

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

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Introduction

On January 3, 2011, the Office of the National Coordinator (ONC) for Health Information Technology (HIT) placed on public display the final rule establishing a permanent certification program for HIT. This final rule will be published in the January 7, 2011 issue of the *Federal Register* and is effective on February 7, 2011. A related proposed rule was published in the March 10, 2010 issue of the *Federal Register*.

The permanent certification program will become operational on January 1, 2012 or on a subsequent date if the program is not fully constituted at that time, replacing the current, temporary certification program (established under a final rule published on June 24, 2010). Under the permanent program, ONC will select a single ONC-Approved Accreditor (ONC-AA), which will be responsible for accrediting ONC-Authorized Certification Bodies (ONC-ACBs). These ONC-ACBs will, in turn, be responsible for certifying HIT products against applicable certification criteria adopted by the Secretary of Health and Human Services (HHS). ONC estimates that 6 organizations will apply for ONC-ACB status under the permanent certification program; 5 organizations are now serving as ONC-

Authorized Testing and Certification Bodies (ONC-ATCBs) under the temporary certification program.

The initial focus of the permanent program will be on the certification of Complete Electronic Health Records (EHRs) and EHR Modules, but the program could eventually be expanded to other types of HIT provided that applicable certification criteria for such additional HIT types have been adopted by the Secretary. In addition to certification, the permanent program also assumes that the National Voluntary Laboratory Accreditation Program (NVLAP), as administered by the National Institute of Standards and Technology (NIST), will solely be responsible for accrediting HIT testing laboratories and determining their competency; accredited laboratory test results would be analyzed by ONC-ACBs as part of their HIT certification process. The final rule confirms that ONC-ACBs may also become accredited HIT testing laboratories.

ONC-AA Status and Responsibilities

ONC had proposed to process ONC-AA applications in the order received. In response to comments, the final rule now provides that the selection of a single ONC-AA will be made under a competitive process that will allow the ONC to select from among competing applications. Thus, interested parties will be given 30 days to submit an application (with the submission period announced by notice in the *Federal Register*) and ONC will have up to 60 days to review all submitted applications and make a selection. Any organization that submits a timely request for ONC-AA status and is denied may request reconsideration but, to be successful, it must demonstrate that clear, factual errors were made in the review of its request for ONC-AA status and that it would have been selected as the ONC-AA if those errors had been corrected. Note that under this policy, the applicant initially informed of its selection as the ONC-AA could lose the award if another party's reconsideration request is successful (the regulation text makes clear that an organization selected as the ONC-AA on a preliminary basis "cannot request reconsideration or further review" if another organization's reconsideration request is ultimately successful). In addition, ONC's reconsideration decision is final and not subject to further review.

The ONC-AA will have a 3-year term (as originally proposed). In response to comments, ONC agrees that requests for ONC-AA status should be accepted at least 180 days prior to expiration of the then-current ONC-AA's status, rather than the proposed 120 days.

In response to comments, ONC says it does not believe that it is necessary or appropriate to require the ONC-AA to be recognized under the NIST National Voluntary Conformity Assessment Evaluation (NVCASE) program or as a signatory to the Internal Accreditation Forum's Mutual/Multilateral Recognition Agreement (MRA). ONC also rejects comments recommending that the ONC-AA submit annual reports of the results of its responsibilities.

Correspondence

The final rule confirms that applicants for ONC-ACB status and ONC-ACBs will generally be required to communicate with ONC by email, and applies the same requirement to organizations submitting requests for ONC-AA status and the ONC-AA.

Certification Options for ONC-ACBs

In response to commenters concerned that ONC-ACBs would have too much discretion related to certification, the final rule notes that the ONC-AA will be required to verify that ONC-ACBs continue to conform to International Organization for Standardization (ISO) Guide 65, General Requirements for Bodies Operating Product Certification Systems, but declines to “dictate every specific aspect related to an ONC-ACB’s certification program operations.” ONC also makes clear that the primary responsibility of ONC-ACBs is to certify HIT products in accordance with certification criteria adopted by the Secretary. The final rule also makes it “explicitly clear” that an ONC-ACB must offer the option for an HIT product to be certified solely to the applicable certification criteria adopted by the Secretary. However, an ONC-ACB may offer multiple options for certification of HIT, some of which could involve additional criteria, but any certifications based solely on the Secretary’s criteria must be “separate and distinct” from any other certification(s) based on other criteria or requirements.

As is the case for ONC-ATCBs under the temporary HIT certification program, ONC-ACBs will not be allowed to seek authorization to certify Complete EHRs for only ambulatory or only inpatient settings. Also, ONC rejects comments seeking inclusion of a mandatory provision requiring ONC-ACBs to certify whether two or more EHR Modules are compatible, arguing that this “would not be prudent due to various impracticalities,” including the number of potential combinations of EHR Modules. However, the final rule adds that nothing precludes an ONC-ACB from offering a service to certify EHR Module-to-EHR Module integration, but emphasizes that any such service would be provided “without specific authorization from the National Coordinator and will not be considered part of the permanent certification program.” Finally, ONC notes that an ONC-ACB is only permitted to certify a pre-coordinated, integrated bundle of EHR Modules (from one or more developers) if the bundle is capable of meeting all of the applicable certification criteria and would otherwise meet the definition of and constitute a Complete EHR.

ONC-ACB Application Process

ONC-ACB applicants planning to certify only EHR Modules will need to identify as part of their application the certification criterion or criteria that they believe should be included within the scope of their authorization.

ONC rejects comments suggesting the need for the personnel of ONC-ACB applicants to pass a certain exam or possess certain credentials.

The final rule provides for a more streamlined process for ONC-ACBs that want to expand the scope of their current authorization; such ONC-ACBs would not be required to re-submit all the information originally required in the first ONC-ACB application unless any of that information had changed since it was last provided to ONC.

In the final rule, ONC maintains the option to conduct either scheduled or unannounced visits of ONC-ACB sites (as originally proposed) but clarifies that any such visits will be conducted during normal business hours. ONC further notes that it expects ONC-ACBs will take the necessary steps to address any potential confidentiality issues with their customers (for example, through a confidentiality agreement that would enable ONC and its authorized representatives to observe the certification of a customer's HIT).

As originally proposed, ONC-ACBs will be required to provide ONC, no less frequently than weekly, with a current list of Complete EHRs and/or EHR Modules that have been certified (since the last weekly report); they may, however, provide more frequent updates, and all updates must be provided electronically. As part of these reports, ONC-ACBs will be required to note the clinical quality measures to which a Complete EHR or EHR Module has been certified and, where applicable, any additional software that a Complete EHR or EHR Module relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary. ONC-ACBs will also be expected to identify any pre-coordinated, integrated bundle of EHR Modules that they certify and the list of constituent EHR Modules that comprise each bundle, and, where applicable, the certification criterion or criteria to which each constituent EHR Module has been certified. ONC agrees that ONC-ACBs may include in the reports submitted to ONC information about certified HIT products beyond what ONC requires. On the other hand, ONC rejects comments recommending that ONC-ACBs report on the number of products in the certification queue, noting that the time needed for the certification of HIT products "will likely vary based on many factors and, in some cases, may not be completed due to various reasons."

The final rule confirms ONC's plan to maintain a Certified Health Information Technology Products List (CHPL) as the single, aggregate source of all certified Complete EHRs and EHR Modules reported to ONC by ONC-ACBs. The CHPL webpage will include a unique identifier (e.g., an alphanumeric identifier) for each certified Complete EHR and each combination of certified EHR Modules that meets the definition of Certified EHR Technology; the unique identifier could subsequently be used to submit to the Centers for Medicare & Medicaid Services (CMS) for attestation purposes. The final rule notes that an ONC-ACB is not

precluded from maintaining on its own website a list of HIT products that it has certified.

The final rule requires ONC-ACBs to retain all records related to the certification of Complete EHRs and/or EHR Modules for a minimum of 5 years (as originally proposed).

The final rule emphasizes that only test tools and test procedures that have been approved by ONC can be used by NVLAP-accredited testing laboratories to test HIT products; any person or entity may submit a test tool or procedure for ONC approval, and approved test tools and procedures will be identified on the ONC website and a notice of their availability published in the *Federal Register*. ONC rejects a comment recommending creation of an advisory board for the development of test tools and procedures but notes that ONC will consider whether public feedback was part of the process for developing any test tool or procedure submitted for ONC approval. ONC further notes that many of the test tools and procedures developed by NIST and approved for the temporary certification program will likely be applicable to and may be approved for use under the permanent program, and that it expects to continue to consult with NIST in the development of test tools and procedures.

The final rule also makes clear that an ONC-ACB may only certify HIT that has been tested by a NVLAP-accredited testing laboratory (or, in some cases, by an ONC-ATCB under the temporary certification program). In addition, consistent with Guide 65, an ONC-ACB will be expected to undertake surveillance activities to determine whether HIT products it has certified continue to perform “in the field” or in a “live” environment as they did when they were certified. Moreover, an ONC-ACB’s surveillance results must indicate the reason(s) behind an HIT product’s failure to function properly, such as an implementation error, a misapplication by a user, or other factors. ONC anticipates issuing guidance on an annual basis in order to identify specific elements of surveillance that it considers to be a priority. Further, in response to a comment, ONC agrees that the ONC-AA should be responsible for ensuring that all ONC-ACBs will use similar and comparable surveillance approaches, including the use of consistent, objective, valid and reliable methods.

The final rule notes that Guide 65, Section 15 instructs an ONC-ACB to ensure that the developers of the HIT that it certifies have a process in place for receiving and addressing complaints related to certified products. ONC also says that eligible professionals (EPs) and eligible hospitals may also have the opportunity to provide feedback about the capabilities of HIT products in those cases where they are contacted by an ONC-ACB to participate in surveillance. ONC also expects that Complete EHR and EHR Module developers will be provided an opportunity to give input to an ONC-ACB, where appropriate, regarding the surveillance results obtained by the ONC-ACB prior to it reporting such results to ONC. Note that while the proposed rule indicated ONC’s

expectation that surveillance results would be publicly available, ONC now says that it has not yet determined “whether or in what form these results will be made available” [emphasis added]. ONC also declines to use the final rule to establish a process for the decertification of Complete EHRs and/or EHR Modules. ONC adds that if it determines that unsatisfactory surveillance results are not being addressed, or if the results indicate certified HIT products are adversely affecting public health or safety or the programmatic goals of the permanent certification program, it “will consider what steps are necessary to respond to the particular situation at issue at that time.”

ONC rejects comments suggesting the need for additional principles of proper conduct for ONC-ACBs (relating to impartiality and business practices), arguing that these matters are already adequately addressed by Guide 65. ONC also rejects a comment urging that ONC-ACBs be required to complete requested HIT product certifications within six months, arguing that a predetermined timeframe “is not realistic because the time it takes for a product to be certified will likely vary based on factors such as the current number of ONC-ACBs, the volume of requests for certification, the type of product that is submitted for certification, and an ONC-ACB’s specific business practices.” ONC also rejects comments recommending restrictions on the number of ONC-ACBs or “arbitrary” eligibility requirements (such as requiring an ONC-ACB applicant to be a not-for-profit organization).

ONC-ACB Application Review, Reconsideration, and ONC-ACB Status

The final rule provides more flexibility for ONC to informally request that ONC-ACB applicants correct errors and omissions in their applications (instead of issuing a deficiency notice) and applies this same flexibility during reviews of revised applications. Further, in response to a comment, ONC agrees to give itself the discretion, upon a showing of good cause by an ONC-ACB applicant, to grant an extension beyond 15 days for an applicant to submit a revised application in response to a deficiency notice (ONC considers it unnecessary to establish a predetermined period of time for good cause extensions). The final rule also allows an unsuccessful applicant to reapply for ONC-ACB status; a denial notice will indicate that the applicant cannot reapply for a period of six months from the date of the denial notice.

The final rule confirms ONC’s intent to reconsider an application for ONC-ACB status only if an applicant can demonstrate that there were clear factual errors in the review of its application that could lead to the applicant obtaining ONC-ACB status.

The final rule clarifies that the requirement that an ONC-ACB identify on its website and in all marketing and communications statements the scope of its authorization only applies to activities conducted by the ONC-ACB under the permanent certification program.

In response to comments, ONC decides to allow an ONC-ACB to maintain its status for three years, rather than the proposed two years.

ONC rejects comments recommending that, as part of ONC-ACB renewals, ONC request and consider a range of information, including HIT developers' evaluations of ONC-ACBs' performance, documentation regarding the handling of customer complaints by ONC-ACBs, the percentage of certifications in relation to requests for certification, the total number of previous certifications granted, the number of certifications granted after two or more attempts, and surveillance results. Instead, ONC believes that by maintaining its accreditation and adhering to the Principles of Proper Conduct for ONC-ACBs, an ONC-ACB "will be more than adequately situated to pursue renewal."

Certification of Complete EHRs, EHR Modules and Other HIT

ONC rejects a commenter's recommendation that it require an ONC-ACB that is authorized to certify Complete EHRs to also certify EHR Modules. ONC confirms that a single certification criterion, the minimum certification unit for an EHR Module, encompasses all of the specific capabilities referenced below the first paragraph level. ONC rejects comments recommending that ONC deem privacy and security certification criteria as "addressable" (akin to what is allowed under the Health Insurance Portability and Accountability Act Security Rule), arguing that such an approach would not translate well into the certification of EHR Modules.

With respect to privacy and security certification criteria applicable to EHR Modules, this final rule adopts essentially the same policy included in the final rule implementing the temporary certification program. It specifies that EHR Module(s) shall be certified to all privacy and security certification criteria adopted by the Secretary, unless the EHR Module(s) is presented for certification in one of the following manners:

- 1) The EHR Modules are presented for 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 demonstrably responsible for providing all of the privacy and security capabilities for the entire bundle of EHR Modules; or
- 2) An EHR Module is presented for certification, and the presenter can demonstrate and provide documentation to the ONC-ACB that a privacy and security certification criterion is inapplicable or that it would be technically infeasible for the EHR Module to be certified in accordance with such certification criterion.

The final rule notes that a pre-coordinated, integrated bundle of EHR Modules, which would otherwise constitute a Complete EHR, will be listed as a Complete EHR (not an EHR Bundle) in the CHPL but with a notation that it is a pre-coordinated, integrated bundle of EHR Modules. ONC adds that it will continue to evaluate whether another method for listing such bundles would be beneficial.

ONC agrees with commenters that ONC-ACB “certificate” documentation should be designed in a way that does not lead to market confusion and establishes a new Principle of Proper Conduct for ONC-ACBs regarding the proper identification of Complete EHRs and EHR Modules.

In terms of the possibility that ONC-ACBs might ultimately certify HIT other than Complete EHRs and EHR Modules, the final rule emphasizes that the Secretary would first have to adopt certification criteria applicable to other types of HIT before ONC could subsequently authorize ONC-ACBs to certify such HIT under the permanent certification program. Note that commenters identified a wide range of HIT that could benefit from such certification, including personal health records, health information organizations, pharmacy and laboratory systems, ancillary clinical systems including radiology information systems, picture archiving and communication systems, cardiology systems, vital signs and point-of-care medical devices, and telehealth and remote patient care solutions.

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). As in the case of the final rule establishing the temporary certification program, this 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-ACBs, Complete EHR or EHR Module developers, or the EPs and eligible hospitals who have implemented certified EHR technology (until the Secretary adopts, that is 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 Certification Methods

As was true in the case of the final rule establishing the temporary certification program, this final rule identifies remote testing (for both development and deployment sites) as the required testing method, in recognition that this is currently the predominant testing method. For this purpose, development site means the physical location where an HIT product is developed, and deployment site means the physical location where such product resides or is being or has been implemented. This final rule also permits (but does not require) the ONC-ACB to offer testing and certification at its facility or at the physical location of a development or deployment site.

This final rule also again 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-ACB, Revocation of ONC-ACB Status, and Effect of Revocation on Certifications Issued by a Former ONC-ACB

This final rule closely follows policies adopted in the final rule establishing the temporary HIT certification program. ONC indicates that it intends to monitor compliance with the Principles of Proper Conduct for ONC-ACBs on an ongoing basis by, among other means, ensuring that ONC-ACBs are attending all mandatory training. It again 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 permanent 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-ACBs and engaging in other inappropriate behavior.

In this final rule, ONC rejects comments suggesting that it should consider revoking an ONC-ACB’s status for committing multiple Type-2 violations even if the violations were corrected (violations would, however, be a matter of public record and could influence HIT developers’ decisions on which ONC-ACB to select for certification of their products). In response to a number of comments, ONC agrees that it should have the ability to suspend an ONC-ACB’s operations when there is reliable evidence indicating that the ONC-ACB committed a Type-1 or Type-2 violation and that the continued certification of Complete EHRs and/or EHR Modules could have an adverse impact on patient health or safety. An ONC-ACB 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 option of revoking an ONC-ACB’s status if the National Coordinator has reliable evidence that the ONC-ACB committed a Type-1 violation, or the ONC-ACB 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. An ONC-ACB would have to refund any fees paid by an HIT developer that seeks to withdraw a request for certification while an ONC-ACB is suspended. In the case of revocations, a decision to revoke an ONC-ACB's status is final and not subject to further review "unless the National Coordinator chooses to reconsider the revocation." In addition, an ONC-ACB whose status is revoked would be barred from reapplying for ONC-ACB status for a period of one year. ONC intends to provide public notification via its website and list serve if an ONC-ACB is suspended, issued a notice proposing its revocation, and/or has its status revoked.

In terms of the effect on the certification status of EHR technology previously certified by an ONC-ACB whose status is subsequently revoked, if ONC determines that a Type-1 violation was committed that calls into question the legitimacy of previous certifications issued by the former ONC-ACB, the final rule specifies that recertification by an ONC-ACB 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), this final rule retains the 120-day period (the same policy adopted as part of the final rule establishing the temporary certification program). 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 EPs and eligible hospitals identify whether the certified status of their EHR technology is still valid.

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 agrees that not every modification would or should require a previously certified EHR or EHR Module to be certified again as self-developed. Further, ONC admits that since many of the certification criteria adopted by the Secretary express minimum capabilities, it would be unrealistic to expect that these capabilities will not be modified in some cases. Nevertheless, ONC also observes that if an EP or eligible hospital "wants complete assurance that a Complete EHR or EHR Module's capabilities for which certification criteria have been adopted were not adversely affected by modifications that were made post-certification, they may choose to have the Complete EHR or EHR Module retested and recertified." ONC also warns that any post-certification modifications that adversely affect a Complete EHR or EHR Module's capabilities for which certification criteria have been adopted may be identified through surveillance conducted by an ONC-ACB.

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

The final rule notes ONC's expectation that the Secretary will adopt certification criteria through rulemaking every two years in correlation with the changes to the meaningful use requirements. For example, ONC anticipates that the Secretary will adopt certification criteria during 2012 for the 2013 and 2014 payment years under the Medicare and Medicaid EHR incentive payment programs. ONC also again calls attention to the possibility that the requirements for an EP 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.

All of 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 EP, 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. This is the same position taken by ONC in the final rule establishing the temporary certification program. This final rule notes that a previously certified EHR product would not need to be certified according to any new optional standard(s) or implementation specifications the Secretary might adopt in the future in order for it to continue to be used to meet the definition of Certified EHR Technology. In addition, the final rule says that EHR products certified under the temporary certification program as meeting the certified criteria for the 2011/2012 payment years will not need to be recertified under the permanent certification program as having met the certification criteria for those payment years.

In light of the above, ONC adds a new Principle of Proper Conduct for ONC-ACBs 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 20[XX]/20[XX] compliant and has been certified by an ONC-ACB 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-ACB 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 a pre-coordinated, 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-ACB for the individual EHR Modules.

The final rule does permit (but not require) ONC-ACBs to provide updated certifications to previously certified EHR Modules after the ONC-ACB has verified that the certification criterion or criteria to which the EHR Module was previously certified have not been revised and that no new certification criteria adopted for privacy and security are applicable to the EHR Module. In doing so, an ONC-ACB would also be allowed to rely on the results of testing previously performed by ONC-ATCBs. Thus, for an individual EHR Module, an updated certification is a potential means for avoiding the need for recertification (for example, for payment years 2013/2014) if that EHR Module is unaffected by future rulemaking.

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 this final rule, ONC clarifies that a previously certified Complete EHR or EHR Module may be updated for routine maintenance or to include new or modified capabilities without the need for recertification. However, ONC believes that an ONC-ACB “should, at a minimum, review an attestation submitted by a Complete EHR or EHR Module developer explaining the changes that were made and the reasons for those changes, as well as other information and supporting documentation that would be necessary for the ONC-ACB to evaluate the potential effects of the changes on previously certified capabilities.” The ONC-ACB 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 based on previous certification. If the ONC-ACB 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-ACB must follow before granting certified status to a newer version of a previously certified EHR product based on the submitted attestation. However, ONC encourages ONC-ACBs to develop streamlined approaches for attestations in order to accommodate different software release models and schedules.

Please note that the final rule requires ONC-ACBs to accept requests for a newer version of a previously certified Complete EHR or EHR Module to inherit the certified status of the previously certified technology without requiring the newer version to be recertified and permits ONC-ACBs to grant certified status to such newer versions.

Differential or Gap Certification

The proposed rule described differential certification as the certification of Complete EHRs and EHR Modules to the differences between the certification criteria adopted by the Secretary associated with one stage of meaningful use and a subsequent stage of meaningful use. Commenters overwhelmingly supported some form of differential certification, which ONC acknowledges is preferentially termed gap certification, and the final rule permits ONC-ACBs to provide the option of and to perform such gap certification. However, ONC notes that the decision on whether to conduct gap certification is best left to each ONC-ACB. The final rule also says that ONC-ACBs “should feel confident in relying upon the test results provided by ONC-ATCBs when performing gap certification under the permanent certification program.”

Barriers to Entry for Potential ONC-ACBs and an ONC-Managed Certification Process

Commenters on the proposed rule stated that the proposed provisions of the permanent certification program did not present high barriers to entry for potential ONC-ACBs. However, ONC says that if it determines at a later time that an insufficient number of ONC-ACBs exists, it will consider what steps may be taken to remedy the situation, which may include implementing a temporary ONC-managed certification process (discussed in the proposed rule) and/or evaluating other means for stimulating the market, such as revising or waiving certain ONC-ACB requirements or taking other actions.

Other Issues

This final rule restates ONC’s position against grandfathering, which would have allowed EHR technology that had been certified prior to the inception of the temporary and/or permanent certification programs to be deemed Certified EHR Technology.

In the final rule, ONC asserts that it has created an environment that is likely to result in multiple ONC-ACBs, and argues that multiple ONC-ACBs and market dynamics, particularly competition, will address commenters’ concerns about potential monopolies, appropriate costs for certification, and the timely and efficient processing of requests for HIT certification.

Future Rulemaking and Program Guidance

In the final rule, ONC notes that it intends to issue “in the near future” a proposed rule that will address improper conduct by an ONC-AA, the potential consequences for engaging in such conduct, a process by which ONC may take corrective action against an ONC-AA, and the implications for ONC-ACBs if an ONC-AA’s status is revoked or other corrective action taken. ONC also says it

plans to address the governance mechanisms for the nationwide health information network through a separate rulemaking.

If necessary, ONC may also issue program guidance to address questions or confusion about the elements and processes of the permanent certification program as well as the eventual transition from testing and certification under the temporary certification program.

Regulatory Impact Analysis

ONC has determined that the final rule is not an economically significant rule because the estimated overall costs and benefits associated with the permanent HIT certification program are less than \$100 million per year.

ONC believes that at most two accreditation organizations will prepare and submit a request for ONC-AA status (only one of which will be selected).

ONC agrees with a commenter's estimate that 200 hours of staff time will be required for an organization to prepare and participate in the ONC-ACB accreditation process, and estimates that the total cost for an organization to become accredited and apply to be an ONC-ACB will be about \$36,177.

As was the case in the final rule establishing the temporary HIT certification program, ONC again rejects any notion that it should dictate the minimum or maximum amount a certification body (in this case, an ONC-ACB) can charge for certifying EHR technology. For purposes of its regulatory impact analysis, ONC uses 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). In terms of the number of EHR products (commercial, open source and self-developed) applying for certification, ONC now estimates the following:

- 93 commercial/open source Complete EHRs and 50 commercial/open source EHR Modules, 9 self-developed Complete EHRs and 12-82 self-developed EHR Modules designed for an ambulatory setting, and 38 self-developed Complete EHRs and 360-1087 self-developed EHR Modules designed for an inpatient setting will be tested and certified to the 2011/2012 certification criteria;
- 88 commercial/open source Complete EHRs and 60 commercial/open source EHR Modules, 5 self-developed Complete EHRs and 12-82 self-developed EHR Modules designed for an ambulatory setting, and 19 self-developed Complete EHRs and 360-1087 self-developed EHR Modules designed for an inpatient setting will seek testing and certification for meaningful use Stage 2; and
- 84 commercial/open source Complete EHRs and 72 commercial/open source EHR Modules, 4 self-developed Complete EHRs and 12-82 self-developed EHR Modules designed for an ambulatory setting, and 14 self-developed

Complete EHRs and 360-1087 self-developed EHR modules designed for an inpatient setting will seek testing and certification for meaningful use Stage 3.

In developing these estimates, ONC assumes that: (1) commercial/open source Complete EHR developers will continue to consolidate due to mergers and acquisition and that this consolidation would occur at a rate of 5% between meaningful use stages; (2) the number of commercial/open source EHR Modules that would need to be tested and certified will grow at a rate of 20% between meaningful use stages since the cost barrier for EHR Modules to enter the market will be much less than a Complete EHR; (3) the number of EPs and eligible hospitals that incur the testing and certification costs for their self-developed Complete EHRs will drop by 50% in 2012 and another 25% in 2014 and level out after 2014; and (4) the number of EPs and eligible hospitals that incur the testing and certification costs for their self-developed EHR Modules will remain stable. Note that the numbers of self-developed EHR modules expected to seek testing and certification are significantly higher than those estimated in the proposed rule.