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March 15, 2010

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-0033-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: NPRM: Medicare and Medicaid Programs; Electronic Health Record Incentive Program

The Notice of Proposed Rulemaking (NPRM) for the Centers for Medicare and Medicaid Services' (CMS) incentive program for the Meaningful Use of electronic health records (EHRs) marks a major, positive step forward in the nation's efforts to improve health and health care by putting modern information technology (IT) tools at the fingertips of medical professionals and consumers alike.

Health Level Seven members strongly support moving forward on the development and widespread implementation of interoperable healthcare IT, including the Nationwide Health Information Network, which includes the maximum participation by all clinician categories across all healthcare delivery settings. A critical first step is ensuring that eligible professionals and hospitals can achieve adoption and meaningful use of qualified, certified, EHR technology. Clearly, the goal of such adoption and use is increased access, quality, and efficiency. Thus, while the Medicare and Medicaid incentive programs should emphasize improvement in these areas as an end result, we should also be mindful that adoption of the right technologies must precede its meaningful use.

Health Level Seven International (HL7) is a not-for-profit, ANSI-accredited standards developing organization (SDO) dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. HL7's 2,300+ members represent approximately 500 organizations who represent more than 90% of the information systems vendors serving healthcare in the US.

Although HL7 is an SDO, the comments below propose reasonable and important modifications we felt were appropriate to the NPRM and represent input from Working Groups within HL7.

Use of ICD-9-CM and ICD-10-CM Codes for Clinical Problems

Comment: ICD-9-CM codes are used in billing systems for reporting diagnosis, problems, and conditions to payers. Providers are required to send ICD-9-CM to payers when they bill for services meant to *eliminate* a diagnosis. In HIPAA X12 837, the ICD-9-CM is accompanied by a flag that indicates whether this code is being used for that purpose. Neither the CCR nor the

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CCD support such a flag, so there is no way to know whether ICD-9-CM codes used in either report format accurately conveys the patient's problems. If EHR technology must be certified as supporting use of ICD-9-CM, then providers may populate the summary records, quality measures, discharge instructions, and referrals with billing ICD codes resulting in false positives about the patient's condition if these codes are used for analysis or decision support.

ICD codes are inappropriate for clinical information. Since the CCD is more clinically focused, ICDs are not an appropriate vocabulary, and their use will impact the ability to implement CCD. HL7 recommends the use of SNOMED with CCD.

X12 HIPAA Transactions

X12 837 Claims and 270/271 Eligibility Verification transactions are included as certification criteria, and as meaningful use measures. While implementation of an ePrescribing module as part of HITECH EHR technology makes sense, we fail to see the priority given for implementation of a module that is typically not considered part of an EHR system, and is typically implemented in a practice management system or out-sourced to a billing service. Any provider who is compliant with HIPAA ought to be doing them anyway.

That aside, we are even less clear why HHS would require providers to implement the X12 4010A1 in 2011 in order to receive HITECH incentives only to have to upgrade to the X12 5010 in 2013, which they are required to do anyway. Instead, we recommend eliminating these as certification criteria and standards and as meaningful use measures in the NPRM.

Concern with CAQH CORE 270/271 and Phishing Prohibitions

HL7 supports development of HL7 Financial Management message and service standards for the Medicaid Information Technology Architecture (MITA). For this reason, HL7 is concerned that a strict interpretation of the HIPAA-mandated ASC X12N 270/271 – Health Care Eligibility Benefit Inquiry and Response, Version 4010 (004010X092) and Addenda to Health Care Eligibility Benefit Inquiry and Response (004010X092A1) as well as ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, Version 5010 (ASC X12N/005010X279) requirements for the use of the AAA Segment to report errors in identifying the patient in the 271 Response transaction likely conflicts with established policies and procedures regarding phishing that many Medicaid agencies have established. This will impede progress on the development of HL7 Financial Management Medicaid Beneficiary Registry messages and service specifications. The specific concern is that a strict interpretation of the 270/271 AAA specification requires the payer to inform the requestor exactly which fields in the search request caused the mismatch with the payer data providing an opportunity for phishing. Further investigation is required to determine the impact of such a strict interpretation of the HIPAA-mandated transaction set and the use the AAA segment may have on privacy and other policies of Medicaid agencies and other governmental bodies. HL7 recommends clarification on the inherent conflict so that its work on MITA standards can progress.

Medication Reconciliation

With respect to the criterion for medication reconciliation¹, please clarify whether reconciliation is to be performed only for current medications, for a particular date range, or for all known medications.

¹ §170.302 (l): Medication reconciliation. Electronically complete medication reconciliation of two or more medication lists by comparing and merging into a single medication list that can be electronically displayed in real-time
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Security and EHR Modules

HL7 recommends that the clarification provided in the proposed Certification rule about the application of the privacy and security certification criteria to complete EHRS or EHR modules be incorporated or referenced in the final rule on Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology

Access Control Standard, and Support for Patient Authorizations and Consents

HL7 recommends that ONC adopt a functional standard for access control and for the electronic capture, management, and conveyance of patient consents and authorizations afforded under HIPAA, 42 CFR Part 2, state laws, The Medicaid program confidentiality requirements^[1], and ARRA. These functional specifications should enable computable enforcement of patient authorizations and consents by means of access control technologies that use standardized role, permission, and purpose of use vocabularies in order to meet the criterion: “Capability to exchange key clinical information among providers of care and *patient authorized entities* electronically.”

We note that the qualifier “patient authorized” that is included in the preamble is dropped from the wording of the regulation. We strongly urge that this qualifier be included in the actual regulation in order for this certification criterion to enable providers to meet multiple jurisdictional laws relating to patient authorizations and consents.

In addition, while the regulatory language does include an access control certification criteria, we are concerned that the NPRM stipulation^[2] that providers must only meet certification criteria for which a standard has been named may preclude any actual certification of access control capabilities.

Finally, we recommend that ONC include a comprehensive definition of access control that includes the notion of object/operation pairs or “permissions” that can be assigned to roles and users under conditions, with obligations, and for specified purposes of use.

The NPRM states that “documentation of progress notes is a medical-legal requirement and a component of basic EHR functionality.”

Comment: The HL7 RM-ES Workgroup strongly believes that progress notes are more than “just a medico-legal requirement.” The HL7 RM-ES Workgroup has reviewed the HIT Policy Committee letter dated February 17, 2010 and agrees with the statement that “Electronic access to progress notes is key to delivering high quality care and for coordination of care for several reasons, including the following:

- Handwritten medical records do not only take more time to decipher, their illegibility often obscures important information.

^[1] [The State Medicaid Manual Chapter 11 Section 11281.1 D. Safeguards](#). – You must insure that appropriate safeguards are in place to protect the confidentiality of eligibility information. The use or disclosure of this information is restricted to purposes directly connected with the administration of the Medicaid program.

^[2] Federal Register / Vol. 75, No. 8 / Wednesday, January 13, 2010 / Proposed Rules, page 1846 "In a related proposed rule, the Department will propose the development of a certification program for health IT. Specifically, we have sought to ensure that the definition of meaningful use of certified EHR technology does not require EPs and eligible hospitals to perform functionalities for which standards have not been recognized or established"

- Information that is not entered electronically at the point of care is lost forever, thus rendering the record less complete.
- Hybrid systems (part electronic, part paper) cause fragmentation of the record and inefficient workflow.
- Maintaining progress notes on paper impedes patients' access to this information because there is no structured way to provide patients with context to those data.
- Sharing electronic progress notes is fundamental to successful care coordination.
- Textual progress notes provide significant information about the patient that is not captured in the structured format elsewhere. Providers use these to know the patient as a human being, and patient focus groups suggest the best way to improve quality of care is for personal clinicians to 'really know me.'"

The HL7 RM-ES Workgroup strongly believes the progress note is an essential component of clinical documentation that is used by the provider as a basis for the development of the treatment plan, decision making and care coordination and management.

The HL7 RM-ES workgroup believes that progress notes are equally as valuable for inpatient care, although at the present time the majority of today's hospital do not maintain EHR systems which provide for documentation of progress notes for each patient encounter.

HL7 Recommends:

Document a progress note for each encounter for Stage 1 Eligible Providers (EP) Meaningful Use Definition. The EHR progress note highlights the importance of unstructured text to communicate a provider's thought process and observations in the development of the treatment plan and ongoing care of the patient.

Provisions should be in place for both EPs and EH's to screen the progress notes for any privacy data and for the provider to be able to send a data blob along with the progress note to indicate that the data has been screened.

Comment: At this point in time, the majority of today's hospitals contain a combination of both paper and electronic and paper documentation of the patient progress notes. The HL7 RM-ES Workgroup strongly believes the patient progress note is more than just a "medico-legal requirement." The patient progress note provides valuable information to providers to be used as the basis for the treatment plan, care coordination and communication of the patient's discharge plans and needs.

HL7 Recommends:

Currently, the majority of today's hospitals do not maintain fully integrated electronic progress notes. Eventually they will become a routine EHR function. Therefore, progress note clinical documentation as a required criterion for Meaningful Use should occur within the Stage 2 for Eligible Hospitals (EH) definitions.