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May 3, 2010

Department of Health and Human Services  
Office of the National Coordinator for Health Information Technology  
Attention: Certification Programs Proposed Rule  
Hubert H. Humphrey Building  
Suite 729D  
200 Independence Ave, S.W.  
Washington, DC 20201

RE: RIN 0991-AB59: Proposed Rule: Proposed Establishment of Certification Programs for Health Information Technology

The Proposed Rule on establishment of certification programs for health information technology (HIT) marks an important step forward in the nation's efforts to improve health care by putting highly functional electronic health record systems (EHR-S) at the fingertips of medical professionals and consumers alike.

Health Level Seven members strongly support moving forward on the development of programs for the voluntary certification of health information technology. A critical first step is ensuring that eligible professionals and hospitals can achieve adoption and meaningful use of qualified, certified, EHR technology. Health Level Seven International believes that these programs, once established, can test and certify other types and aspects of HIT in the future.

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 that represent more than 90% of the information systems vendors serving healthcare in the US.

The comments below propose reasonable and important modifications to the Proposed Rule and represent input from Working Groups within HL7. They replace our initial April 9 response and reflect updated responses to the proposed temporary and permanent certification process rules.

**(1) Comment:**

HL7 notes that the proposed rule, particularly with respect to **§170.423 Principles of proper conduct for ONC-ATCBs**, does not make any provision for consultation with authoritative bodies with respect to interpretation of standards and implementation guides when such questions arise. These SDOs or expert organizations can provide NIST with vital input and review of its testing criteria. For example, in recently published NIST MU certification tests for modifying Patient Vital Signs and modifying Patient Active Medication Allergy Lists, the criteria does not make clear distinctions about when data cannot be modified, nor what additional data should be captured (e.g., for attestation and non-repudiation) in order to satisfy the medico-legal purposes of the EHR. Without such clarification, the criteria may put the healthcare delivery organization in legal

jeopardy and introduce patient safety issues.

**HL7 Recommends:**

HL7 recommends that NIST and the National Voluntary Laboratory Accreditation Program (NVLAP) be required to consult with these bodies, and that a formal relationship between NIST and NVLAP and the developers of standards selected under 170 CFR Part 45 be established under this rule. Further we recommend the addition of a requirement that test scripts based on standards and implementation specifications be reviewed by the publisher of the standards and/or implementation specifications and that NIST or NVLAP be required to consider comments from the SDO resulting from this review, prior to publication of final test scripts. We suggest that this formal relationship be incorporated into the governance of the new ONC Interoperability Framework discussed at the March 24<sup>th</sup> HIT Standards Committee meeting.

**(2) Comment:**

The proposed rules are focusing NIST and NVLAP on the needed testing environment (i.e., the test cases, test data and scripts, and hardware and software requirements, etc.). Once the environment is established, tooling will be needed to automate the process.

**HL7 Recommends:**

HL7 recommends that existing and off-the-shelf tools, where and when they exist, be used to automate testing. HL7, for example, has developed and approved as an ANSI standard, a set of Conformance Profiles that are used with the Messaging Workbench to directly support automated conformance testing in Version 2. Similar tools available through HL7 and other SDOs should be used when possible.

**(3) Comment:**

HL7 notes that in 2003, CMS and HHS approached HL7 to develop common definitions of functional capabilities of EHR systems, so that such definitions can be used in certification programs to define certification criteria in support of, e.g., EHR adoption incentives. Since 2003, HL7 has produced the Electronic Health Record System Functional Model (EHR-S FM), and a number of derived Functional Profiles. The EHR-S FM, as well as a number of profiles—namely the Emergency Department, Long Term and Post Acute Care, Behavioral Health, Child Health, Records Management and Evidentiary Support—have already been used by CCHIT to develop certification criteria. Thus, the value of the EHR-S FM and the profiles for certification purposes has already been established.

**HL7 Recommends:**

HL7 strongly recommends that ONC continue to utilize the HL7 EHR-S FM definitions as part of the certification program.

**(4) Comment:**

NIST was heavily involved in developing both the EHR-S FM and the methodology to conform to the Profiles. Indeed, NIST hosts the website where HL7 profiles derived from the EHR-S FM can be registered.

**HL7 Recommends:**

NIST is already familiar with the HL7 EHR-S FM and its profiles. Therefore, HL7 recommends that NIST uses the tests and criteria that certifying bodies such as CCHIT have derived from them in the NIST criteria for test labs for the certification criteria in scope for the EHR Incentive Program.

**(5) Comment:**

ONC is specifically seeking input as to whether HIT other than EHR systems such as personal health record (PHR) systems and health information exchange (HIE) systems should be certified.

**HL7 Recommends:**

HL7 strongly recommends that HIT other than EHR systems be certified. To support and accelerate the certification of other HIT, HL7 has developed the PHR System Functional Model (PHR-S FM), which can be used in a manner similar to that in which the EHR-S FM has been used for certification purposes. Specifically, HL7 recommends that interoperability of EHR systems across the continuum of care be certified to ensure that not only can EHRs communicate data in an agreed to format with specific vocabularies, but connected systems (e.g., PHRs offered by vendors that must be treated as business associates under HITECH) can also communicate accordingly. To support that effort, the current profiles for the Emergency Department, Long Term and Post Acute Care, Behavioral Health, and Child Health can be used.

**(6) Comment:**

HL7 supports the spirit of the HIT Policy Committee comment on the Certification NPRM recommending EHR module labeling to start to create clarity on inter-module interoperability.

**HL7 Recommends:**

We recommend that the ONC encourage EHR vendors to label their EHRs and EHR modules to clearly identify the certification attained, including in-scope elements and exclusions (i.e., inter-module interoperability). We also see value in vendors documenting for those providers who purchase their systems information regarding the standard(s), version(s) and implementation guide(s) available to interoperate with other vendor's EHR modules. For example, a vendor could indicate the version of HL7 used for an interface that supports medication reconciliation or the HL7 EHR functional model capability which the module supports or upon which the module depends. We suggest that ONC begin promoting such documentation while it is not subject to certification.

Sincerely,



Robert H. Dolin, MD  
Chair, HL7 International



Charles Jaffe, MD, PhD  
Chief Executive Officer