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September 27, 2019

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services (HHS)
Attention: CMS-1715-P
P.O Box 8016
Baltimore, MD 21244-8016

Submitted electronically to: https://www.regulations.gov/

Re: Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations.

Dear Administrator Verma:

Health Level Seven (HL7®) International welcomes the opportunity to submit comments on the *Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations.*

As you know, HL7 is the global authority on healthcare interoperability and a critical leader and driver in the standards arena. The products of our organization provide the underpinnings for connected, patient-centered health care and an information highway for precision medicine. HL7 is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related interoperability standards, including the rapidly evolving Fast Healthcare Interoperability Resources (HL7 FHIR®), the Consolidated Clinical Document Architecture (C-CDA®), and the widely used V2 messaging standards. HL7 has more than 1,600 members from over 50 countries, including 500+ corporate members representing healthcare consumers, providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms.

HL7 appreciates CMS' continued efforts to refine and advance the Quality Payment Program (QPP) and its associated Advanced Alternative Payment Models (APMs) and the Merit-based Incentive Payment System (MIPS). We are pleased that the 2020 QPP proposed rule supports these efforts and the overarching CMS goals of:

- Improving patient outcomes;
- Encouraging and rewarding meaningful participation;
- Reducing reporting burden; and

- Helping to drive the fundamental movement toward value in our healthcare system.

HL7 and its standards are a critical piece in successfully achieving important objectives in this proposed rule, such as better integration of patient health data in electronic health records (EHRs) related to MIPS. Therefore, we provide our brief comments on this and other issues below. Our organization continues to emphasize that HL7 stands ready, as an active, innovative partner, to concretely plan for and support CMS' priorities in 2019 and beyond, to ensure the seamless flow of data among providers, payers and, beneficiaries.

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 to CMS.

Sincerely,

Charles Jaffe, MD, PhD
Chief Executive Officer
Health Level Seven International
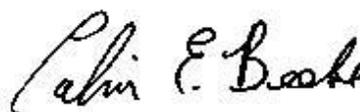
Calvin Beebe
Board of Directors, Chair
Health Level Seven International

Select Detailed HL7 Comments

MIPS Performance Interoperability Performance Category – CMS seeks comments in the proposed rule on several key areas related to changes in the MIPS Promoting Interoperability performance category. HL7 outlines its thoughts below on two of these concepts:

- Integration of patient-generated health data (PGHD) into EHRs using certified electronic health record technology (CEHRT); and
- Issues related to the standards-based API criterion in the ONC 21st Century Cures Act proposed rule related to establishing an alternative measure under the Provider to Patient Exchange that would require providers to give patients their complete data contained within an EHR.

Regarding integration of PGHD into EHRs outlined on page 40783 of the proposed rule, HL7 recommends that a standards-based approach be used in any future MIPS provisions that rely on integration of PGHD into EHRs. We emphasize that all three main HL7 standards (HL7 V2, HL7 C-CDA, and HL7 FHIR) could be used support this objective in future iterations of the MIPS program and associated ONC health IT certification program requirements. HL7 FHIR is especially important to achieve integration of PGHD into EHRs and our experts stand ready to engage with CMS on this topic.

In addition, to avoid confusion or the potential for regulatory conflicts, CMS should not propose its own set of standards here but rather adopt ONC's standards and technologies by reference, as applicable. To the extent CMS proposes to require covered entities to use API technology, ONC should adopt standards for specified uses in the U.S. Core Data for Interoperability (USCDI). CMS should not require these functions until after such standards are added to the USCDI.

Lastly, it is important for CMS adopt or incorporate by reference only accredited American National Standards, or consensus consortia standards meeting all conditions of the World Trade Organization Agreement on Technical Barriers to Trade (WTO TBT) or the ANSI Essential Requirements. Implementation guidance for these standards should be made available in subregulatory publications so that they may be updated more rapidly and more flexibly than can be managed though the regulatory rulemaking process.

Regarding CMS' Requests for Information (RFI) on issues related to the standards-based API criterion in the ONC 21st Century Cures Act proposed rule, we address two issues:

- **API Access Measure** – CMS seeks comment on page 40781 of the proposed rule about revising the API access measure to support ONC's proposed changes to the 2015 edition certification requirements that specify use of HL7 FHIR. *We believe that it is premature to determine a token refresh period for CMS providers. More industry experience and lessons learned are needed.*

  Early Certified FHIR-Based API Adoption and Bonus – CMS emphasizes its support for the ONC 21st Century Cures Act interoperability-focused proposed rule (84 FR 7424) proposal to move to an HL7 FHIR®-based API under 2015 Edition certification (84 FR 7479). CMS asks on page 40782 of the proposed rule "if ONC's proposed FHIR-based API certification criteria is finalized, would stakeholders support a possible bonus under the Promoting Interoperability performance category for early adoption of a certified FHIR-based API in the intermediate time before ONC's final rule's compliance date for implementation of a FHIR standard for certified APIs?" *HL7 supports rapid adoption and early use of FHIR-based APIs. We appreciate – in proposing a possible bonus under the Promoting Interoperability performance category for early adoption of a certified FHIR-*

based API in the intermediate time before ONC's final rule's compliance date for implementation of a FHIR standard for certified APIs – CMS' recognition of the value in early adoption of the FHIR standard. HL7 urges with the implementation of any such bonus, that focused attention is paid to fairness and equity given variations in developer and provider capabilities and readiness, as well as budget-neutrality requirements for calculating MIPS payment updates. We suggest that CMS also pursue other means to encourage early adoption.

Finally, regarding additional CMS requests for comment related to interoperability, HL7 strongly supports:

- CMS support for health information exchange (HIE) for transitions of care, across the care continuum using adopted national health care standards, especially for entities that generally do not have certified EHR technology (e.g. long-term and post-acute care facilities); and
- CMS consideration of alternative Promoting Interoperability measures for connecting to any HIE network (e.g. connected nationwide via any Carequality implementer).