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September 6, 2013

Ms. Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention:
CMS-1600-P
P.O. Box 8016
Baltimore, MD 21244-8016

Dear Ms. Tavenner:

Below are comments from Health Level Seven International (HL7) on file CMS-1600-P which is the CMS proposed rule entitled "Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014" published in the July 19, 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 U.S. 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".

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
Health Level Seven International

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1. For PQRS Program and Direct Data Submission from EHR to CMS for EHR Incentive Program
[From 78 FR 43372 (PQRS) and 78 FR 43481 (EHR Incentive Program)]

“We [CMS] propose[s] that for purposes of PQRS, however, that the eligible professional’s direct EHR product or EHR data submission vendor must be tested and certified to the most recent, updated version of an electronically specified clinical quality measure. For example, for purposes of reporting clinical quality measures that are electronically specified during the PQRS reporting periods that occur in 2014, we would only accept the reporting of clinical quality measures from direct EHR products or EHR data submission vendors that have been tested and certified to versions of the electronic specifications that were updated and posted on June 2013. **We seek comment on our proposals to require eligible professionals to both use the most recent, updated version of an electronically specified clinical quality measure to report for PQRS and to use a direct EHR product or EHR data submission vendor that has been tested and certified to the most recent, updated version of the clinical quality measure’s electronic specifications for PQRS purposes.**”

HL7 Comment

HL7 strongly supports the continued harmonization of electronic clinical quality measures (eCQMs), their definitions and reporting methods across the various CMS programs to create consistency, to improve the value and reliability of these measures, and ultimately to deliver better more cost-effective health care and health outcomes to the American people.

Measures used for PQRS reporting at any point in time need to be consistent and be generated consistently from underlying EHR data. This consistency is essential if reporting is to be sufficiently accurate to enable valid analysis and comparison of quality outcomes that meaningfully support effective clinical practice. In order to maintain consistency, eligible professionals (EPs) across the health care spectrum will need to migrate to newer versions of eCQMs and update their supporting systems and processes in a uniform and timely manner.

HL7, therefore, supports CMS’ overall goal in requiring EPs and the suppliers of EHR products and services to migrate to updated versions of eCQM specifications progressively, in a uniform and timely manner. Nevertheless, the health industry is still in the early stages of the transition from chart abstraction to electronic capture of measures from EHRs and the measures themselves are also evolving and maturing rapidly as experience is gained with their adoption and use. Before a new/updated measure is ready to be used by providers, whether that measure has been retooled from an existing measure or developed de novo for reporting from the EHR, the eCQMs and associated value sets must have been:

- * Defined or updated, trialed, clinically validated and generally released for use in CEHRT;
- * Incorporated into, tested and certified as part of each suppliers’ CEHRT capability, so the relevant data can be collected and made available; and
- * Integrated into clinical workflow processes to ensure the measure is being collected correctly.

It is **not** reasonable to expect EPs to measure themselves against a new or updated eCQM before their CEHRT has had sufficient opportunity to release certified capability that implements the eCQM and before the EPs can implement the capability and conduct the necessary testing to ensure the relevant data is properly captured.

Therefore, **HL7 recommends that:**

- a. CMS seek to further harmonize eCQMs and their reporting across various CMS programs.
- b. The timetable for adoption, introduction and uptake of each release of updated eCQMs must allow sufficient time for suppliers to incorporate new and updated eCQMs into their EHRs and for EPs to implement and test their reporting of the eCQMs.

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Documented success in the implementation of any new health IT standard should be a pre-requisite for CMS choosing to require its use in CMS quality measurement and quality incentive programs. As a general rule, **HL7 recommends that** CMS consider using the ONC Health IT Standards Committee criteria for evaluating the maturity and adoptability of health IT standards.

To further enable adoption of new/updated eCQMs and their reporting, standards such as HL7's Healthcare Quality Measures Format (HQMF/eMeasure) and Quality Reporting Document Architecture (QRDA) are essential to propagate and automatically implement new versions quickly and efficiently. We recognize, however, that until automated implementation of HQMF and QRDA is available, a requirement to use the most current version of the eCQM specifications will be burdensome, both for providers and CEHRT vendors. In addition, when the necessary data to report on the eCQM is not yet available, as indicated above, even more time is required to accommodate the uptake of those eCQMs.

HL7's Healthcare Quality Measures Format (HQMF/eMeasure) and Quality Reporting Document Architecture (QRDA) standards, which are used to specify and report the eCQMs, will continue to be evolving standards. It is important during this maturation process that these standards be pilot tested before being adopted and mandated in any subsequent CMS final rules. HL7 cautions CMS that the adoption of new standards without the proven validity and feasibility of these standards in practice, will lead to failures and data inconsistencies. For example, HQMF Release 1 (R1), a known standard, has yet to be successfully used within an EHR, despite its widespread use to express eCQMs. Furthermore, HQMF Release 2 (R2) will soon be published as a Draft Standard for Trial Use (DSTU) is designed to support automatic evaluation of eCQMs. It may be considered for use to represent eCQMs as part of MU Stage 3 after it is adequately tested. Successful implementation and testing in this context is necessary, as it may suggest further needed changes. Through the work of the HL7 Clinical Quality Information (CQI) workgroup, members are developing recommendations for addressing the readiness of these standards for widespread use. As the release of HQMF R2 approaches, it is essential to establish clearly defined criteria for successful testing this new standard in advance of an implementation requirement.

Documented success in the implementation of any new health IT standard should be the basis upon which CMS chooses to adopt new standards for use in its quality measurement and quality incentive programs. HL7 recommends that the parameters for defining and demonstrating successful testing include the following:

- a. Conformance to the standard, including successful implementation in an EHR system (e.g., once a measure is represented in HQMF, testing the degree to which the measure meets the needs or works well in the EHR environment).
- b. Successful transmission of data to CMS for example, using the most recent version of the HL7 QRDA standard to submit data from an EP to CMS.

As noted earlier, HL7 recommends that CMS consider using the ONC Health IT Standards Committee criteria for evaluating the maturity and adoptability of health IT standards. HL7 also recommends that vendors and providers be given adequate time after a final rule is published to implement and comply with new standards versions (i.e., HQMF R2) so that they are prepared for a successful transition to a new platform. HL7 strongly recommends that confirmation of successful testing should be a requirement before any standard is adopted and included in a CMS final rule.

Finally, it will be important for CMS to coordinate the transition from HQMF R1 to HQMF R2 with the requirements for Meaningful Use Stage 3. Thoughtful efforts to coordinate these changes will avoid the cumulative, sequential effects of having multiple regulatory requirements at different time periods.

2. Proposal to Require Clinical Data Registries to be Certified [From 78 FR 43480]

“As EPs are required to use CEHRT under section 1848(o) (2)(A)(iii) of the Act, **we propose that for the Medicare EHR Incentive Program, an EP who seeks to report using a qualified clinical data registry that meets the criteria established for PQRS must also ensure that the registry selected is certified for the functionality that it is intended to fulfill and is a certified EHR Module that is part**

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of the EP's CEHRT. For example, if the registry would collect patient level data from EPs, calculate the CQMs, then submit to CMS the calculated results on behalf of the EP in either an aggregate level Quality Reporting Document Architecture (QRDA) Category III file or patient level QRDA-I files, then the registry would need to be certified for the CQM criteria listed at 45 CFR 170.314(c)(2) ("import and calculate") for each CQM that will be submitted and 45 CFR 170.314(c)(3) ("electronic submission"). We note that EPs would still need to include a certified EHR Module as part of their CEHRT that is certified to the CQM criteria listed at 45 CFR § 170.314(c)(1) ("capture and export") for each of the CQMs that would be submitted to CMS for the purposes of meeting the CQM requirements of the Medicare EHR Incentive Program.

If the qualified clinical data registry is performing the function of data capture for the CQMs that would be submitted to CMS, then the registry would need to be certified to the "capture and export" criteria listed at 45 CFR 170.314(c)(1).

The certified EHR Module must be part of the EP's CEHRT. **We intend to revisit the certification criteria with ONC in the Stage 3 rulemaking for the purpose of developing a more flexible clinical data registry reporting option and certification criteria for the EHR Incentive Program when Stage 3 begins. We welcome public comment and recommendations on a more flexible clinical data registry reporting option for meeting the CQM reporting requirement for MU and on the certification criteria that ONC could incorporate for clinical data registries."**

HL7 Comment

HL7 supports the proposal to require a clinical registry to be certified for the functionality it is intended to fulfill as well as the additional requirement to include an EHR module that is certified to the eCQM criteria as part of the CEHRT. Furthermore, **HL7 recommends** that, where possible, clinical quality reporting from a clinical data registry meet the same standards that apply to clinical quality reporting from an EHR system.

An important consideration is that as EHR functionality and versions evolve, over time, registry capabilities would need to keep up with these enhancements. For example, the eCQM specification used for a clinical data registry should be consistent with the eCQM specification used for reporting from an EHR (i.e., HQMF), and the data reporting formats for both clinical data registries and EHR technology should also use the same standards (i.e., QRDA Category I or QRDA Category III).

HL7 has addressed some basic registry requirements in section TI3 of the EHR Functional Model Release 2 standard (EHR-FM R2). While HL7 is aware that the requirements for registries included in the EHR-FM R2 are general in nature, HL7 encourages the use of existing standards for registries as CMS further develops the criteria and requirements for the clinical data registries in order to harmonize standards across registries.

Finally, **HL7 recommends** that if CMS allows clinical data registries to serve as an alternative to CEHRT-based reporting mechanisms, these registries be evaluated and certified in a similar manner to the way EHRs are evaluated. **HL7 also recommends** that explicit criteria for acceptance be established by way of an open consensus process. CMS is strongly encouraged to engage with healthcare standards organizations such as HL7 in the development of criteria and requirements for clinical data registries well in advance of any proposed rulemaking, to determine how these requirements can best be incorporated into CMS programs.