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September 11, 2017

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1676-P
Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Sir or Madam,

Health Level Seven (HL7) International welcomes the opportunity to submit comments to CMS' *Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program* proposed rule.

HL7 is a global authority and driver of interoperability standards in healthcare. The products of our organization – including the rapidly evolving FHIR standards - provide the underpinnings for connected, patient-centered health care and an information highway for precision medicine.

Our focus in the 2018 PFS NPRM is the section on Appropriate Use Criteria where the Centers for Medicare and Medicaid Services (CMS) provides various data requirements to communicate applicability of appropriate use criteria for ordered imaging services on the claim. While the format of the electronic claim is established through X12N, HL7 standards are or can be used in the flow leading up to the claim, effectively starting with the Provider Led Entity communicating appropriate use criteria method data to the CDS (Clinical Decision Support) Mechanism provider. In that context, we seek further clarification to inform any necessary updates to our standards as well as associated implementation guides/profiles (such as those provided by IHE (Integrating the Healthcare Enterprise) in this space) enable electronic flow of the relevant data up to the claim's producing system.

Sincerely,

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

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

Appropriate Use Criteria for Advanced Diagnostic Imaging Services
Section III.E. - Page 34091-34096

General Overview Comments:

- We believe there are a number of technical concerns and issues related to the orchestration/interactions between 1) the EHR (Electronic Health Record) of the Ordering Provider; 2) a CDS (Clinical Decision System) Mechanism (CDSM) – to be used by the Ordering Provider; 3) Provider-Led Entities' (PLE) Appropriate Use Criteria (AUC) – to be consumed by the CDS Mechanisms in supporting ordering providers; 4) the EHR of the Furnishing Provider (Radiologist) – receiving the order for advanced radiology imaging test and ensuring all information expected is in the order, that will then be passed to Furnishing Provider's Billing System; and lastly 5) the Billing System of the Furnishing Provider – to generate the claim for radiology service that will be submitted to the Centers of Medicare and Medicaid (CMS), with all the required data elements associated with AUC.

- We are concerned with the complexities of the multiple interactions expected to occur to fulfill the AUC goals. Having an EHR interact with one or potentially multiple CDSMs, which in turn must be able to consume and utilize appropriate use criteria developed by one or more PLEs, and have all this operate and function smoothly when a provider is making a determination of the need of an advanced radiology test, in real time, at the point of care, will be challenging – even for large organizations with resource capabilities. It is also important to note that the party that has much of the impact/effort (ordering provider) to make this successful does not stand to benefit clearly from the process, as the benefit is with the furnishing provider, thus making it challenging to ensure all parties are fully engaged.

- We recommend CMS consider that the implementation of AUC be done in a phased approach, rather than all-at-once, starting with a pilot implementation on a limited number of priority clinical areas, with a group of volunteer organizations, to allow the testing and correction of possible implementation issues, given the number of interactions, and the multiple points of risk of failure. We urge that this focused pilot approach target 2018 and 2019, when there is expected to be "early adopter" use of the AUCs as part of the Merit-based Incentive Payment System (MIPS) and then in 2019 when furnishing providers will not be penalized for not correctly including AUC information on their claims.

Comments Regarding Provider-Led Entities (PLEs) and Clinical Decision Support Mechanisms (CDSMs)

- We note that one CDSM may reflect one or more PLE-developed AUC methods (one-to-one or one-to-many relations), and one PLE-AUC may be utilized by more than one CDSM. For many health care provider organizations that are ordering tests that apply to multiple clinical priority areas for the AUC program (for example, coronary artery disease, suspected pulmonary embolism, headache, hip pain, low back pain, etc.), it is likely they will need to use AUCs developed by different PLEs, since each PLE tend to specialize in a specific clinical area. However, it is not clear in the proposed rule whether one single CDSM utilizing one single set of PLE-developed appropriate use criteria will be acceptable for an ordering provider to use (if that ordering provider is ordering tests for different priority clinical areas of the AUC program), or whether the ordering provider will need to use more than one set of appropriate use criteria thus requiring more than one CDSM if the CDSM does not support the relevant appropriate use criteria. We recommend that this be clarified in the final rule, particularly if the ordering provider need only consult one CDSM and that CDSM does not address the relevant appropriate use criteria for the imaging service being ordered.

- AUC methods generally generate a score (represented in the CDSM) that comes out of the CDS process for providers to know the degree to which they met the AUC. This score must be mapped to the three-class modifier expected to be coded in the Medicare claim from the furnishing provider. We ask CMS for clarification that, as part of authorizing a PLE and their AUC Method, it is also accepting the mapping from the AUC Method's scoring approach to the three-class modifier to assure consistent mapping regardless of who performs the mapping, e.g., CDSM, ordering provider, furnishing provider, or billing system. This way, the SDOs will be then able to ensure their standards can support this wherever AUC data is communicated, while the industry can determine the optimum place to perform the mapping (e.g., the CDSM at time of providing a score also provides the mapping).

Comments Regarding Clinical Workflow

- To achieve the goals of AUC, ordering providers will need to address not only the technical issues related to the interoperability of their EHR systems with one or more CDSMs (and ensure that the EHR utilizes the CDSM in support of the ordering provider), but they will also need to re-define important parts of the clinical practice workflow, whenever

there is the possibility of considering ordering an advanced radiology service that falls under AUC. We recommend that in the final rule, CMS highlight the need for such clinical workflow adjustments.

Comments Regarding Data Issues

- CDSM Identification mechanism: CMS is proposing to assign each qualified CDSM (those listed in the CMS AUC Website) a unique HCPCS "G-code", which the facility and radiologist must put on their claim along with the study's CPT code. The ordering provider's system will need to submit to the furnishing provider either the name of the CDSM mechanism, the G-Code assigned to it, or both. Capturing and maintaining such information, and then submitting it to the furnishing provider (as part of the order for service), for each applicable imaging service ordered will require EHR and workflow adjustments. It is not clear that, in the long run, the best way to identify the CDSM from one system to another is to use the G-Codes and the best way to acknowledge adherence is through a three-option modifier. We believe that this approach does not support other analysis opportunities requiring a more expansive vocabulary. We suggest that CMS revisit this approach after it has finalized and had some experience with it, while such expansive vocabulary is developed by SDOs

- Criteria Adherence: CMS is proposing to implement a series of modifiers to indicate whether the consult adhered or did not adhere to the criteria, or if the criteria did not apply. This determination must be made for each imaging service being ordered by the ordering provider. In order to automate this process, and avoid having the ordering provider to do this coding manually, CMS should acknowledge that, as part of authorizing a PLE and their AUC Method, it is also accepting the mapping from the AUC Method's scoring approach to the three-class modifier.

- NPI of Ordering Provider: NPI is already in place and used within the industry. We do not have any comments on this.

- CDS Session Identifier: A CDS session identifier (the identifier for the consultation instance between the ordering provider and the CDSM) is not required at this time, and we understand is not likely to ever going to be required by Medicare. However, it might be important to have this information in order to validate that the consult was performed (and for other audit/control purposes, including pre-authorizations, post-pay audits, etc.) and documentation was done accordingly. In the absence of the CDS Session Identifier, we would ask what CMS plans to use to validate that what is on the claim is what was communicated from the CDSM and whether such data is indeed on the claim and can be expected to be persisted on the respective upstream system(s).

- Which AUC was used: It seems that CMS is not going to require the identification of the AUC (and PLE) used by the CDSM, in turn used by the ordering provider. However, it might be also important to capture and retain this information for audit purposes. We request that CMS clarify whether there is any long-term consideration by CMS to capture the AUC method used by the CDSM, not just the CDSM, and who is expected to retain such other information.

Comments Regarding Standards

- HL7 submitted comments on the ONC 2017 ISA about correcting the categorization used to describe and organize AUC standards. We recommend CMS work with ONC to identify applicable standards for the AUC program that HIT should be able to support at a minimum, while in the process we also request ONC to re-classify the CDS-OAT profile reference as that is a messaging profile, not a decision support service capability. In general, we believe that current standards to support the AUC program are rapidly emerging for market adoption, although not yet ready for federal adoption through, e.g., ONC's certification program while we are awaiting clarifications from CMS on data requirements on AUC data retention and communication.

- We are pleased to see that the proposed regulation does not require a specific standard for the multi-layer integration needed between the various systems (EHRs, CDSMs, Billing, etc.). However, we strongly recommend CMS consider investing in helping further define, pilot and encourage implementation of key standards and standards-based interactions associated with Appropriate Use Criteria, including the use of FHIR, CDS Hooks, FHIR Clinical Reasoning, V2 Messaging specifications, and others to support the larger workflow to manage consultation and communication of AUC data. In particular, FHIR-based standards for the interaction between shareable clinical decision support systems and EHRs (e.g., communication of AUC Method updates and score mapping from PLE to CDSM) and CDS service standards to consume CDS rules are promising, with initial versions available, and would benefit from support and focus to get them ready for wide-spread adoption. HL7 is also working with IHE to update the relevant V2 Messaging standards and associated profiles to enable communication from the ordering provider to the furnishing provider and the billing/claims

system.

- The orchestration of all the technical interactions between various systems to make the AUC program work will require the use of multiple electronic standards developed and maintained (or yet to be developed) by various standards development organizations, including HL7 and X12N standards (for billing, electronic ordering, and interaction between the CDSM and the EHRs – including FHIR-based standards), as well as IHE profiles based on these HL7 standards to cover the entire workflow. We are encouraged by preliminary work being done by these SDOs to define, develop and disseminate such guidelines, but believe that without having those guidelines finalized, tested and adjusted (as appropriate), it will be very challenging to implement the AUC program most efficiently. The proposed transition from 2018 through 2019 into 2020 to start with early adopters and no penalties on absence of AUC data on a claim will be critical to focus CMS and ONC efforts with the industry to streamline the necessary workflow to make it widely adoptable.