



May 30, 2019

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services (HHS)
Attention: CMS-9115-P
P.O Box 8016
Baltimore, MD 21244-8016

Re: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally Facilitated Exchanges and Health Care Providers CMS-9115-P

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

Dear Administrator Verma:

Health Level Seven (HL7®) International welcomes the opportunity to submit comments on the *Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally Facilitated Exchanges and Health Care Providers*.

As you know, 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. We have more than 1,600 members from over 50 countries. HL7 greatly values its on-going collaboration with CMS and other federal government agencies to ensure that the products of our organization positively impact the lives of many Americans, providing the underpinnings for connected, patient-centered health care and an information highway for precision medicine.

HL7 appreciates the proposed rule's role in moving healthcare forward and the increased emphasis on the lynchpins of:

- Improving the interoperability of electronic health information;
- Enhancing care coordination; and
- Fostering innovation that promotes patient access to and control over their health information.

Given the centrality of HL7 and its standards in this proposed rule -- particularly in supporting the proposed deployment of application programming interfaces (APIs) for CMS-regulated health plans and programs (Covered Plans and Programs) that allow patient information to be shared more readily between patients, health care providers and payors -- we provide our detailed comments in the appendix to this letter.

Key topics addressed in the comment appendix include:

- **CMS/ONC Alignment** - HL7 emphasizes the importance of CMS and ONC aligning the technical standards and API language of their respective proposed rules and we outline practical considerations. HL7 also believes that CMS should consistently use “FHIR for APIs” in the final rule.
- **Implementation Timelines** - HL7 believes the proposed implementation timelines are unreasonably aggressive. Initial implementations should not be required until 24 months after publication of the final rule, and compliance should not be required until 36 months after publication.
- **FHIR Release 4 (R4)** - HL7 strongly supports and recommends ONC Option 4 for the designated HL7 FHIR version, which would adopt FHIR Release 4 as the base standard in the companion ONC final rule (and through incorporation by reference) in the CMS final rule. HL7 comments on the ONC companion rule also indicate the need for strong guidance on implementation specifications, in addition to adoption of FHIR Release 4 in the regulation.
- **HL7 Da Vinci Project and Its Prototype Documentation Requirement Lookup Service for the Medicare FFS Program** - HL7 strongly supports CMS encouragement of all payers on page 7613 of the proposed rule to follow its example and align with the Da Vinci Project in developing a lookup service like the HL7 Da Vinci prototype Documentation Requirement Lookup Service for the Medicare FFS program.
- **Electronic Event Notification: Patient Admission, Discharge, Transfer** - At present, a variety of standards are used in different ways to accomplish the desired event notifications. New methods are being developed and deployed on an ongoing basis. HL7 believes it could be counterproductive to mandate the use of any one standard at this time.

Our organization also will reach out to you to with more specific information and to request a meeting to discuss how HL7 can best meet the needs of CMS, in alignment with the HL7-related provisions in this proposed rule. Issues for discussion in this meeting should include expected resource requirements, work priorities and timelines. We were pleased that CMS, in a February 5, 2019 letter to our organization, recognized the importance of HL7’s work in “moving forward to a truly collaborative, interoperable health system that supports patients in seeking low cost, high quality care.” We appreciate CMS recognizing and supporting the work of the Da Vinci Project. There is much work to be done and 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, not only from provider to provider, but also including payers and, beneficiaries. We also see enormous opportunity to facilitate innovation by unleashing data for use by researchers, application developers and others.

HL7 Work Groups have put forth a dedicated effort to submit specific and substantive feedback on relevant questions posed by CMS in the proposed rule. HL7 Work Groups contributing to these comments include:

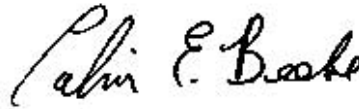
- Clinical Interoperability Council
- Clinical Quality Information
- Community-Based Care and Privacy
- Public Health
- Security
- Structured Documents

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 HHS and CMS.

Sincerely,



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



Calvin Beebe
Board of Directors, Chair
Health Level Seven International

Appendix: HL7 Detailed Responses to CMS Proposed Rule

Below are HL7's detailed responses to the proposed rule *Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally Facilitated Exchanges and Health Care Providers*.

Overarching Comments

Conformance with ONC Standards and API Language Comments:

- CMS and ONC should align the technical standards of their respective proposed rules. HL7 agrees with the agency that CMS should not propose its own set of standards but rather adopt ONC's standards and technologies by reference, as applicable. To the extent CMS proposes to require health plans to use API technology based on FHIR and other HL7 standards, for administrative data exchange CMS should coordinate with ONC to adopt standards for data classes and data elements for such exchange in the U.S. Core Data for Interoperability (USCDI). CMS should not require these functions until after such standards are added to the USCDI.

Implementation Timelines

Comments:

HL7 believes the proposed timelines are unreasonably aggressive. Standards development and refinement, technology development and certification, testing, operational implementation, and user training all are factors that should be considered in establishing required implementation timing. Initial implementations should not be required until 24 months after publication of the final rule, and compliance should not be required until 36 months after publication. CMS proposes requiring compliance by January 1, 2020 for Medicare Advantage (MA) plans and QHP issuers in FFEs, and by July 1, 2020 for Medicaid FFS, Medicaid managed care plans and CHIP. These timelines should be extended and also aligned with the effective date of the ONC's final rule.

- In addition, a phased implementation approach should be seriously considered for individual plans given the range of technical and operational changes that will need to be made and the range of technical capability of different plans. Additional time will be needed when CMS requires new data capture or new formats, versus making existing data in existing formats available through payer to payer APIs.

I. Background and Summary of Provisions (Past Efforts)

HL7 Da Vinci Project and Its Prototype Documentation Requirement Lookup Service for the Medicare FFS Program

Comments:

- CMS encourages all payers (page 7613) to follow its example and align with the Da Vinci Project in developing a lookup service like the HL7 Da Vinci prototype Documentation Requirement Lookup Service for the Medicare FFS program. (CMS-cited payers include but are not limited to Medicare Advantage (MA) organizations, Medicaid managed care plans and CHIP managed care entities, and QHP issuers in FFEs.) *HL7 strongly supports this recommendation.*

II. Technical Standards Related to Interoperability (Use of FHIR for APIs)

FHIR Release 4 (R4)

Comments:

- HL7 strongly supports and recommends ONC Option 4 for the designated HL7 FHIR version, which would adopt FHIR Release 4 as the base standard in the companion ONC final rule (and through incorporation by reference) in the CMS final rule. HL7 comments on the ONC companion rule also indicate the need for strong guidance on implementation specifications in addition to adoption of FHIR Release 4 in the regulation.

API Standard: Overarching FHIR Language

Comments:

- CMS' descriptive API language in the proposed regulation varies between "Open API" and "FHIR for APIs." This variation in API references should be reconciled. HL7 believes that CMS should consistently use "FHIR for APIs." Also, on this topic, page 7618 contains a "Use of FHIR for APIs" section but does not mention FHIR until a later section on page 7624. It would be useful to be more descriptive or change the heading.

III. Patient Access Through APIs (Open API Proposal for MA, Medicaid, CHIP, and QHP Issuers in FFEs)

API Standard: Patient Education Materials

Comments:

- CMS requests in various sections of the proposed rule that payers provide education materials to patients related to API use. HL7 agrees with this recommendation; we publish standards, such as Infobutton, that could be used to make educational materials available.

X. Revisions to the Conditions of Participation for Hospitals and Critical Access Hospitals (Proposal for Hospitals -Proposed 42 CFR 482.24(d))

Electronic Event Notification: Patient Admission, Discharge, Transfer

Comments:

- At present, a variety of standards are used in different ways to accomplish the desired event notifications. New methods are being developed and deployed on an ongoing basis. HL7 believes it could be counterproductive to mandate the use of any one standard at this time.

