



HEALTH INFORMATION TECHNOLOGY: INITIAL SET OF STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA FOR ELECTRONIC HEALTH RECORD TECHNOLOGY

Facts-At-A-Glance

- Section 3004(b)(1) of the Public Health Service Act, as added by the Health Information Technology for Economic and Clinical Health Act (HITECH), requires the Secretary of the Department of Health and Human Services (HHS) to adopt an initial set of standards, implementation specifications, and certification criteria to enhance the interoperability, functionality, utility, and security of health information technology (HIT).
- Under this authority, the Office of the National Coordinator for Health Information Technology (ONC) has issued an Interim Final Rule (IFR) that specifies the Secretary's adoption of an initial set of standards, implementation specifications, and certification criteria for electronic health record (EHR) technology.
- The IFR will become effective 30 days after publication and will be open for public comment for 60 days after publication. The final rule will be issued sometime in 2010.
- The American Recovery and Reinvestment Act of 2009 also authorized the Centers for Medicare & Medicaid Services (CMS) to provide incentives to providers for the adoption and meaningful use of certified EHR technology. CMS will issue a separate proposed regulation that proposes to accomplish these statutory requirements. The proposed rule may be viewed at <http://www.federalregister.gov/inspection.aspx#special>.
- The certification criteria adopted in the IFR specify the capabilities and related standards that certified EHR technology must include in order to support the proposed meaningful use Stage 1 requirements for eligible professionals and eligible hospitals under the Medicare EHR incentive program. Medicaid providers can receive incentives to adopt, implement, and upgrade to certified technology in their first year of participation but then they too must become meaningful users to receive their second year incentive payment.
- The standards, implementation specifications, and certification criteria adopted in the IFR are meant to serve as the basis for the testing and certification of complete EHRs and EHR Modules. ONC will issue a separate Notice of Proposed Rulemaking (NPRM) relating to the testing and certification of complete EHRs and EHR Modules in 2010.
- To inform the rulemaking processes, ONC and CMS received input from hundreds of technical subject matter experts, health care providers, and other stakeholders who provided input through three HHS Federal advisory committees: the National Committee on Vital and Health Statistics, the HIT Policy Committee, and the HIT Standards Committee.

Specific Requirements within the Interim Final Rule

- ONC established the following goals to guide its approach to adopting the standards, implementation specifications, and certification criteria within the IFR:
 - Promote interoperability and where necessary be specific about certain content exchange and vocabulary standards to establish a path forward toward semantic interoperability;
 - Support the evolution and timely maintenance of adopted standards;
 - Promote technical innovation using adopted standards;
 - Encourage participation and adoption by all vendors, including small businesses;
 - Keep implementation costs as low as reasonably possible;
 - Consider best practices, experiences, policies, frameworks, and the input of the HIT Policy Committee and HIT Standards Committee in current and future standards;
 - Enable mechanisms such as the Nationwide Health Information Network (NHIN) to serve as a test-bed for innovation and as an open-source reference implementation of best practices; and
 - To the extent possible, adopt standards that are modular and not interdependent.
- The standards adopted in the rule are consistent with current industry practices.
- The adopted standards rely heavily on existing standards for the interoperability of health information technologies, including those established and/or promoted by Health Level 7, Inc. (HL7), the National Institute of Standards and Technology (NIST), and Integrating the Healthcare Enterprise (IHE). The standards also rely on existing classification and nomenclature systems including SNOMED CT, ICD-9 and 10, X12, LOINC, NCPDP, and RxNorm. These standards were chosen in an attempt to provide a minimum set of transport, content, and vocabulary standards required to drive or enhance the predictability of data exchange when used in EHR technologies, thus driving adoption.
- Subsequent rules will contain standards that will provide greater detail and specificity to achieving interoperability.
- There is a 60-day public comment period on the IFR which begins on the date of publication. The IFR may be viewed at <http://www.federalregister.gov/inspection.aspx#special>.

Additional information is available at <http://HealthIT.HHS.Gov/standardsandcertification>.