

**Summary of Final Rule
Temporary Certification Program for Health Information Technology**

[RIN 0991-AB59]

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Introduction

On June 18, 2010, the Office of the National Coordinator (ONC) for Health Information Technology (HIT) put on public display at the Office of the *Federal Register* a final rule establishing a temporary certification program for HIT. The final rule will be effective upon publication in the *Federal Register*, which is slated for June 24, 2010 (the Secretary finds good cause for waiving the usual 30-day delay in the effective date).

Under the temporary certification program, ONC will select one or more ONC-Authorized Testing and Certification Bodies (ONC-ATCBs) to both test and certify complete electronic health records (EHRs) and/or EHR Modules. ONC now anticipates that 5 organizations will apply for ONC-ATCB status (compared to the 3 estimated in the proposed rule). The temporary certification program 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.

The final rule responds to the 84 comments received regarding the proposed temporary certification program.

Testing and Certification

In response to concerns that ONC-ATCBs would have too much discretion in applying certification criteria, the final rule makes clear that the primary responsibility of ONC-ATCBs is to apply the certification criteria adopted by the Secretary. Further, the final rule specifies that ONC-ATCBs must offer a testing and accreditation option using only the certification criteria adopted by the Secretary, although they may also offer options that include additional requirements. With respect to options involving such additional requirements, ONC says it would expect an ONC-ATCB to give due notice of any changes it intends to make in its certification requirements and take into account the views of interested parties before deciding on the precise form and effective date of the changes.

The final rule retains the option for ONC-ATCBs to request approval for testing and certifying either Complete EHRs or EHR Modules. In response to comments recommending that ONC-ATCBs testing and certifying complete EHRs be allowed to focus only on ambulatory or inpatient EHRs, ONC says this would be “inappropriate at this time” but adds that it will “reconsider this option for the permanent certification program.” The final rule does retain the provision

allowing an ONC-ATCB to apply to test and certify EHR Modules that address only an ambulatory or inpatient setting. In addition, the final rule makes clear that an ONC-ATCB authorized to test and certify Complete EHRs “would also have the capability and, more importantly, the authorization from the National Coordinator to test and certify EHR Modules” but adds that ONC does not believe it would be appropriate to require them to do so.

In response to comments asking that ONC-ATCBs testing and certifying EHR Modules be required to determine whether a Module integrates or is compatible with other Modules, ONC says this “is inappropriate for the temporary certification program due to various impracticalities” although it also adds that nothing in the final rule would preclude an ONC-ATCB from offering a service to test and certify Module-to-Module integration.

Application Process

The final rule retains the requirement that ONC-ATCBs fully comply with International Organization for Standardization (ISO) 17025 (General Requirements for the Competence of Testing and Calibration Laboratories) and ISO Guide 65 (General Requirements for Bodies Operating Product Certification Systems), thereby rejecting comments recommending only “material compliance” with these requirements or a “glide path that would allow qualified organizations to move towards compliance in a systematic way.”

The final rule also retains the proposed two-part application.

The final rule notes that ONC has requested the assistance of the National Institute of Standards and Technology (NIST) in developing test tools and test procedures that ONC-ATCBs could use to properly and consistently test and certify EHR products, and states ONC’s expectation that NIST will develop a test tool and test procedure for each and every EHR certification criterion. In response to questions about NIST’s role and scope of authority with respect to test tools and procedures, the final rule revises the Principles of Proper Conduct for ONC-ATCBs to clearly state that the National Coordinator will play the central role in determining which test tools and test procedures are approved for ONC-ATCB use (thereby removing the vague reference to “functionally equivalent” test tools and procedures published by an entity other than NIST). The final rule emphasizes that these approved test tools and procedures could include not only NIST test tools and procedures but those identified or developed by other organizations. It also notes that when the National Coordinator has approved test tools or procedures, a notice of availability will be published in the *Federal Register* and the approved test tools and procedures will also be identified on the ONC website.

In terms of ONC oversight of ONC-ATCBs, the final rule retains the option to either conduct scheduled or unannounced visits. In response to concerns about

potential privacy or confidentiality issues that might arise during such visits, ONC says it expects that any confidentiality agreement executed between an ONC-ATCB and a customer, such as Complete EHR and EHR Module developers, would include ONC and its authorized representatives as parties who may observe the testing and certification of the customer's EHR product(s).

The final rule retains the proposed requirement for ONC-ATCBs to provide ONC, no less frequently than weekly, a current list of Complete EHRs and/or EHR Modules that have been tested and certified, but clarifies that the weekly reports would be "updates" (requiring the identification of EHR products tested and certified since the last report, rather than a full listing of all products tested and certified to date). ONC rejects a comment recommending that ONC-ATCBs also identify products in the testing and certification queue.

The final rule does add two elements to the list of information to be reported by ONC-ATCBs: (1) the clinical quality measures to which a Complete EHR or EHR Module has been tested; and (2) any additional software a Complete EHR or EHR Module relied upon to demonstrate its compliance with a certification criterion or criteria. Further, ONC notes that it does not preclude ONC-ATCBs from including in their weekly reports information not specifically required but that prospective purchasers and users of EHR products would find useful, such as a product's compatibility with other software or other EHR Modules; if such information is not reported to ONC, ONC-ATCBs are encouraged to consider making the additional information available on their own websites. In any case, ONC intends to make a master Certified HIT Products List (CHPL) available on its website, and adds that only ONC should maintain the CHPL (rather than allowing individual ONC-ATCBs to do so) to ensure that it is accurate and complete. An ONC-ATCB could, nevertheless, maintain on its website a list of products it has tested and approved and/or create a link to the CHPL.

The final rule also maintains the proposed requirement for ONC-ATCBs to retain all records related to tests and certifications in accordance with Guide 65 and ISO 17025, but clarifies that ONC-ATCBs will be required to provide copies of the final results of all completed tests and certifications to ONC upon conclusion of the temporary certification program. The final rule also states that ONC will retain all records received from ONC-ATCBs "in accordance with applicable federal law" but fails to directly respond to comments indicating that the record retention period for ATCBs and ONC should be 10 years (the proposed retention period for eligible professionals and eligible hospitals under a related regulation issued by the Centers for Medicare & Medicaid Services) "plus two or more additional years to ensure that records are available during an audit."

The final rule clarifies the proposed refund requirement for ONC-ATCBs to specify that refunds are required only in situations where an ONC-ATCB's conduct caused testing and certification not to be completed, which would include situations where an EHR product must be recertified because of the

conduct of an ONC-ATCB and where an EHR product developer withdraws a request for testing and certification while an ONC-ATCB is under suspension (see below for additional discussion).

In response to comments regarding the Principles of Proper Conduct for ONC-ATCBs, ONC states that the requirements of Guide 65 and ISO 17025 require ONC-ATCBs to develop an impartial process for handling requests for EHR testing and certification (for example, one not conditioned upon the size of the product developer, membership in any association or group, or the number of certificates already issued). Further, ONC rejects comments recommending that ONC-ATCBs be required to complete EHR testing and certification within six months of a request, arguing that such a requirement would not be “equitable or enforceable” in light of the uncertainty about how many ONC-ATCBs will exist and how many requests for EHR product testing and certification will be received.

Application Review, Application Reconsideration, and ONC-ATCB Status

The final rule retains the proposed two-part application review process and the plan to review applications in the order they are received. In response to comments, it revises language under which ONC could have requested corrections only of “inadvertent errors or minor omissions” to give the National Coordinator more flexibility to request corrections to an application rather than issue a formal deficiency notice. In addition, the final rule now provides an opportunity for an applicant for ONC-ATCB status to request an extension of the 15-day period to submit a revised application in response to a deficiency notice; such a request could be granted “upon a showing of good cause” (for example, factors such as a change in ownership or control of the applicant organization; the unexpected loss of a key member of the applicant’s personnel; and damage to or loss of use of the applicant’s facilities, working environment or other resources). While commenters had suggested a 15-day extension, ONC considers it unnecessary to establish a predetermined length of time, preferring to base the extension period on an applicant’s particular circumstances that constitute good cause for an extension.

ONC also revises the proposed rule to permit the National Coordinator to request clarification of statements and the correction of errors or omissions in a revised application during the 15-day period that the National Coordinator has to review such revised application.

The final rule adopts as final ONC’s proposal to reconsider an ONC-ATCB application only if the applicant can demonstrate that there was a clear factual error in the review of the application that could lead to the applicant obtaining ONC-ATCB status. In addition, as originally proposed, it states that ONC will make publicly available the names of ONC-ATCBs, including the date each was authorized and the type(s) of testing and certification each has been authorized to perform.

Testing and Certification of Complete EHRs and EHR Modules

The final rule adopts as final the requirement that EHR Module testing and certification be at the paragraph level of a certification criterion, rather than allowing testing and certification to occur at a lower (subparagraph) level. However, ONC acknowledges comments about apparent problems with the “drug-drug, drug-allergy, drug-formulary checks” certification criterion and the “incorporate clinical lab-test results into EHR as structured data” certification criterion but concludes that these matters are more appropriately suited for discussion and resolution in the forthcoming final rule on the certification criteria themselves.

In terms of privacy and security certification criteria, ONC rejects comments recommending that ONC deem them “addressable.” The final rule does significantly change the proposed handling of EHR Modules. In the proposed rule, each such Module would need to meet privacy and security certification criteria unless one of the following applied:

- The EHR Module(s) are presented as a pre-coordinated, integrated “bundle” of EHR Modules, which could otherwise constitute a Complete EHR, and which would be tested and certified in the same manner as a Complete EHR (rather than testing and certifying each Module), unless the coordinated bundles of EHR Modules include EHR Module(s) that would not be part of an eligible professional or eligible hospital’s local system and under its direct control (e.g., a patient portal EHR Module that is not hosted and maintained).
- The EHR Module developer demonstrates that it would be technically infeasible for the EHR Module to be tested and certified in accordance with some or all of the privacy and security certification criteria (e.g., in the case of an EHR Module that does not store or maintain any health information).
- The EHR Module developer demonstrates that the EHR Module is designed to perform a specific privacy and security capability (not all of them).

In contrast, the final rule includes only the first and second exceptions, and also modifies the second exception to refer to “inapplicable” criteria as well as those where testing and certification would be “technically infeasible.” ONC also clarifies that where an integrated bundle of EHR Modules is presented for testing and certification and one or more of the constituent Modules is/are demonstrably responsible for providing all of the privacy and security capabilities for the entire bundle, that the other Modules in the bundle would be exempt from being tested and certified to adopted privacy and security certification criteria. The final wording on this matter is as follows:

EHR Modules shall be tested and certified to all privacy and security certification criteria adopted by the Secretary unless the EHR Module(s) is/are presented for testing and certification in one of the following manners:

- 1) The EHR Module(s) is/are presented for testing and certification as a pre-coordinated, integrated bundle of EHR Modules, which would otherwise meet the definition of and constitute a Complete EHR...and one or more of the constituent EHR Modules is/are demonstrably responsible for providing all of the privacy and security capabilities for the entire bundle of EHR Module(s); or
- 2) An EHR Module is presented for testing and certification, and the presenter can demonstrate to the ONC-ATCB that a privacy and security certification criterion is inapplicable or that it would be technically infeasible for the EHR Module to be tested and certified in accordance with such certification criterion.

Note that EHR Modules tested and certified as an integrated bundle will be listed as such on ONC's master CHPL.

The Testing and Certification of "Minimum Standards"

The proposed rule had spoken to the issue of treating certain vocabulary code set standards as "minimum standards," thereby allowing a Complete EHR and/or EHR Module to be tested and certified to a permitted newer version of an adopted code set without the need for additional rulemaking and allowing certified EHR technology to be upgraded to a permitted newer version of a code set without adversely affecting its certified status. Further, ONC had proposed two methods for identifying new versions of adopted "minimum standard" code sets (notification of the National Coordinator by the general public and proactive identification by the Secretary). The final rule retains the concept of "minimum standards" and adopts as final both methods for identifying new versions of such standards. In doing so, ONC emphasizes that if the Secretary accepts a newer version of a "minimum standard" code set, nothing is required of ONC-ATCBs, Complete EHR or EHR Module developers, or the eligible professionals and eligible hospitals who have implemented certified EHR technology (until the Secretary incorporates by reference a newer version of that code set).

In terms of such newer versions, the National Coordinator would ask the HIT Standards Committee to assess and solicit public comment on a new version. And after considering the recommendation of the HIT Standards Committee, the National Coordinator would determine whether or not to seek the Secretary's acceptance of the new version.

Authorized Testing and Certification Methods

The proposed rule had identified the ONC-ATCB's facility as the primary EHR testing site and also proposed that an ONC-ATCB have the capacity to test and certify EHR technology through one of three secondary methods (at the site where the technology has been developed, at the site where the technology resides, or remotely, i.e., through other means, such as through secure electronic transmissions and automated web-based tools, or at a location other than the ONC-ATCB's facilities). The final rule instead identifies remote testing (for both development and deployment sites) as the required testing method, in recognition that this is currently the predominant testing method. It also permits (but does not require) the ONC-ATCB to offer testing and certification at its facility or at the physical location of a development or deployment site (that is, where EHR technology was developed, or where it resides or is being or has been implemented, respectively).

The final rule also clarifies that a Complete EHR or EHR Module need not be "live at a customer's site" in order to qualify for testing and certification.

Good Standing as an ONC-ATCB, Revocation of ONC-ATCB Status, and Effect of Revocation on Certifications Issued by a Former ONC-ATCB

In the final rule, ONC indicates that it intends to monitor compliance with the Principles of Proper Conduct for ONC-ATCBs on an ongoing basis. It preserves the concept of Type-1 and Type-2 violations, with Type-1 violations including violations of law or temporary certification program policies that threaten or significantly undermine the integrity of the temporary certification program (such as false, fraudulent, or abusive activities) and Type-2 violations including failure to adhere to the Principles of Proper Conduct for ONC-ATCBs and engaging in other inappropriate behavior.

In the final rule, ONC rejects comments suggesting that it should consider revoking an ONC-ATCB's status for committing multiple Type-2 violations even if the violations were corrected. However, in response to a number of comments, ONC agrees that it should have the ability to suspend an ONC-ATCB's operations when there is reliable evidence indicating that the ONC-ATCB committed a Type-1 or Type-2 violation and that the continued testing and certification of Complete EHRs and/or EHR Modules could have an adverse impact on patient health or safety (although ONC adds that it believes that such suspension would be appropriate "in only limited circumstances"). An ONC-ATCB would have up to 3 days to submit a written response to the National Coordinator explaining why its operations should not be suspended and the National Coordinator would have up to 5 days to review this written response and make a determination. The suspension authority would be in addition to the proposed option of revoking an ONC-ATCB's status if the National Coordinator has reliable evidence that the ONC-ATCB committed a Type-1 violation, or the

ONC-ATCB has been notified of a Type-2 violation and failed to rebut the finding of violation (with sufficient evidence showing that the violation did not occur or has been corrected) or to respond to the notification.

In terms of the effect on the certification status of EHR technology previously tested and certified by an ONC-ATCB whose status is subsequently revoked, the final rule begins by asserting ONC's belief that "it would be an extremely rare occurrence for an ONC-ATCB to have its status revoked and for the National Coordinator to determine that Complete EHRs and/or EHR Modules were improperly certified." However, if this should occur, the final rule specifies that retesting and recertification by an ONC-ATCB are the only means by which to ensure that the EHR technology satisfies the certification criteria.

The proposed rule had specified that affected technology would retain its certified status only for 120 days after publication of the ONC notice that the technology had been improperly certified. Although many commenters recommended a much longer "grace period" (6 to 18 months), the final rule retains the 120-day period and does not directly respond to the comments recommending a longer "grace period." Finally, ONC says that any decertification of EHR technology will be made widely known by ONC through publication on its website and list serve, which ONC believes will help eligible professionals or eligible hospitals identify whether the certified status of their EHR technology is still valid.

Sunset of the Temporary Certification Program

As noted earlier, the final rule specifies that the temporary certification program 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. On and after the sunset date, ONC-ATCBs will be prohibited from accepting new requests to test and certify EHR technology (as originally proposed). Further, they will be permitted up to six months after the sunset date to complete all testing and certification activities associated with respect to requests received prior to the sunset date (the proposed rule had not specified a time limit for this work); if these activities are not completed prior to the end of the 6-month period, the EHR technology would have to be resubmitted for testing and certification under the permanent certification program.

In response to comments recommending that the temporary certification program not sunset until there were at least two ONC-Authorized Certification Bodies (ONC-ACBs) under the permanent certification program, the final rule states that in determining whether the permanent certification program is fully constituted, ONC will consider whether there are a sufficient number of ONC-ACBs and accredited testing laboratories to address the current market demand. ONC rejects comments recommending that the temporary certification program apply during meaningful use Stage 1 and that the permanent certification program

apply to subsequent stages, arguing that this framework could mean that the temporary program would last longer than is necessary.

Recognized Certification Bodies as Related to the Physician Self-Referral Prohibition and Anti-Kickback EHR Exception and Safe Harbor Final Rules

ONC adopts as final its proposal to treat the ONC-ATCB and ONC-ACB authorization processes as the EHR certification body “recognition” process for purposes of the physician self-referral prohibition exception and anti-kickback statute safe harbor for donations of EHR software. Thus, the currently recognized body, the Certification Commission for Health Information Technology (CCHIT), will lose its “recognition status” upon the effective date of the final rule (June 24, 2010) and would need to reapply to become an ONC-ATCB (and in the future an ONC-ACB) in order to be a “recognized certification body” for physician self-referral and anti-kickback rule purposes. However, the final rule emphasizes that the loss of recognition status on June 24, 2010, does not impact certifications made by CCHIT while it was recognized.

Grandfathering

Many commenters suggested that ONC and the Centers for Medicare & Medicaid Services provide for some kind of grandfathering in determining whether a given EHR technology is or is not certified for purposes of qualifying for Medicare and Medicaid EHR incentive payments (for example, by recognizing previous certifications by CCHIT). Despite this, ONC concludes that grandfathering is inappropriate and would be inconsistent with the statutory requirements for certified EHR technology specified under the Health Information Technology for Economic and Clinical Health (HITECH) Act.

Concept of “Self-Developed”

Multiple hospitals and hospital associations requested that ONC clarify the definition of “self-developed” EHR technology, fearing that custom configurations or settings or other changes made to certified EHR might trigger the need to have the modified EHR technology certified as a self-developed product at the hospital’s or hospital system’s expense. In response, ONC says it would be “unrealistic” to expect that certified EHR technology will remain “100% unmodified in all cases” and agrees that it is possible for an eligible professional or eligible hospital to modify a Complete EHR to EHR Module’s certified capability “provided that due diligence is taken to prevent such a modification from adversely affecting the certified capability or precluding its proper operation.” Nevertheless, it concludes by saying that 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.”

Validity of Complete EHR and EHR Module Certification and Expiration of Certified Status

In the final rule, ONC calls attention to 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 2011 and 2012. This causes ONC to conclude that the certification status of EHR technology cannot be “by stage” and that, for example, a Complete EHR would need to be retested and recertified as being compliant with a newly adopted standard for the 2013/2014 certification period in order for a Complete EHR developer, an eligible professional, or an eligible hospital to validly assert that the certification issued for the Complete EHR enables it to meet the definition of Certified EHR Technology. In other words, “[r]egardless of the year and meaningful use stage at which an eligible professional or eligible hospital enters the Medicare or Medicaid EHR Incentive Program, the Certified EHR Technology that they would need to use would have to include the capabilities necessary to meet the most current certification criteria adopted by the Secretary.” ONC goes on to say that it anticipates that “the testing and certification of Complete EHRs and EHR Modules to the [planned] 2013/2014 certification criteria would need to begin by mid-2012 in order for Complete EHRs and EHR Modules to be retested and recertified prior to the start of the next meaningful use reporting period.”

In light of the above, ONC adds a new Principle of Proper Conduct for ONC-ATCBs mandating that all certifications require that a Complete EHR or EHR Module developer conspicuously include the following text on its website and in all marketing materials, communications statements, and other assertions related to the EHR technology’s certification:

- “This [Complete EHR or EHR Module] is 201[X]/201[X] compliant [with ONC-ATCBs expected to put 2011/2012 here] and has been certified by an ONC-ATCB in accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services. This certification does not represent an endorsement by the U.S. Department of Health and Human Services or guarantee the receipt of incentive payments.”; and
- The information an ONC-ATCB is required to report to the National Coordinator for the specific Complete EHR or EHR Module at issue.

The final rule also makes clear that a certification issued to an integrated bundle of EHR Modules must be treated the same as a certification issued to a Complete EHR for the purposes of the above requirements except that it must also indicate each EHR Module that comprises the bundle. Further, it notes that individual EHR Modules certified as part of a bundle would not separately “inherit

a certification just because they were certified as part of a bundle” unless the EHR Module developer sought and received a positive certification decision from an ONC-ATCB (or an ONC-ACB) for the individual EHR Modules.

ONC also received comments about the implications for an EHR technology’s certification status of “bug-fixes and other maintenance upgrades” (normally identified by a new “dot release” such as version 7.1.1 when 7.1 received certification). In the final rule, ONC clarifies that 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 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 such information and supporting documentation that would be necessary to properly assess the potential effects the new version would have on previously certified capabilities.” The ONC-ATCB would determine whether the updates and/or modifications adversely affect previously certified capabilities and therefore need to be retested and recertified, or whether to grant certified status to the new version without additional testing. If the ONC-ATCB awards a certification to a newer version of a previously certified EHR product, it would need to include this action in its weekly report to the National Coordinator. ONC adds that it is not specifying the fees or any other processes an ONC-ATCB may determine necessary before granting certified status to a newer version of a previously certified EHR product based on the submitted attestation. ONC also does not attempt to estimate the volume of work that reviews of newer versions of previously certified EHR technology will entail.

A discussion of the issue of differential certification is deferred to the final rule relating to the permanent certification program.

Collection of Information Requirements

In the final rule, ONC estimates that two of the applicants for ONC-ATCB status may need to perform more upfront work to prepare to apply for such status. More specifically, ONC estimates that such applicants would need about 400 hours each to perform a gap analysis and become conformant with Guide 65 and ISO 17025. The other three expected applicants are presumed to already be Guide 65- and ISO 17025-compliant.

Regulatory Impact Analysis

In the final rule, ONC states that it is open to revising its cost estimates based on public comment but that commenters did not provide alternative estimates or reference additional information from which ONC could base revisions. The final rule does assume that there will now be 5 (rather than 3) applicants for ONC-

ATCB status and also assumes a potentially larger number of self-developed EHR Modules will seek ONC-ATCB testing and certification (10 to 67 designed for the ambulatory setting and 318 to 959 designed for the inpatient setting; the proposed rule assumed that there would only be commercial or open source EHR Modules seeking ONC-ATCB testing and certification).

ONC rejects any notion that it should dictate the minimum or maximum amount an ONC-ATCB can charge for testing and certifying EHR technology. It does assume that competition in the testing and certification market will reduce the costs of testing and certification as estimated by CCHIT (\$30,000 to \$50,000 for Complete EHRs and \$5,000 to \$35,000 per EHR Module) but says it is unable to provide a reliable estimate at this time of what the potential reduction in costs might be.

The regulatory impact analysis ignores the potential implications of ONC's expectation that EHR technology developers will seek ONC-ATCB review of new versions of previously certified EHR technology (that is, those due to "bug-fixes and other maintenance upgrades").