August 30, 2016

Mr. Andy Slavitt  
Acting Administrator  
Centers for Medicare & Medicaid Services (CMS)  
Department of Health and Human Services  
Attention: CMS-1654-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

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

Dear Acting Administrator Slavitt:

Health Level Seven (HL7) International welcomes the opportunity to submit comments on the proposed rule 81 FR 46161 published by CMS in the July 15, 2016 issue of the Federal Register entitled “Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model, CMS-1654-P.”

HL7 is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related interoperability standards, including the rapidly emerging Fast Healthcare Interoperability Resources (FHIR), the Consolidated Clinical Document Architecture (C-CDA), and the widely used V2 messaging standards. HL7 is comprised of more than 1,600 members from over 50 countries, including 500+ corporate members representing healthcare providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms.

HL7’s comments are as follows:

• We appreciate and agree with the approach taken that specific standards for interoperability between Electronic Health Records (EHR), Clinical Decision Support Mechanism (CDSM), Imaging Center systems, and other Health Information Technology (HIT) involved in the exchange of Appropriate Use Criteria (AUC) related data should not be prescribed at this early stage of the program.

• Regarding this area, it is important to note that the specific Clinical Decision Support and API standards referenced in the 2016 Interoperability Standards Advisory (ISA) issued by ONC that are relevant to the exchange of AUC data are emerging standards and have not yet been widely deployed (e.g., IHE GAO and OAT profiles using HL7 V2 and FHIR standards). Before they can be widely deployed, these standards require further input and updates to address what data is to be communicated when: (1) sharing AUCs between a Provider Led Entity (PLE) that created the AUC and a CDSM; (2) there is interaction between an EHR and a CDSM to obtain relevant AUC information to accompany the order and to provide guidance and associated information based on the AUC; and (3) the EHR forwards the order to the fulfilling provider’s HIT with the relevant AUC.
information, and then on to a patient accounting system preparing and sending the claims from the ordering and rendering providers to CMS.

- We encourage CMS to work with ONC and relevant standards organizations (e.g., HL7, IHE, and X12) to progress the work to enable end-to-end interoperability across the relevant HIT components so adoption of these standards can be progressed earlier in the program. Absence of such standards and profiles for these use of these standards could lead to a variety of proprietary exchange mechanisms for the same purpose (e.g., each CDSM having its own exchange formats that EHRs need to support), unnecessarily increasing cost and effort.

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

Patricia Van Dyke
Board of Directors, Chair
Health Level Seven International