



Frequently Asked Questions
on Establishment of the Temporary Certification Program
for Health Information Technology
Final Rule
June 21, 2010

Q: What is this Final Rule?

A: This final rule establishes a temporary certification program for the purposes of testing and certifying health information technology. The National Coordinator will utilize the temporary certification program to authorize organizations to test and certify Complete Electronic Health Records (EHRs) and/or EHR Modules, thereby making Certified EHR Technology available prior to the date on which health care providers seeking incentive payments available under the Medicare and Medicaid EHR Incentive Programs may begin demonstrating meaningful use of Certified EHR Technology.

Q: What is a Complete EHR?

A: EHR Technology that has been developed to meet all applicable certification criteria.

Q: What is an EHR Module?

A: Any service, component, or combination thereof that can meet the requirements of at least one certification criterion.

Q: When does this rule become effective?

A: This regulation becomes effective the day it is published in the Federal Register. The 30-day delay in the effective date of this final rule has been waived.

Q: What is the purpose of the Temporary Certification Program?

A: The temporary certification program provides a process by which an organization or organizations may become an ONC-Authorized Testing and Certification Body (ONC-ATCB) and be authorized by the National Coordinator to perform the testing and certification of Complete EHRs and/or EHR Modules.

Q: Who are the ONC-ATCBs?

A: In order to become an ONC-ATCB, an organization or organizations must submit an application to the National Coordinator to demonstrate its competency and ability to test and certify Complete EHRs and/or EHR Modules. ONC anticipates that only a few organizations will qualify and become ONC-ATCBs under the temporary certification program. These organizations will be required to remain in good standing by following the Principles of Proper Conduct for ONC-ATCBs.

Q: Can an ONC-ATCB specialize, testing and certifying only one type of HIT?

A: At this time, applicants for ONC-ATCB status must be able to test for either ambulatory or inpatient settings. This provision will be reconsidered based upon comments for the proposed permanent certification program.

Current as of June 21, 2010

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Q: Is the temporary certification program indefinite?

A: No, it will sunset on December 31, 2011, or if the permanent certification program is not fully constituted at that time, then upon a subsequent date that is determined to be appropriate by the National Coordinator.

Q: Is this final rule identical to the NPRM that was proposed in March 2010?

A: No, this final rule incorporates changes suggested by the 84 comments on the NPRM received by ONC for consideration prior to finalization of the temporary certification program.

Q: Is there a difference between “testing” and “certification?”

A: There is a distinct difference between testing and certification. Testing is intended to result in objective, unanalyzed data. In contrast, certification is expected to result in an overall assessment of the test results, consideration of their significance, and consideration of other factors to determine whether the prerequisites for certification have been obtained.

Q: Is there an “almost complete” EHR?

A: This final rule reiterates that for EHR technology to be considered a Complete EHR it would have to meet all applicable certification criteria.

Q: Can EHR Modules added together comprise a Complete EHR?

A: If EHR Modules are presented for testing and certification as an integrated bundle that would otherwise constitute a Complete EHR, ONC will consider them a Complete EHR for the purposes of being certified by an ONC-ATCB.

Q: Will EHR Modules be tested to ensure integration between different EHR Modules?

A: EHR Module-to-EHR Module integration will not be tested due to the impracticalities presented by the numerous combinations possible and the associated technical, logistical, and financial costs.

Q: What is a CHPL?

A: The National Coordinator intends to make a master Certified HIT Products List (CHPL) of all Complete EHRs and EHR Modules tested and certified by ONC-ATCBs available on the ONC website. The CHPL will be a public service and would integrate into a single aggregate source all certified product information. The CHPL would also represent all of the Complete EHRs and EHR Modules that could be used to meet the definition of Certified EHR Technology.

Q: What does “testing to the first paragraph level” mean?

A: In the preamble of the Proposed Rule, ONC clarified that a single certification criterion would encompass all of the specific capabilities referenced below the first paragraph level. For example, a certification criterion (first paragraph) relates to recording and charting vital signs. This criterion includes three specific capabilities (second paragraph); the ability to record, modify, and retrieve patients’ vital signs; and the ability to calculate body mass index (BMI); and the ability to plot display growth charts. The entire set of specific capabilities required by the paragraph is one certification criterion.



Q: Can testing and certification be accomplished on-site?

A: On-site testing and certification can be costly and inefficient. Therefore, an ONC-ATCB is not required to provide this service. However, some ONC-ATCBs might want to offer such testing and certification if justified by market demand.

Q: Does a Complete EHR or EHR Module have to “be live at a customer’s site” in order to qualify for testing and certification?

A: No, an ONC-ATCB is required to provide remote testing and certification for both development and deployment sites.

Q: What happens to the certifications issued by previous recognized certification bodies?

A: As noted in the Proposed Rule, CCHIT is the only organization that has both applied and been granted “recognized certification body” status under the ONC’s Certification Guidance Document (CGD). As implied in the Proposed Rule and the CGD, all “recognized certification bodies” will lose their status upon the effective date of the final rule. As a result, they will need to reapply to become an ONC-ATCB in order to be a “recognized certification body” after the effective date of the final rule.

Q: What happens to certifications made in 2009 and 2010 by a “recognized certification body?”

A: It is important to note that regardless of whether EHRs certified in 2009 and 2010 by a “recognized certification body” qualify for donation under the EHR exception and safe harbor, these EHRs will not meet the definition of Certified EHR Technology and therefore must be recertified by an ONC-ATCB in order to be used by an eligible professional or eligible hospital to demonstrate meaningful use.

Q: My EHR was CCHIT certified in 2009. Do I have certified technology to demonstrate meaningful use?

A: No. Grandfathering would essentially involve a determination by the National Coordinator that existing EHR systems developed by vendors and self-developers, as well as those systems being used by providers in a possible modified state, are equivalent to the definition of Certified EHR Technology and thus are capable of being used to achieve meaningful use.

Q: Will my EHR lose certification if a modification is made after achieving certification?

A: Any modification to a Complete EHR or EHR Module after it has been certified has the potential to jeopardize the proper operation of the Complete EHR or EHR Module and thus the eligible professional or eligible hospital’s ability to achieve meaningful use. If an eligible professional or eligible hospital would like absolute assurance that any modifications made did not impact the proper operation of certified capabilities, they may find it prudent to seek to have the Complete EHR or EHR Module(s) retested and recertified.



Q: Can my previously certified Complete EHR or EHR Module be updated for routine maintenance without its certification becoming invalid?

A: A previously certified Complete EHR or EHR Module may be updated for routine maintenance or to include new capabilities that both affect capabilities related and unrelated to the certification criteria adopted by the Secretary without its certification becoming invalid. However, ONC does not believe that it would be wise to simply permit a Complete EHR or EHR Module developer to claim without any verification that the routine maintenance or new/modified capabilities included in a new version did not adversely affect the proper functioning of the previously certified capabilities. ONC believes that an ONC-ATCB should, at a minimum, review an attestation submitted by a Complete EHR or EHR Module developer indicating the changes that were made, the reasons for those changes, and other information and supporting documentation necessary to properly assess the potential effects the new version would have on previously certified capabilities.

Q: How often will certification criteria be changed?

A: ONC and CMS anticipate that the requirements for meaningful use will be adjusted every two years. They do not expect to adjust certification criteria more frequently than every two years. Additionally, there is the possibility that the requirements for an eligible professional or eligible hospital to meet meaningful use Stage 1 in 2013 (or 2014) could be different and possibly more demanding than they were for meaningful use Stage 1 in 2012. The potential exists that an eligible professional or eligible hospital who becomes a meaningful user in 2012 would need additional, not currently present, capabilities from Certified EHR Technology in order to meet meaningful use Stage 1 requirements in 2013.

Q: How will open source Complete EHRs and EHR Modules be tested?

A: Open source Complete EHRs and EHR Modules will be tested and certified in the same manner as proprietary Complete EHRs and EHR Modules under the temporary certification program.