

ONC Fact Sheet: 2014 Edition Standards & Certification Criteria (S&CC) Final Rule

Summary

The 2014 Edition S&CC final rule completes the Office of the National Coordinator for Health IT's (ONC) second full rulemaking cycle to adopt standards, implementation specifications, and certification criteria for EHR technology. This final rule complements the newly released Centers for Medicare & Medicaid Services (CMS) final rule which establishes Stage 2 of the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs, updates Stage 1, and includes other program modifications.

The 2014 Edition S&CC final rule reflects ONC's commitment to reduce regulatory burden; promote patient safety and patient engagement; enhance EHR technology's interoperability, electronic health information exchange capacity, public health reporting, and security; enable clinical quality measure data capture, calculation, and electronic submission to CMS or States; and introduce greater transparency and efficiency to the certification process.

Specific Highlights

The 2014 Edition S&CC final rule:

- Redefines the meaning of Certified EHR Technology as well as introduces more efficient means for certification to permit greater innovation and reduce regulatory burden;
- Adopts vocabulary, content exchange, transport, functional, and security standards in certification criteria;
- Adopts certification criteria for transitions of care that will ensure EHR technology supports standards-based electronic health information exchange;
- Requires that test reports used for EHR technology certification be made publicly available and that EHR technology developers follow certain price transparency practices related to the types of costs (i.e., one-time, ongoing, or both) associated with EHR technology implementation for meaningful use; and
- Makes available for the first time, "gap certification" for certain certification criteria, which will enable more efficient EHR technology certification.

Certified EHR Technology (CEHRT) Definition

The revised CEHRT definition enables providers to have the option to have only the EHR technology they need to meet the meaningful use stage they seek to meet. Changes to the CEHRT definition allow for providers to choose and customize the EHR technology that works for them and their patients:

For EHR reporting periods *prior to* the fiscal year (FY)/calendar year (CY) 2014, the
final rule includes additional flexibilities for eligible providers. Eligible providers will be
able to meet the CEHRT definition in any one of the following three ways:

- Adopt EHR technology certified to the 2011 Edition EHR certification criteria that meets all applicable certification criteria (the original CEHRT definition established in the S&CC July 2010 final rule);
- 2. Upgrade parts of their 2011 Edition EHR technology to the equivalent 2014 Edition EHR technology (same as way # 1, but with a mix of EHR technology certified to either the 2011 or equivalent 2014 Edition); or
- 3. Adopt EHR technology that meets the CEHRT definition for FY/CY 2014.
- For EHR reporting periods during and after FY/CY 2014, eligible providers will need to have EHR technology certified to the 2014 Edition EHR certification criteria that meets a required base amount of functionality and then any other functionality they need to achieve meaningful use.
- EHR technology certified to the 2014 Edition EHR certification criteria will be able to support an eligible provider's attempt to achieve either meaningful use Stage 1 or 2.

<u>Improved Security, Interoperability, Data Portability, and Other Requirements</u> Adopted in the 2014 Edition S&CC Final Rule

Privacy and Security

- Adopted a certification criterion that focuses on the encryption of health information if it is stored on end-user devices.
- Adopted a new certification criterion that would require EHR technology to be able to support corrections and amendments to a patient record.
- Adopted a new certification criterion that enables secure messaging between a provider and a patient.
- Adopted a new certification criterion that permits a patient to securely view, download, and electronically transmit his or her health information, including the ability to track the use of these patient capabilities.

Interoperability

- In many instances, certification criteria reference single vocabulary and context exchange standards for recording and representing clinical health information for use during electronic health information exchange.
- Adopted transport standards for the exchange of transitions of care/referral summaries as well as the transmission of patient summaries as part of the view, download, and transmit to a third party certification criterion.
- The "transitions of care" certification criterion focused on receipt was revised to include the display of previously adopted summary care record standards: CCD/C32 and CCR, providing a form of backwards compatibility.
- The test procedure for the transitions of care/referral certification criteria is expected to ascertain EHR technology's ability to engage in standards-based exchange with any other EHR technology that has also implemented the adopted transport standards.
- Adopted a new certification criterion focused on improving the exchange of laboratory test results between hospitals and ambulatory providers as well as a certification criterion focused on the receipt of laboratory test results which references a common interface standard for ambulatory EHR technology.

 Adopted certification criteria that improve EHR technology's ability to report information to public health agencies, including reporting cancer case information to cancer registries.

Data Portability

 Adopted a new certification criterion that will enable providers to create a set of "patient summaries." In the event a provider switches EHR technology, this capability will help prevent the need to manually re-enter basic patient information into the new EHR.

Safety and Usability

Adopted two new certification criteria related to patient safety – one that focuses on the
application of user-centered design to medication-related certification criteria and
another that focuses on the quality management system (QMS) used during the EHR
technology design.

Clinical Quality Measures

 Adopts three certification criteria for clinical quality measures (CQMs) that focus on electronic data capture, calculation, and enabling electronic submission of CQM data to CMS.

Reducing Regulatory Burden and Increasing Flexibility

- The final rule allows for EHR technology that had been certified to the 2011 Edition to be used through 2013.
- Newer versions of adopted minimum standards code sets can be efficiently used for certification and routinely incorporated into EHR technology without requiring additional certification.
- Adopted a requirement that will make EHR Module certification more efficient than previously established under the temporary certification program.

EHR Technology Price Transparency

To promote transparency and limit purchasing confusion, the final rule requires ONC-ACBs (authorized certification bodies) to ensure that an EHR technology developer notifies eligible providers about additional types of costs (i.e., one-time, ongoing, or both) that affect a certified Complete EHR or certified EHR Module's total cost of ownership for the purposes of achieving meaningful use.

Test Result Transparency

- The final rule requires that ONC-ACBs (authorized certification bodies) submit a
 hyperlink of the test results used to issue a certification to a Complete EHR or EHR
 Module. This transparency requirement enables providers to access the test results
 used to certify EHR technology and provides a potential starting point from which to
 assess any implementation issues associated with certified Complete EHRs and
 certified EHR Modules.
- Test results will be made publicly available on ONC's Certified HIT Products List (CHPL) along with all of the other information ONC-ACBs report to ONC.