ONC Notice of Proposed Ruling Making Stage 2 Certification Rule Fact Sheet

Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology

The Health Information Technology for Economic and Clinical Health (HITECH) Act lays the groundwork for improved health care quality, safety, and efficiency through the use of health information technology (HIT), including electronic health records (EHRs) and private and secure electronic health information exchange.

The HITECH Act directs the Office of the National Coordinator for Health Information Technology (ONC) to support and promote meaningful use of certified EHR technology nationwide through the adoption of standards, implementation specifications, and certification criteria as well as the establishment of certification programs for HIT.

2014 Edition Standards and Certification Criteria (S&CC) Proposed Rule

- ONC's proposed rule complements the newly released Centers for Medicare & Medicaid Services' (CMS) proposed rule for Stage 2 of the Medicare and Medicaid EHR Incentive Programs which provides incentive payments to eligible health care providers as they adopt and "meaningfully use" certified EHR technology (CEHRT).
- The ONC rule proposes capabilities and related standards and implementation specifications that CEHRT will need to include to, at a minimum, support the achievement of "meaningful use" by eligible health care providers for the EHR reporting periods beginning in fiscal year/calendar year (FY/CY) 2014 and beyond.

Highlights of the Standards & Certification Criteria Proposed Rule

Overview of the Proposed EHR Certification Criteria

- The certification criteria proposed for adoption are referred to as the "2014 Edition EHR certification criteria" and the currently adopted certification criteria are now referred to as the "2011 Edition EHR certification criteria."
- The "2014 Edition EHR certification criteria" support the proposed changes to the Medicare and Medicaid EHR Incentive Programs, including the new and revised objectives and measures for Stages 1 and 2 of meaningful use. These certification criteria seek to enhance care coordination, patient and family engagement, interoperability, and the security, safety, and efficacy of EHR technology.
- While drafting the proposed rule, ONC evaluated each 2011 Edition EHR certification criterion for clarity and considered each of the HIT Standards Committee's recommendations.
- To permit efficient certification methods and reduce regulatory burden, the proposed rule identifies certain "unchanged" 2014 Edition EHR certification criteria that would permit, where

applicable, an EHR technology developer to use prior test results for certification (referred to as "gap certification").

Redefining CEHRT

- Based on feedback from stakeholders and the recommendations from the HIT Standards Committee, ONC is proposing a revised definition of CEHRT that, beginning with the EHR reporting periods in FY/CY 2014, would provide more flexibility for eligible health care providers.
- The proposed revised definition of CEHRT would require eligible health care providers to have a Base EHR (EHR technology that includes fundamental capabilities all providers would need to have) as well as the additional EHR technology necessary to meet the meaningful use objectives and measures for the stage of meaningful use that they seek to meet and to capture, calculate, and report clinical quality measures, but not more than necessary to meet those objectives. A Base EHR would include such fundamental capabilities as the ability to provide clinical decision support, to support physician order entry, the capacity to exchange health information with other sources, and the capacity to protect the confidentiality, integrity and availability of health information stored and exchanged. The revised definition of CEHRT would also enable eligible providers to upgrade and adopt EHR technology certified to the 2014 Edition EHR certification criteria as early as 2012 if they so choose.

Key Changes to the ONC HIT Certification Program

- The anticipated sunset of the temporary certification program is expected to occur upon the effective date of a final rule for this proposed rule. At that time, the permanent certification program would become effective and would be known as the "ONC HIT Certification Program" based on our proposal to change the name of the program.
- Proposed changes aim to increase regulatory clarity and transparency, reduce regulatory burden, and add flexibility for the HIT community. We propose changes to the certification processes for EHR Modules that remove certain certification requirements and provide clear direction for certifying to proposed new certification criteria. We propose a revised process that would provide the industry with flexibility to quickly utilize newer versions of "minimum standard" code sets. We also propose to increase certification transparency and clarity by making publicly available the test results used to certify EHR technology and clearly representing EHR technology that has been certified.

Request for Public Input to Improve Safety, Data Portability, and Transparency

• As recommended by the recent Institute of Medicine report on HIT and patient safety, the proposed rule proposes certification criteria that are intended to improve patient safety through the application of user-centered design processes and adherence to appropriate quality systems principles. We seek public comment on these proposals and other proposals related to patient safety that will improve the overall safety of patient care in general and EHR technology in particular.

- Data portability (including the migration from one EHR to the next) is a key factor in the EHR technology market where agility and innovation is necessary. We request public input on ways to improve data portability, including comment on a proposal to improve data portability for providers.
- Comment is sought on the concept of price transparency related to the price associated with a certified Complete EHR or certified EHR Module. We request feedback from the public on whether we should require EHR technology developers to disclose the full cost of a certified Complete EHR or certified EHR Module.

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