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June 25, 2018

The Honorable Seema Verma, MPH
Administrator
Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1694-P

Dear Administrator Verma:

Health Level Seven International (HL7) welcomes the opportunity to comment on the CMS proposed rule, "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates; Proposed Quality Reporting Requirements for Specific Providers; Proposed Medicare and Medicaid Electronic Health Record (EHR) Incentives Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims."

As a global authority on interoperability in healthcare, HL7 is a critical leader and driver in the healthcare standards arena, in the U.S. and internationally. The products of our organization – including the widely adopted and rapidly evolving HL7 FHIR® standards – provide the underpinnings for connected, patient-centered health care on a global scale and an information highway for improving patient safety, advancing research into improved treatments, and achieving ambitious visionary programs such as precision medicine. HL7 is comprised of members from over 50 countries and is integrally involved in global standards policy, regulation and harmonization. HL7 Work Groups are important resources for the organization's work and contributed to this comment letter.

HL7's key high-level comments are below. Overall, we appreciate the proposed shift in focus from Meaningful Use to Promoting Interoperability, comprehensive nature and thoughtfulness of this proposal, and its many positive developments for patients, providers and the health care marketplace.

Interoperability Spotlight – HL7 commends CMS for proposing to overhaul the Medicaid and Medicare EHR Incentive Program to focus on interoperability. Interoperability is a critical, complex national imperative and requires the widespread, focused and continuous efforts of both the public and private sector to be achieved. CMS' efforts are an important step on the path to better health care. Shifting the Meaningful Use program to "Promoting Interoperability" also promotes these goals and is a material change that goes far beyond simply changing the program name.

We emphasize that, as these steps proceed, CMS must recognize and leverage current and in-flight interoperability successes and capabilities inherent in federal government and private sector health programs. Notable examples include CMS' Blue Button 2.0, HIE network initiatives including the CommonWell Health Alliance, DirectTrust, and the Sequoia Project's eHealth Exchange as well as its Carequality interoperability framework and the Strategic Health Information Exchange Collaborative (SHIEC) Patient Centered Data Home project.

Agency Coordination – HL7 urges CMS to work in tandem with other federal agencies – and in particular with the Office of the National Coordinator for Health Information Technology (ONC) – on the interoperability-related initiatives in the proposed rule. Many federal agencies are now tackling paradigm-changing health care initiatives such as the federal `government-wide Precision Medicine Initiative (PMI), the National Institutes of Health (NIH) *All of Us* Research Program, the U.S. Food and Drug Administration (FDA) Digital Health Innovation Plan and many others. Coordination is essential to ensure consistent selection and implementation of interoperability standards that are referenced by multiple initiatives and reducing ambiguity while driving a concerted effort to improve data liquidity.

Data Focus – CMS seeks, through the proposed rule, to encourage patient-empowered, value-based health care, with patients having "the information they need to become active healthcare consumers." HL7 strongly supports these aims, including the continued focus on ready provider access to their patients' data and especially. the enhanced focus on patients' access to their data. At the same time, we urge CMS to maintain a balanced approach to HIE and interoperability that incentivizes and supports both usability and use of these data in addition to their mere availability. We note, in this regard, that the revised numerators and denominators for the consolidated HIE "receive" measures may reduce the incentives to query or seek external electronic patient data by only focusing on reconciliation, rather than also incentivizing query or receipt of electronic patient summaries. In addition, the proposed Conditions of Participation (CoP) seem to focus only on data availability and not on external access and use of such data. Overall, we urge CMS to continue to emphasize health data query, use, and usability, all of which are critical to ensuring patient safety and important to all patient care experience participants.

HL7 Standards Supporting CMS Vision – CMS states in its proposed rule announcement that the potential program changes support empowering patients, better health outcomes, improving patient access to EHRs, making it easier for providers to spend time with their patients and promoting interoperability. HL7 maintains many standards that are available to support CMS in achieving these advancements. Our organization looks forward to extending its active work with your agency on these issues and further leveraging its standards to increase value-based, interoperable healthcare.

Regarding HL7 FHIR® standards in particular, HL7 encourages CMS to work with ONC to identify, for applicable federal government programs, a minimum HL7 FHIR® U.S. Core Implementation Guide release to adopt across providers, CMS and other public and private sector payers, and relevant other programs and stakeholders, that would enable and support consumer access to data. The U.S. Core Implementation Guide is based on FHIR Version 3.0.1, which specifies the minimum conformance requirements for accessing patient data as defined by the Argonaut pilot implementations and the ONC 2015 Edition Common Clinical Data Set (CCDS). It can be accessed at: https://www.hl7.org/fhir/us/core/. Consistent adoption will strengthen programs such as Blue Button 2.0, Promoting Interoperability, and other CMS and HHS initiatives that promote a vibrant consumer access and app ecosystem.

Consolidated Clinical Document Architecture (CCDA) Templates – HL7 supports CMS's approach to CCDA templates in the proposed rule. It will enable additional flexibility and efforts to ensure that the information sent to support a transition of care and closing referral loops is relevant. This increased flexibility includes: (1) CMS' intention to encourage eligible hospitals and CAHs to use the document template available within the CCDA that contains the most clinically relevant and required information; and (2) the proposal for eligible hospitals and CAHs to be permitted to use any document template within the CCDA standard for purposes of the measures under the Health Information Exchange objective rather than be limited to the three templates included in the 2015 Certification Edition (CCD/Patient Summary, Discharge Summary, and Referral Note).

CMS should recognize that, although not all parties may yet support those templates, we support the CMS proposal to allow use of any applicable CCDA template. We seek two clarifications be made: (1) lack of the ability to send or receive templates that were not part of ONC certification should not place a provider or developer at risk for allegations of potential information blocking; and (2) as other document types/templates are added to the CCDA by HL7, providers should be able to use these without specific action on these templates by CMS or ONC. Further, we believe that the specifics of data sets should be maintained outside of the annual payment rule process. Instead, this task might be accomplished, through mechanisms such as ONC certification updates and the forthcoming ONC USCDI and TEF.

2015 Certification Edition – HL7 supports the requirement for all eligible hospitals and critical access hospitals (CAHs) to use the 2015 Edition of certified EHR technology (CEHRT) beginning with the CY 2019 EHR reporting period. This

requirement will enhance the range of interoperability capabilities embodied in this proposed rule. We recommend that CMS work with ONC to identify at the earliest opportunity a common standard for consumer-facing APIs. The 2015 Certification Edition currently does not indicate a minimum standard that would enable further portability of consumer facing applications across providers.

Scoring Methodology and Interoperability Focused Objectives – HL7 believes that the proposed new scoring methodology is reasonable, with its increased emphasis on performance and participation and with each measure contributing to the overall Promoting Interoperability (PI) score, including measure selection and weighting that emphasizes interoperability and patient access components.

Application Programming Interface Functionality (APIs) – HL7 agrees with the importance of the API functionality requirement in the 2015 Edition of CEHRT and in the Promoting Interoperability Programs (PIP). We also support CMS' assessment that API functionality is critical to building on the substantial interoperability advances to date and enhancing electronic access to health information for patients and providers. HL7 believes that the proposed rule is positive in its balanced approach to the use of both API and portal-based patient access models. We also recommend alignment of the open API referenced by CMS in its potential Patient Access "Activity-based measure" with the 2015 CEHRT Edition API that is being deployed and implemented by EHR and app developers as a result of ONC and CMS requirements. We likewise anticipate and recommend that what ONC will be formulating for open APIs relative to its implementation of the 21st Century Cures Act will also be aligned with the 2015 Edition API.

We also ask CMS to confirm that its focus in the Patient Access measure is on measuring a provider's making available APIs and a portal to patients, rather than on actual patient use and that it will indeed not hold providers accountable for whether their patients use this capability.

HL7 urges CMS and other federal government entities to appropriately support easy and clear API implementation, and for providers in particular, to clarify what exactly is meant by "provide API access" in the potential new Activity-based measure for Patient Access.

e-Prescribing Measures and PDMP - In the proposed scoring methodology, the e-Prescribing objective would have three measures, each weighted differently to reflect their potential availability and applicability to the hospital community. In addition to the existing e-Prescribing measure, CMS proposes to add two new measures to the e-Prescribing objective: Query of Prescription Drug Monitoring Program (PDMP) and Verify Opioid Treatment Agreement. The Query of Prescription Drug Monitoring Program (PDMP) and Verify Opioid Treatment Agreement measures would be optional for EHR reporting periods in 2019.

Regarding the PDMP Query, HL7 asks CMS to confirm that use of a specific PDMP integration standard would not be required for credit at this time. While there are clear benefits to standardization and uniformity here, HL7 believes use of standards in this area should not be required initially. We do encourage CMS to carefully track and engage with relevant standards work in this area, notably the NCPDP SCRIPT 2017071 standard and/or emerging HL7 FHIR based standards, such as CDS for Clinical Decision Support (CDS Hooks), that would enable a variety of API-based data access methods that can benefit both provider and consumer. Overall, we believe that this measure will ultimately benefit from availability of applicable mature standards and urge CMS to work with ONC, other federal agencies, standard organizations and relevant other parties on development and maturation of applicable PDMP integration and query standards.

RFI and Conditions of Participation (CoP) – HL7 commends CMS for soliciting feedback on potential revision of hospital Conditions of Participation (CoP) to better achieve data sharing. CoPs are strong levers to support interoperability. This approach may, however, be unnecessary to address potential information blocking. It would also bring significant compliance costs, a need for sub-regulatory guidance to address complex scenarios and conflicting or overlapping HHS rules, and other unintended consequences. If CMS does decide to take this approach, we suggest that it pursue a corresponding reduction or elimination of other requirements aimed at interoperability and information blocking to ensure that compliance burdens and costs can be held to the lowest level possible. If CoPs are revised as proposed, we also suggest that CMS consider elements that address query and use of electronic patient data and not only making such data accessible.

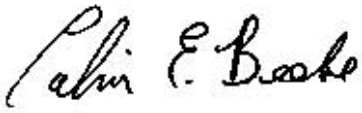
Pilots and health IT Activities – In general, HL7 supports the potential shift from percentage -based measures to activity-based measures. We suggest that CMS look to broaden the potential TEFCA-associated HIE activity measure to engagement with the TEFCA *and/or other trust agreements*, such as CommonWell or Carequality, with non-participation not interpreted as information blocking given that other approaches to interoperability remain available. HL7 also supports a potential "health IT activity under which an eligible hospital or CAH would participate in a pilot, and eventually implement in production, use of an API based on the emerging update to the HL7 FHIR standard. At the same time, we are not certain that such an activity is best used as a substitute for public health reporting. Overall, HL7 more generally encourages credit under an Activity approach for pilots that evaluate new information flows and standards, as well as other innovations to improve data liquidity across providers.

Attached we have provided also detailed comments in the area of electronic clinical quality measures.

Please do not hesitate to contact us to discuss the consultation document and our suggestions in more detail. Should you have any questions about our attached comments, please contact Charles Jaffe, MD, PhD, Chief Executive Officer of Health Level Seven International at cjaffe@HL7.org or 734-677-7777. We look forward to continuing this discussion and offer our assistance.

Sincerely,

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



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Specific Comments

eCQM (Electronic Clinical Quality Measures)

General Comments:

1. HL7 supports CMS continued use of the QRDA Category I standard for eCQM electronic submissions for the Medicare EHR Incentive (now Promoting Interoperability) Program.
2. HL7 also supports States continuing to have the option, subject to CMS' prior approval, to allow or require QRDA–III for eCQM reporting.
3. HL7 supports CMS' ongoing plans to align the eCQM reporting requirements for the Promoting Interoperability Programs (formerly Meaningful Use Programs) with the Hospital IQR Program, and, specifically, the proposed removal of 8 eCQMs (from the 16 eCQMs currently in the measurement set) to develop an even more streamlined set of the most meaningful eCQMs for hospitals. We do however, acknowledge that this reduction in available eCQMs could present a burden for some hospitals that have chosen to use the eliminated eCQMs. The rule proposes to implement this reduction of eCQMs beginning with the reporting period for CY2020. However, to increase flexibility and accelerate the alignment of programs, we recommend CMS consider beginning this change with the reporting period of CY2019.
4. HL7 strongly supports CMS' transition from the Quality Data Model (QDM) to Clinical Quality Language (CQL) to better express logic defining measure populations to improve the accuracy and clarity of eCQMs, including that all eCQM specifications published in CY 2018 for the CY 2019 reporting period/FY 2021 payment determination and subsequent years will use the CQL (beginning with the Annual Update that will be published in Spring 2018 and for implementation in CY 2019).
5. HL7 recommends that CMS consider introducing in the final rule a discussion that CMS is monitoring and evaluating developments around the newer HL7 FHIR®-based standards for quality measurement, improvement and reporting, including QI Core, CQL-based HQMF, and the Clinical Quality Framework. We also recommend that CMS encourage the use of HL7 FHIR® Terminology Services with code system supplements with CQL-based HQMF eCQMs, and to support distribution of terminology knowledge using standard formats, particularly as HL7 FHIR® terminology services are potentially moving to normative status later in 2018. QI Core represents a transition and translation from existing QDM efforts to help those implementing CDS.

Responses to CMS Questions:

- What program and policy changes, such as improved regulatory alignment, would have the greatest impact on addressing eCQM costs?

  HL7 Recommendations
  - The most important potential change is 100% regulatory alignment between and across quality reporting programs
  - Also very important is the definition of the standards for quality reporting, particularly the use of the newer HL7 FHIR®-based standards after appropriate piloting
  - Consider increasing alignment between the CMS-defined QRDA IG and the base HL7 QRDA standard, and, if possible, avoid creating and requiring a separate CMS-defined QRDA version of the standard

- What specifically would stakeholders like to see us do to reduce costs and maximize the benefits of eCQMs?

  HL7 Recommendations
  - Consider moving to improved standards-based eCQM development and reporting, such as, in the future, QI Core and HL7 FHIR®-based standards, encouraging the use of HL7 FHIR® Terminology Services with code system supplements with CQL-based HQMF eCQMs, and to support distribution of terminology

knowledge using standard formats, particularly as HL7 FHIR® terminology services are potentially moving to normative status later in 2018. QI Core represents a transition and translation from existing QDM efforts to help those implementing CDS.
    - Better alignment of eCQM requirements across CMS programs.

- How could we encourage hospitals and health IT vendors to engage in improvements to existing eCQMs?

  HL7 Recommendations
    - Provide better, expanded education on CQL implementation issues
    - Provide better alignment and expansion/increase in the incentives towards the use of improved eCQMs

- How could we encourage hospitals and health IT vendors to engage in testing new eCQMs?

  HL7 Recommendations
    - Offer 'bonus' points – similar to the 'bonus' points being proposed to be used in the Promoting Interoperability Program
    - An Implementation-A-Thon

- How can CMS incentivize/reward innovative uses of health IT that could reduce costs for hospitals?

  HL7 Recommendations
    - Similar to the previous point, offering 'bonus' points for demonstrable innovative uses of health IT
    - Establish technology 'challenges' to foster innovative developments in health IT
    - Paying more attention to the CDS component of the Quality cycle would be a more effective in improving care.

- What additional resources/tools would be valuable to have publicly available to support testing, implementation and reporting of eCQMs?

  HL7 Recommendations
    - Simplification of the measure development tools
    - Expansion of the guidance related to the use of CQL and other newer HL7 FHIR®-based standards for quality measurement and reporting
    - Increase participation in HL7 FHIR® Development Days and HL7 Connect-a-thons for testing capabilities of vendors