<DATE>

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,

Charles Jaffe, MD, PhD Donald T. Mon, PhD

Chief Executive Officer Board of Directors, Chair

Health Level Seven International Health Level Seven International

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 supports the proposal to require EPs to use the most recent version of the CQM specifications, including the most recent version of the value sets published in the Value Set Authority Center (VSAC), if EPs will submit data directly to CMS. It is important to note that HL7’s Healthcare Quality Measures Format (HQMF/eMeasure) standard and Quality Reporting Document Architecture (QRDA), which are used to specify the eCQMs, will continue to be evolving standards. As the standards mature, the differences between the chart-abstracted and electronic measure specifications and reports attributable to the standards should be reduced. HL7 requests that CMS continue to adopt the newest version of the standard in which to specify the eCQMs and their respective reports used within their quality reporting programs.

Recognizing that *new* releases of health care standards will be published in the near future, HL7 advises that these standards must be pilot tested before being applied to CQMs 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 R1, a known standard, has yet to be successfully implemented into an EHR, despite its widespread use. Furthermore, HQMF Release 2 (R2) will soon be published as a Draft Standard for Trial Use (DSTU) and may be considered for use to represent eCQMs as part of MU Stage 3. Through the work of the HL7 Clinical Quality Information (CQI) workgroup, members are developing recommendations for addressing the readiness of such standards for widespread use. As the release of HQMF R2 approaches, it is essential to establish clearly defined criteria for successful testing of 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 CMS consider using the ONC Health IT Standards Committee criteria for evaluating the maturity and adoptability of health IT standards. HL7 also recommends that successful testing will demonstrate the following:

* 1. 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).
  2. Successful transmission of data to CMS for example, using the HL7 QRDA standard to submit data from an EP to CMS.

HL7 also recommends that vendors and providers be given adequate time, at a minimum 18 months, to implement the 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.

1. **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 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 CQM criteria as part of the CEHRT. Furthermore, HL7 supports the notion that the standards in use for quality reporting from an EHR be applied to the requirements for quality reporting from a clinical data registry. An important consideration is that as EHR functionality and versions evolve, over time, the registry capabilities would need to keep up with these enhancements. For example, the CQM specification used for the clinical data registry should be consistent with the specification used for reporting from an EHR (i.e., HQMF), and the data reporting format for the 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 registry standards 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 registries to serve as alternative reporting mechanisms to CEHRT, registries must be evaluated and certified in a similar manner to the way EHRs are evaluated. The criteria for acceptance need to be established and should be explicit. CMS is strongly encouraged to engage healthcare standards organizations such as HL7 in the development of the criteria and requirements for the clinical data registries at this time, well in advance of any proposed rulemaking, to determine how these requirements would be incorporated into CMS programs.