



Health Level Seven® International

For Immediate Release

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Health Level Seven International Comments on Proposed Establishment of Certification Programs for Health Information Technology

Ann Arbor, MI – April 14, 2010 - Health Level Seven® International (HL7®), the global authority for interoperability and standards in healthcare information technology, has released comments supporting moving forward on the development of programs for the voluntary certification of health information technology.

HL7 believes the proposed rule marks an important step forward in the nation's efforts to improve healthcare by putting highly functional electronic health record systems (EHR-S) at the fingertips of medical professionals and consumers alike. Once established, these programs can test and certify other types and aspects of HIT in the future. However, HL7 has submitted comments to the Office of the National Coordinator for Health Information Technology which propose reasonable and important modifications to the Proposed Rule.

In its comments, HL7 notes that the organization has a history working with the federal government. In 2003, the Centers for Medicare & Medicaid Services (CMS) and Health and Human Services (HHS) approached HL7 to develop functional requirements for EHR systems, so that such requirements could be used to certify EHR systems and support EHR adoption incentives. As a result of this relationship, HL7 produced the EHR-S Functional Model (EHR-S FM) as well as derived functional profiles such as Emergency Health, Child Health, Behavioral Health and Long Term and Post Acute Care that specify a number of conformance criteria. The Certification Commission for Health Information Technology (CCHIT) has already used the EHR-S FM and its profiles to develop certification criteria. Therefore, the value of these standards for certification purposes has already been established and HL7 recommends that the ONC continue to include functional requirements as part of the certification program.

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HL7 also points out that The National Institute of Standards and Technology (NIST) was heavily involved in the development of the EHR-S FM and the methodology to conform to the profiles. In fact, NIST hosts the website where profiles derived from the HL7 EHR-S FM can be registered. NIST is developing a process for testing certification for its National Voluntary Laboratory Accreditation Program (NVLAP). Since NIST is already familiar with the EHR-S FM and its profiles, HL7 recommends that it include the criteria that certifying bodies such as CCHIT have derived from these standards in the NIST criteria for test labs.

Additionally, the ONC is seeking input as to whether HIT other than EHR systems should be certified. HL7 strongly recommends that other HIT be certified, including Personal Health Record (PHR) systems. To support and accelerate this goal, HL7 has developed the PHR System Functional Model (PHR-S FM). The PHR-S FM can be used in a manner similar to that in which the EHR-S FM has been used for certification purposes. Moreover, HL7 recommends that interoperability of EHR systems across the continuum of care be certified. 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.

Finally, HL7 comments that the proposed rule 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. HL7 recommends that NIST and the NVLAP be required to consult with these bodies, including HL7. Furthermore, HL7 advises that this rule establish a formal relationship between NIST, NVLAP and the developers of the standards selected in 170 CFR Part 45. HL7 also proposes 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.

To see the full document detailing HL7 International's comments, please visit:

http://www.hl7.org/documentcenter/public/newsroom/HL7%20response%20to%20Certification%20NPRM%20v5%20_2_.pdf.

About HL7 International

Founded in 1987, Health Level Seven International is the global authority for healthcare Information interoperability and standards with affiliates established in more than 30 countries. HL7 is a non-profit, ANSI accredited standards development organization 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 more than 2,300 members represent approximately 500 corporate members, which include more than 90 percent of the information systems vendors serving healthcare. HL7 collaborates with other standards developers and provider, payer, philanthropic and government agencies at the highest levels to ensure the development of comprehensive and reliable standards and successful interoperability efforts.

HL7's endeavors are sponsored, in part, by the support of its benefactors: Abbott; Accenture; Booz Allen Hamilton; Centers for Disease Control and Prevention; Duke Translational Medicine Institute (DTMI); Eclipsys Corporation; Eli Lilly & Company; Epic Systems Corporation; European Medicines Agency; the Food and Drug Administration; GE Healthcare Information Technologies; GlaxoSmithKline; Intel Corporation; InterSystems Corporation; Kaiser Permanente; Lockheed Martin; McKesson Provider Technology; Microsoft Corporation; NHS Connecting for Health; NICTIZ National Healthcare; Novartis Pharmaceuticals Corporation; Oracle Corporation; Partners HealthCare System, Inc.; Pfizer, Inc.; Philips Healthcare; QuadraMed Corporation; Quest Diagnostics Inc.; Siemens Healthcare; St. Jude Medical; Thomson Reuters; the U.S. Department of Defense, Military Health System; and the U.S. Department of Veterans Affairs.

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