronic Clinical Quality Measures (page 27695 of the Federal Register Notice)

“These four measure sets are also already included in the Hospital IQR Program as chart-abstracted measures. The measures in three of these four measure sets—STK, VTE, ED—(15 measures) are already included in the Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs (76 FR 74489). With regard to the measure set perinatal care (PC), we stated in the 2013 IPPS/LTCH PPS final rule that we would consider electronic reporting when the e-specification of the PC-01 measure became available. The electronic specifications for these measures are included in the electronic clinical quality measure library at: http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html.”

HL7's Comment

HL7 supports the approach of formally designating a single national central and external reference library for eQMs and referring to this external location of the electronic clinical quality measure (eCQM) library instead of referring to a specific version of the measures within the rule.

HL7 requests that CMS keep the eCQM library current with clinical practice and update the value sets as needed, based on changes to the national vocabularies.

In addition, it is important to note that HL7's Healthcare Quality Measures Format (HQMF /eMeasure) standard, which is used to specify the eQMs, will continue to be an evolving standard. As the standard matures, the differences between the chart-abstracted and electronic measure specifications attributable to the standard should be reduced. HL7 requests that CMS continue to adopt the newest version of the standard in which to specify the eQMs used within their quality reporting programs.

HL7 also requests that CMS provide the process they will use to develop and release new versions of the eQMs and their associated value sets; and how they will document the timeframe for which each version is active within the applicable quality-reporting programs, including Hospital Inpatient Quality Reporting (HIQR) and Hospital Value-Based Purchasing (HVBP).

2. Electronic Clinical Quality Measures (Page 27695)

“We do not believe the measures, in their electronically specified form, are substantively different than they are in their chart-abstracted form, although we recognize that the EHR-based extraction methodology is different from the chart abstraction data collection methodology.”

HL7's Comment

While the intent of an electronically specified measure is the same as its associated chart-abstracted measure, HL7 believes there are still substantial differences in the data element definitions and algorithm logic that can lead to unintended modifications to the measure.

It is often difficult to express a chart-abstracted measure (with less structured data elements) as a more structured electronic measure. In addition, the current workflow design of most EHRs and limitations within the national vocabulary, especially SNOMED-CT[®], (e.g. limited availability of cross-walks, vocabulary not matching use cases) makes capturing requisite data difficult.

For example, the CMS SCIP-Inf-1 (NQF 527) and SCIP-Inf-2 (NQF 528) measures contain criteria, which exclude a patient from the denominator if they have documentation of an infection pre-operatively. The chart-based data element “Infection Prior to Anesthesia” instructs the abstractor to search the chart for preoperative documentation of an infection or possible/suspected infection versus certain symptoms such as a fever or elevated WBC. It is not feasible to represent a possible or suspected infection in an electronic measure. In the chart-based world, it is left up to the discretion of the abstractor, but it is still something that requires human intervention/interpretation, and is a gray area that is not adequately represented in the electronic world.

Given these difficulties and the fact that computerized EHR data *extraction* is not the same as manual chart *abstraction*, the results of the electronic measure may be different from the chart-abstracted measure. Without robust field testing, it is not possible to ensure the electronic and chart-abstracted measures will provide comparable results.

HL7 believes that a hard cut-off between manually abstracted and electronic “retooled” measures is not practical in the near term. While we understand continued manual abstraction of measures in combination with deployed electronic measures will create a burden for both hospitals and their vendors, HL7 recommends that CMS pick the best electronic measures and evaluate them via a parallel process to determine if the electronic specifications are indeed capturing the intent of the original measures. A testing, evaluation, and feedback mechanism is needed to ensure hospitals and vendors can share feedback related to electronic measure implementation with CMS, measure stewards, and other hospitals and vendors.

3. Possible New Quality Measures and Measure Topics for Future Years (Page 27695)

“We anticipate that, as EHR technology evolves, hospitals will electronically report all chart-abstracted clinical process of care and healthcare-associated infection measures which are currently part of the Hospital IQR Program or which have been proposed for adoption into the Program. As stated above, we intend for the future direction of electronic quality measure reporting to significantly reduce administrative burden on hospitals under the Hospital IQR Program.”

HL7’s Comment

HL7 commends CMS for working towards alignment in their quality reporting programs in an effort to reduce provider burden. However, insufficient testing of HVPB program electronic measures could result in unintended consequences that might adversely affect patient safety, health care quality, and hospitals’ financial soundness.

Not only should the measures be tested by the measure steward to ensure validity, but organizations should test their implementation of each measure to assure they have correct and effective information flows that support safe, quality care. For example, consider a measure that evaluates whether platelet aggregation antagonists (e.g., aspirin) are provided at discharge for all patients with a diagnosis of stroke. One vendor may implement the data capture by requiring a field be checked on the discharge form to indicate the medication was prescribed. A hospital client of that vendor utilizes clinical decision support in the medication reconciliation path to ensure the proper medication is prescribed. To accommodate the required reporting of both the vendor and the hospital, physicians would have to change their documentation practices to either perform duplicate documentation or interrupt the medication reconciliation, which is a potential patient safety issue for that hospital. If testing within the organization requires that data capture addresses effective workflows and considers end-user input, usability and safety concerns are mitigated.

4. Possible New Quality Measures and Measure Topics for Future Years (Page 27695)

“We intend to propose that hospitals report additional electronic measures in an effort to reduce the burden associated with reporting chart abstracted measures and to continue to promote the adoption of CEHRT.

We are inviting public comment on our intention to add 5 new measures to be collected via EHRs in the future. The five new measures listed below were reviewed by the MAP for inclusion in the Hospital IQR Program:

- Severe Sepsis and Septic Shock Management Bundle NQF #0500 (MAP supported)
- PC–02 Cesarean Section NQF #0471 (MAP supported)
- PC–05 Exclusive Breast Milk Feeding NQF #0480 (MAP supported)
- Healthy Term Newborn NQF #0716 (MAP supported the direction of this measure)
- Hearing Screening Prior to Hospital Discharge NQF #1354 (MAP supported).”

HL7’s Comment

HL7 suggests that instead of increasing the volume of electronically reported measures by adding the Severe Sepsis (NQF 0500) and Cesarean Section (NQF 0471) measures to the HIQR program, CMS

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should choose the best “retooled” electronic measures specified to date and evaluate them to ensure they truly meet the intent of the measure and will not cause unintended consequences.

In addition, we suggest that the Severe Sepsis and Cesarean Section measures not be included in the HIQR program until the standard and reporting challenges surrounding composite (severe sepsis) and risk-adjusted outcome (cesarean section) measures have been resolved within the health information technology (HIT) standards and clinical quality measure framework. HL7 suggests that the electronic specifications for these two measures be developed within the context of Meaningful Use Stage 3, to ensure there is sufficient time to evaluate if the HIT standards and quality measure framework are functioning as expected. With regard to the HIT standards, HL7 is actively working on solutions to address these challenges.

5. Proposed Data Submission Requirements for Quality Measures That May be Voluntarily Electronically Reported for the FY 2016 Payment Determination (Page 27696)

“We are proposing the following approach to begin to align quality measure reporting under the Hospital IQR and Medicare EHR Incentive Programs. ... Under the Hospital IQR Program, for the FY 2016 payment determination, hospitals may choose to either (1) electronically report at least one quarter of CY 2014 quality measure data for each measure in each of four Hospital IQR measure sets (STK, VTE, ED and PC), or (2) to continue reporting all of these measures using chart-abstracted data for all four quarters of CY 2014.

We strongly recommend hospitals electronically report the 16 measures in these four measure sets in CY 2014, to provide hospitals and CMS with the ability to test systems and adjust workflow in CY 2014 in order to prepare for required electronic reporting that we intend to propose for CY 2015 in the Hospital IQR Program. We believe this will simplify quality reporting and submission for the Hospital IQR Program, and will reduce the reporting burden on hospitals.”

HL7’s Comment

HL7 supports CMS allowing hospitals to begin voluntary reporting electronically specified measures as part of HIQR starting in CY 2014. However, we again caution that moving too quickly could result in unintended consequences and suggest that hospitals be allowed to continue to use manually abstracted measures until the validity of the electronically specified “retooled” measures is proven. In addition, since the data sources of the chart-abstracted and electronically reported measures are in fact different, HL7 cautions CMS against comparing results across these data sources.

HL7 requests that CMS provide a more detailed transition plan for the industry with defined targeted milestones that provides for 1) the appropriate testing and comparative analysis and evaluation of electronically derived measured vs. chart-abstracted measures, and 2) the processes, methodologies, statistical analysis, and timelines CMS will follow in replacing the existing chart-abstracted measures in the HIQR program with electronically reported measures. This includes the plans for transitioning the usage of electronic measure data into public reporting on Hospital Compare and into other programs such as HVBP. The transition plan needs to include information for all stakeholders, including hospitals, clinicians, vendors, HIT standard developers, and measure developers.

6. Proposed Data Submission Requirements for Quality Measures That May be Voluntarily Electronically Reported for the FY 2016 Payment Determination (Page 27696)

“To further incentivize hospitals to choose this option, we also intend to use the electronically reported data to determine whether the hospital has satisfied the Medicare EHR Incentive Program clinical quality measure reporting requirement. The hospital must also satisfy all other requirements for the Medicare EHR Incentive Program.”

HL7’s Comment

HL7 further supports CMS decision to align the programs and simplify the process for hospitals. This also reduces the burden for vendors because the measures will be aligned.

7. Proposed Data Submission Requirements for Quality Measures That May be Voluntarily Electronically Reported for the FY 2016 Payment Determination (Page 27697)

“For hospitals choosing to report electronically in the Hospital IQR Program, we are proposing that hospitals submitting these four measure sets electronically must use the Medicare EHR Incentive Program process for electronically submitting quality measure data into QualityNet (for EHR-based reporting). We are proposing Hospital IQR Program hospitals follow the submission requirements finalized in the Medicare EHR Incentive Program Stage 2 final rule (77 FR 54080). ...

In preparation for this transition to electronic quality measure reporting under the Hospital IQR Program, we are proposing that if a hospital chooses to report the four measure sets (STK, VTE, ED and PC) electronically during CY 2014, the hospital's data will be extracted from the Certified Electronic Health Record Technology (CEHRT) and submitted to CMS using the Health Level Seven (HL7) Quality Reporting Document Architecture (QRDA) Category I Revision 2 standard. Certified EHR Technology is defined for the Medicare EHR Incentive Program at 42 CFR § 495.4 and 45 CFR § 170.102.”

HL7's Comment

HL7 recommends that the IPPS rule cite alignment with ONC's EHR Standards and Certification requirements for QRDA based reporting rather than citing a specific version of QRDA. Referring to the QRDA standard more generally allow CMS and the industry to move to new versions of the standard as needed, keeping in mind that vendors need sufficient time to adopt and install new versions. We suggest CMS adopts this change to the language in all quality reporting programs, including HIQR and MU.

8. Proposed Data Submission Requirements for Quality Measures That May be Voluntarily Electronically Reported for the FY 2016 Payment Determination (Page 27698)

“We are not proposing to validate any of the data that is electronically reported for the FY 2016 Hospital IQR Program. However, we share the concern among hospitals, vendors, and other stakeholders that there is a need to develop a comprehensive validation process that applies to electronically reported data. We intend to develop and propose to adopt a data validation strategy for electronically reported quality measure data in the FY 2015 IPPS/LTCH PPS proposed rule. This strategy will be informed, in part, by comments we receive in response to this proposed rule. We invite public comment regarding potential data validation methodologies.”

HL7's Comment

HL7 requests that CMS include their data validation strategy within their fulsome transition plan, referenced above. We also recommend that hospitals be provided adequate time to implement complementary internal data validation strategies in conjunction with their vendor(s) before they are held accountable for their electronically reported measure results in programs such as HVBP.