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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 170

RIN 0991-AB59

Establishment of the Temporary Certification Program for Health Information Technology

AGENCY: Office of the National Coordinator for Health Information Technology, Department of Health and Human Services

ACTION: Final rule.

SUMMARY: This final rule establishes a temporary certification program for the purposes of testing and certifying health information technology. This final rule is established under the authority granted to the National Coordinator for Health Information Technology (the National Coordinator) by section 3001(c)(5) of the Public Health Service Act (PHSA), as added by the Health Information Technology for Economic and Clinical Health (HITECH) Act. 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.

DATES: These regulations are effective [INSERT DATE OF PUBLICATION IN THE **FEDERAL REGISTER]**. The incorporation by reference of certain publications listed

in the rule is approved by the Director of the Federal Register as of [INSERT DATE OF PUBLICATION IN THE **FEDERAL REGISTER]**.

FOR FURTHER INFORMATION CONTACT: Steven Posnack, Director, Federal Policy Division, Office of Policy and Planning, Office of the National Coordinator for Health Information Technology, 202-690-7151.

SUPPLEMENTARY INFORMATION:

Acronyms

APA	Administrative Procedure Act
ARRA	American Recovery and Reinvestment Act of 2009
CAH	Critical Access Hospital
CCHIT	Certification Commission for Health Information Technology
CGD	Certification Guidance Document
CHPL	Certified Health Information Technology Products List
CMS	Centers for Medicare & Medicaid Services
CORE	Committee on Operating Rules for Information Exchange®
EHR	Electronic Health Record
FACA	Federal Advisory Committee Act
FFP	Federal Financial Participation
FFS	Fee for Service (Medicare Program)
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HIT	Health Information Technology
HITECH	Health Information Technology for Economic and Clinical Health

ISO	International Organization for Standardization
IT	Information Technology
MA	Medicare Advantage
NHIN	Nationwide Health Information Network
NIST	National Institute of Standards and Technology
OIG	Office of Inspector General
OMB	Office of Management and Budget
ONC	Office of the National Coordinator for Health Information Technology
ONC-ACB	ONC-Authorized Certification Body
ONC-ATCB	ONC-Authorized Testing and Certification Body
OPM	Office of Personnel Management
PHSA	Public Health Service Act
RFA	Regulatory Flexibility Act
RIA	Regulatory Impact Analysis
SDO	Standards Development Organization
SSA	Social Security Act

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I. Background

A. Previously Defined Terminology

In addition to new terms and definitions created by this rule, the following terms have the same meaning as provided at 45 CFR 170.102.

- Certification criteria
- Certified EHR Technology
- Complete EHR
- Disclosure
- EHR Module
- Implementation specification
- Qualified EHR
- Standard

B. Legislative and Regulatory History

1. Legislative History

The Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5), was enacted on February 17, 2009.

The HITECH Act amended the Public Health Service Act (PHSA) and created "Title XXX – Health Information Technology and Quality" (Title XXX) to improve health care quality, safety, and efficiency through the promotion of health information technology (HIT) and electronic health information exchange. Section 3001 of the PHSA establishes the Office of the National Coordinator for Health Information Technology (ONC). Title XXX of the PHSA provides the National Coordinator for Health Information Technology (the National Coordinator) and the Secretary of Health and Human Services (the Secretary) with new responsibilities and authorities related to HIT. The HITECH Act also amended several sections of the Social Security Act (SSA) and in doing so established the availability of incentive payments to eligible professionals and eligible hospitals to promote the adoption and meaningful use of interoperable HIT.

a. Standards, Implementation Specifications, and Certification Criteria

With the passage of the HITECH Act, two new Federal advisory committees were established, the HIT Policy Committee and the HIT Standards Committee (sections 3002 and 3003 of the PHSA, respectively). Each is responsible for advising the National Coordinator on different aspects of standards, implementation specifications, and certification criteria. The HIT Policy Committee is responsible for, among other duties, recommending priorities for the development, harmonization, and recognition of standards, implementation specifications, and certification criteria, while the HIT Standards Committee is responsible for recommending standards, implementation specifications, and certification criteria for adoption by the Secretary under section 3004 of the PHSA consistent with the ONC-coordinated Federal Health IT Strategic Plan (the "strategic plan").

Section 3004 of the PHSA defines how the Secretary adopts standards, implementation specifications, and certification criteria. Section 3004(a) of the PHSA defines a process whereby an obligation is imposed on the Secretary to review standards, implementation specifications, and certification criteria and identifies the procedures for the Secretary to follow to determine whether to adopt any group of standards, implementation specifications, or certification criteria included among National Coordinator-endorsed recommendations.

b. Medicare and Medicaid EHR Incentive Programs

Title IV, Division B of the HITECH Act establishes incentive payments under the Medicare and Medicaid programs for eligible professionals and eligible hospitals that meaningfully use Certified Electronic Health Record (EHR) Technology. The Centers for Medicare & Medicaid Services (CMS) is charged with developing the Medicare and Medicaid EHR incentive programs.

i. Medicare EHR Incentive Program

Section 4101 of the HITECH Act added new subsections to section 1848 of the SSA to establish incentive payments for the meaningful use of Certified EHR Technology by eligible professionals participating in the Medicare Fee-for-Service (FFS) program beginning in calendar year (CY) 2011 and beginning in CY 2015, downward payment adjustments for covered professional services provided by eligible professionals who are not meaningful users of Certified EHR Technology. Section 4101(c) of the HITECH Act added a new subsection to section 1853 of the SSA that provides incentive payments to Medicare Advantage (MA) organizations for their affiliated eligible professionals who meaningfully use Certified EHR Technology beginning in CY 2011

and beginning in CY 2015, downward payment adjustments to MA organizations to account for certain affiliated eligible professionals who are not meaningful users of Certified EHR Technology.

Section 4102 of the HITECH Act added new subsections to section 1886 of the SSA that establish incentive payments for the meaningful use of Certified EHR Technology by subsection (d) hospitals (defined under section 1886(d)(1)(B) of the SSA) that participate in the Medicare FFS program beginning in Federal fiscal year (FY) 2011 and beginning in FY 2015, downward payment adjustments to the market basket updates for inpatient hospital services provided by such hospitals that are not meaningful users of Certified EHR Technology. Section 4102(b) of the HITECH Act amends section 1814 of the SSA to provide an incentive payment to critical access hospitals that meaningfully use Certified EHR Technology based on the hospitals' reasonable costs beginning in FY 2011 and downward payment adjustments for inpatient hospital services provided by such hospitals that are not meaningful users of Certified EHR Technology for cost reporting periods beginning in FY 2015. Section 4102(c) of the HITECH Act adds a new subsection to section 1853 of the SSA to provide incentive payments to MA organizations for certain affiliated eligible hospitals that meaningfully use Certified EHR Technology and beginning in FY 2015, downward payment adjustments to MA organizations for those affiliated hospitals that are not meaningful users of Certified EHR Technology.

ii. Medicaid EHR Incentive Program

Section 4201 of the HITECH Act amends section 1903 of the SSA to provide 100 percent Federal financial participation (FFP) to States for incentive payments to eligible

health care providers participating in the Medicaid program and 90 percent FFP for State administrative expenses related to the incentive program.

c. HIT Certification Programs

Section 3001(c)(5) of the PHSA provides the National Coordinator with the authority to establish a certification program or programs for the voluntary certification of HIT. Specifically, section 3001(c)(5)(A) specifies that the "National Coordinator, in consultation with the Director of the National Institute of Standards and Technology, shall keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted under this subtitle" (i.e., certification criteria adopted by the Secretary under section 3004 of the PHSA). The certification program(s) must also "include, as appropriate, testing of the technology in accordance with section 13201(b) of the [HITECH] Act."

Section 13201(b) of the HITECH Act requires that with respect to the development of standards and implementation specifications, the Director of the National Institute of Standards and Technology (NIST), in coordination with the HIT Standards Committee, "shall support the establishment of a conformance testing infrastructure, including the development of technical test beds." The United States Congress also indicated that "[t]he development of this conformance testing infrastructure may include a program to accredit independent, non-Federal laboratories to perform testing."

2. Regulatory History and Related Guidance

a. Initial Set of Standards, Implementation Specifications, and Certification Criteria Interim Final Rule

In accordance with section 3004(b)(1) of the PHSA, the Secretary issued an interim final rule with request for comments entitled "Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology" (HIT Standards and Certification Criteria interim final rule) (75 FR 2014), which adopted an initial set of standards, implementation specifications, and certification criteria. The standards, implementation specifications, and certification criteria adopted by the Secretary establish the capabilities that Certified EHR Technology must include in order to, at a minimum, support the achievement of what has been proposed for meaningful use Stage 1 by eligible professionals and eligible hospitals under the Medicare and Medicaid EHR Incentive Programs proposed rule (see 75 FR 1844 for more information about meaningful use and the proposed Stage 1 requirements).

b. Medicare and Medicaid EHR Incentive Programs Proposed Rule

On January 13, 2010, CMS published in the Federal Register (75 FR 1844) the Medicare and Medicaid EHR Incentive Programs proposed rule. The rule proposes a definition for meaningful use Stage 1 and regulations associated with the incentive payments made available under Division B, Title IV of the HITECH Act. CMS has proposed that meaningful use Stage 1 would begin in 2011 and has proposed that Stage 1 would focus on "electronically capturing health information in a coded format; using that information to track key clinical conditions and communicating that information for care coordination purposes (whether that information is structured or unstructured), but in structured format whenever feasible; consistent with other provisions of Medicare and Medicaid law, implementing clinical decision support tools to facilitate disease and

medication management; and reporting clinical quality measures and public health information."

c. HIT Certification Programs Proposed Rule and the Temporary Certification Program Final Rule

Section 3001(c)(5) of the PHSA, specifies that the National Coordinator "shall keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted [by the Secretary] under this subtitle." Based on this authority, we proposed both a temporary and permanent certification program for HIT in a notice of proposed rulemaking entitled "Proposed Establishment of Certification Programs for Health Information Technology" (75 FR 11328, March 10, 2010) (RIN 0991-AB59) (the "Proposed Rule"). In the Proposed Rule, we proposed to use the certification programs for the purposes of testing and certifying HIT. We also specified the processes the National Coordinator would follow to authorize organizations to perform the certification of HIT.

We stated in the Proposed Rule that we expected to issue separate final rules for each of the certification programs. This final rule establishes a temporary certification program whereby the National Coordinator will authorize organizations to test and certify Complete EHRs and/or EHR Modules, thereby assuring the availability of Certified EHR Technology prior to the date on which health care providers seeking the incentive payments available under the Medicare and Medicaid EHR Incentive Programs may begin demonstrating meaningful use of Certified EHR Technology.

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

In August 2006, HHS published two final rules in which CMS and the Office of Inspector General (OIG) promulgated an exception to the physician self-referral prohibition and a safe harbor under the anti-kickback statute, respectively, for certain arrangements involving the donation of interoperable EHR software to physicians and other health care practitioners or entities (71 FR 45140 and 71 FR 45110, respectively). The exception and safe harbor provide that EHR software will be "deemed to be interoperable if a certifying body recognized by the Secretary has certified the software no more than 12 months prior to the date it is provided to the [physician/recipient]." ONC published separately a Certification Guidance Document (CGD) (71 FR 44296) to explain the factors ONC would use to determine whether to recommend to the Secretary a body for "recognized certification body" status. The CGD serves as a guide for ONC to evaluate applications for "recognized certification body" status and provides the information a body would need to apply for and obtain such status. To date, the Certification Commission for Health Information Technology (CCHIT) has been the only organization that has both applied for and been granted "recognized certification body" status under the CGD.

In section VI of the CGD, ONC notified the public, including potential applicants, that the recognition process explained in the CGD would be formalized through notice and comment rulemaking and that when a final rule has been promulgated to govern the process by which a "recognized certification body" is determined, certification bodies

recognized under the CGD would be required to complete new applications and successfully demonstrate compliance with all requirements of the final rule.

In the Proposed Rule, we began the formal notice and comment rulemaking described in the CGD. We stated that the processes we proposed for the temporary certification program and permanent certification program, once finalized, would supersede the CGD, and the authorization process would constitute the new established method for "recognizing" certification bodies, as referenced in the physician self-referral prohibition and anti-kickback EHR exception and safe harbor final rules. As a result of our proposal, certifications issued by a certification body "authorized" by the National Coordinator would constitute certification by "a certifying body recognized by the Secretary" in the context of the physician self-referral EHR exception and anti-kickback EHR safe harbor. We requested public comment on this proposal and have responded to those comments in Section III of this final rule.

II. Overview of the Temporary Certification Program

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.

Under the temporary certification program, the National Coordinator will accept applications for ONC-ATCB status at any time. 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. An applicant will need to be able to both test and certify Complete EHRs

and/or EHR Modules. We anticipate 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 adhering to the Principles of Proper Conduct for ONC-ATCBs. ONC-ATCBs will also be required to follow the conditions and requirements applicable to the testing and certification of Complete EHRs and/or EHR Modules as specified in this final 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.

III. Provisions of the Temporary Certification Program; Analysis and Response to Public Comments on the Proposed Rule

A. Overview

This section discusses the 84 timely received comments on the Proposed Rule's proposed temporary certification program and our responses. We have structured this section of the final rule based on the proposed regulatory sections of the temporary certification program and discuss each regulatory section sequentially. For each discussion of the regulatory provision, we first restate or paraphrase the provision as proposed in the Proposed Rule as well as identify any correlated issues for which we sought public comment. Second, we summarize the comments received. Lastly, we provide our response to the comments, including stating whether we will finalize the provision as proposed in the Proposed Rule or modify the proposed provision in response to public comment. Comments on the incorporation of the "recognized certification body" process, "grandfathering" of certifications, the concept of "self-

developed," validity and expiration of certifications, general comments, and comments beyond the scope of this final rule are discussed towards the end of the preamble.

B. Scope and Applicability

In the Proposed Rule, we indicated in section 170.400 that the temporary certification program would serve to implement section 3001(c)(5) of the Public Health Service Act, and that subpart D would also set forth the rules and procedures related to the temporary certification program for HIT administered by the National Coordinator. Under section 170.401, we proposed that subpart D would establish the processes that applicants for ONC-ATCB status must follow to be granted ONC-ATCB status by the National Coordinator, the processes the National Coordinator would follow when assessing applicants and granting ONC-ATCB status, and the requirements of ONC-ATCBs for testing and certifying Complete EHRs and/or EHR Modules in accordance with the applicable certification criteria adopted by the Secretary in subpart C of this part.

Comments. We received many comments that expressed support for our proposal for a temporary certification program that would provide the opportunity for Complete EHRs and EHR Modules to be tested and certified in advance of meaningful use Stage 1. The commenters expressed an understanding of the rationale we provided for proposing a temporary certification program and the urgency we associated with establishing the temporary certification program.

Some commenters suggested that we use the terms "interim," "transitional" or "provisional" to describe the temporary certification program. One commenter asserted that the term "interim" is particularly appropriate because it is used in Federal rulemaking to denote regulatory actions that are fully in effect but will be replaced with more refined

versions in the future. Other commenters contended that using the term "temporary" to describe the short-term program and its associated certifications may cause confusion in the market and prolong, instead of reduce, uncertainty among eligible professionals and eligible hospitals. One commenter recommended that we establish a comprehensive educational program about our proposed certification programs.

Some commenters stated that the certification programs should not be vague and expansive by encompassing various, unidentified areas of HIT, but instead should be targeted to the objectives of achieving meaningful use of Certified EHR Technology. One commenter also mentioned the need for the certification programs to focus on the implementation of the Nationwide Health Information Network (NHIN).

Response. We appreciate the commenters' expressions of support for the temporary certification program. We also appreciate the commenters' suggestions and rationale for renaming the temporary certification program. We believe, however, that we have described the temporary certification program in the Proposed Rule and this final rule in a manner that clearly conveys its purpose and scope such that renaming the program is not necessary. Furthermore, as generally recommended by a commenter, we will continue to communicate with and educate stakeholders about the temporary certification program and the eventual transition to the proposed permanent certification program.

We believe that we clearly indicated in the Proposed Rule's preamble and the proposed temporary certification program's scope and applicability provisions that one of the goals of the temporary certification program is to support the achievement of meaningful use by testing and certifying Complete EHRs and EHR Modules to the

certification criteria adopted by the Secretary in subpart C of part 170. Therefore, we do not believe that the programs are overly vague or expansive. We believe that the commenters who expressed these concerns focused on our proposals to permit other types of HIT to be certified under the permanent certification program. We plan to address this issue in the final rule for the permanent certification program, but in the interim, we remind these commenters of a fact we stated in the Proposed Rule. The Secretary would first need to adopt certification criteria for other types of HIT before we would consider authorizing, in this case, ONC-ACBs to certify those other types of HIT.

We are revising §170.401 to clearly state that this subpart includes requirements that ONC-ATCBs must follow to maintain good standing under the temporary certification program. This reference was inadvertently left out of §170.401 in the Proposed Rule.

C. Definitions and Correspondence

We proposed in the Proposed Rule to define three terms related to the temporary certification program and to establish a process for applicants for ONC-ATCB status and ONC-ATCBs to correspond with the National Coordinator.

1. Definitions

a. Days

We proposed in the Proposed Rule to add the definition of "day or days" to section 170.102. We proposed to define "day or days" to mean a calendar day or calendar days. We did not receive any comments on this provision. Therefore, we are finalizing this definition without modification.

b. Applicant

We proposed in section 170.402 to define applicant to mean a single organization or a consortium of organizations that seeks to become an ONC-ATCB by requesting and subsequently submitting an application for ONC-ATCB status to the National Coordinator.

Comments. One commenter recommended that we encourage and support the establishment of coalitions or partnerships for testing and certification that leverage specialized expertise. Another commenter asked whether third-party organizations will be allowed to become testing laboratories for the temporary and permanent certification programs.

Response. We agree with the commenter that coalitions or partnerships for testing and certification are capable of leveraging specialized expertise and we continue to support such an approach. We noted in the Proposed Rule that single organizations and consortia would be eligible to apply for ONC-ATCB status under the temporary certification program. We also stated that we would expect a consortium to be comprised of one organization that would serve as a testing laboratory and a separate organization that would serve as a certification body. We further stated that, as long as such an applicant could perform all of the required responsibilities of an ONC-ATCB, we would fully support the approach. Accordingly, we are finalizing this provision without modification.

Although we are unclear as to what the commenter meant by a "third-party organization," we can state that a testing laboratory could apply to become an ONC-ATCB in a manner described above (i.e., as a member or component of a consortium) or the laboratory could apply independently to become an ONC-ATCB, but it would need to

meet all the application requirements, including the requisite certification body qualifications as specified in ISO/IEC Guide 65:1996 (Guide 65). In the Proposed Rule, we proposed that a testing laboratory would need to become accredited by the testing laboratory accreditor under the permanent certification program. This process and whether an organization that becomes an ONC-ACB under the permanent certification program can be affiliated with an accredited testing laboratory are matters we requested the public to comment on in the Proposed Rule and will be more fully discussed when we finalize the permanent certification program.

c. ONC-ATCB

We proposed in section 170.402 to define an ONC-Authorized Testing and Certification Body (ONC-ATCB) to mean an organization or a consortium of organizations that has applied to and been authorized by the National Coordinator pursuant to subpart D to perform the testing and certification of Complete EHRs and/or EHR Modules under the temporary certification program. We did not receive any comments on this provision. Therefore, we are finalizing this definition without modification.

2. Correspondence

We proposed in section 170.405 to require applicants for ONC-ATCB status and ONC-ATCBs to correspond and communicate with the National Coordinator by email, unless otherwise necessary. We proposed that the official date of receipt of any email between the National Coordinator and an applicant for ONC-ATCB status or an ONC-ATCB would be the day the email was sent. We further proposed that in circumstances where it was necessary for an applicant for ONC-ATCB status or ONC-ATCB to

correspond or communicate with the National Coordinator by regular or express mail, the official date of receipt would be the date of the delivery confirmation. We did not receive any comments on these proposals. We are, however, revising this section to include "or ONC-ATCB" in paragraph (b) to clarify that either an applicant for ONC-ATCB status or an ONC-ATCB may, when necessary, utilize the specified correspondence methods. This reference was inadvertently left out of §170.405(b) in the Proposed Rule.

D. Testing and Certification

1. Distinction Between Testing and Certification

We stated in the Proposed Rule that there is a distinct difference between the "testing" and "certification" of a Complete EHR and/or EHR Module. We described "testing" as the process used to determine the degree to which a Complete EHR or EHR Module can meet specific, predefined, measurable, and quantitative requirements. We noted that such results would be able to be compared to and evaluated in accordance with predefined measures. In contrast, we described "certification" as the assessment (and subsequent assertion) made by an organization, once it has analyzed the quantitative results rendered from testing along with other qualitative factors, that a Complete EHR or EHR Module has met all of the applicable certification criteria adopted by the Secretary. We noted that qualitative factors could include whether a Complete EHR or EHR Module developer has a quality management system in place, or whether the Complete EHR or EHR Module developer has agreed to the policies and conditions associated with being certified (e.g., proper logo usage). We further stated that the act of certification typically promotes confidence in the quality of a product (and the Complete EHR or EHR Module

developer that produced it), offers assurance that the product will perform as described, and helps consumers to differentiate which products have met specific criteria from others that have not.

To further clarify, we stated that a fundamental difference between testing and certification is that 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 achieved. To illustrate an important difference between testing and certification, we provided the example that we recite below.

An e-prescribing EHR Module developer that seeks to have its EHR Module certified would first submit the EHR Module to be tested. To successfully pass the established testing requirements, the e-prescribing EHR Module would, among other functions, need to transmit an electronic prescription using mock patient data according to the standards adopted by the Secretary. Provided that the e-prescribing EHR Module successfully passed this test it would next be evaluated for certification. Certification could require that the EHR Module developer agree to a number of provisions, including, for example, displaying the EHR Module's version and revision number so potential purchasers could discern when the EHR Module was last updated or certified. If the EHR Module developer agreed to all of the applicable certification requirements and the EHR Module achieved a passing test result, the e-prescribing EHR Module would be certified. In these situations, both the EHR Module passing the technical requirements tests and the EHR Module vendor meeting the other certification requirements would be required for the EHR Module to achieve certification.

Comments. Multiple commenters asked for additional clarification for the distinction between testing and certification. Commenters were concerned that ONC-ATCBs would have too much discretion related to certification. The commenters asserted that ONC-ATCBs should only be empowered to assess whether adopted certification criteria have been met or whether other applicable policies adopted by the National Coordinator through regulation, such as "labeling" policies, have been complied with. Commenters expressed specific concern with one of our examples of potential qualitative factors, which was the need to have "a quality management system in place." The commenters suggested that a requirement to have a quality management system in place is vague and gave too much discretion to an ONC-ATCB.

Response. We require as a Principle of Proper Conduct that ONC-ATCBs shall operate their certification programs in accordance with Guide 65. Guide 65 specifies the requirements that an organization must follow to operate a certification program. Moreover, because Guide 65 states in section 4.6.1 that a "certification body shall specify the conditions for granting, maintaining and extending certification," we believe that it would be inappropriate to dictate every specific aspect related to an ONC-ATCB's certification program operations. We understand the concerns expressed by commenters over our example of a "quality management system" as another factor that ONC-ATCBs may choose to include, in accordance with Guide 65, as part of their certification requirements for assessing Complete EHRs and/or EHR Modules and have considered how to best address such concerns.

With respect to those commenters who requested that we clarify the purview of ONC-ATCBs related to certification and expressed concerns about the discretion

afforded to ONC-ATCBs, we agree that additional clarity is necessary regarding our intent and expectations of ONC-ATCBs in our discussion of the differences between testing and certification in the Proposed Rule. We believe commenters were expressing a concern that certification could include other factors beyond the certification criteria adopted by the Secretary in subpart C of part 170, which could prevent them from receiving a certification in a timely manner if they were not aware of those factors. We agree with commenters that this is a legitimate concern and did not intend to convey, through our examples, that we would adopt additional requirements for certification in this final rule beyond the certification criteria adopted by the Secretary in subpart C of part 170 and the other responsibilities specified in subpart D of part 170 that we require an ONC-ATCB to fulfill in order to perform the testing and certification of Complete EHRs and/or EHR Modules.

We seek to make clear that the primary responsibility of ONC-ATCBs under the temporary certification program is to test and certify Complete EHRs and/or EHR Modules in accordance with the certification criteria adopted by the Secretary. In consideration of the comments and the preceding discussion, we have revised §170.445 and §170.450 to make it explicitly clear that an ONC-ATCB must offer the option of testing and certification of a Complete EHR or EHR Module solely to the certification criteria adopted by the Secretary and no other certification criteria. In other words, an ONC-ATCB must comply with a request made by a Complete EHR or EHR Module developer to have its Complete EHR or EHR Module tested and certified solely to the certification criteria adopted by the Secretary and not to any other factors beyond those we require ONC-ATCBs to follow when issuing a certification as discussed above (i.e.,

responsibilities specified in subpart D of part 170). However, this does not preclude an ONC-ATCB from also offering testing and certification options that include additional requirements beyond the certification criteria adopted by the Secretary. If an ONC-ATCB chooses to offer testing and certification options that specify additional requirements as a matter of its own business practices, we expect that in accordance with Guide 65, section 6, the ONC-ATCB would "give due notice of any changes it intends to make in its requirements for certification" and "take account of views expressed by interested parties before deciding on the precise form and effective date of the changes."

We note, however, that while we do not preclude an ONC-ATCB from certifying HIT in accordance with its own requirements that may be unrelated to and potentially exceed the certification criteria adopted by the Secretary, such activities are not within the scope of an ONC-ATCB's authority granted under the temporary certification program and are not endorsed or approved by the National Coordinator or the Secretary. Accordingly, we have added as a component of a new principle in the Principles of Proper Conduct for ONC-ATCBs (discussed in more detail in section O. Validity of Complete EHR and EHR Module Certification and Expiration of Certified Status) that any certifications issued to HIT that would constitute a Complete EHR or EHR Module and based on the applicable certification criteria adopted by the Secretary at subpart C must be separate and distinct from any other certification(s) that are based on other criteria or requirements. To further clarify, HIT which constitutes a Complete EHR or EHR Module that is tested and certified to the certification criteria adopted by the Secretary as well as an ONC-ATCB's own certification criteria would need to have its certified status as a Complete EHR or EHR Module noted separately and distinctly from

any other certification the ONC-ATCB may issue based on the successful demonstration of compliance with its own certification criteria. For example, an ONC-ATCB should indicate that the HIT has been certified as a "Complete EHR in accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services" and, if applicable, separately indicate that the HIT meets "XYZ certification criteria as developed and/or required by [specify certification body]."

2. Types of Testing and Certification

We proposed in section 170.410 that applicants for ONC-ATCB status may seek authorization from the National Coordinator to perform Complete EHR testing and certification and/or EHR Module testing and certification.

We received multiple comments on the types of testing and certification that ONC-ATCBs can and should perform. Many of these comments were in response to our requests for public comments on whether ONC-ATCBs should test and certify the integration of EHR Modules and on whether applicants should be permitted to apply to either test and certify only Complete EHRs designed for an ambulatory setting or Complete EHRs designed for an inpatient setting.

a. Complete EHRs and EHR Modules

We proposed that potential applicants have the option of seeking authorization from the National Coordinator to perform Complete EHR testing and certification and/or EHR Module testing and certification.

Comments. We received comments expressing support for our proposal because of the flexibility it would provide to applicants and the industry. We also received a few comments expressing positions contrary to our proposal. One commenter recommended

that we add more flexibility by allowing applicants, similar to our proposals for the proposed permanent certification program, to either do only testing or certification. Conversely, a few commenters recommended that we not give applicants the option to select, but instead require ONC-ATCBs to perform testing and certification for both Complete EHRs and EHR Modules. One commenter wanted us to ensure that there were at least two ONC-ATCBs for both Complete EHR and EHR Module testing and certification.

Response. We have attempted to create a temporary certification program that allows for as many qualified applicants to apply and become authorized as possible in the limited time allotted under the temporary certification program. We do not agree with the commenters that recommended that we pattern the applicant requirements after the proposed permanent certification program or that we ensure that there will be at least two ONC-ATCBs for both Complete EHR and EHR Module testing and certification. As discussed in the Proposed Rule, the temporary certification program's processes and requirements are different than the permanent certification program because of the urgency with which the temporary certification program must be established. We are also unable to ensure that there will be any specific number of ONC-ATCBs. We believe it is best to let the marketplace dictate the amount of qualified applicants that will apply for ONC-ATCB status. We are, however, confident that there are sufficient incentives for applicants to apply and that the program is structured in a manner that will maximize the number of qualified applicants.

b. Complete EHRs for Ambulatory or Inpatient Settings

We requested public comment in the Proposed Rule on whether the National Coordinator should permit applicants to seek authorization to test and certify only Complete EHRs designed for an ambulatory setting or, alternatively, Complete EHRs designed for an inpatient setting. Under our proposal, an applicant seeking authorization to perform Complete EHR testing and certification would be required to test and certify Complete EHRs designed for both ambulatory and inpatient settings.

Comments. We received comments ranging from support for providing the option for applicants to test and certify Complete EHRs for either ambulatory or inpatient settings to support for our proposal to require an ONC-ATCB to perform testing and certification for both settings. Some commenters thought that our proposal could stifle competition and expressed concern that there may not be enough entities capable of performing Complete EHR testing and certification for both settings. These commenters stated that allowing for Complete EHR testing and certification for either an ambulatory or inpatient setting could add competition and expedite certifications. Conversely, a few commenters stated that providing the option would multiply the National Coordinator's application workload and slow the authorization of ONC-ATCBs. One commenter also thought that the option may lead to applicants for ONC-ATCB status competing for limited resources, such as specialized staff for conducting testing and certification.

Some commenters expressed concern that if the National Coordinator were to allow applicants to test and certify Complete EHRs for either ambulatory or inpatient settings, there would not be enough ONC-ATCBs to test and certify Complete EHRs for each setting. Therefore, these commenters' support for the option was conditioned on the National Coordinator ensuring that there were an adequate number of ONC-ATCBs for

each setting. One commenter only supported giving ONC-ATCBs an option to test and certify Complete EHRs for either ambulatory or inpatient settings if the option included testing and certification of EHR Module level interactions necessary for the exchange of data between ambulatory and inpatient Complete EHRs.

Some commenters stated that the option could lead to "almost complete" EHRs, which could then lead to eligible professionals and eligible hospitals paying large sums for niche EHR Modules based on complicated certification criteria such as biosurveillance or quality reporting. One commenter asserted that under our current proposal an applicant for ONC-ATCB status could seek authorization to test and certify EHR Modules that together would essentially constitute a Complete EHR for an ambulatory setting (or an inpatient setting). Therefore, the commenter contended that we should allow an applicant for ONC-ATCB status the option to seek authorization to test and certify Complete EHRs for either ambulatory or inpatient settings because an applicant for ONC-ATCB status could essentially choose that option by seeking all the necessary EHR Module authorizations for either ambulatory or inpatient settings.

Response. We believe that based on the concerns expressed by the commenters that it would be inappropriate at this time to allow applicants for ONC-ATCB status to seek authorization for the testing and certification of Complete EHRs for either ambulatory settings or inpatient settings. We will, however, reconsider this option for the permanent certification program based on the comments received on the proposed permanent certification program.

To address the commenters' concerns about "almost complete" EHRs, we want to reiterate that for EHR technology to be considered a Complete EHR it would have to

meet all applicable certification criteria adopted by the Secretary. For example, a Complete EHR for an ambulatory setting would have to meet all certification criteria adopted at §170.302 and §170.304. Therefore, if we had provided the option for ONC-ATCBs to seek authorization to test and certify Complete EHRs for either ambulatory or inpatient settings, the Complete EHRs that ONC-ATCBs tested and certified would have had to meet all the applicable certification criteria adopted by the Secretary.

We agree with the one commenter that an applicant for ONC-ATCB status could seek authorization to test and certify EHR Modules that together would potentially cover all the applicable certification criteria for an ambulatory setting. In fact, in relation to the privacy and security testing and certification of EHR Modules, we state in this final rule that if EHR Modules are presented for testing and certification as an integrated bundle that would otherwise constitute a Complete EHR we would consider them a Complete EHR for the purposes of being certified by an ONC-ATCB. The important distinction between the commenter's suggested approach and the option we proposed is that under the commenter's approach the ONC-ATCB would not be able to issue a "Complete EHR certification" for a combination of EHR Modules because the ONC-ATCB had not received authorization to test and certify Complete EHRs. Consequently, if a Complete EHR developer wanted to obtain Complete EHR certification, they could not seek such certification from an ONC-ATCB that did not have authorization to grant Complete EHR certifications. We would assume that a potential applicant for ONC-ATCB status would consider this impact on its customer base when determining what type of authorization to seek.

c. Integrated Testing and Certification of EHR Modules

In the Proposed Rule, we requested public comment on whether ONC-ATCBs should be required to test and certify that any EHR Module presented by one EHR Module developer for testing and certification would properly work (i.e., integrate or be compatible) with other EHR Modules presented by different EHR Module developers.

Comments. Multiple commenters stated that testing and certifying EHR Modules to determine whether they can integrate with one another is a worthwhile endeavor. These commenters stated that such testing and certification would make it easier for eligible professionals and eligible hospitals to purchase certified EHR Modules that are compatible and could be used together to achieve meaningful use and could increase or improve interoperability among HIT in general. Conversely, many other commenters strongly disagreed with requiring EHR Modules to be tested and certified for compatibility. Overall, these commenters asserted that it would be technically infeasible as well as both logistically (e.g., multiple testing and certification sites and multiple EHR Module developers) and financially impractical to attempt to test and certify for integration given the huge and shifting numbers of possible combinations. Some commenters, however, suggested that EHR Modules could be tested and certified as integrated bundles. One commenter recommended that if we were to pursue any type of EHR Module-to-EHR Module integration, it should be no earlier than when we adopt the next set of standards, implementation specifications, and certification criteria, and then it should only be done selectively based on meaningful use requirements. Another commenter suggested that ONC-ATCBs be given the option, but not be required, to determine if EHR Modules are compatible.

Response. We believe that the testing and certification of EHR Modules for the purposes of integration is inappropriate for the temporary certification program due to various impracticalities. We believe that EHR Module-to-EHR Module integration is inappropriate primarily because of the impracticalities pointed out by commenters related to the numerous combinations of EHR Modules that will likely exist and the associated technical, logistical, and financial costs of determining EHR Module-to-EHR Module integration. To the extent that an EHR Module developer or developers present EHR Modules together as an integrated bundle for testing and certification, we would allow the testing and certification of the bundle only if it was capable of meeting all the applicable certification criteria and would otherwise constitute a Complete EHR. In all other circumstances, we would not require testing and certification for EHR Module-to-EHR Module integration as part of the temporary certification program. Nothing in this final rule precludes an ONC-ATCB or other entity from offering a service to test and certify EHR Module-to-EHR Module integration. However, to be clear, although we do not require or specifically preclude an ONC-ATCB from testing and certifying EHR Module-to-EHR Module integration, any EHR Module-to-EHR Module testing and certification done by an ONC-ATCB or other entity will be done so without specific authorization from the National Coordinator and will not be considered part of the temporary certification program. We understand that testing and certification for EHR Module-to-EHR Module integration may be advantageous in certain instances, but we do not believe, for the reasons discussed above, that we could set all the necessary parameters for testing EHR Module-to-EHR Module integration within the allotted timeframe of the temporary certification program.

E. Application Process

As outlined in greater detail below, the proposed application process consisted of an applicant abiding by certain prerequisites before receiving an application, adhering to the application requirements and submitting the application by one of the proposed methods.

1. Application Prerequisite

We proposed in section 170.415 that applicants would be required to request, in writing, an application for ONC-ATCB status from the National Coordinator. We further proposed that applicants must indicate the type of authorization sought pursuant to §170.410, and if seeking authorization to perform EHR Module testing and certification, the specific type(s) of EHR Module(s) they seek authorization to test and certify. Finally, we proposed that applicants would only be authorized to test and certify the types of EHR Modules for which the applicants sought and received authorization.

Comments. A commenter expressed agreement with our proposal to limit an applicant's authorization to test and certify EHR Modules to the EHR Modules specified in the applicant's application. The commenter requested, however, that we establish a process for allowing ONC-ATCBs to apply for additional authorization to test and certify additional EHR Modules and to allow for the expansion of authorization over time. Another commenter asked that we clarify that ONC-ATCBs that choose to only test and certify EHR Modules be allowed to limit their testing and certification to one health care setting, such as testing and certifying a "laboratory" EHR Module solely for an ambulatory setting.

Response. The only process that we intend to use to authorize ONC-ATCB's under the temporary certification program is the application process that we have proposed. Therefore, if an ONC-ATCB authorized to test and certify a certain type(s) of EHR Module(s) wanted to seek additional authorization for the testing and certification of other types of EHR Modules, it would need to submit another application requesting that specific authorization. We would anticipate in that situation, however, that the application process and review would proceed fairly quickly. In addition, we will consider whether an alternative method would be appropriate for such a situation under the proposed permanent certification program. Lastly, we note, in response to a commenter's question about whether an ONC-ATCB authorized to test and certify a certain type of EHR Module is required to test and certify for both ambulatory and inpatient settings, that the answer would depend on what type of EHR Module authorization the applicant for ONC-ATCB status sought. As previously noted, it is possible to seek authorization to test and certify EHR Modules that address only an ambulatory or inpatient setting. Accordingly, we are finalizing this provision without modification.

2. Application

We proposed in section 170.420 that the application for ONC-ATCB status would consist of two parts. We further proposed that applicants would be required to complete both parts of the application and submit them to the National Coordinator for the application to be considered complete.

a. Part 1

In Part 1 of the application, we proposed that an applicant provide general identifying information including the applicant's name, address, city, state, zip code, and website. We proposed that an applicant also designate an authorized representative and provide the name, title, phone number, and email address of the person who would serve as the applicant's point of contact. We proposed that an applicant complete and submit self audits to all sections of Guide 65 and ISO/IEC 17025:2005 (ISO 17025) as well as submit additional documentation related to Guide 65 and ISO 17025. We also proposed that an applicant had to agree to adhere to the Principles of Proper Conduct for ONC-ATCBs.

Comments. We received several comments expressing agreement with the application requirements, including the use of Guide 65 and ISO 17025. One commenter specifically stated that requiring applicants for ONC-ATCB status to demonstrate their conformance to both Guide 65 and ISO 17025 is an appropriate and effective means to demonstrate an applicant's competency and ability to test and certify Complete EHRs and/or EHR Modules and, therefore, an appropriate means for initiating our proposed testing and certification program. However, we also received multiple comments requesting that we provide more explanation about Guide 65 and ISO 17025. The commenters requested information about how Guide 65 and ISO 17025 are related to Complete EHRs and EHR Modules, why we selected Guide 65 and ISO 17025 as conformance requirements for the temporary certification program, and how Guide 65 and ISO 17025 are related to one another, including explaining why ISO 17025 is appropriate for the temporary certification program but not for the permanent certification program. Commenters also recommended that we consult with NIST to

develop an “information paper” or other supplemental guidance document to assist the industry with understanding Guide 65 and ISO 17025 and how they will apply to the certification programs.

One commenter stated that conformance to ISO 17025 was not a barrier to entry because there are at least two commercial laboratories currently accredited to ISO 17025 and performing testing in a similar government program (USGv6 Testing Program). Conversely, other commenters expressed concern that Guide 65 and ISO 17025 were possible barriers to entry. Some commenters thought that the documentation requirements would be too high an administrative burden for applicants, while others thought there was not enough time for applicants to demonstrate compliance with Guide 65 and ISO 17025 in time to apply for, and receive authorization, under the temporary certification program.

The commenters offered various recommendations for addressing their stated concerns. One commenter suggested that we delay compliance with Guide 65 and ISO 17025 until the permanent certification program is implemented. A second option recommended by commenters was to not require strict compliance with Guide 65 and ISO 17025, but rather allow for material compliance. In support of this recommendation, one commenter contended that certain provisions of ISO 10725 (i.e., provisions on uncertainty of measurements, sampling, calibration methods, and environmental conditions that impact results) do not appropriately address HIT testing and therefore should not apply. A third option presented by commenters was for us to embrace a glide path that would allow qualified organizations to move towards compliance in a systematic way. A more specific recommendation illustrating this sentiment was to allow

applicants for ONC-ATCB status to meet certain requirements on a timeline that would enable a new entrant to build and demonstrate their capabilities throughout the application process while still requiring full adherence to the application requirements before an applicant is granted ONC-ATCB status.

Response. With respect to those comments that requested further explanation about Guide 65 and ISO 17025, we would note that the International Organization for Standardization (ISO) developed both standards. As explained in the Introduction of Guide 65, the observance of the Guide's specifies requirements is intended to ensure that certification bodies operate third-party certification systems in a consistent and reliable manner, which will facilitate their acceptance on a national and international basis. ISO 17025 is also an international standard intended to serve as a basis for accreditation, which accreditation bodies use when assessing the competence of testing and calibration laboratories. We note that both standards have been developed by a voluntary consensus standards body, as required by the National Technology Transfer and Advancement Act of 1995 and the Office of Management and Budget (OMB) Circular A-119, and we are aware of no alternative voluntary consensus standards that would serve the purpose for which these standards are intended to serve.

Guide 65 will be utilized to determine if an applicant for ONC-ATCB status is capable of conducting an appropriate certification program for certifying Complete EHRs and/or EHR Modules. ISO 17025 will be utilized to determine if an applicant for ONC-ATCB status is capable of conducting an appropriate testing program for testing Complete EHRs and/or EHR Modules. We believe that Guide 65 and ISO 17025 are clear in the requirements they impose on a testing and certification body, and therefore,

we do not see the need for an "information" paper or additional guidance at this time. We would, as appropriate, consider issuing guidance to further clarify any requirements of this final rule.

We agree with the commenters that stated that our application requirements for the temporary certification program are appropriate and do not constitute a barrier to entry. As stated by commenters, requiring applicants for ONC-ATCB status to demonstrate their conformance to both Guide 65 and ISO 17025 is an appropriate and effective method for determining an applicant's competency and ability to test and certify Complete EHRs and/or EHR Modules and, therefore, an appropriate method for initiating our proposed temporary certification program. By proposing these requirements, we have not only indicated that we believe them to be appropriate measures of applicants' competencies, but that they are also not overly burdensome and that applicants will have sufficient time to meet the requirements in time to apply under the temporary certification program. As we noted in the Proposed Rule, applicants under the permanent certification program may have to meet potentially more comprehensive requirements in order to meet the proposed accreditation requirement. In regard to the commenter's question about the application of ISO 17025 to the proposed permanent certification program, we have proposed that a separate accreditation process for testing laboratories would exist through the National Voluntary Laboratory Accreditation Program (NVLAP) and anticipate that process would include compliance with ISO 17025.

By ensuring that an ONC-ATCB is capable of performing its responsibilities related to testing and certification we believe industry and consumer confidence will be established in the temporary certification program and in the Complete EHRs and EHR

Modules tested and certified under the program. Based on these reasons and our stated belief that there is sufficient time for an applicant to apply for ONC-ATCB status, we do not believe that any type of application or authorization process that would provide for any less than full achievement and compliance with the application requirements of the temporary certification program is appropriate, including allowing for material compliance or a glide path to full compliance. As to the one commenter's contention that certain provisions of ISO 17025 do not apply to the testing of HIT, it is incumbent upon an applicant for ONC-ATCB status to demonstrate in its self audit to ISO 17025 and/or Guide 65 why provisions or requirements do not apply to its request for authorization to test and certify Complete EHRs and/or EHR Modules.

We are finalizing this provision without modification.

b. Part 2

We proposed for Part 2 of the application that an applicant must submit a completed proficiency examination. We did not receive any comments on this provision. Therefore, we are finalizing this provision without modification.

3. Principles of Proper Conduct for ONC-ATCBs

We received multiple comments on the proposed Principles of Proper Conduct for ONC-ATCBs. We did not, however, receive any comments on the Principles of Proper Conduct proposed in paragraphs (c), (d) and (f) of §170.423. Therefore, we are finalizing these Principles of Proper Conduct without modification. While we received comments on all the other proposed Principles of Proper Conduct for ONC-ATCBs and suggestions for additional principles of proper conduct, the majority of the comments were focused on compliance with Guide 65 and ISO 17025, the proposed use of NIST test tools and

test procedures, the requirement that ONC-ATCBs provide ONC, no less frequently than weekly, a current list of Complete EHRs and EHR Modules that have been tested and certified, the proposed records retention requirement, and our proposed requirement that ONC-ATCBs issue refunds for tests and certifications that were not completed.

a. Operation in Accordance with Guide 65 and ISO 17025 including Developing a Quality Management System

We proposed in section 170.423(a) that an ONC-ATCB would be required to operate its certification program in accordance with Guide 65 and its testing program in accordance with ISO 17025. We also proposed in §170.423(b) that an ONC-ATCB be required to maintain an effective quality management system which addresses all requirements of ISO 17025.

The comments we received on Guide 65 and ISO 17025 were repetitive and essentially indistinguishable from the comments we received on Guide 65 and ISO 17025 in relation to our proposed application process. Therefore, we do not discuss them again in this section and we are finalizing this Principle of Proper Conduct for ONC-ATCBs without modification.

b. Use of NIST Test Tools and Test Procedures

We proposed in section 170.423(e), that an ONC-ATCB would be required to "[u]se testing tools and procedures published by NIST or functionally equivalent testing tools and procedures published by another entity for the purposes of assessing Complete EHRs and/or EHR Modules compliance with the certification criteria adopted by the Secretary."

We received a number of comments on this proposed Principle of Proper Conduct for ONC-ATCBs. We have divided the comments into two categories, which are: establishment of test tools and test procedures; and public feedback process.

i. Establishment of Test Tools and Test Procedures

Comments. While some commenters expressed agreement with the use of NIST test tools and test procedures, many commenters requested clarification on NIST's role and scope of authority. A commenter specifically asked whether NIST would be the author of both the test tools and test procedures for each and every certification criterion. Other commenters requested clarification of the phrase "functionally equivalent testing tools and procedures published by another entity" and specifically requested that we create a process for the timely establishment of functionally equivalent test tools and test procedures, with one commenter recommending that "functionally equivalent" be determined by ONC during the application process. Commenters noted that NIST has published draft versions of test procedures that will likely change once the final rules for both the HIT Standards and Certification Criteria interim final rule and the CMS Medicare and Medicaid EHR Incentive Programs proposed rule are issued. One commenter concluded that "functionally equivalent" would not be able to be determined until the final NIST test procedures are issued. To address this issue, the commenter recommended that we adopt CCHIT "IFR Stage 1 Certification" procedures (with appropriate modifications once a final rule is published) for testing at the start of the temporary certification program and that ONC-ATCBs use NIST test procedures once they became available at which point the NIST test procedures could serve as an option for the temporary certification program, and subsequently be deemed the only acceptable

set of test procedures for the proposed permanent certification program. Another commenter expressed a lack of confidence in functionally equivalent test tools and test procedures and requested that we confirm that Complete EHR and EHR Module developers would have no liability regarding the functional equivalence of an ONC-ATCB's test tools and test procedures. The commenter stated that if this assurance could not be provided then only NIST test tools and test procedures should be utilized. Commenters also asked for clarification on the extent to which ONC-ATCBs are permitted to modify test procedures/test scripts and how test procedures/test scripts could be corrected, if necessary. Some commenters expressed a preference for consistency of test data and test criteria across all testing organizations and were concerned about allowing ONC-ATCBs to define their own test scripts or test procedures. The commenters reasoned that some ONC-ATCBs may have "easier" tests than others, and therefore, the credibility of the process will be uneven and questionable. Finally, a commenter also asked who would develop implementation guidance for standards adopted in the HIT Standards and Certification Criteria interim final rule and how this guidance would be linked to the test methods in a way that would accurately reflect a common interpretation of a standard.

Response. First and foremost, we reiterate that the National Coordinator is responsible for administering the temporary certification program. Consistent with the HITECH Act, we are in consultation with NIST to learn from its resident experts and have requested NIST's assistance in the development of test tools and test procedures that all ONC-ATCBs could use to properly and consistently test and certify Complete EHRs and EHR Modules in accordance with the standards, implementation specifications, and

certification criteria adopted by the Secretary. We expect that NIST will develop a test tool and test procedure for each and every certification criterion.

We have reviewed the commenters' concerns and requests for clarification. After further consideration, we have decided to modify this Principle of Proper Conduct for ONC-ATCBs to more thoroughly clarify our intent. We have revised the Principle of Proper Conduct for ONC-ATCBs to remove the concept of "functionally equivalent" and to clearly state that the National Coordinator would play the central role in determining which test tools and test procedures will be approved for ONC-ATCBs to use. The revised Principle of Proper Conduct requires ONC-ATCBs to "[u]se test tools and test procedures approved by the National Coordinator for the purposes of assessing Complete EHRs' and/or EHR Modules' compliance with the certification criteria adopted by the Secretary."

We believe that this revision provides the National Coordinator with greater flexibility and discretion to ensure that Complete EHRs and EHR Modules are being tested and certified by ONC-ATCBs according to the best test tools and test procedures available. In that regard, we believe that NIST test tools and test procedures will likely be a primary source for ONC-ATCBs to use as they develop their test scripts. We understand that NIST may establish test tools and test procedures based on multiple sources, such as NIST-developed tools, industry-developed tools, or open source tools, as appropriate. NIST has been exploring and will likely utilize all three of these options. That being said, this revised Principle of Proper Conduct for ONC-ATCBs will provide the National Coordinator with the ability to approve not only NIST test tools and test procedures, but potentially other test tools and test procedures that are identified or

developed by other organizations. We understand that commenters would prefer to have the National Coordinator serve as the locus of control with respect to which test tools and test procedures ONC-ATCBs are permitted to use. We also inferred from the comments that such an approach would provide greater certainty to Complete EHR and EHR Module developers as to which test tools and test procedures may be used by ONC-ATCBs, as well as greater consistency among ONC-ATCBs' testing and certification processes.

A person or entity may submit a test tool and/or test procedure to the National Coordinator to be considered for approval to be used by ONC-ATCBs. The submission should identify the developer of the test tool and/or test procedure, specify the certification criterion or criteria that is/are addressed by the test tool and/or test procedure, and explain how the test tool and/or test procedure would evaluate a Complete EHR's or EHR Module's compliance with the applicable certification criterion or criteria. The submission should also provide information describing the process used to develop the test tool and/or test procedure, including any opportunity for the public to comment on the test tool and/or test procedure and the degree to which public comments were considered. In determining whether to approve a test tool and/or test procedure, the National Coordinator will consider whether it is clearly traceable to a certification criterion or criteria adopted by the Secretary, whether it is sufficiently comprehensive (assesses all required capabilities) for ONC-ATCBs to use in testing and certifying a Complete EHR's or EHR Module's compliance with the certification criterion or criteria adopted by the Secretary, whether an appropriate public comment process was used during the development of the test tool and/or test procedure, and any other relevant

factors. When the National Coordinator has approved test tools and/or test procedures, we will publish a notice of availability in the Federal Register and identify the approved test tools and test procedures on the ONC website.

Once test tools and test procedures have been approved by the National Coordinator, ONC-ATCBs will have the responsibility and flexibility to configure their own test scripts (i.e., specific scenarios using the test tools and test procedures), to create, for example, a testing sequence that an ONC-ATCB believes is the most efficient way for testing a certain suite of capabilities. Given the level and type of adjustments that we expect ONC-ATCBs to make, we do not believe that it will be possible for ONC-ATCBs to include significant variations in their test scripts such that a Complete EHR or EHR Module will pass a test administered by one ONC-ATCB but fail a test administered by a different ONC-ATCB. As to the commenter's inquiry about how "implementation guidance" will link to test tools and test procedures, we believe that, where implementation specifications have been adopted in the HIT Standards and Certification Criteria interim final rule, they will be considered in the development of test tools and test procedures.

Comments. A commenter recommended, based on the increased focus on the safety of EHRs, that the NIST testing framework be developed using auditable quality guidelines, including documentation on the purpose, installation, configuration, use and traceability of the NIST testing framework. Some commenters provided recommendations on the processes for the development of test tools and test procedures. A commenter suggested that NIST look to adopt existing test tools and test procedures currently operational and developed via industry consensus, while other commenters

specifically recommended that we utilize HL7 EHR-S FM and its profiles and the Committee on Operating Rules for Information Exchange® (CORE) testing processes. Other commenters contended that the scope of the test procedures currently developed by NIST is too narrow and does not take into account clinical realities when systems are implemented in a clinical setting. Another commenter recommended that the test tools and test procedures support end-user needs.

Response. The NIST test tools and test procedures include components to help ensure traceability of a specific certification criterion. The test tools and test procedures also have documentation for installation, configuration and use. As noted above, the National Coordinator may approve test tools and test procedures for the temporary certification program based on multiple sources, as appropriate. We would further note that while we recognize the utility of other sources, such as HL7 EHR-S FM or CORE testing processes, the temporary certification program's primary focus is to test and certify Complete EHRs and EHR Modules to the certification criteria adopted by the Secretary. The scope of the test tools and test procedures is defined by the applicable certification criterion or criteria. Therefore, the test tools and test procedures are not currently focused on addressing matters outside the scope of adopted certification criteria such as usability or "end-user needs."

ii. Public Feedback Process

Comments. Commenters expressed concern that there was a lack of a specified process for stakeholders, particularly Complete EHR and EHR Module developers, to participate in the development, review and validation of test procedures. Multiple commenters asked for a formal role for Complete EHR and EHR Module developers as

well as eligible professionals and eligible hospitals to give feedback to NIST. A commenter noted that the Proposed Rule stated that the test tools and test procedures would be published by NIST on its website or through a notice in the **Federal Register**, but that the Proposed Rule did not clearly delineate the processes, how the processes will be managed, and a timeline. Another commenter stated that when "test scripts" involve or relate to the implementation of an adopted standard, NIST should be required to consult with the standards development organization (SDO) publisher of the standard for review of proposed "test scripts," and should be required to consider comments made by the SDO prior to publication of final "test scripts." A final comment expressed concern that the test tools and test procedures being developed by NIST are not following the government protocol for openness and transparency by allowing for an open, public comment period on the test tools and test procedures before adoption.

Response. We noted in the Proposed Rule that the test tools and test procedures would be published in some manner and suggested, as examples, that publication on NIST's website or by notice in the **Federal Register** would be acceptable methods. As noted above, NIST has published drafts of the test tools and test procedures on its website and has been accepting and reviewing public comments since releasing the drafts. Specifically, NIST began publishing test tools and test procedures on its website on February 23, 2010. The test tools and test procedures have been published in four "waves" or groups of test tools and test procedures. At the time this final rule was prepared, NIST had received over 100 public comments on its drafts. In response, NIST has issued revised drafts of the test tools and test procedures and is developing "frequently asked questions and answers" that it plans to post on its website to address

common comments on the draft test tools and test procedures. NIST intends to continue to seek and consider public feedback until the test tools and test procedures are finalized, which will likely occur in conjunction with the publication of the final rules for both the HIT Standards and Certification Criteria interim final rule and the Medicare and Medicaid EHR Incentive Programs proposed rule.

It is not within the scope of this rulemaking to instruct NIST to consult with other entities. However, we note that all stakeholders, including Complete EHR and EHR Module developers and SDO publishers, may participate in the public comment process described above. Furthermore, we believe that the feedback process currently employed by NIST is an appropriate and acceptable method for soliciting, accepting and meaningfully considering public comments on the test tools and test procedures.

c. ONC Visits to ONC-ATCB Sites

We proposed in section 170.423(g) to require an ONC-ATCB to allow ONC, or its authorized agent(s), to periodically observe on site (unannounced or scheduled), during normal business hours, any testing and/or certification performed to demonstrate compliance with the requirements of the temporary certification program.

Comments. A commenter stated that if visits are unannounced, then there can be no assurance that a test or certification will actually be underway upon arrival of an ONC representative. Therefore, the commenter recommended that we should revise the requirement to require that an ONC-ATCB respond within 2 business days to an ONC request to observe testing and/or certification by providing the date, time, and location of the next scheduled test or certification. The commenter further stated that ONC observers for site visits would likely need to execute confidentiality and/or business

associate agreements because some HIT vendors treat their software screens and other elements as trade secrets. Additionally, the commenter stated that during site testing of hospital-developed EHRs, protected health information may inadvertently appear on screen in reports or audit trails. The commenter contended that if ONC or its authorized agent(s) were unable to execute such confidentiality and/or business associate agreements, then ONC observation may have to be limited to those elements of testing that do not risk revealing vendor trade secrets or protected health information; or ONC might have observation of testing limited to Complete EHR or EHR Module developers who waive their confidentiality requirements for ONC observers.

Response. Our original proposal gave us the option to either conduct scheduled or unannounced visits. After considering the comments, we believe it is appropriate to maintain both options. If we determine that there is a specific testing and/or certification that would be appropriate for us or our authorized agent(s) to observe, we may find it is more prudent to schedule a visit. However, to monitor compliance with the provisions of the temporary certification program and to maintain the integrity of the program, we believe that unannounced visits are appropriate. In addition, we expect that any confidentiality agreement executed between an ONC-ATCB and a customer, such as Complete EHR and EHR Module developers, for the purposes of testing and certification under the temporary certification program would include ONC and its authorized representatives as parties who may observe the testing and certification of the customer's Complete EHR or EHR Module. We would also expect that the confidentiality agreement would cover any proprietary information, trade secrets, or protected health

information. Therefore, we are finalizing this Principle of Proper Conduct without modification.

d. Lists of Tested and Certified Complete EHRs and EHR Modules

i. ONC-ATCB Lists

We proposed in section 170.423(h) to require an ONC-ATCB to provide ONC, no less frequently than weekly, a current list of Complete EHRs and/or EHR Modules that have been tested and certified which includes, at a minimum, the vendor name (if applicable), the date certified, product version, the unique certification number or other specific product identification, and where applicable, the certification criterion or certification criteria to which each EHR Module has been tested and certified.

Comments. Many provider organizations expressed appreciation for the proposed requirement and the proposed frequency for which the lists were to be updated. In relation to what ONC-ATCBs report, a commenter specifically expressed support for making timely, complete, and useful information available to eligible professionals and eligible hospitals as they work to purchase and implement Certified EHR Technology that will enable them to demonstrate meaningful use.

Some commenters requested clarification and made recommendations for revisions to the provision. One commenter suggested that the provision should be revised to require an ONC-ATCB to notify ONC within a week of successful testing and certification of new Complete EHRs and/or EHR Modules. Additionally, the commenter contended that the proposed provision was unclear as to whether an ONC-ATCB was required to send a complete, current list or only new additions and whether the list could be sent via email. Another commenter suggested revising the provision to require an

ONC-ATCB to also report a current list of "applicants" and their status in the testing or certification queue.

Response. We will, as proposed, require that ONC-ATCBs provide the National Coordinator with a current list of Complete EHRs and/or EHR Modules that have been tested and certified no less frequently than weekly. We anticipate only requiring weekly updates, but ONC-ATCBs are free to provide more frequent updates. We believe that weekly updates are sufficient for providing current information to the market on the status of Complete EHRs and EHR Modules without placing an administrative burden on ONC-ATCBs. In this regard, we have previously stated and continue to expect that the information would be provided electronically, such as through email. We also agree with the commenter that it would be unnecessary for an ONC-ATCB to continue to report on previously certified Complete EHRs and/or EHR Modules and, therefore, only expect these weekly reports to include new certifications issued between the last weekly report and the newly submitted weekly report. Additionally, we do not believe that any substantial benefit would come from having an ONC-ATCB report on the status of Complete EHRs and/or EHR Modules currently being tested and certified. The time needed for testing and certification of Complete EHRs and EHR Modules will likely vary based on many factors and, in some cases, may not be completed due to various reasons. Therefore, we do not believe that the reporting of products in an ONC-ATCB's queue should be a requirement at this time.

We agree with the commenter who indicated that useful information should be made available to eligible professionals and eligible hospitals as they decide which Certified EHR Technology to adopt. Moreover, we note that much of the information

reported by ONC-ATCBs will be included in the Certified HIT Products List (CHPL) that will be available on ONC's website. After consideration of public comments and our own programmatic objectives, we accordingly believe that two additional elements should be reported by ONC-ATCBs in order to improve transparency and assist eligible professionals and eligible hospitals who seek to adopt certified Complete EHRs and EHR Modules. The two additional elements we will require ONC-ATCBs to report are the clinical quality measures to which a Complete EHR or EHR Module has been tested and certified and, where applicable, any additional software a Complete EHR or EHR Module relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary. As with the other information that ONC-ATCBs must report, these two additional elements, as suggested by the commenter, will enable eligible professionals and eligible hospitals to make informed purchasing decisions.

The reporting of clinical quality measures to which a Complete EHR or EHR Module has been tested and certified will enable an eligible professional or eligible hospital to identify and adopt a Complete EHR or EHR Module that includes the clinical quality measures they seek to implement. Knowledge of the additional software a Complete EHR or EHR Module has relied upon to demonstrate compliance with a certification criterion or criteria will be useful, and in some cases essential, for eligible professionals and eligible hospitals who are deciding which Complete EHR or EHR Module to adopt. With this information, eligible professionals and eligible hospitals would be able to assess whether a specific certified Complete EHR or EHR Module may be incompatible with their current information technology (IT) or would require them to install additional IT. We stress that this reporting requirement only relates to software

that is relied upon by a Complete EHR or EHR Module to demonstrate compliance with a certification criterion or criteria adopted by the Secretary. We do not intend or expect this requirement to be construed as a comprehensive specifications list or similar type of inclusive list. Rather, our rationale for including this requirement is to ensure that eligible professionals and eligible hospitals who adopt a certified Complete EHR or EHR Module understand what is necessary for the Complete EHR or EHR Module to operate in compliance with the certification criterion or criteria to which it was tested and certified.

For example, if a Complete EHR relied upon an operating system's automatic log-off functionality to demonstrate its compliance with this certification criterion, we would expect the operating system relied upon to be reported. Conversely, if a Complete EHR included its own automatic log-off capability, even though the Complete EHR may have been tested and certified on a particular operating system, we would not require the operating system to be reported because it was not relied upon to demonstrate compliance with the certification criterion.

Finally, we note that our required reporting elements constitute a minimum. We do not preclude ONC-ATCBs from including in their weekly reports additional information that prospective purchasers and users of Complete EHRs and EHR Modules would find useful, such as specifying the Complete EHR or EHR Module's compatibility with other software or compatibility with other EHR Modules. If not reported to the National Coordinator, we encourage ONC-ATCBs to consider making such information available on their own websites to better inform prospective purchasers and users of Complete EHRs and EHR Modules.

We are revising §170.423(h) consistent with our discussion above.

ii. Certified HIT Products List

We stated in the Proposed Rule that in an effort to make it easier for eligible professionals and eligible hospitals to cross-validate that they have in fact adopted Certified EHR Technology, the National Coordinator intends to make a master CHPL of all Complete EHRs and EHR Modules tested and certified by ONC-ATCBs available on the ONC website. The CHPL would be a public service and would be a single, aggregate source of all the certified product information ONC–ATCBs provide to the National Coordinator. 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. We also noted that, over time, we anticipate adding features to the website, which could include interactive functions to enable eligible professionals and eligible hospitals to determine whether a combination of certified EHR Modules could constitute Certified EHR Technology.

Comments. Many commenters expressed support for our decision to create a list of certified Complete EHRs and EHR Modules and to post a link to that list on our website. Many commenters also provided recommendations for how to enhance the list. One commenter endorsed an online system whereby physicians could type in or select information on the Complete EHR or EHR Module they planned on using to determine whether their selected combination would enable them to meet the CMS Medicare and Medicaid EHR Incentive Programs requirements. The commenter reasoned that the steps were necessary because eligible professionals, especially in smaller practices, did not have the technical expertise or support to ascertain whether or not a Complete EHR, EHR

upgrades, EHR Module(s), or a combination of EHR Modules would enable them to perform the meaningful use requirements. Another commenter requested an explicit commitment from ONC that the use of certified Complete EHRs and/or EHR Modules on the CHPL will support their ability to report all required meaningful use measures.

Some commenters expressed a preference that the CHPL contain information on the capabilities of certified Complete EHRs and EHR Modules associated with adopted certification criteria. Other commenters requested that the CHPL contain information on whether certified Complete EHRs or EHR Modules are compatible with other HIT. In particular, commenters stated that it was important to eligible professionals and eligible hospitals for Complete EHR and EHR Module developers to fully disclose the functions for which their products are certified, which software components are necessary to meet certification criteria, and to also fully disclose any compatibility issues. A few commenters also suggested that the CHPL contain data on usability features of certified Complete EHRs and EHR Modules.

One commenter recommended that ONC and each ONC-ATCB maintain a list of certified Complete EHRs and EHR Modules. Another commenter recommended that, in order to prevent the conveyance of potentially inaccurate information and confusion in the market, an ONC-ATCB should not maintain on its own website a current list of the Complete EHRs and/or EHR Modules that it has certified, but instead reference the CHPL on ONC's website for the complete list of certified Complete EHRs and EHR Modules.

Response. We appreciate the commenters' support for the CHPL and their recommendations for its enhancement. We intend for the CHPL to be a single, aggregate

source of all certified Complete EHRs and EHR Modules reported by ONC-ATCBs to the National Coordinator. The CHPL will comprise all of the certified Complete EHRs and EHR Modules that could be used to meet the definition of Certified EHR Technology. It will also include the other pertinent information we require ONC-ATCBs to report to the National Coordinator, such as a certified Complete EHR's version number. Eligible professionals and eligible hospitals that elect to use a combination of certified EHR Modules may also use the CHPL webpage to validate whether the EHR Modules they have selected satisfy all of the applicable certification criteria that are necessary to meet the definition of Certified EHR Technology. The CHPL webpage will include a unique identifier (such as a code or number) for each certified Complete EHR and each combination of certified EHR Modules that satisfies all of the applicable certification criteria necessary to meet the definition of Certified EHR Technology. The unique code or number listed on the CHPL webpage could subsequently be used to submit to CMS for attestation purposes.

We believe that only ONC should maintain the CHPL to ensure that the CHPL is accurate and comprehensive. However, we do not believe that it is appropriate to preclude an ONC-ATCB from maintaining on its own website a list of Complete EHRs and/or EHR Modules that it tests and certifies. An ONC-ATCB's own list could have benefits for the market in identifying the specific ONC-ATCB that tested and certified a Complete EHR or EHR Module. The ONC-ATCB may also create a link on its website to the CHPL, which conceivably would be a user-friendly feature.

e. Records Retention

We proposed in section 170.423(i) to require an ONC-ATCB to retain all records related to the testing and certification of Complete EHRs and/or EHR Modules for the duration of the temporary certification program and to provide copies of all testing and certification records to ONC at the sunset of the temporary certification program.

Comments. A commenter asserted that requesting "all" testing and certification records will lead to ONC receiving a voluminous amount of records that we likely never intended to receive. The commenter recommended that we be more specific about the records ONC-ATCBs will need to provide copies of to ONC.

Many commenters noted that CMS has proposed in its Medicare and Medicaid EHR Incentive Programs proposed rule to require providers to maintain records demonstrating meaningful use, which includes the use of Certified EHR Technology, for 10 years. The commenters noted that in the event of an audit, eligible professionals and eligible hospitals may need to go back to the certification body or ONC, in the case of the temporary certification program, to verify that a particular product was indeed certified at a particular point in time. Therefore, the commenters recommended that our proposed retention period for certification bodies needs to be equal to the length of time that eligible professionals and eligible hospitals must maintain records under CMS's proposal, plus two or more additional years to ensure that records are available during an audit process. A commenter also requested that ONC specify how long it would retain copies of records provided by ONC-ATCBs at the sunset of the temporary certification program.

Response. To address the commenter's concern about voluminous records being provided to ONC and to provide clarity to ONC-ATCBs about their records retention responsibility, we are clarifying the language of this Principle of Proper Conduct. For the

duration of the temporary certification program, an ONC-ATCB will be required to retain all records related to tests and certifications in accordance with Guide 65 and ISO 17025. Upon the conclusion of testing and certification activities under the temporary certification program, ONC-ATCBs will be required to provide copies of the final results of all completed tests and certifications to ONC (i.e., all passed and failed results). ONC will retain all records received from ONC-ATCBs in accordance with applicable federal law and may use the records for assessing compliance with temporary certification program requirements. Our records retention requirement should be construed as an independent requirement. Any other records retention requirements or potential legal compliance requirements should be complied with fully and not in association or correlation with our records retention requirements.

We are revising §170.423(i) consistent with our discussion above.

f. Refunds

We proposed in section 170.423(j) to require an ONC-ATCB to promptly refund any and all fees received for tests and certifications that will not be completed.

Comments. While a vendor organization expressed agreement with our proposed refund requirement, potential applicants for ONC-ATCB status requested that we clarify that refunds would only be required where an ONC-ATCB's conduct caused the testing and certification to be incomplete as opposed to a Complete EHR or EHR Module developer's conduct or a Complete EHR's or EHR Module's failure to achieve a certification. One commenter asked whether this clause was meant to apply only when an ONC-ATCB had its status revoked. Another commenter suggested that our proposed requirement for ONC-ATCBs to return funds should also apply to situations where

Complete EHR or EHR Module developers are required to recertify their products because of misconduct by an ONC-ATCB.

Response. We agree with the commenters that suggested our proposed refund requirement needs clarification. As advocated by the commenters, it was our intention to require ONC-ATCBs to issue refunds only in situations where an ONC-ATCB's conduct caused testing and certification to not be completed. We also agree with the one commenter that this would include situations where a Complete EHR or EHR Module is required to be recertified because of the conduct of an ONC-ATCB. Similarly, if an ONC-ATCB were to be suspended by the National Coordinator under the suspension provisions we have incorporated in this final rule, an ONC-ATCB would be required to refund all fees paid for testing and certification if a Complete EHR or EHR Module developer withdraws a request for testing and certification while the ONC-ATCB is under suspension.

We are revising §170.423(j) consistent with our discussion above.

g. Suggested New Principles of Proper Conduct

We received a few comments that suggested we adopt additional principles of proper conduct. These comments concerned the impartiality and business practices of ONC-ATCBs.

Comments. A commenter recommended that applicants for ONC-ATCB status should be required to not have an interest, stake and/or conflict of interest in more than one entity receiving ONC-ATCB status nor have any conflict of interest with EHR product companies actively promoting EHR products in the marketplace.

Response. Applicants for ONC-ATCB status and ONC-ATCBs must adhere to the requirements of Guide 65 and ISO 17025. These requirements explicitly obligate testing and certification bodies to conduct business in an impartial manner. For instance, an applicant for ONC-ATCB status and/or an ONC-ATCB must have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity and must ensure that activities of related bodies do not affect the confidentiality, objectivity and impartiality of its certifications. We believe these provisions as well as other impartiality provisions contained in Guide 65 and ISO 17025 adequately address any potential conflicts of interest or other situations that might jeopardize the integrity of the temporary certification program.

Comments. We received a few comments recommending that ONC-ATCBs' business practices be considered and evaluated. In particular, one commenter recommended that we adopt a principle of proper conduct that requires an ONC-ATCB to establish, publish and adhere to a non-discriminatory protocol to ensure that requests for testing and certification are processed in a timely manner beginning on the date the ONC-ATCB sets for accepting requests for testing and certification. The commenter asserted that no one should be allowed to make a request prior to the date set by the ONC-ATCB and requests should be processed in the order in which they are received without regard to whether they are for Complete EHRs or EHR Modules. The commenter further asserted that in the event of simultaneously submitted requests, the National Coordinator should conduct a randomized, fair and transparent method for selecting the order in which the requests will be reviewed. Conversely, another commenter suggested that

requests for testing and certification of Complete EHRs and/or EHR Modules that cover the largest market share should be processed first. One commenter recommended that all requests for testing and certification be required to be processed within six months of receipt by an ONC-ATCB.

Response. We have established the Principles of Proper Conduct for ONC-ATCBs. ONC-ATCBs must abide by these Principles of Proper Conduct to remain in good standing. As noted in the previous response, a Principle of Proper Conduct for ONC-ATCBs requires ONC-ATCBs to adhere to the provisions of Guide 65 and ISO 17025, which require an ONC-ATCB to have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity as well as have a documented structure that safeguards impartiality including provisions that ensure the impartiality of its operations. The National Coordinator will review the policies, procedures, and documented structure of applicants for ONC-ATCB status during the application process to ensure that a potential ONC-ATCB meets the impartiality requirements. An ONC-ATCB would also have to maintain impartiality in its operations to remain in good standing under the temporary certification program.

We believe that the requirements of Guide 65 and ISO 17025 clearly require ONC-ATCBs to develop an impartial process for handling requests for the testing and certification of Complete EHRs and EHR Modules. Guide 65 specifically states that "access shall not be conditional upon the size of the [Complete EHR or EHR Module developer] or membership [in] any association or group, nor shall certification be conditional upon the number of certificates already issued." As for the one commenter's

recommendation that we require requests for testing and certification to be completed within six months, we will not adopt such a requirement. Due to factors such as the uncertainty of how many ONC-ATCBs will exist and how many requests for the testing and certification of Complete EHRs and EHR Modules will be received by each ONC-ATCB, we do not believe such a requirement would be equitable or enforceable.

4. Application Submission

We proposed in section 170.425 to allow an applicant for ONC-ATCB status to submit its application either electronically via email (or web submission if available), or by regular or express mail at any time during the existence of the temporary certification program. We did not receive any comments on this provision. Therefore, we are finalizing this provision without modification.

5. Overall Application Process

We received a few comments regarding the overall application process.

Comment. One commenter suggested that applicants for ONC-ATCB status preferably be not-for-profit companies, while another commenter suggested that the number of applicants be limited to five.

Response. We believe it is appropriate to allow all qualified applicants to apply and obtain ONC-ATCB status. We believe that the more applicants that can obtain ONC-ATCBs status the more the market will benefit in terms of increased competition and more options for the testing and certification of Complete EHRs and EHR Modules. Restrictions on the number of applicants that can apply or requiring an applicant for ONC-ATCB status to be a not-for-profit entity will only limit these potential benefits.

Comment. A commenter recommended as part of the ONC-ATCB application process that an applicant indicate the testing site methods it is capable of supporting. The commenter reasoned that this would provide another basis for vendors to select an ONC-ATCB.

Response. An ONC-ATCB is required to provide the types of testing and certification methods that we have specified in §170.457. We believe that an applicant will make such methods and any additional methods it offers known to the market as a means of attracting customers.

Comment. A commenter recommended that the temporary certification program serve as a "test bed" for the accreditation process so that the permanent certification program may limit the frequency with which applicants can reapply for ONC-ACB status.

Response. As discussed in the Proposed Rule, we are unable to establish an accreditation process for the temporary certification program due to the need to establish a certification program as soon as possible. Although we do not have sufficient time to establish an accreditation program, we believe that we have established sufficiently stringent requirements for ONC-ATCB applicants and ONC-ATCBs that, if an ONC-ATCB chose to apply for accreditation under the proposed permanent certification program, it would be well situated to successfully navigate the process.

F. Application Review, Application Reconsideration and ONC-ATCB Status

We proposed in the Proposed Rule to review an application for ONC-ATCB status and, in most circumstances, issue a decision within 30 days. We proposed that if an application was rejected and certain criteria were met, an applicant could seek

reconsideration of the denial. We proposed that if an application were deemed satisfactory, we would make it publicly known that the applicant had achieved ONC-ATCB status and the ONC-ATCB would be able to begin testing and certifying consistent with the authorization granted by the National Coordinator. In association with these proposals, we specifically requested that the public comment on whether we should review an entire application at once or as proposed, in parts; and whether we should reconsider a twice deficient application for any reason besides a clear factual error.

1. Review of Application

We proposed in section 170.430 that we would review applications in the order in which we received them, that the National Coordinator would review Part 1 of the application and determine whether Part 1 of the application was complete and satisfactory before proceeding to review Part 2 of the application, and that the National Coordinator would issue a decision within 30 days of receipt of an application submitted for the first time.

We proposed that the National Coordinator would be able to request clarification of statements and the correction of inadvertent errors or minor omissions. We proposed that the National Coordinator would identify any deficiencies in an application part and provide an applicant with an opportunity to both correct any deficiencies and submit a revised application in response to a deficiency notice on each part of the application. We further proposed that if the National Coordinator determined that a revised application still contained deficiencies, the applicant would be issued a denial notice related to that part of the application. We proposed that the denial notice would indicate that the

applicant would no longer be considered for authorization under the temporary certification program, but that the applicant could request reconsideration of the decision in accordance with §170.435. In association with these proposals, we specifically requested that the public comment on whether it would be preferable for applicants to have their entire application reviewed all at once and then issued a formal deficiency notice or whether we should, as proposed, review applications in parts.

We proposed that an application would be deemed satisfactory if it met all the application requirements. We further proposed that once the applicant was notified of this determination, the applicant would be able to represent itself as an ONC-ATCB and begin testing and certifying Complete EHRs and EHR Modules consistent with its authorization.

Comments. A commenter requested that the National Coordinator clarify that an application will be deemed satisfactory based on the submission of an application that substantially or materially complied with the requirements set forth in regulation. Another commenter recommended that we develop an expeditious internal review and approval process for ONC-ATCB applications. The commenter suggested that this process include a fast-track reprocessing system, as necessary, to allow ONC-ATCB applicants to swiftly correct initial errors and deficiencies.

A commenter expressed agreement and support for the proposed process affording the National Coordinator discretion to request clarifications of statements or corrections of errors or omissions, but the commenter did not agree that such requests should be limited to only inadvertent or minor errors. The commenter reasoned that given the time constraints and complexity of the application process, the National

Coordinator should be able to consider requesting clarifications or corrections in a collaborative process with applicants, as appropriate. The commenter also expressed general agreement with our proposal that an applicant be provided up to fifteen (15) days to respond to a formal deficiency notice. The commenter suggested, however, that considering the National Coordinator's opinion that few organizations will be able to meet the criteria in the temporary certification program, the National Coordinator should have the discretion to grant an extension beyond the 15 days upon a showing of good cause by the applicant. The commenter asserted that this proposal would provide flexibility and assist in ensuring that the process for approving ONC-ATCBs is successful.

We received two comments that expressed agreement with our proposal to review ONC-ATCB applications in parts and two comments recommending that we review the whole application before issuing a deficiency notice. One commenter recommended processing the application based on the request of the applicant or the needs of the reviewer. Both sides contended that their recommended method was more efficient and better for the applicant and reviewer. A couple of commenters requested that, if the review process were to remain a two part process, we make clear that each part of the application will be reviewed in its entirety before a deficiency notice would be issued. One of the commenters also requested that we make clear that each part receives two review opportunities.

Response. We believe that applicants should be required to fully meet all the requirements of the application process to ensure that they are properly qualified to be an ONC-ATCB. We believe that our proposed process provides for a thorough and

expeditious review of an application, which is in the best interest of all parties. We also believe that reviewing applications in two parts is the most efficient method, offers the most flexibility, and provides an applicant with the best opportunity to be successful. We do believe, however, that making some modifications to the application review process in response to comments will benefit both the applicants and the National Coordinator.

We agree with the commenter that additional clarity can be provided by specifically stating that the National Coordinator will review each part of the application in its entirety. Therefore, we have modified §170.430(a)(2) to emphasize this point. We also can confirm that an applicant will have its initial Part 1 application reviewed and then have an opportunity to submit a revised application if necessary. Part 2 of an applicant's application will be given these same two opportunities for review only if Part 1 of the application is deemed satisfactory.

We agree with the commenter that the process for the National Coordinator to seek corrections of errors and omissions should be revised. Therefore, as recommended by the commenter, we are removing the words "inadvertent" and "minor" from §170.430(b)(1). Although we anticipate that the National Coordinator would likely only seek correction of minor errors or omissions, these revisions provide the National Coordinator with more flexibility to allow an error or omission to be corrected instead of issuing a deficiency notice. This flexibility will be beneficial for both applicants and the National Coordinator considering the limited opportunities and short timeframes for correcting applications. In an effort to further increase the flexibility of the process, we are making additional revisions to §170.430 in response to a commenter's recommendation. The commenter recommended that the National Coordinator should

have the discretion, upon a showing of good cause by the applicant, to grant an extension beyond 15 days for an applicant to submit a revised application in response to a deficiency notice.

We agree with the commenter's recommendation and are revising §170.430 to allow 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 and to provide the National Coordinator with the option of granting an applicant's request for additional time to respond to a deficiency notice upon a showing of good cause by the applicant. In determining whether good cause exists, the National Coordinator will consider factors such as: change in ownership or control of the applicant organization; the unexpected loss of a key member of the applicant's personnel; damage to or loss of use of the applicant's facilities, working environment or other resources; or other relevant factors that would prevent the applicant from submitting a timely response to a deficiency notice.

We believe it is unnecessary to establish a predetermined length of time for a good cause extension in the regulation text. The length of time for an extension will be based on an applicant's particular circumstances that constitute good cause for an extension. For example, if an applicant lost a key member of its personnel, then the timeframe extension would reflect a reasonable period of time in which the applicant could remedy that particular issue.

We believe that another means of adding greater flexibility to the application review process as sought by the commenter is to provide the National Coordinator with the same ability to request clarification of statements and the correction of errors or omissions in a revised application as the National Coordinator can do prior to issuing a

deficiency notice. Accordingly, we are revising §170.430 to state that the National Coordinator may request clarification of statements and the correction of errors or omissions during the 15-day period provided for review of a revised application.

2. ONC-ATCB Application Reconsideration

We proposed in section 170.435 that an applicant may request that the National Coordinator reconsider a denial notice issued for each part of an application only if the applicant can demonstrate that a clear, factual error(s) was made in the review of the application part and that the error's correction could lead to the applicant obtaining ONC-ATCB status. We proposed that the National Coordinator would have up to 15 days to consider a timely reconsideration request. We further proposed that if, after reviewing an applicant's reconsideration request, the National Coordinator determined that the applicant did not identify any factual errors or that correction of those factual errors would not remove all identified deficiencies in the application, the National Coordinator could reject the applicant's reconsideration request and that this decision would be final and not subject to further review.

In association with these proposals, we specifically requested that the public comment on whether there are instances, besides an applicant demonstrating that a clear, factual error was made in the review of its application and that the error's correction could lead to the applicant receiving ONC-ATCB status, in which the National Coordinator should reconsider an application that has been deemed deficient multiple times.

Comments. A commenter expressed agreement with our proposed ONC-ATCB application reconsideration process. Another commenter stated, however, that the

National Coordinator should have discretion to reconsider an application that has been deemed deficient multiple times for reasons besides a clear factual error that could lead to the applicant receiving ONC-ATCB status. The commenter concluded that the National Coordinator is in the unique position to determine on a case-by-case basis whether multiple deficiencies should prevent reconsideration of a particular application. The commenter suggested that the National Coordinator should consider several factors in determining whether to reconsider an application that has been deemed deficient multiple times, including the severity and type of the deficiency, the implications of the deficiencies, the applicant's level of responsiveness and cooperation, and the remedial efforts taken by the applicant. The commenter also requested that, due to the differences between the proposed temporary and permanent certification programs and the timeframes associated with each, we consider applications for each program independently (i.e., a reconsideration denial of an application under the temporary certification program would not impact an applicant's ability to apply to be an ONC-ACB under the permanent certification program).

Response. We appreciate the one commenter's expression of support for our proposals. We do not agree with the commenter that the National Coordinator should reconsider all twice-deficient applications for any reason. Rather, we continue to believe that the National Coordinator should only reconsider an application if the applicant for ONC-ATCB status can demonstrate that there was a clear factual error in the review of its application that could lead to the applicant obtaining ONC-ATCB status. We believe that the application requirements and application review processes that we have proposed ensure that only qualified applicants are timely authorized to be ONC-ATCBs. The

application requirements proposed are designed to ensure that applicants are qualified to both test and certify Complete EHRs and/or EHR Modules. Our review process is designed to establish the veracity of an application and to test and verify that an applicant has the necessary capabilities to be authorized to conduct the testing and certification sought by the applicant. Our review process is also designed to reach final decisions in a manner that will allow the temporary certification program to become operational in a timely manner. We believe the application review process contains sufficient opportunities for an applicant to demonstrate that it is qualified to be an ONC-ATCB, including opportunities under both Parts 1 and 2 of an application for the National Coordinator to request clarifications and corrections to the application, opportunities for an applicant to respond to a deficiency notice, and opportunities to request reconsideration of a denial notice if there is a clear, factual error that, if corrected, could lead to the applicant obtaining ONC-ATCB status. Accordingly, we have finalized this provision without modification.

We do, however, want to assure the commenter that a negative reconsideration decision regarding an application under the temporary certification program will not impact an applicant's ability to apply to be an ONC-ACB under the permanent certification program.

3. ONC-ATCB Status

We proposed in section 170.440 that the National Coordinator will acknowledge and 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. We proposed that each ONC-ATCB would be required to prominently and

unambiguously identify on its website and in all marketing and communications statements (written and oral) the scope of its authorization. We also proposed that an ONC-ATCB would not need to renew its status during the temporary certification program, but that an ONC-ATCB's status would expire upon the sunset of the temporary certification program in accordance with §170.490.

Comments. A commenter expressed support for our proposal that an ONC-ATCB may only test and certify HIT that it is authorized to test and certify. Another commenter expressed an opinion that is important to the industry that the National Coordinator makes distinctions as to what a certifying body is approved to certify. One commenter recommended that our requirements related to marketing and communications be limited to the ONC-ATCB's website and all marketing and communications pertaining to its role in the testing and certification of EHRs and HIT. As currently written, the commenter contended that the requirements apply to all marketing and communications made by the entity even if unrelated to their ONC-ATCB status.

A commenter recommended that the authorization status of ONC-ATCBs should be limited to Stage 1 certification. Based on this recommendation, the commenter stated that the authorization should remain valid as long as Stage I incentives are available (i.e., through 2014) and not expire upon the proposed sunset of the temporary certification program.

Response. We appreciate the support for our proposals and reiterate that, as proposed, an ONC-ATCB will only be able to test and certify Complete EHRs and/or EHR Modules consistent with the scope of authorization granted by the National Coordinator. Additionally, as proposed, the ONC-ATCB will have to prominently and

unambiguously display the scope of authorization granted to it by the National Coordinator. To address the commenter's concern about the overreach of our proposed requirement that an ONC-ATCB "identify on its website and in all marketing and communications statements (written and oral) the scope of its authorization" we have clarified the language to clearly state that the requirement only applies to activities conducted by the ONC-ATCB under the temporary certification program. Specifically, we have revised the provision to state, in relevant part, "each ONC-ATCB must prominently and unambiguously identify the scope of its authorization on its website, and in all marketing and communications statements (written and oral) pertaining to its activities under the temporary certification program."

We do not accept the commenter's recommendation to associate authorization and the expiration of authorization to the stages of meaningful uses. As previously noted, 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. Therefore, the temporary certification program must be capable of conducting testing and certification for the applicable stage(s) of meaningful use.

G. Testing and Certification of Complete EHRs and EHR Modules

We proposed in the Proposed Rule the scope of authority granted to ONC-ATCBs by ONC authorization. We also specified which certification criteria or certification criterion ONC-ATCBs would be required to use to test and certify Complete EHRs and EHR Modules.

1. Complete EHRs

We proposed in section 170.445 that to be authorized to test and certify Complete EHRs under the temporary certification program, an ONC-ATCB would need to be capable of testing and certifying Complete EHRs to all applicable certification criteria adopted by the Secretary at subpart C of part 170. We further proposed that an ONC-ATCB that had been authorized to test and certify Complete EHRs would also be authorized to test and certify all EHR Modules under the temporary certification program.

Comments. Commenters expressed agreement with our proposals that, in order to be authorized to test and certify Complete EHRs under the temporary certification program, an ONC-ATCB must be capable of testing and certifying Complete EHRs to all applicable certification criteria and that such an ONC-ATCB would also be authorized to test and certify all EHR Modules under the temporary certification program. One commenter recommended that we require ONC-ATCBs authorized to test and certify Complete EHRs to also test and certify EHR Modules.

Response. We appreciate the commenters' support for our proposals, but we do not adopt the one commenter's recommendation that we require an ONC-ATCB that is authorized to test and certify Complete EHRs to also test and certify EHR Modules. We clearly acknowledged in the preamble of the Proposed Rule and in our proposed regulatory provision 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. We do not, however, believe that we should regulate a private entity's business practices to require it to test and certify EHR Modules. An ONC-ATCB, despite authorization to do so, might have multiple business

justifications for not testing and certifying EHR Modules, such as an insufficient number of qualified employees to conduct the testing and certification of EHR Modules in addition to conducting testing and certification of Complete EHRs, or that doing both would not be as profitable a business model.

Based on consideration of the comments received and review of the proposed provision, we are revising §170.445(a) to state that "An ONC-ATCB must test and certify Complete EHRs to all applicable certification criteria adopted by the Secretary at subpart C of this part." This revision is consistent with our description of testing and certification of Complete EHRs in the Proposed Rule preamble. It also makes explicit that ONC-ATCBs must not only be capable, but as with EHR Modules, are required to test and certify Complete EHRs to the applicable certification criteria adopted by the Secretary under subpart C of Part 170.

2. EHR Modules

a. Applicable Certification Criteria or Criterion

We proposed in sections 170.450(a) and (b) that an ONC-ATCB must test and certify EHR Modules in accordance with the applicable certification criterion or criteria adopted by the Secretary at subpart C of Part 170. In the preamble of the Proposed Rule, we clarified that a single certification criterion would encompass all of the specific capabilities referenced below the first paragraph level. For example, 45 CFR 170.302, paragraph "(e)" (the first paragraph level) identifies that this certification criterion relates to recording and charting vital signs. It includes three specific capabilities at (e)(1), (2), and (3) (the second paragraph level): the ability to record, modify, and retrieve patients' vital signs; the ability to calculate body mass index (BMI); and the ability to plot and

display growth charts. We stated that we viewed the entire set of specific capabilities required by paragraph "(e)" (namely, (e)(1), (2), and (3)) as one certification criterion. The specific capability to calculate BMI, for example, would not be equivalent to one certification criterion.

Comments. We received two comments on our proposal. One commenter expressed agreement with our proposal, including the appropriateness of requiring an EHR Module to be capable of performing all the functions specified at the paragraph level of a certification criterion. The commenter reasoned that to allow testing and certification at a lower level (subparagraph) would result in a very large number of modules that would overcomplicate the certification program. The commenter stated that the only exception might be if there were a very large number of subparagraphs within a criterion or a very large number of criterion within a single objective (e.g., if the number of quality measures remains very high). In that case, the commenter asserted that the module might be divided into two or more logically related groups. But in general, the commenter stated that having a range of 20-25 certification criteria, and therefore potential EHR Modules, was an appropriate level of granularity.

The other commenter stated that requiring a module to perform all of the listed functions or capabilities associated with a specific certification criterion would create a significant problem. In particular, the commenter stated that for the "drug-drug, drug-allergy, drug-formulary checks" certification criterion, there did not appear to be a single EHR Module in the current HIT marketplace that performs all of the four listed capabilities under the criterion. The commenter also surmised that the "incorporate clinical lab-test results into EHR as structured data" certification criterion may cause

similar problems due to its multiple capabilities. Based on these considerations, the commenter recommended that we narrow the scope of EHR Module testing and certification to one of the capabilities or functions (subparagraphs) of a criterion. The commenter stated that this solution would necessitate that the ONC-ATCB provide modules that only perform such discrete functions with a "conditional certification" that carries the caveat that the module must be used in conjunction with other certified modules to offer full and complete functionality for the applicable criterion.

Response. We agree with the first commenter that, as proposed, EHR Modules should be tested and certified to the first paragraph level of a certification criterion, as described in the example above. We believe that this is the most appropriate level for testing and certification of EHR Modules because, in most cases, this level of a criterion most fully represents the capabilities that are needed to perform the associated meaningful use objectives.

We believe that the specific concerns raised by the commenter related to the "drug-drug, drug-allergy, drug-formulary checks" criterion and the "incorporate clinical lab-test results into EHR as structured data" criterion are more appropriately suited for discussion and resolution in the forthcoming final rule to finalize the certification criteria adopted in the HIT Standards and Certification Criteria interim final rule.

We are finalizing paragraph (a) of §170.450 without modification, but we are modifying §170.450 to remove paragraph (b) because it is repetitive of the requirements set forth in paragraph (a).

b. Privacy and Security Testing and Certification

With respect to EHR Modules, we discussed in the Proposed Rule when ONC-ATCBs would be required to test and certify EHR modules to the privacy and security certification criteria adopted by the Secretary. We proposed that EHR Modules must 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:

- The EHR Module(s) are presented for testing and certification as a pre-coordinated, integrated "bundle" of EHR Modules, which could otherwise constitute a Complete EHR. In such instances, the EHR Module(s) shall be tested and certified in the same manner as a Complete EHR. Pre-coordinated bundles of EHR Module(s) which include EHR Module(s) that would not be part of a local system and under the end user's direct control are excluded from this exception. The constituent EHR Modules of such an integrated bundle must be separately tested and certified to all privacy and security certification criteria;
- An EHR Module is presented for testing and certification, and the presenter can demonstrate to the ONC-ATCB 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; or
- An EHR Module is presented for testing and certification, and the presenter can demonstrate to the ONC-ATCB that the EHR Module is designed to perform a specific privacy and security capability. In such instances, the EHR Module may only be tested and certified in accordance with the applicable privacy and security certification criterion/criteria.

Comments. A number of commenters supported our proposed approach and agreed that EHR Modules should be tested and certified to all adopted privacy and security certification criteria unless there were justifiable reasons for which they should not. Other commenters suggested changes to one or more of the stated exceptions and posed questions for our consideration. Some commenters recommended that we deem certification criteria "addressable" similar to the Health Insurance Portability and Accountability Act (HIPAA) Security Rule's application of the word "addressable" to certain implementation specifications (in the HIPAA context) within a security standard (in the HIPAA context). Other commenters noted that with respect to the second exception, involving the demonstration that it would be technically infeasible for an EHR Module to be tested and certified to some or all privacy and security certification criteria, that the term "inapplicable" should be added as a condition in addition to "technically infeasible." Another commenter stated that we should remove the third exception, involving the demonstration that an EHR Module is designed to perform a specific privacy and security capability, because, depending on how the privacy and security EHR Module is developed, it may also need to include certain capabilities, such as an audit log.

Response. We appreciate commenters' support for our proposed approach and the thoughtfulness of the responses. While we understand and appreciate the similarities some commenters saw with respect to the HIPAA Security Rule and leveraging the "addressable" concept, we do not believe that making each privacy and security certification criterion "addressable" in the way it is implemented under the HIPAA

Security Rule is an appropriate approach for the purposes of testing and certifying EHR Modules.

In the context of the HIPAA Security Rule, HIPAA covered entities must assess whether each addressable implementation specification (in the HIPAA Security Rule) is a reasonable and appropriate safeguard in its environment. If a HIPAA covered entity determines that an addressable implementation specification is reasonable and appropriate, then the covered entity is required to implement it. If a HIPAA covered entity determines that an addressable implementation specification is not reasonable and appropriate, the covered entity is required to: 1) document why it would not be reasonable and appropriate to implement the addressable implementation specification; and 2) implement an equivalent alternative measure if reasonable and appropriate. While this is a sensible approach for HIPAA covered entities, we do not believe that it translates well into the testing and certification of EHR Modules.

All HIPAA covered entities are required to comply with the HIPAA Security Rule with respect to their electronic protected health information, regardless of their size and resources. Accordingly, the HIPAA Security Rule provides for a flexible approach, allowing a HIPAA covered entity to implement safeguards that are reasonable and appropriate for its unique environment. We do not believe that this approach is appropriate for testing and certifying EHR Modules because one purpose of certification is to assure eligible professionals and eligible hospitals that an EHR Module includes a specified capability or set of capabilities. For these reasons, we believe that the proposed standard of "technically infeasible" is more appropriate than the HIPAA Security Rule's "addressable" concept for the purposes of testing and certifying EHR Modules. Thus, an

EHR Module developer must satisfy each privacy and security criterion where it is technically feasible.

To complement our "technically infeasible" standard, we agree with those commenters that recommended the addition of the word "inapplicable" to the second proposed exception. We believe that in some cases a privacy and security certification criterion may be inapplicable to an EHR Module while technically feasible to implement, and in other cases a privacy and security certification criterion may be applicable but technically infeasible to implement. For example, it may be technically feasible to implement an automatic log-off or emergency access capability for several types of EHR Modules, but such capabilities may be inapplicable given the EHR Module's anticipated function and/or point of integration.

We require that an EHR Module developer provide sufficient documentation to support a claim that a particular privacy and security certification criterion is inapplicable or that satisfying the certification criterion is technically infeasible. Based on this documentation, the ONC-ATCB should independently assess and make a reasonable determination as to whether the EHR Module should be exempt from having to include a particular privacy or security capability.

We also agree with the commenter that stated that we should remove the third exception and simply require all modules, if not included in a pre-coordinated integrated bundle, to follow the same approach. As a result, only the first and second exception will be included in the final rule. We recognize that, with respect to an EHR Module that is focused exclusively on providing one or more privacy and security capabilities, the remaining privacy and security certification criteria may be inapplicable or compliance

with them may be technically infeasible. However, we do not believe it is prudent to presume that this will always be the case.

Comments. Several commenters asked for clarification on the circumstances under which the first exception we proposed applied in relation to a pre-coordinated, integrated "bundle" of EHR Modules, the carve out to this exception related to EHR Modules that were "not be part of a local system," and our use of the term "end user."

Response. Overall, the premise behind the first exception is to release the general requirement that each individual EHR Module be tested and certified to all adopted privacy and security criteria. We believe that it would be pragmatic to release this requirement in situations where several EHR Module developers (e.g., different vendors) or a single EHR Module developer presents a collection of EHR Modules as a pre-coordinated, integrated bundle to an ONC-ATCB for testing and certification. In these circumstances, the integrated bundle of EHR Modules would otherwise constitute a Complete EHR. Therefore, we clarify that in the circumstances where an integrated bundle of EHR Modules is presented for testing and certification 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 Modules, that those other EHR Modules would be exempt from being tested and certified to adopted privacy and security certification criteria. To illustrate, four EHR Module developers each develop one EHR Module (EHR Modules A, B, C, and D) and form an affiliation. The EHR Module developers present their EHR Modules for testing and certification as an integrated bundle and identify that EHR Module "C" is responsible for providing the privacy and security capabilities for the rest of the entire bundle (EHR Modules A, B, and D). In this

scenario, EHR Modules A, B, and D would be exempt from also being tested and certified to the adopted privacy and security certification criteria.

With respect to the proposed carve out to this exception related to EHR Modules that were "not be part of a local system," we sought to limit those circumstances where a group of EHR Module developers could claim that a collection of EHR Modules was an "integrated bundle," yet it would be technically infeasible for one or all of the EHR Modules in the collection to be demonstrably responsible for providing all of the privacy and security capabilities for the rest of the EHR Modules. We believe this would occur in situations where a presented "integrated bundle" of EHR Modules includes one or more services offered by different EHR Module developers that have been implemented on different technical architectures or hosted over the Internet on one or multiple different servers. In this situation we do not believe that it would be possible for one or more of the EHR Modules to be demonstrably responsible for providing all of the privacy and security capabilities for the rest of the EHR Modules. For example, we do not believe that it is possible, at the present time, for a web-based EHR Module to offer authentication for another EHR Module that may be installed on an eligible professional's laptop, nor do we believe that one or more web-based services could provide an audit log for actions that took place outside of that service.

We believe that with this additional clarity the explicit mention of the first exception's carve out is no longer necessary and have revised the first exception accordingly to include the clarifying concepts we discuss above. This revision has also resulted in the removal of the term "end user," which commenters requested we clarify. The entire provision, including the changes from both our responses above, will read:

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 (as defined in 45 CFR 170.102), 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.

We would like to clarify two points related to integrated bundles of EHR Modules. First, an integrated bundle of EHR Modules will only qualify for this special treatment if, and only if, the integrated bundle would otherwise constitute a Complete EHR. In other words, three EHR Modules that have been integrated and "bundled" but do not meet the definition of Complete EHR, would not qualify for this specific certification. In those cases, we would view such a bundle as an EHR Module that provides multiple capabilities. Second, because an integrated bundle of EHR Modules would otherwise constitute a Complete EHR, we would treat it as a Complete EHR and when listing it as part of our master certified HIT products list, we would provide a designation, noting that it was an integrated bundle of EHR Modules.

Comments. A few commenters requested that we clarify whether there could be specific privacy and security-focused EHR Modules. That is, in the context of the definition of EHR Module, whether we intended to permit EHR Modules to exist that only addressed one or more adopted privacy and security certification criteria. One commenter asked for clarification as to whether a specific privacy and security-focused EHR Module would meet a certification criterion if its purpose was to call or assign the actual capability required by a certification criterion to another function or service.

Response. Yes, we believe that there could be specific privacy and security-focused EHR Modules and do not preclude such EHR Modules from being presented for certification. However, with respect to the second comment and request for clarification, we believe that an EHR Module, itself, must be capable of performing a capability required by an adopted privacy and security certification criterion and that delegating the responsibility to another service or function would not be acceptable. In those cases there would be no proof that the EHR Module could actually perform the specific capability, only that it could tell something else to do it.

c. Identification of Certified Status

We proposed in section 170.450(d) to require ONC-ATCBs authorized to test and certify EHR Modules to clearly indicate the certification criterion or criteria to which an EHR Module has been tested and certified in the EHR Module's certification documentation.

Comments. We received two comments requesting that we standardize the certification documentation requirements or at least provide clear guidelines for certificate design. The commenters were concerned that if left to the discretion of ONC-

ATCBs, the resulting certification certificates could look quite different and result in marketplace confusion. One commenter recommended that the certification certificate, which will figure prominently in EHR software vendor marketing, should be uniform in appearance and depict HHS authority and assurance.

Response. We agree with the commenters that certificate documentation should be designed in a way that does not lead to market confusion. Therefore, we are establishing a new Principle of Proper Conduct for ONC-ATCBs regarding the proper identification of Complete EHRs and EHR Modules. We further discuss the basis for this new Principle of Proper Conduct under the heading titled "O. Validity of Complete EHR and EHR Module Certification and Expiration of Certified Status" later in this section. Consistent with this decision, we are modifying proposed §170.450 to remove paragraph (d). This modification will eliminate any potential redundancy with the new Principle of Proper Conduct on the proper identification of Complete EHRs and EHR Modules.

H. The Testing and Certification of "Minimum Standards"

In the Proposed Rule, we summarized the approach set forth in the HIT Standards and Certification Criteria interim final rule (75 FR 2014) to treat certain vocabulary code set standards as "minimum standards." We noted that the establishment of "minimum standards" for specific adopted code sets would, in certain circumstances, allow 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. Additionally, we noted that this approach would enable Certified EHR Technology to be upgraded to a permitted newer version of a code set without adversely affecting its certified status.

At the end of this summary, we reiterated a previously identified limitation of the "minimum standards" approach with respect to significant revisions to adopted code sets.

We stated that a newer version of an adopted "minimum standard" code set would be permitted for use in testing and certification unless it was a significant revision to a code set that represented a "modification, rather than maintenance or a minor update of the code set." In those cases, we reiterated that the Secretary would likely proceed with notice and comment rulemaking to adopt a significantly revised code set standard.

We proposed two methods through which the Secretary could identify new versions of adopted "minimum standard" code sets. The first method would allow any member of the general public to notify the National Coordinator about a new version. Under the second method, the Secretary would proactively identify newly published versions. After a new version has been identified, a determination would be issued as to whether the new version constitutes maintenance efforts or minor updates of the adopted code set and consequently would be permitted for use in testing and certification. We further proposed that once the Secretary has accepted a new version of an adopted "minimum standard" code set that:

1) Any ONC-ATCB may test and certify Complete EHRs and/or EHR Modules according to the new version;

2) Certified EHR Technology may be upgraded to comply with the new version of an adopted minimum standard accepted by the Secretary without adversely affecting the certification status of the Certified EHR Technology; and

3) ONC-ATCBs would not be required to test and certify Complete EHRs and/or EHR Modules according to the new version until we updated the incorporation by reference of the adopted version to a newer version.

Finally, we stated that for either method, we would regularly publish on a quarterly basis, either by presenting to the HIT Standards Committee or by posting a notification on our website, any Secretarial determinations that have been made with respect to "minimum standard" code sets. We requested public comment on the frequency of publication, any other approaches we should consider to identify newer versions of adopted code set standards, and whether both methods described above should be used.

Comments. Many commenters supported our proposed approaches. These commenters also encouraged us to pursue both of the proposed approaches (notification of the National Coordinator by the general public and proactive identification by the Secretary). Some commenters recommended that we establish open lines of communication with the organizations responsible for maintaining identified "minimum standard" code sets in order to facilitate the process of identifying newer versions.

Response. We appreciate the commenters' support for our proposals. Based on this feedback, we have decided to adopt both of the approaches we have proposed. In addition, we expect to work, as appropriate, with the maintenance organizations for the "minimum standard" code sets, as well as the HIT Standards Committee, to identify new versions when they become available.

Comments. A few commenters recommended that ONC-ATCBs not be required to use an accepted newer version of a "minimum standard" code set for certification. Along those lines, a few other commenters recommended that there be a delay period between the Secretary's acceptance of a new version and when it would be required for testing and certification. One commenter noted that supporting multiple versions of

standards should be avoided and that there would be differences in what was certified versus what was implemented, while another noted that even permitting the use of a minor update could affect interoperability. Some commenters specifically requested clarification regarding the timeline associated with the Secretary's acceptance of a newer version and its publication and what requirement there would be for its inclusion in testing and certification.

Response. We believe that some commenters misunderstood the implications of the Secretary's acceptance of a newer version of a "minimum standard" code set. We therefore clarify 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. In the Proposed Rule, we used a three-pronged approach in order to provide greater flexibility and accommodate industry practice with respect to code sets that must be maintained and frequently updated. The first prong would permit, but not require, ONC-ATCBs to use an accepted newer version of a "minimum standard" code set to test and certify Complete EHRs and/or EHR Modules if the accepted newer version has been incorporated into a product by a Complete EHR or EHR Module developer. In these instances, we believe this approach benefits Complete EHR or EHR Module developers because they would be able to adopt a newer version of a code set voluntarily and have their Complete EHR or EHR Module certified according to it, rather than having to use an older version for certification. The second prong would permit, but not require, eligible professionals and eligible hospitals who are already using Certified EHR Technology to receive an upgrade from their Complete EHR or EHR Module

developer or voluntarily upgrade themselves to an accepted newer version of a "minimum standard" code set without adversely affecting the certification status of their Certified EHR Technology. Again, we believe this is a benefit to eligible professionals and eligible hospitals and provides greater flexibility. The third prong explicitly states that an ONC-ATCB would not be required to use any other version of a "minimum standard" code set beyond the one adopted at 45 CFR 170 subpart B until the Secretary incorporates by reference a newer version of that code set.

We recognize that a few different versions of adopted "minimum standards" could all be implemented at the same time and before a subsequent rulemaking potentially changes what constitutes the "minimum." We also understand the point raised by the commenter who expressed concerns about this approach because it could potentially create a situation where there could be differences in what was certified versus what was implemented. Along those lines, we also appreciate the point made by the commenter that a minor update could affect interoperability. We acknowledge these concerns and considered them as part of our analysis in determining whether to adopt minimum standards and to permit such standards to be exceeded when newer versions had been made available for use. However, we would like to make clear that we provide this flexibility on a voluntary basis and believe that the benefit of accepting newer versions of a "minimum standard" (namely, enabling the HIT industry to keep pace with new code sets) outweighs any potential or temporary risk to interoperability.

In light of the discussion above, we do not believe it is necessary to change any of our proposals, and we hope the additional clarification above addresses the concerns and questions raised by commenters.

Comments. Some commenters requested that we clarify the process the Secretary would follow before accepting a newer version of an adopted "minimum standard" code set.

Response. We expect that after a new version of an adopted "minimum standard" code set has been identified (either through the general public's notification of the National Coordinator or the Secretary proactively identifying its availability), the National Coordinator would ask the HIT Standards Committee to assess and solicit public comment on the new version. We expect that the HIT Standards Committee would subsequently issue a recommendation to the National Coordinator which would identify whether the Secretary's acceptance of the newer version for voluntary implementation and testing and certification would burden the HIT industry, negatively affect interoperability, or cause some other type of unintended consequence. 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 of the adopted "minimum standard" code set. If the Secretary approves the National Coordinator's request, we would issue guidance on an appropriate but timely basis indicating that the new version of the adopted "minimum standard" code set has been accepted by the Secretary.

I. Authorized Testing and Certification Methods

We proposed in section 170.457 that, as a primary method, an ONC-ATCB would be required to be capable of testing and certifying Complete EHRs and/or EHR Modules at its facility. We also proposed that an ONC-ATCB would be required to have the capacity to test and certify Complete EHRs and/or EHR Modules through one of the

following secondary methods: at the site where the Complete EHR or EHR Module has been developed; or at the site where the Complete EHR or EHR Module 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).

Comments. We received many comments on our proposal. We received varying recommendations and proposals, but the majority of commenters did not agree with testing and certification at an ONC-ATCB's facility as the primary method. Commenters noted that to require eligible professionals or eligible hospitals with self-developed Complete EHRs to physically move their Complete EHRs to another location for testing and certification would not only be burdensome but in many cases impossible. Instead, many commenters recommended that we require ONC-ATCBs to have the capacity to certify products through all of the secondary methods we proposed. Some commenters supported secondary methods without preference, while many commenters recommended that we require ONC-ATCBs to offer remote testing as the primary method because of its efficiency and low cost to Complete EHR and EHR Module developers. Commenters also noted that ONC-ATCBs could offer other methods, including performing testing and certification at an ONC-ATCB's facility. One commenter recommended that, as the primary method, ONC-ATCBs should be required to support testing and certification at the Complete EHR or EHR Module developer's site, which could include a development or deployment site. Another commenter stated that each method should be considered equal because different methods may be appropriate for different developers. Some commenters recommended that we clarify whether we expected Complete EHRs and EHR Modules to be "live" at customer sites before they can be tested and certified. The

commenters asserted that such a prerequisite will significantly delay the roll out of customer upgrades.

Response. We appreciate the many options and preferences expressed by the commenters. We believe that in order to adequately and appropriately address the commenters' concerns, an ONC-ATCB must have the capacity to provide remote testing and certification for both development and deployment sites. A development site is the physical location where a Complete EHR or EHR Module was developed. A deployment site is the physical location where a Complete EHR or EHR Module resides or is being or has been implemented. As discussed in the Proposed Rule, remote testing and certification would include the use of methods that do not require the ONC-ATCB to be physically present at the development or deployment site. This could include the use of web-based tools or secured electronic transmissions. In addition to remote testing and certification, an ONC-ATCB may also offer testing and certification at its facility or at the physical location of a development or deployment site, but we are not requiring that an ONC-ATCB offer such testing and certification. As indicated by commenters and our own additional research, the market currently utilizes predominantly remote methods for the testing and certification of HIT. On-site testing and certification was cited as costly and inefficient. Therefore, we are not requiring ONC-ATCBs to offer such testing and certification, but anticipate that some ONC-ATCBs will offer on-site testing and certification if there is a market demand. In response to those commenters who requested clarification, we also want to make clear that we do not believe that a Complete EHR or EHR Module must be "live at a customer's site" in order to qualify for testing and certification by an ONC-ATCB. As stated above, a Complete EHR or EHR Module

could be tested and certified at a Complete EHR and/or EHR Module developer's development site. Consistent with this discussion, we have revised §170.457 to require an ONC-ATCB to provide remote testing and certification for both development and deployment sites and have included the definitions of "development site," "deployment site," and "remote testing and certification" in §170.402.

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

We proposed in the Proposed Rule requirements that ONC-ATCBs would need to meet in order to maintain good standing under the temporary certification program, the processes for revoking an ONC-ATCB's status for failure to remain in good standing, the effects that revocation would have on a former ONC-ATCB, and the potential effects that revocation could have on certifications issued by the former ONC-ATCB.

1. Good Standing as an ONC-ATCB

We proposed in section 170.460 that, in order to maintain good standing, an ONC-ATCB would be required to adhere to the Principles of Proper Conduct for ONC-ATCBs and refrain from engaging in other types of inappropriate behavior, such as misrepresenting the scope of its authorization or testing and certifying Complete EHRs and/or EHR Modules for which it was not given authorization. In order to maintain good standing, we also proposed that an ONC-ATCB would be expected to follow all applicable Federal and state laws.

Comments. Commenters expressed opinions that ONC-ATCBs should be expected to meet high standards for ethics and compliance, and therefore were appreciative of our proposed standards of conduct for ONC-ATCBs. One commenter

encouraged us to evaluate ONC-ATCBs' compliance with the Principles of Proper Conduct on an ongoing basis and at the time for re-authorization, particularly if either a Type-1 or Type-2 violation had occurred.

Response. We believe that our proposed Principles of Proper Conduct for ONC-ATCBs are essential to maintaining the integrity of the temporary certification program, as well as ensuring public confidence in the program and the Complete EHRs and EHR Modules that are tested and certified under the program. We intend to monitor compliance with the Principles of Proper Conduct for ONC-ATCBs on an ongoing basis by, among other means, following up on concerns expressed by Complete EHR and EHR Module developers and the general public. It is also expected that ONC-ATCBs will maintain relevant documentation of their compliance with the Principles of Proper Conduct for ONC-ATCBs because such documentation would be necessary, for instance, to rebut a notice of noncompliance with the Principles of Proper Conduct issued by the National Coordinator. We continue to believe that a violation of the Principles of Proper Conduct for ONC-ATCBs, a violation of law, or other inappropriate behavior must be promptly and appropriately addressed to maintain the program's integrity and the public's confidence in the program and the products that are certified. If a violation or other inappropriate behavior were to occur, it would be addressed in accordance with section 170.465. With consideration of the public comments received, we are finalizing section 170.460 without modification.

2. Revocation of ONC-ATCB Status

We proposed in section 170.465 that the National Coordinator could revoke an ONC-ATCB's status if it committed a Type-1 violation or if it failed to timely or

adequately correct a Type-2 violation. We defined Type-1 violations to include violations of law or temporary certification program policies that threaten or significantly undermine the integrity of the temporary certification program. These violations include, but are not limited to: false, fraudulent, or abusive activities that affect the temporary certification program, a program administered by HHS or any program administered by the Federal government.

We defined Type-2 violations as noncompliance with §170.460, which would include without limitation, failure to adhere to the Principles of Proper Conduct for ONC-ATCBs and engaging in other inappropriate behavior. We proposed that if the National Coordinator were to obtain reliable evidence that an ONC-ATCB may no longer be in compliance with §170.460, the National Coordinator would issue a noncompliance notification. We proposed that an ONC-ATCB would have an opportunity to respond and demonstrate that no violation occurred or that the alleged violation had been corrected. We further proposed that the National Coordinator would review the response and determine whether a violation had occurred and whether it had been adequately corrected.

We proposed that the National Coordinator could propose to revoke an ONC-ATCB's status if the National Coordinator has evidence that the ONC-ATCB committed a Type-1 violation. We proposed that the National Coordinator could propose to revoke an ONC-ATCB's status if the ONC-ATCB failed to rebut an alleged Type-2 violation with sufficient evidence showing that the violation did not occur or that the violation had been corrected, or if the ONC-ATCB did not submit a written response to a Type-2 noncompliance notification within the specified timeframe. We proposed that an ONC-

ATCB would be able to continue its operations under the temporary certification program during the time periods provided for the ONC-ATCB to respond to a proposed revocation notice and the National Coordinator to review the response.

We proposed that the National Coordinator could revoke an ONC-ATCB's status if it is determined that revocation is appropriate after considering the ONC-ATCB's response to the proposed revocation notice or if the ONC-ATCB does not respond to a proposed revocation notice within the specified timeframe. We further proposed that a decision to revoke an ONC-ATCB's status would be final and not subject to further review unless the National Coordinator chose to reconsider the revocation.

We proposed that a revocation would be effective as soon as the ONC-ATCB received the revocation notice. We proposed that a testing and certification body that had its ONC-ATCB status revoked would be prohibited from accepting new requests for testing and certification and would be required to cease its current testing and certification operations under the temporary certification program. We further proposed that if a testing and certification body had its ONC-ATCB status revoked for a Type-1 violation, it would be prohibited from reapplying for ONC-ATCB status under the temporary certification program for one year. If the temporary certification program sunset during this time, the testing and certification body would be prohibited from applying for ONC-ACB status under the permanent certification program for the remainder of the one year prohibition period.

We proposed that failure to promptly refund any and all fees for uncompleted tests and/or certifications of Complete EHRs and EHR Modules after the revocation of ONC-ATCB status would be considered a violation of the Principles of Proper Conduct

for ONC-ATCBs. We proposed that the National Coordinator would consider such violations in the event that a testing and certification body reapplied for ONC-ATCB status under the temporary certification program or applied for ONC-ACB status under the permanent certification program.

In association with these proposals, we specifically requested that the public comment on two additional proposals. First, we requested that the public comment on whether the National Coordinator should consider proposing the revocation of an ONC-ATCB's status for repeatedly committing Type-2 violations even if the ONC-ATCB adequately corrected the violations each time. In conjunction with this request, we asked how many corrected Type-2 violations would be sufficient for proposing revocation of an ONC-ATCB and to what extent the frequency of these violations should be a consideration. Second, we requested that the public comment on whether the National Coordinator should also include a process to suspend an ONC-ATCB's status.

Comments. We received general support for our proposed revocation process with commenters encouraging us to take a stringent position regarding Type-1 and Type-2 violations out of fear that a lack of confidence in the qualifications or integrity of an ONC-ATCB could seriously undermine the temporary certification program's objectives. Commenters requested that vendors, self-developers and providers be notified if an ONC-ATCB is suspended, the National Coordinator proposes to revoke an ONC-ATCB's status, and/or an ONC-ATCB's status is revoked. One commenter recommended that there not be a "broad" categorical Type-1 violation bar on reapplying for ONC-ATCBs that had their status revoked, while other commenters suggested that we extend the timeframe for barring ONC-ATCBs that have committed Type-1 violations from reapplying to at least three years and to require that a "re-authorized" former ONC-ATCB serve a probationary period.

We received a few comments on whether we should revoke an ONC-ATCB's status under the temporary certification program for committing multiple Type-2 violations even if the violations were corrected. A couple of commenters suggested that an ONC-ATCB should have its status revoked for committing multiple violations. One commenter reasoned that if an ONC-ATCB committed three or more violations in the short time of the anticipated existence of the temporary certification program then it deserved to have its status revoked. Another commenter recommended that the National Coordinator retain the discretion to review and judge each situation as opposed to setting a certain threshold for automatic revocation.

We received multiple comments on our proposed alternative of a suspension process with all of the commenters suggesting that there could be value in a suspension process. One commenter stated that our goal should be first and foremost to protect the needs of product purchasers and patients. Commenters stated that suspension could be warranted in lieu of proposing revocation and/or during the period between a proposed revocation and a final decision on revocation. Some commenters recommended that an ONC-ATCB be allowed to continue operations during a suspension or be provided "due process" rights before being suspended, while others suggested that allowing an ONC-ATCB to continue during instances where an investigation is ongoing and violations are being resolved could jeopardize the industry's confidence level in the certification process. One commenter suggested that an ONC-ATCB be allowed to continue operations unless the alleged violation would or could adversely impact patient safety and/or quality of care.

Response. We do not believe that it is appropriate to initiate revocation proceedings against an ONC-ATCB for any amount of corrected Type-2 violations under the temporary certification program. We did not originally propose to initiate revocation proceedings for multiple corrected Type-2 violations, but requested public comment on the possibility. Commenters appeared to agree that initiating revocation proceedings against an ONC-ATCB for committing multiple Type-2 violations, even if corrected, was an acceptable proposition under certain conditions. While we agree that committing multiple Type-2 violations, even if corrected, is cause for concern, it would be difficult to establish a sufficiently objective and equitable standard for initiating revocation proceedings on that basis against an ONC-ATCB. As evidenced by the comments, it is difficult to determine the appropriate number of corrected Type-2 violations that would lead to revocation proceedings. An ONC-ATCB could commit and correct two Type-2 violations involving a missed training or a timely update to ONC on a key personnel change. In such a situation, we do not believe that automatically initiating revocation proceedings would be warranted. We also do not believe it would be appropriate to adopt the one commenter's recommendation to allow the National Coordinator to use discretion to address such instances. This would not give an ONC-ATCB sufficient notice of what Type-2 violation, even if corrected, could lead to revocation proceedings nor an indication of the amount or frequency of the violations that could lead to revocation proceedings. Therefore, we believe that an ONC-ATCB should remain in good standing if it sufficiently corrects a Type-2 violation, no matter how many times an ONC-ATCB commits a Type-2 violation. Such violations will be a matter of public record that may

influence Complete EHR and EHR Module developers' decisions on which ONC-ATCB to select for the testing and certification of their Complete EHRs and/or EHR Modules.

We believe that Type-1 violations as described are not too "broad" in that they must also "threaten or significantly undermine the integrity of the temporary certification program." In such cases, we believe that barring a former ONC-ATCB from reapplying for ONC-ATCB status for one year is an appropriate remedy under the temporary certification program, which we do not anticipate lasting beyond December 31, 2011. As noted in the Proposed Rule, a Type-1 violation could significantly undermine the public's faith in our temporary certification program. Therefore, removing the ONC-ATCB from the program is an appropriate remedy. The l-year bar on reapplying will allow the former ONC-ATCB sufficient time to address the reasons for the Type-1 violation before reapplying. We will, however, reconsider the appropriate length of a bar on reapplying for ONC-ACB status and whether a probationary period would be appropriate for the permanent certification program when we finalize the permanent certification program.

We agree with the commenters that suspension could be an effective way to protect purchasers of certified products and ensure patient health and safety. As a result, we agree with the commenter and believe that the National Coordinator should have the ability to suspend an ONC-ATCB's operations under the temporary certification program 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. As mentioned in the Proposed Rule, the National Coordinator's process for obtaining reliable evidence would involve one or more of the following methods: fact-gathering; requesting

information from an ONC-ATCB; contacting an ONC-ATCB's customers; witnessing an ONC-ATCB perform testing or certification; and/or reviewing substantiated complaints.

Due to the disruption a suspension may cause for an ONC-ATCB, and more so for the market, we believe that suspension is appropriate in only the limited circumstances described above and have revised §170.465 to provide the National Coordinator with the discretion to suspend an ONC-ATCB's operations accordingly. An ONC-ATCB would first be issued a notice of proposed suspension. Upon receipt of a notice of proposed suspension, an ONC-ATCB will be permitted up to 3 days to submit a written response to the National Coordinator explaining why its operations should not be suspended. The National Coordinator will be permitted up to 5 days to review the ONC-ATCB's response and issue a determination. In the determination, the National Coordinator will either rescind the proposed suspension, suspend the ONC-ATCB's operations until it has adequately corrected a Type-2 violation, or propose revocation in accordance with §170.465(c) and suspend the ONC-ATCB's operations for the duration of the revocation process. The National Coordinator may also make any one of the above determinations if an ONC-ATCB fails to submit a timely response to a notice of proposed suspension. A suspension will become effective upon an ONC-ATCB's receipt of a notice of suspension. We believe that this process addresses the commenters' concerns regarding due process and maintaining the industry's confidence in the temporary certification program by not allowing an ONC-ATCB to continue operations while an investigation is ongoing and/or violations are being resolved related to the patient health or safety.

As discussed in a previous section of this preamble, we have revised §170.423(j) to clarify that an ONC-ATCB would have to refund any fees paid by a Complete EHR or EHR Module developer that seeks to withdraw a request for testing and certification while an ONC-ATCB is suspended.

We intend to provide public notification via our website and list serve if an ONC-ATCB is suspended, issued a notice proposing its revocation, and/or has its status revoked. We also note that we revised §170.465(c)(1) to state that "[t]he National Coordinator may propose to revoke an ONC-ATCB's status if the National Coordinator has reliable evidence that the ONC-ATCB committed a Type-1 violation." The term "reliable" was inadvertently left out of the Proposed Rule.

3. Effect of Revocation on Certifications Issued by a Former ONC-ATCB

We proposed in section 170.470 to allow the certified status of Complete EHRs and/or EHR Modules certified by an ONC-ATCB that subsequently had its status revoked to remain intact unless a Type-1 violation was committed that called into question the legitimacy of the certifications issued by the former ONC-ATCB. In such circumstances, we proposed that the National Coordinator would review the facts surrounding the revocation of the ONC-ATCB's status and publish a notice on ONC's website if the National Coordinator believed that Complete EHRs and/or EHR Modules were fraudulently certified by a former ONC-ATCB and the certification process itself failed to comply with regulatory requirements. We further proposed that if the National Coordinator determined that Complete EHRs and/or EHR Modules were improperly certified, the "certified status" of affected Complete EHRs and/or EHR Modules would remain intact for 120 days after the National Coordinator published the notice. We

specifically requested that the public comment on our proposed approach and the timeframe for re-certification.

Comments. Multiple commenters expressed agreement and understanding with the need to protect the integrity of the temporary certification program by ensuring the legitimacy of certifications issued by a former ONC-ATCB and requiring recertification of Complete EHRs and/or EHR Modules where it is found that they were improperly certified. Many commenters stated, however, that we should determine whether an improperly certified product negatively and substantially affected the performance of a Complete EHR or EHR Module in achieving a meaningful use objective before requiring recertification. Other commenters stated that "good faith" eligible professionals and eligible hospitals who can demonstrate meaningful use with a previously certified Complete EHR or EHR Module should continue to qualify for payments under the Medicare and Medicaid EHR Incentive Programs. Commenters further stated that providers should be allowed to replace the previously certified product when new certification criteria have been finalized for the affected meaningful use criteria, or when their own strategic and technical requirements necessitate an upgrade, whichever comes first. Commenters contended that the only overriding factor that should require recertification is if there is a demonstrable risk to patient safety from the use of improperly certified Complete EHRs and/or EHR Modules.

A few commenters expressed concerns about the potential negative financial impact recertification would have on Complete EHR and EHR Module developers, eligible professionals and eligible hospitals as well as the potential for legal liability

related to eligible professionals and eligible hospitals making attestations to federal and state agencies that they are using Certified EHR Technology.

Some commenters agreed with our 120-day proposal, while many commenters recommended 6, 9, 12, and 18-month "grace periods" for improperly certified Complete EHRs and/or EHR Modules. One commenter recommended an extension of the 120-day grace period if there were less than 3 ONC-ATCBs at the time of decertification. One commenter noted that the revocation process through potential decertification of Complete EHRs and/or EHR Modules could take longer than the life of the temporary certification program and likely overlap with the issuance of new standards and certification criteria, which itself will require "recertification" under the permanent certification program.

Response. In instances where the National Coordinator determines that Complete EHRs and/or EHR Modules were improperly certified, we believe that recertification is necessary to maintain the integrity of the temporary certification program and to ensure the efficacy and safety of certified Complete EHRs and EHR Modules. By requiring recertification, eligible professionals and eligible hospitals as well as Complete EHR and EHR Module developers can have confidence in the temporary certification program and, more importantly, in the Complete EHRs and EHR Modules that are certified under the program. As we stated in the Proposed Rule, we believe 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. If such events were to occur, the regulatory provisions enable the National Coordinator to focus recertification on specific Complete EHRs and/or EHR Modules

that were improperly certified in lieu of requiring recertification of all Complete EHRs and EHR Modules tested and certified by the former ONC-ATCB.

In this regard, the National Coordinator has a statutory responsibility to ensure that Complete EHRs and EHR Modules certified under the temporary certification program are in compliance with the applicable certification criteria adopted by the Secretary. We do not believe that the alternatives suggested by the commenters, such as whether a "good faith" eligible professional or eligible hospital can demonstrate meaningful use with a previously certified Complete EHR or EHR Module, would enable the National Coordinator to fulfill this statutory responsibility. Consequently, if the National Coordinator determines that a Complete EHR or EHR Module was improperly certified, then retesting and recertification by an ONC-ATCB are the only means by which to ensure that the Complete EHR or EHR Module satisfies the certification criteria. Moreover, an attestation by a Complete EHR or EHR Module developer and/or user of a Complete EHR or EHR Module would not be an acceptable alternative to retesting and recertification because the National Coordinator could not sufficiently confirm that all applicable certification criteria are met.

We appreciate the concerns expressed by commenters related to the potential financial burden of recertification, the potential legal liability for providers attesting to the use of Certified EHR Technology, and the perceived insufficient amount of time to have a Complete EHR and/or EHR Modules recertified. We believe, however, that some of these concerns may be unfounded. Any decertification of a Complete EHR or EHR Module will be made widely known to the public by ONC through publication on our website and list serve, which we believe will help eligible professionals or eligible

hospitals identify whether the certified status of their Certified EHR Technology is still valid. We also believe that programmatic steps, such as identifying ONC-ATCB(s) that could be used for retesting and recertification, could be taken to assist Complete EHR and/or EHR Module developers with achieving timely and cost effective recertifications. Most importantly, in the rare circumstance that recertification is required, we believe that the need to protect the public from potentially unsafe Complete EHRs and/or EHR Modules outweighs the concerns expressed by the commenters. Accordingly, we are finalizing this provision without modification.

K. Sunset of the Temporary Certification Program

We proposed in section 170.490 that the temporary certification program would sunset on the date when the National Coordinator authorized at least one ONC-ACB under the permanent certification program. We further proposed that on the date the sunset occurred, ONC-ATCBs under the temporary certification program would be prohibited from accepting new requests to certify Complete EHRs or EHR Modules. ONC-ATCBs would, however, be able to complete the processing of Complete EHRs and EHR Modules that were being tested and certified at the time the sunset occurred. We clarified that ONC-ATCBs would be able to review any pending applications that they had received prior to the termination date of the temporary certification program and complete the certification process for those Complete EHRs and EHR Modules.

We requested that the public comment on whether we should establish a set date for the temporary certification program to sunset, such as 12/31/2011, instead of a date that depends on a particular action – the authorization of at least one ONC-ACB. We noted that a set date would provide certainty and create a clear termination point for the

temporary certification program by indicating to any ONC-ATCBs and other certification bodies that in order to be authorized to certify Complete EHRs and/or EHR Modules after 12/31/2011, they would need to be accredited and reapply to become ONC-ACBs. We further noted that one potential downside to a set date would be the possibility that it would temporarily prevent certifications from being issued during the time period it takes potential ONC-ACB applicants to get accredited and receive their authorizations from the National Coordinator.

Comments. Commenters recommended various methods and means for ending the temporary certification program. The predominant suggestion from commenters was to devise a method for ending the temporary certification program that would limit the amount of uncertainty for vendors, self-developers, and providers. In this regard, multiple commenters recommended a date certain with 12/31/2011 being the only date specified by commenters. Commenters reasoned that a set date would give the industry and market a target for planning purposes. Many commenters, however, stated that a set date was only viable if there were at least one ONC-ACB. Some commenters recommended that there be two ONC-ACBs and some also requested that we ensure that there are one or two accredited testing labs before we sunset the temporary certification program. Commenters contended that having more than one ONC-ACB would help prevent a backlog and potential monopolies.

Multiple commenters recommended that we tie the certification programs with the meaningful use stages (i.e., use the temporary certification program for Stage 1 and the permanent certification program for Stage 2 and beyond) and allow the temporary certification program to continue to certify for Stage 1 until it was no longer needed. One

commenter recommended that the temporary certification program should be phased out only after it has been determined that a significant percentage of the industry is ready to move to Stage 2 of the Medicare and Medicaid EHR Incentive Programs.

One commenter proposed that there be a period of overlap of up to a year between the temporary certification program and the permanent certification program to enable ONC-ATCBs to complete the testing and certification of products that were presented prior to the beginning of the permanent certification program. As part of the proposal, the commenter stated that products not completely tested and certified by an ONC-ATCB by the end date would need to be resubmitted under the permanent certification program.

Another commenter recommended that the rules for the transition period must be flexible enough to accommodate an ONC-ATCB to apply to become a testing lab and/or an ONC-ACB under the permanent certification program.

Response. The commenters' recommendation to link the certification programs to the proposed stages of meaningful use illustrates a misunderstanding of the purpose of the certification programs. Consistent with statutory instruction, the primary purpose of the certification programs is to ensure that Complete EHRs, EHR Modules, and possibly other HIT, meet the standards, implementation specifications, and certification criteria adopted by the Secretary. We have proposed a temporary certification program in order to ensure that Certified EHR Technology will be available for the start of the Medicare and Medicaid EHR Incentive Programs and to allow sufficient time for the development of a more rigorous permanent certification program. Linking the temporary certification program to a proposed stage of meaningful use could cause the program to last longer than is necessary, which would be inconsistent with the purpose of the program.

We agree with the majority of commenters that we should strive to achieve as much certainty as possible for the market while also ensuring the existence of a sufficient supply of authorized testing and/or certification bodies so as to enable eligible hospitals and eligible providers to achieve meaningful use. Therefore, we have modified our proposed timeframe such 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 temporary certification program sunset date, ONC-ATCBs will be prohibited from accepting new requests to test and certify Complete EHRs or EHR Modules. ONC-ATCBs will, however, be permitted up to six months after the sunset date to complete all testing and certification activities associated with requests for testing and certification of Complete EHRs and/or EHR Modules received prior to the sunset date.

We believe that our proposal provides the appropriate balance between market certainty and ensuring that there remains a body authorized to test and certify Complete EHRs and EHR Modules. We believe that many applicants will seek to become ONC-ACBs and that there is sufficient flexibility in the transition to the permanent certification program for ONC-ATCBs either to apply to become ONC-ACBs or to become accredited testing labs. We further believe that applicants will be motivated by business dynamics, such as capturing an increased market share, to become authorized as soon as possible under the permanent certification program. Therefore, we believe that there will be multiple ONC-ACBs by December 31, 2011.

In the event that the National Coordinator is unable to begin the permanent certification program on January 1, 2012, we believe it is appropriate for the temporary certification program to remain operational until the National Coordinator determines that the permanent certification program is fully constituted. As stated above, keeping the temporary certification program operational will help ensure that a body authorized to test and certify Complete EHRs and EHR Modules remains available. This flexibility provided to the National Coordinator will help to alleviate the "consumer" concerns expressed by commenters related to the potential existence of backlogs or monopolies at the start of the permanent certification program. In determining whether the proposed permanent certification program is fully constituted, the National Coordinator will consider whether there are a sufficient number of ONC-ACBs and accredited testing laboratories to address the current market demand. For example, if multiple ONC-ATCBs exist, but only one ONC-ACB has been authorized and no testing laboratories are accredited (or alternatively one or more testing laboratories exist, but no ONC-ACBs), and the Secretary will soon issue newly adopted standards, implementation specifications and certification criteria, then it is unlikely that the permanent certification program would be considered fully constituted. We believe this approach sufficiently addresses the concerns expressed by various commenters and provides the most assurance to the market, particularly for Complete EHR and EHR Module developers that seek testing and certification of Complete EHRs and/or EHR Modules.

Consistent with our original proposal, we are allowing ONC-ATCBs to complete the processing of all requests for the testing and certification of Complete EHRs and/or EHR Modules received prior to the sunset date. By completing the processing of a

request, we expect that all testing and certification activities would be completed including the issuance of a certification, if appropriate. We are limiting the time to complete the processing of requests to a period of six months after the sunset date of the temporary certification program. We agree with the commenter that a limitation is necessary to bring finality to the temporary certification program. We believe that six months is a more appropriate period than "up to a year" because, as previously stated, we anticipate the next set of standards, implementation specifications, and certification criteria to be published in late summer of 2012. Therefore, market confusion can be avoided by ending all vestiges of the temporary certification program before the start of testing and certification to newly adopted standards, implementation specifications, and certification criteria. If the testing and certification of a Complete EHR or EHR Module is not completed prior to end of the 6-month period, the Complete EHR or EHR Module would have to be resubmitted for testing and certification under the permanent certification program.

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

The physician self-referral prohibition exception and anti-kickback statute safe harbor for donations of EHR software (42 CFR § 411.357(w) and 42 CFR § 1001.952(y), respectively) include among their conditions a provision that donated software must be interoperable and that, for purposes of the exception and safe harbor, software is deemed to be interoperable "if a certifying body recognized by the Secretary has certified the software within no more than 12 months prior to the date it is provided to the [recipient]." This final rule addresses the process in which the Secretary

recognizes a certifying body. As to the process, we requested comment in the Proposed Rule on whether we should construe the proposed "authorization" process for ONC-ATCBs and ONC-ACBs as the Secretary's method for "recognizing" certification bodies.

Comments. The vast majority of commenters supported replacing the Secretary's current method for "recognizing" certification bodies with the proposed "authorization" process for ONC-ATCBs and ONC-ACBs. The commenters reasoned that our proposal offered consistency and efficiency for all stakeholders involved. Only one commenter recommended that the current process for "recognizing" certification bodies not be superseded by the proposed "authorization" process, but that commenter did so based on a concern expressed by multiple commenters. The concern was over whether the proposed "authorization" process would negatively affect donations of "certified EHRs" currently in progress, including the invalidation of existing investments and the disruption of pending and executed contracts as well as ongoing EHR installations. To address these concerns, some commenters recommended that EHRs certified by a "recognized certification body" continue to be permitted for donation under the exception and safe harbor if they still satisfied the parameters set by the physician self-referral prohibition exception and anti-kickback statute safe harbor final rules. The commenters also recommended that the subsequent "rollout" of EHR installations to physician offices should be deemed to qualify for the exception and safe harbor based on certification status as of the original purchase date, regardless of the date of actual installation in physician offices.

Some commenters recommended that the term of recognition for certified EHR technology under the exception and safe harbor should be equal to the "certification time

period of two (2) years, and not 12 months as currently specified." Another commenter recommended that any EHR certified by the Certification Commission for Health Information Technology (CCHIT) should continue to qualify for the exception and safe harbor at least through the end of Stage 1 of the Medicare and Medicaid EHR Incentive Programs.

One commenter noted that the physician self-referral prohibition exception and anti-kickback statute safe harbor final rules define "interoperability" and that an EHR's ability to be interoperable is a factor in its ability to be donated under those rules. The commenter requested that the National Coordinator clarify and provide guidance on the standards and interoperability requirements to which ONC-ATCBs and ONC-ACBs would test and certify EHRs for purposes of the exception and safe harbor.

A commenter recommended that we clarify that Complete EHRs and EHR Modules that are certified under the temporary or permanent certification programs may be deemed interoperable and may qualify for the physician self-referral prohibition exception or the anti-kickback statute safe harbor for EHR donations. The commenter also recommended that we state that Complete EHRs and EHR Modules will also be required to meet other regulatory provisions outlined in 42 CFR §411.351 et seq. or §1001.952 in order to qualify for the exception or safe harbor (e.g., an EHR must be used for any patient without regard to payer status). The commenter proposed that we include a new requirement that a certifying body cannot certify EHRs or EHR Modules if they unnecessarily limit or restrict their use or compatibility with other HIT (e.g., if an entity binds physicians to a particular entity to receive the EHR or the EHR Module, or uses a combination of certified EHR Modules that do not work together).

Response. We appreciate the commenters' support for our proposal to incorporate the current "recognition" of certification bodies into the ONC-ATCB and ONC-ACB "authorization" processes. We agree with commenters that folding the "recognition" process into the ONC-ATCB and ONC-ACB "authorization" processes will lead to greater clarity and consistency for all stakeholders. Accordingly, the ONC-ATCB and ONC-ACB "authorization" processes will constitute the Secretary's "recognition" of a certification body.

This final rule only addresses the issue of how the Secretary recognizes a certifying body. It does not address issues related to the application of the exception or safe harbor, as those issues are beyond the scope of this final rule and are better directed to CMS and OIG, respectively. As noted in the Proposed Rule, CCHIT is the only organization that has both applied for and been granted "recognized certification body" status under 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 this final rule. As a result, they will need to reapply to become an ONC-ATCB (and in the future an ONC-ACB) in order to be a "recognized certification body" after the effective date of this final rule. Loss of "recognized" status under the CGD upon the effective date of this final rule does not impact the fact that certifications made by CCHIT while recognized under the CGD were made by a "recognized certification body."

With respect to the request for clarification regarding the standards and interoperability requirements to which ONC-ATCBs and ONC-ACBs would test and certify Complete EHRs and EHR Modules, we clarify that we will not adopt different or

additional certification criteria to which Complete EHRs or EHR Modules must be tested and certified in order to meet the deeming provision, and we do not expect ONC-ATCBs and ONC-ACBs to use different certification criteria to test and certify Complete EHRs and EHR Modules. We believe that the certification criteria adopted by the Secretary specify several important interoperability requirements and build the foundation for more advanced interoperability in the future. It is also important to note that regardless of whether EHRs certified in 2009 or 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.

All other issues raised by commenters are outside the scope of this rulemaking and in many cases would require notice and comment rulemaking in order to be appropriately addressed.

M. Grandfathering

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. Although we did not propose or discuss the concept of grandfathering in the Proposed Rule, several commenters made recommendations on the subject.

Comments. On all three recent meaningful use related rulemakings (the HIT Standards and Certification Criteria interim final rule, the Medicare and Medicaid EHR Incentive Programs proposed rule, and the HIT Certification Programs proposed rule), HHS received comments related to the concept of "grandfathering" existing EHRs in some form or another. Some comments requested that we deem all CCHIT-certified EHRs from 2008 onward to be Certified EHR Technology. Others requested that we deem all existing EHRs regardless of whether these EHRs had been certified by CCHIT. In both cases, these commenters argued that this would enable eligible professionals and eligible hospitals who were early adopters to possess HIT that met the definition of Certified EHR Technology right away. One commenter offered a variant to this suggestion by adding a qualification that we should only deem EHRs if the EHR currently in the possession of an eligible professional or eligible hospital could enable them to meet some (at least 5) number of meaningful use objectives. While other commenters using this same line of reasoning believed that an EHR should qualify for grandfathering if it could enable an eligible professional or eligible hospital to meet all applicable objectives and measures, but that such certification would only be valid until the temporary certification program was operational. One commenter specifically recommended that ONC establish a petition process whereby an individual eligible professional or eligible hospital could apply directly to ONC for a waiver to use a non-certified EHR to qualify for meaningful use.

Response. We believe that this final rule is the most appropriate rulemaking to address comments on grandfathering. The definition of Certified EHR Technology specified by Congress at section 3000 of the PHSA set forth clear parameters that dictate

when HIT will be considered Certified EHR Technology. To be Certified EHR Technology, HIT must first meet the definition of a Qualified EHR, which in turn must be certified pursuant to the certification program(s) established under section 3001(c)(5) by the National Coordinator as meeting standards adopted under section 3004 by the Secretary. Certification is used to provide consumers with assurance and confidence that the product or service they seek to purchase and use will work as expected and will include the capabilities for which it was purchased.

While grandfathering may appear convenient in that it would allow eligible professionals and eligible hospitals to use the HIT they already have in place, we believe that in this context grandfathering is inappropriate and would be inconsistent with the statutory requirements for Certified EHR Technology specified in the PHSA. Grandfathering provides neither assurance nor confidence for eligible professionals and eligible hospitals that their existing HIT will have the capacity to support their attempts to meet meaningful use Stage 1 objectives and measures. In this regard, we do not believe that the variations to "grandfathering" some commenters suggested (that an EHR should be grandfathered if it could enable an eligible professional or eligible hospital to meet some or all applicable meaningful use objectives and measures) are valid approaches. Conversely, we believe those approaches are risky from a programmatic perspective with respect to the potential for fraud, and from an eligible professional or eligible hospital's perspective in that they would have no demonstrable proof that their EHR possessed the capabilities necessary to meet the certification criteria adopted by the Secretary. More importantly, if we were to permit grandfathering according to the logic expressed by these commenters, the only way we, and the commenters, would be able to tell if an EHR

should legitimately be deemed grandfathered would be if the eligible professional or eligible hospital had successfully achieved meaningful use. We question whether commenters would be willing to take the risk of attempting meaningful use without the certainty of knowing that their EHR provided the capabilities they would need to attempt to achieve it.

Furthermore, while a deeming of this sort may address a very short term need of existing HIT users, we believe it would significantly undercut our long-term policy goals and objectives, as well as provide eligible professionals and eligible professionals with a false sense of security. Without the assurances provided by the testing and certification process, grandfathering would require HHS to permit eligible professionals and eligible hospitals to use HIT that may be incapable from the start of supporting their achievement of meaningful use Stage 1. Along those lines, we do not believe that the petition and waiver process a commenter suggested is a feasible option because HHS would incur the risk that eligible professionals and eligible hospitals would fail to achieve meaningful use Stage 1 because their existing HIT is incapable of meeting the applicable objectives and measures even though we had deemed it "certified."

N. Concept of "Self-developed"

We stated in the Proposed Rule that we interpreted the HIT Policy Committee's use of the word "self-developed" to mean a Complete EHR or EHR Module that has been designed, modified, or created by, or under contract for, a person or entity that will assume the total costs for its testing and certification and will be a primary user of the Complete EHR or EHR Module. We noted that self-developed Complete EHRs and EHR Modules could include brand new Complete EHRs or EHR Modules developed by

a health care provider or their contractor. We further noted that it could also include a previously purchased Complete EHR or EHR Module which is subsequently modified by the health care provider or their contractor and where such modifications are made to capabilities addressed by certification criteria adopted by the Secretary. We specifically stated that we would limit the scope of "modification" to only those capabilities for which the Secretary has adopted certification criteria because other capabilities (e.g., a different graphical user interface (GUI)) would not affect the underlying capabilities a Complete EHR or EHR Module would need to include in order to be tested and certified. Accordingly, we stated that we would only refer to the Complete EHR or EHR Module as "self-developed" if the health care provider paid the total costs to have the Complete EHR or EHR Module tested and certified.

Comments. Multiple hospitals and hospital associations requested that we clarify the definition of "self-developed" to include an indication of the extent to which modifications can be made to previously certified Complete EHRs or EHR Modules without requiring a system to be certified as "self-developed." The commenters noted that we have clearly stated that eligible professionals and eligible hospitals bear full responsibility for making certified EHR Modules work together. Therefore, the commenters contended that providers must have the ability to make needed modifications to certified EHR Modules to achieve that purpose. The commenters stated that often there is a need for custom configurations or settings within the parameters of certified EHRs, including modifications that may be necessary to ensure that the EHR works properly when implemented within an organization's entire HIT environment. The commenters further stated that such modifications may affect, or even enhance, the capabilities addressed by the certification criteria by providing additional and specific decision-support functions

or allowing for additional quality improvement activities. The commenters asserted that as long as the system can still perform the function for which it was originally certified, these modifications should not trigger the need for a self-developed certification, even if the changes are made to the capabilities addressed by the certification criteria.

The commenters stated clarity was needed due to the substantial resources that will be required for certification of self-developed systems. In addition, commenters stated that, for legal compliance purposes, clarity will allow providers to confidently submit attestations to federal and state agencies about the certification status of the Certified EHR Technology they use.

Response. We understand the unique needs and requirements eligible professionals and eligible hospitals have with respect to successfully implementing and integrating HIT into operational environments. We provided a description of the term "self-developed" in the Proposed Rule's preamble for two reasons. First, in order to provide greater clarity for stakeholders regarding who would be responsible for the costs associated with testing and certification and, second, to clearly differentiate in our impact analysis those Complete EHRs and EHR Modules that would be certified once and most likely sold to many eligible professionals and eligible hospitals from those that would be certified once and used primarily by the person or entity who paid for the certification. We believe that many commenters were not concerned about the fact that brand new, built from scratch self-developed Complete EHRs and EHR Modules would need to be tested and certified. Rather, it appeared that commenters were concerned about whether any modification to an already certified Complete EHR or EHR Module, including those that would be enhancements or required to integrate several EHR Modules, would

invalidate a certification or certifications and consequently require the eligible professional or eligible hospital to seek a new certification because it would be considered self-developed. We believe this concern stems from the following statement we made in the preamble of the Proposed Rule.

> "Self-developed Complete EHRs and EHR Modules could include brand new Complete EHRs or EHR Modules developed by a health care provider or their contractor. It could also include a previously purchased Complete EHR or EHR Module which is subsequently modified by the health care provider or their contractor and where such modifications are made to capabilities addressed by certification criteria adopted by the Secretary. We limit the scope of "modification" to only those capabilities for which the Secretary has adopted certification criteria because other capabilities (e.g., a different graphical user interface (GUI)) would not affect the underlying capabilities a Complete EHR or EHR Module would need to include in order to be tested and certified."

In response to these concerns, we would like to further clarify the intent of our statements, specifically the statement that a self-developed Complete EHR or EHR Module "could also include a previously purchased Complete EHR or EHR Module which is subsequently modified by the health care provider or their contractor and where such modifications are made to capabilities addressed by certification criteria adopted by the Secretary." We agree with commenters that not every modification would or should constitute a modification such that a Complete EHR or EHR Module's certified status would become invalid. We provided an example in the proposed rule, quoted above, that spoke to modifications not related to any of the capabilities addressed by certification criteria adopted by the Secretary. We did not, however, provide any additional information regarding what we would consider an appropriate or inappropriate modification to an already certified Complete EHR or EHR Module and now take the opportunity to provide that clarification.

We recognize that a certified Complete EHR or certified EHR Module may not automatically work "out of the box" once it is implemented in an operational environment. We also cautioned eligible professionals and eligible hospitals in the HIT Standards and Certification Criteria interim final rule that, if they chose to use EHR Modules to meet the definition of Certified EHR Technology, they alone would be responsible for properly integrating multiple EHR Modules. Given that many of the certification criteria adopted by the Secretary express minimum capabilities, which may be added to or enhanced by eligible professionals and eligible hospitals to meet their health care delivery needs (e.g., more than five rules could be added to the clinical decision support capability), we believe that it is unrealistic to expect that the certified capabilities of a Complete EHR or EHR Module will remain 100% unmodified in all cases. As a result, we believe it is possible for an eligible professional or eligible hospital to modify a Complete EHR or 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. While we cannot review every eligible professional and eligible hospital's use of Certified EHR Technology and every potential modification that may be made to determine whether such modification may have invalidated a Complete EHR or EHR Module's certification, we strongly urge eligible professionals and eligible hospitals to consider the following. Certification is meant to provide assurance that a Complete EHR or EHR Modules will perform according to the certification criteria to which they were tested and certified. 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.

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

In the Proposed Rule, we discussed the validity of "certified status" of Complete EHRs and EHR Modules, as well as the expiration of that status as it related to the definition of Certified EHR Technology. We stated that certification represented "a snapshot, a fixed point in time, where it has been confirmed that a Complete EHR or EHR Module has met all applicable certification criteria adopted by the Secretary." We went on to say that as the Secretary adopts new or modified certification criteria, the previously adopted set of certification criteria would no longer constitute all of the applicable certification criteria to which a Complete EHR or EHR Module would need to be tested and certified. Thus, we clarified that after the Secretary has adopted new or modified certification criteria, a previously certified Complete EHR or EHR Module's certification would no longer be valid for purposes of meeting the definition of Certified EHR Technology. In other words, because new or modified certification criteria had been adopted, previously issued certifications would no longer indicate that a Complete EHR or EHR Module possessed all of the capabilities necessary to support an eligible professional's or eligible hospital's achievement of meaningful use. Accordingly, we noted that Complete EHRs and EHR Modules that had been certified to the previous set of adopted certification criteria would no longer constitute "Certified EHR Technology."

We also discussed that the planned two-year schedule for updates to meaningful use objectives and measures and correlated certification criteria created a natural expiration with respect to the validity of a previously certified Complete EHR's or EHR Module's certified status and its continued ability to be used to meet the definition of Certified EHR Technology. We stated that after the Secretary has adopted new or modified certification criteria, previously certified Complete EHRs and EHR Modules must be retested and recertified in order to continue to qualify as Certified EHR Technology.

We offered further clarification by stating that regardless 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 would need to be used would have to include the capabilities necessary to meet the most current certification criteria adopted by the Secretary at 45 CFR 170 subpart C in order to meet the definition of Certified EHR Technology. Finally, we asked for public comment on the best way to assist eligible professionals and eligible hospitals who begin meaningful use in 2013 or 2014 (at Stage 1) in identifying Complete EHRs and/or EHR Modules that have been certified to the most current set of adopted certification criteria and therefore could be used to meet the definition of Certified EHR Technology.

Comments. Several commenters disagreed with our position. Other commenters agreed and contended that Certified EHR Technology should always be as up-to-date and as current as possible. Of those commenters that disagreed, their concerns focused on two areas: the validity/expiration of certified status and how eligible professionals and eligible hospitals who adopt Certified EHR Technology in the year before we anticipate

updating adopted standards, implementation specifications, and certification criteria for a future stage of meaningful use would be affected.

Commenters asserted that some certification criteria were unlikely to change between meaningful use stages and that a Complete EHR or EHR Module's certification should remain valid and not expire until the Secretary had adopted updated certification criteria. These commenters requested that ONC only make changes to certification criteria on a cyclical basis and only when necessary for meaningful use or to advance interoperability. Finally, within the context of their responses, many of these commenters signaled favorable support for our proposal to include "differential certification" in the permanent certification program. In that regard, some commenters noted that we should not require Complete EHRs and EHR Modules certified under the purview of the temporary certification program to be fully retested and recertified once the permanent certification program has been initiated.

A number of commenters expressed concerns about our position and contended that it required eligible professionals and eligible hospitals who adopt Certified EHR Technology in 2012 (to attempt meaningful use Stage 1) to upgrade their Certified EHR Technology twice in two years (according to the proposed meaningful use stage staggering) in order to continue to be eligible for meaningful use incentives during 2013 when they would only still have to meet meaningful use Stage 1. Some of these commenters viewed this as a penalty and disagreed with our position that eligible professionals and eligible hospitals should have to use Certified EHR Technology that had been certified to the most recently adopted certification criteria. Additionally, these commenters conveyed their belief that it is not in the best interest of eligible professionals

and eligible hospitals to require that they use Certified EHR Technology that includes more advanced capabilities than are necessary to qualify for the meaningful use stage that they are attempting to meet. Finally, one commenter requested that we offer a graphical depiction to more clearly convey our position.

Response. We appreciate commenters' support for our proposal for differential certification. Because this concept is solely relevant to the policies of the permanent certification program, we do not address it in this final rule.

As previously mentioned in both the HIT Standards and Certification Criteria interim final rule and the Medicare and Medicaid EHR Incentive Programs proposed rule, ONC and CMS anticipate that the requirements for meaningful use will be adjusted every two years. We do not expect to adopt certification criteria more frequently than every two years. In its proposed rule (75 FR 1854), CMS also indicated that "[t]he stages of criteria of meaningful use and how they are demonstrated are described further in this proposed rule and will be updated in subsequent proposed rules to reflect advances in HIT products and infrastructure. This could include updates to the Stage 1 criteria in future rulemaking." (Emphasis added.)

We believe that commenters who expressed concerns and objected to our discussion of the expiration/validity of a Complete EHR or EHR Module's certified status did not account for the real 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. Contrary to some commenters' assumptions, it is possible that while establishing the objectives and measures for meaningful use Stage 2 (in a subsequent rulemaking) that

CMS could revise what it means to meet meaningful use Stage 1 in 2013. Consequently, such revisions could include additional requirements, based on advances in HIT, beyond the requirements that will be established in the forthcoming final rule that specifies what meaningful use Stage 1 will require in 2011 and 2012. Therefore, the potential remains 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.

In this regard, and consistent with the caveat many commenters articulated, we identified that an eligible professional or eligible hospital would no longer be able to assert that a Complete EHR or EHR Module's certification was valid for purposes of satisfying the definition of Certified EHR Technology in subsequent years for at least two reasons: 1) the certification criteria related to particular capabilities had been modified; and/or 2) the standard(s) and implementation specification(s) associated with a certification criterion had been modified (newly adopted or replaced). With respect to either of these two reasons, in order for a Complete EHR or EHR Module to continue to meet the definition of Certified EHR Technology, it would need to be retested and recertified to the new certification criteria or newly adopted standards and/or implementation specifications for the subsequent years for which they had been adopted. Only then would an eligible professional or eligible hospital be able to assert that it continues to possess a Complete EHR or EHR Module with a valid certification that could be used to meet the definition of Certified EHR Technology. 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. As we stated in the Proposed Rule, if the previously certified Complete EHR were not retested and recertified as being compliant with the newly adopted standard, it would not "lose its certification." However, the previous certification would no longer enable the Complete EHR to meet the definition of Certified EHR Technology. Many commenters recognized this fact by indicating that in situations where interoperability was a focus, retesting and recertification would be needed and justified. With respect to the validity of a Complete EHR or EHR Module's certification, we ask commenters to consider how they would expect to meet a subsequent stage of meaningful use without the technical capabilities necessary to do so. A Complete EHR or EHR Module's certification is only as good as the capabilities that can be associated with that certification. If the Secretary adopts new standards, implementation specifications, or certification criteria, a Complete EHR or EHR Module may no longer provide a valid set of capabilities to satisfy the definition of Certified EHR Technology or support an eligible professional's or eligible hospital's attempt to achieve a particular meaningful use stage.

Accordingly, and because the HITECH Act requires eligible professionals and eligible hospitals to use Certified EHR Technology in order to qualify for incentive payments, we reaffirm our previous position. Regardless 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 at 45 CFR 170 subpart C. We believe that this position takes into account the best interests of eligible professionals and eligible hospitals. It will also serve to assure eligible professionals and eligible hospitals who implement HIT that meets the definition of Certified EHR Technology that they will have the requisite technical capabilities to attempt to achieve meaningful use. Just as important, this position ensures that all Certified EHR Technology will have been tested and certified to the same standards and implementation specifications and provide the same level of interoperability, which would not be the case if we were to permit different variations of Certified EHR Technology to exist.

To further address concerns raised by the commenters, we clarify that if the temporary certification program sunsets on December 31, 2011 and the permanent certification program is fully constituted at the start of 2012, Complete EHRs and EHR Modules that were previously certified by ONC-ATCBs to the 2011/2012 certification criteria adopted by the Secretary will not need to be retested and recertified as having met the certification criteria for those years. In other words, the fact that the permanent certification program had replaced the temporary certification program would not automatically invalidate certifications that were previously issued by ONC-ATCBs pursuant to the 2011/2012 certification criteria.

However, we reiterate for commenters what we stated in the Proposed Rule (75 FR 11351): "[S]ince a new certification program would exist, which would include different processes, we emphasize that Complete EHRs and EHR Modules tested and certified under the temporary certification program by an ONC-ATCB would need to be tested and certified according to the permanent certification program once the Secretary

adopts certification criteria to replace, amend, or add to previously adopted certification criteria." Thus, once the permanent certification program is fully constituted and after the Secretary has adopted additional or revised certification criteria (which we expect will occur approximately two years from now), all Complete EHRs and EHR Modules that were previously certified under the temporary certification program by ONC-ATCBs will need to be tested by an accredited testing laboratory and certified by an ONC-ACB. Pursuant to our discussion regarding the sunset of the temporary certification program combined with the two year cycle on which we expect to adopt certification criteria, we anticipate the testing and certification of Complete EHRs and EHR Modules to the 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.

We provide the following illustration overlaid on CMS's proposed staggered payment year/adoption year chart for the Medicare program to more clearly convey the discussion above. This illustration would also be applicable to the Medicaid program.

First Payment Year	Payment Year			
	2011	2012	2013	2014
2011	Stage 1	Stage 1	Stage 2	Stage 2
2012	…..	Stage 1	Stage 1	Stage 2
2013	…..	…..	Stage 1	Stage 2
2014	…..	…..	…..	Stage 1
	Complete EHRs and EHR Modules certified by **ONC-ATCBs or ONC-ACBs**[1] to certification criteria adopted for 2011 & 2012 meet the definition of Certified EHR Technology		Complete EHRs and EHR Modules certified by **ONC-ACBs** to certification criteria adopted for 2013 & 2014 meet the definition of Certified EHR Technology	

[1] If the permanent certification program is fully constituted and the temporary certification program sunsets on 12/31/2011, all new requests made after 12/31/2011 for certification of Complete EHRs or EHR Modules to the 2011/2012 certification criteria will be processed by an ONC-ACB.

Comments. In response to our question about how to best indicate to eligible professionals and eligible hospitals those Complete EHRs and/or EHR Modules certified to the most current set of adopted certification criteria (which could be used to meet the definition of Certified EHR Technology), several commenters offered suggestions regarding "labeling" conventions for Complete EHRs and EHR Modules. Overall, commenters indicated that specific "labeling" parameters would help clarify the "currency" of a Complete EHR or EHR Module's certification and whether the certification was valid. These commenters offered a variety of suggested techniques, including identifying Complete EHRs and EHR Modules according to: the applicable meaningful use stage they could be used for; the month and year they had been tested and certified; and the year associated with the most current set of adopted standards, implementation specifications, and certification criteria. Additionally, in light of the EHR Module "bundle" concept we proposed with respect to when EHR Modules need to be tested and certified to adopted privacy and security criteria, one commenter recommended that we assign specific "labeling" constraints to certifications issued to pre-coordinated, integrated bundles of EHR Modules. Another comment suggested "labeling" constraints be assigned when a Complete EHR or EHR Module had been tested at an eligible professional or eligible hospital's site (e.g., at the hospital where the Complete EHR is deployed).

Response. We agree with the commenters who requested more specific requirements surrounding how a Complete EHR or EHR Module's certified status should be represented and communicated and believe that it will provide the most benefit to eligible professionals and eligible hospitals who are interested in easily identifying

Complete EHRs and EHR Modules that have been tested and certified by an ONC-ATCB. In fact, Guide 65, Section 14, requires evidence of policies and procedures for use and display of certificates (e.g., logos). We proposed and, as discussed above, will require applicants for ONC-ATCB status to provide the National Coordinator with a copy of their policies related to the use and display of certificates. We believe that the most effective method to ensure that the certified status of a Complete EHR or EHR Module is appropriately represented and communicated is through the addition of a new principle to the Principles of Proper Conduct for ONC-ATCBs. This new Principle of Proper Conduct will also provide additional clarity for applicants in terms of the information that the National Coordinator expects to be contained in the copy of the policies and procedures associated with the use and display of certificates submitted by an applicant as part of its application.

Accordingly, we also believe that this new Principle of Proper Conduct for ONC-ATCBs related to how a Complete EHR or EHR Module's certification is communicated is a logical extension of our proposals, is similar to the requirement we place on ONC-ATCBs with respect to how they represent themselves, and provides more specificity and clarity around requirements to which ONC-ATCBs would already be subject. The new Principle of Proper Conduct requires that:

- All certifications must 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 Complete EHR or EHR Module's certification:

- "This [Complete EHR or EHR Module] is 201[X]/201[X] compliant 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 o EHR Module at issue.

- A certification issued to an integrated bundle of EHR Modules shall be treated the same as a certification issued to a Complete EHR for the purposes of the above requirement except that it must also indicate each EHR Module that comprises the bundle.

With respect to the requirement that includes "201[X]/20`[X]," we expect ONC-ATCBs to put the years "2011/2012" where we have provided for variability in the date range and have only provided this flexibility in the rare circumstance that the temporary certification program does not sunset according to the schedule that we have discussed. Given our clarifications about the validity of a Complete EHR or EHR Module's certification, we believe that it would be inappropriate and misleading to adopt an identification requirement solely associated with meaningful use stages. We also believe that it would be inappropriate to constrain a particular certification based on whether the certification could be attributed to a particular entity at a particular location. While unlikely, we do not want to presume that such a certified Complete EHR or EHR Module would or could not be useful to another eligible professional or eligible hospital.

We do, however, agree with the commenter who suggested the specific constraint for a bundle of EHR Modules. Such bundles, by their very nature, would otherwise constitute a Complete EHR and therefore must be integrated in such a way in order to even be tested and certified as a bundle. In the case of a bundle of EHR Modules, the bundle is greater than the sum of each individual EHR Module, and for that reason, we would like to clarify that EHR Modules, once certified as part of a bundle, would not separately inherit a certification just because they were certified as part of a bundle. For example, if EHR Modules A, B, C, and D, are certified as an integrated bundle, EHR Module C would not on its own be certified, just by virtue of the fact that it was part of a certified bundle. If an EHR Module developer wanted to make EHR Module C available for uses outside the bundle, then they would have to seek to have EHR Module C separately tested and certified.

Comments. Several commenters requested that we clarify whether every single updated version of a Complete EHR or EHR Module would need to be retested and recertified in order to have a valid certification and whether there would be a mechanism available to accommodate routine changes and product maintenance without the need to fully retest and recertify each instantiation of a previously certified Complete EHR or EHR Module. Some of these commenters stressed that they provide bug-fixes and other maintenance upgrades to customers on a regular basis and that those versions are normally denoted by a new "dot release" (e.g., version 7.1.1 when 7.1 received certification).

Response. We understand that Complete EHR and EHR Module developers will conduct routine maintenance. We also recognize that at times Complete EHR and EHR

Module developers will provide new or modified capabilities to either make the Complete EHR or EHR Module perform more efficiently and/or to improve user experiences related to certain functionality (e.g., a new graphical user interface (GUI)). Our main concern, as we stated in the preamble, is whether these changes adversely affect the capabilities to which a Complete EHR or EHR Module has already been tested and certified and whether those changes are such that the Complete EHR or EHR Module would no longer support an eligible professional or eligible hospital's achievement of meaningful use. Accordingly, we clarify 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.[2] However, we do 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. We believe 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.

[2] We understand that Complete EHR and EHR Module developers typically consider a "minor version release" to be, for example, a version number change from 3.0 to 3.1 and consider a "major version release" to be, for example, a version number change from 4.0 to 5.0. In providing for this flexibility, we do not presume the version numbering schema that a Complete EHR or EHR Module developer may choose to utilize. As a result, we do not preclude a Complete EHR or EHR Module developer from submitting an attestation to an ONC-ATCB for a Complete EHR or EHR Module whose version number may represent a minor or major version change.

As a result, we have added to both §170.445 and §170.450 a requirement that an ONC-ATCB must accept requests for an updated version of a previously certified Complete EHR or EHR Module to inherit the previously certified Complete EHR or EHR Module's issued certification without being retested and recertified. However, the Complete EHR or EHR Module developer must submit an attestation as described above in the form and format specified by the ONC-ATCB that the newer version does not adversely affect the proper functionality of previously certified capabilities. Upon receipt of the attestation, an ONC-ATCB would be permitted to determine whether the updates and/or modifications are such that the new version would adversely affect previously certified capabilities and therefore need to be retested and recertified, or whether to grant certified status to the new version derived from the previously certified Complete EHR or EHR Module.

If the ONC-ATCB awards a certification to a newer version of a previously certified Complete EHR or EHR Module, we expect the ONC-ATCB to include this issued certification in its weekly report to the National Coordinator. We note that aside from specifying an ONC-ATCB must provide this mechanism and review the submitted attestation, we do not specify the fees or any other processes an ONC-ATCB may determine necessary before granting certified status to a newer version of a previously certified Complete EHR or EHR Module based on the submitted attestation.

P. General Comments

We received comments that were not attributable to a specific provision or proposal in the Proposed Rule, but were still within the scope of the temporary certification program. These comments were on such matters as the timing of the

temporary certification program, the use of elements in the proposed permanent certification program for the temporary certification program, the potential for a backlog of requests for testing and certification, the costs of testing and certification, the use and testing of open source Complete EHRs or EHR Modules, and the safety of Complete EHRs and EHR Modules.

Comments. One commenter suggested that we not implement the temporary certification program. Rather, the commenter suggested that we proceed straight to implementing the permanent certification program. Some other commenters suggested we were moving too fast, while still other commenters suggested we were not moving fast enough in implementing the temporary certification program. Some commenters suggested utilizing elements that we proposed for the permanent certification program, such as accreditation and post market surveillance in the temporary certification program.

Response. We discussed in detail the urgency for establishing the temporary certification program, particularly the need for making Certified EHR Technology available so that eligible professionals and eligible hospitals would have the ability to attempt to achieve meaningful use Stage 1. In discussing this urgency and the differences between the temporary certification program and the permanent certification program, we explained how there was not sufficient time to implement such elements as accreditation and post market surveillance. If we were to attempt to establish an accreditation process, Certified EHR Technology would likely not be available in a timely manner. Further, the limited time that we anticipate the temporary certification program being in existence prevents us from establishing a post market surveillance program. By the time we would

be able to establish and get results from a post market surveillance program, the temporary certification program will likely have sunset.

Comments. Commenters requested that we prevent testing and certification monopolies and backlogs of requests for testing and certification. Commenters also requested that we mandate pricing for testing and certification or at least establish a reasonable fee requirement.

Response. We believe that through the policies we have established in this final rule that the temporary certification program is inclusive of as many potential applicants for ONC-ATCB status as possible and that we have created an environment that is likely to result in multiple ONC-ATCBs. Further, we believe that multiple ONC-ATCBs and market dynamics, particularly competition, will address the commenters' concerns about potential monopolies, appropriate costs for testing and certification, and the timely and efficient processing of requests for the testing and certification of Complete EHRs and EHR Modules. Guide 65 also requires ONC-ATCBs to make their services accessible to all applicants whose activities fall within its declared field of operation (i.e., the temporary certification program), including not having any undue financial or other conditions. As noted throughout this rule, an ONC-ATCB must be in compliance with Guide 65 to remain in good standing under the temporary certification program.

Comments. One commenter requested that we only allow the testing and certification of open source Complete EHRs and EHR Modules under the temporary certification program and exclude proprietary Complete EHRs and EHR Modules. Commenters also inquired as to how we would test open source Complete EHRs and EHR Modules.

Response. We do not agree with the commenter that the temporary certification program should be limited to only open source Complete EHRs and EHR Modules. Proprietary Complete EHRs and EHR Modules will likely be widely purchased and/or utilized by the HIT market and we see no valid reason to exclude them from the temporary certification program. 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.

Comments. A few commenters expressed concern over the potential safety risks that could be associated with poorly planned, implemented, and used EHR technology and suggested that patient safety should be considered in the same context as the speed with which we develop and implement the temporary certification program.

Response. We understand and are acutely aware of the concerns expressed by the commenters regarding patient health and safety. We believe that the temporary certification program has been sufficiently constituted to ensure that ONC-ATCBs will competently test and certify Complete EHRs and EHR Modules. Further, we have established a process in the temporary certification program that the National Coordinator could use to immediately suspend an ONC-ATCB's ability to perform testing and certification if there is reliable evidence indicating that allowing an ONC-ATCB to continue its testing and certification processes would pose an adverse risk to patient health and safety.

Q. Comments Beyond the Scope of this Final Rule

In response to the Proposed Rule, some commenters chose to raise issues that are beyond the scope of our proposals. We do not summarize or respond to those comments

in this final rule. However, we will review the comments and consider whether other actions may be necessary, such as addressing the comments in the permanent certification program's rulemaking or clarifying program operating procedures, based on the information or suggestions in the comments.

IV. Provisions of the Final Regulation

For the most part, this final rule incorporates the provisions of the Proposed Rule. Those provisions of this final rule that differ from the Proposed Rule are as follows:

- In §170.401, we added "the requirements that ONC-ATCBs must follow to remain in good standing" to properly identify that this subpart contains requirements that ONC-ATCBs must follow to remain in good standing under the temporary certification program. This reference was inadvertently left out of the Proposed Rule.
- In §170.402, we added the definitions of "development site," "deployment site," and "remote testing and certification."
- In §170.405(b), we added "or ONC-ATCB" to clarify that either an applicant for ONC-ATCB status or an ONC-ATCB may, when necessary, utilize the specified correspondence methods. This reference was inadvertently left out of the Proposed Rule.
- In §170.423, in response to public comments, we added a new Principle of Proper Conduct designated as paragraph (k). The new Principle of Proper Conduct will require ONC-ATCBs to ensure that all Complete EHRs and EHR Modules are properly identified and marketed.
- In §170.423(e), we modified the language to require that ONC-ATCBs "[u]se test tools and test procedures approved by the National Coordinator for the purposes of

assessing Complete EHRs and/or EHR Modules compliance with the certification criteria adopted by the Secretary."

- In §170.423(h), we have specified that an ONC-ATCB will be additionally required to report the clinical quality measures to which a Complete EHR or EHR Module has been tested and certified and, where applicable, any additional software a Complete EHR or EHR Module relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary.
- In §170.423(i), in response to comments, we made revisions to clarify that an ONC-ATCB must retain all records related to tests and certifications according to ISO Guide 65 and ISO 17025 for the duration of the temporary certification program and provide copies of the final results of all completed tests and certifications to ONC at the conclusion of testing and certification activities under the temporary certification program.
- In §170.423(j), we made revisions to clarify that an ONC-ATCB will only be responsible for issuing refunds in situations where the ONC-ATCB's conduct caused testing and certification to be suspended and a request for testing and certification is withdrawn, and in instances where the ONC-ATCB's conduct caused the testing and certification to not to be completed or necessitated the recertification of Complete EHRs or EHR Modules it had previously certified.
- In §170.430(a)(2), to provide clarity in response to public comments, we have stated that the National Coordinator will review each part of the application "in its entirety."
- In §170.430(b)(1), we have removed the terms "inadvertent" and "minor" in response to public comment.

- In §170.430(c), to respond to public comments, we have revised paragraph (c)(1) to allow an applicant for ONC-ATCB status to request an extension of the 15-day period provided to submit a revised application in response to a deficiency notice. We have revised paragraph (c)(2) to state that the National Coordinator can grant an applicant's request for an extension of the 15-day period based on a finding of good cause. We have also revised paragraph (c)(3) 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 a revised application.
- In §170.440(b), to respond to public comments, we have revised the paragraph to state, in relevant part, "Each ONC-ATCB must prominently and unambiguously identify the scope of its authorization on its website, and in all marketing and communications statements (written and oral) pertaining to its activities under the temporary certification program."
- In §170.445(a), we revised the paragraph to state that "An ONC-ATCB must test and certify Complete EHRs to all applicable certification criteria adopted by the Secretary at subpart C of this part." This revision addresses public comments and ensures consistent requirements for ONC-ATCBs with regard to testing and certification requirements for Complete EHRs and EHR Modules. An ONC-ATCB must not just be capable of conducting the applicable testing and certification, but they are required to perform the appropriate testing and certification.
- In §170.445, we re-designated paragraph (b) as paragraph (d). We then added a new provision, designated as paragraph (b), which states that an ONC-ATCB must

provide the option for a Complete EHR to be tested and certified solely to the applicable certification criteria adopted by the Secretary at subpart C of this part. We also added another new provision, designated as paragraph (c), that requires an ONC-ATCB to accept requests for an updated version of a previously certified Complete EHR to inherit the previously certified Complete EHR issued certification without being retested and recertified.

- In §170.450, we removed proposed paragraphs (b) and (d) because they are redundant of other regulatory requirements within this subpart. We then added a new provision, designated as paragraph (b), which states that an ONC-ATCB must provide the option for an EHR Module or a bundle of EHR Modules to be tested and certified solely to the applicable certification criteria adopted by the Secretary at subpart C of this part. We also added another new provision, designated as paragraph (d), that requires an ONC-ATCB to accept requests for an updated version of a previously certified EHR Module or bundle of EHR Modules to inherit the previously certified EHR Module or bundle of EHR Modules issued certification without being retested and recertified.
- In §170.450(c), we revised the paragraph to state that 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 (as defined in 45 CFR 170.102), 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 and provide documentation 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.

- In §170.457, we revised the section to require that an ONC-ATCB provide remote testing and certification for both development and deployment sites.
- In §170.465, we revised the section to provide the National Coordinator with the discretion to suspend an ONC-ATCB's operations if there is reliable evidence indicating that the ONC-ATCB has committed a Type-1 or Type-2 violation and that the continued testing and certification of Complete EHRs and/or EHR Modules by the ONC-ATCB could have an adverse impact on patient health or safety. An ONC-ATCB will have 3 days to respond to a notice of proposed suspension by explaining in writing why its operations should not be suspended. The National Coordinator will be permitted up to 5 days to review the response and issue a determination to the ONC-ATCB. The National Coordinator will make a determination to either rescind the proposed suspension, suspend the ONC-ATCB until it has adequately corrected a Type-2 violation, or propose revocation in accordance with §170.465(c) and suspend the ONC-ATCB's operations for the duration of the revocation process. The National Coordinator may also make any one of the above determinations if an ONC-ATCB fails to submit a timely response to a notice of proposed suspension. A suspension will become effective upon an ONC-ATCB's receipt of a notice of suspension.

- In §170.465(c)(1) we revised the provision to state that "[t]he National Coordinator may propose to revoke an ONC-ATCB's status if the National Coordinator has reliable evidence that the ONC-ATCB committed a Type-1 violation." The term "reliable" was inadvertently left out of the Proposed Rule.
- In §170.490, we revised the section to state 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. We clarified that ONC-ATCBs will be prohibited from accepting new requests to test and certify Complete EHRs or EHR Modules "on and after the temporary certification program sunset date." We also revised the section to state that ONC-ATCBs are permitted up to six months after the sunset date to complete all testing and certification activities associated with requests for testing and certification of Complete EHRs and/or EHR Modules received prior to the sunset date.
- We added §170.499 to incorporate by reference ISO/IEC Guide 65:1996 and ISO/IEC 17025:2005.

V. Technical Correction to §170.100

We are making a technical correction to §170.100. We inadvertently left out a citation to section 3001(c)(5) of the PHSA, which provides the statutory basis for the National Coordinator to establish certification program(s) for HIT. We have revised §170.100 to include reference to this statutory authority.

VI. Waiver of the 30-day Delay in the Effective Date

We ordinarily provide a 30-day delay in the effective date of a final rule as required by section 553(d) of the Administrative Procedure Act (APA). 5 U.S.C. § 553(d). However, we can waive the 30-day delay in the effective date if the Secretary finds, for good cause, that the delay is impracticable, unnecessary, or contrary to the public interest, and includes a statement of the finding and the reasons in the rule issued. The Secretary finds that good cause exists to waive the 30-day delay in the effective date of this final rule. A delayed effective date would be contrary to the public interest because it would restrict the ability of eligible professionals and eligible hospitals to adopt and implement Certified EHR Technology

As previously discussed, the HITECH Act provides incentive payments beginning in 2011 under the Medicare and Medicaid programs for eligible professionals and eligible hospitals that demonstrate meaningful use of Certified EHR Technology. The rules promulgated by ONC and CMS establish the regulatory framework through which eligible professionals and eligible hospitals may seek to qualify for those incentive payments. The Medicare and Medicaid EHR Incentive Programs proposed rule would establish meaningful use Stage 1 beginning in 2011. The HIT Standards and Certification Criteria interim final rule adopted certification criteria that directly support the proposed meaningful use Stage 1 objectives. This final rule establishes a temporary certification program that will allow Complete EHRs and EHR Modules to be tested and certified to the adopted certification criteria.

As a result, Certified EHR Technology will not be available to eligible professionals and eligible hospitals until the temporary certification program begins. Eligible professionals and eligible hospitals will need time to select, adopt, and

implement Certified EHR Technology before they attempt to demonstrate meaningful use in 2011. In addition, before testing and certification can begin, ONC must review and deem satisfactory applications that are submitted by organizations that seek ONC-ATCB status. A delayed effective date for this final rule would delay the process for making Certified EHR Technology available to eligible professionals and eligible hospitals prior to the proposed beginning of meaningful use Stage 1 in 2011.

Several commenters voiced their strong concern that the temporary certification program needs to be established immediately so as to enable organizations to apply and be authorized to serve as ONC-ATCBs, to enable Complete EHR and EHR Module developers to have their Complete EHRs and/or EHR Modules certified, and to enable eligible professionals and eligible hospitals to obtain and implement Certified EHR Technology that will support their achievement of meaningful use. These commenters encouraged us to take immediate steps to issue this final rule and to permit organizations to apply for ONC-ATCB status. These commenters explained that it is necessary to have ONC-ATCBs in place as soon as possible in order for them to be positioned and prepared to test and certify Complete EHRs and EHR Modules in a timely manner.

For the reasons stated above, we believe that a delayed effective date for this final rule would be contrary to the public interest. Therefore, we find there is good cause to waive the 30-day delay in the effective date of this final rule.

VII. Collection of Information Requirements

In accordance with section 3507(j) of the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 et seq., the information collection included in this final rule has been submitted for emergency approval to OMB.

The two information collections specified under sections A and B below were previously published in the **Federal Register** as part of the Proposed Rule and HHS invited interested persons to submit comments on any aspect of each of the two information collections, including the following: (1) necessity and utility of the information collection; (2) the accuracy of the estimate of the burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of collection without reducing the quality of the collected information.

The final rule contains one new information collection requirement pertaining to records retention and disclosure to ONC that was inadvertently left out of the Proposed Rule, but included in the emergency request to OMB. Please refer to section C below for this new information collection.

A. Collection of Information: Application for ONC-ATCB Status under the Temporary Certification Program

Section 170.420 requires an applicant for ONC-ATCB status to submit to the National Coordinator a completed application. The application consists of two parts. Part 1 requires an applicant to submit general identifying information, complete self audits to Guide 65 and ISO 17025, and agree to adhere to the Principles of Proper Conduct for ONC-ATCBs. Part 2 requires an applicant to complete a proficiency examination. The proficiency examination is not, however, considered "information" for PRA collection purposes because it falls under the exception to the definition of information at 5 CFR § 1320.3(h)(7). We estimated in the Proposed Rule that there would be no more than 3 applicants for ONC-ATCB status. We also assumed that these

applicants would be familiar with the relevant requirements found in Guide 65 and ISO 17025 and would have a majority, if not all, of the documentation requested in the application already developed and available before applying for ONC-ATCB status. Therefore, with the exception of completing a proficiency examination, we concluded that an applicant would only spend time collecting and assembling already developed information to submit with their application. Based on these assumptions, we estimated that it would take approximately:

- 10 minutes for an applicant to provide the general identifying information requested in the application;
- 2 hours to complete the Guide 65 self audit and assemble associated documentation;
- 2 hours to complete the ISO 17025 self audit and assemble associated documentation; and
- 20 minutes to review and agree to the "Principles of Proper Conduct for ONC-ATCBs."

Comments. One commenter expressed a concern that we had underestimated the potential burden hours associated with applying for the temporary certification program. The commenter cited that while they had significant familiarity with testing and certification, their organization was not totally conformant to both Guide 65 and ISO 17025. The commenter stated that it had taken 120 hours to perform a gap analysis and that it would take approximately another several hundred more hours to properly conform to our proposed requirements in order to be ready to apply for ONC-ATCB status.

Response. We agree with this commenter. As noted, we previously assumed and based on that assumption, estimated that applicants for ONC-ATCB status would already be conformant with Guide 65 and ISO 17025 and would have "in hand" the documentation we requested copies of as part of the ONC-ATCB application ("conformant applicants"). Given this commenter's analysis, we believe that it is reasonable to expect that one or two potential applicants for ONC-ATCB status ("partially conformant applicants") may need to perform more upfront work than other potential applicants. As a result, we have revised our estimates below to account for the fact that, at most, two potential applicants may need to perform more upfront work to prepare to apply for ONC-ATCB status and to account for the fact that we now anticipate that there may be up to five applicants for ONC-ATCB status.

In consultation with NIST, we believe that the 120 hours to perform a gap analysis is reasonable and have estimated that the remaining time it may take a potential applicant to become conformant with both Guide 65 and ISO 17025 would be a maximum of 280 hours. Thus, in order to be ready to apply for ONC-ATCB status, we believe that it will take approximately a maximum of 400 hours for a potential applicant to become conformant with Guide 65 and ISO 17025 and have equally distributed the burden among these two requirements. Our revised analysis is expressed in the table below.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Burden Hours per Response	Total Burden Hours
Conformant Applicant	ONC-ATCB Application	3	1	4.5	13.5
Partially	ONC-ATCB	2	1	400.5	801

Conformant Applicant	Application				
Total					814.5

B. Collection of Information: ONC-ATCB Collection and Reporting of Information Related to Complete EHR and/or EHR Module Certifications

Section 170.423(h) requires an ONC-ATCB to provide ONC, no less frequently than weekly, a current list of Complete EHRs and/or EHR Modules that have been tested and certified as well as certain minimum information about each certified Complete EHR and/or EHR Module.

We did not receive any comments on this collection of information. We have, however, specified in this final rule two additional reporting elements that must be submitted by ONC-ATCBs on a weekly basis (i.e., clinical quality measures to which a Complete EHR or EHR Module has been tested and certified and, where applicable, any additional software a Complete EHR or EHR Module relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary). ONC-ATCBs will be capturing these additional reporting elements in conjunction with the other information we request that they report on a weekly basis. Consequently, we do no believe that the reporting of these two additional elements will increase the reporting burden for ONC-ATCBs.

Based on our new estimate that there may be up to 5 applicants that apply for ONC-ATCB status, we have revised our overall annual burden estimate. In doing so, we have maintained our prior assumptions. For the purposes of estimating the potential burden, we assume that all of the estimated applicants will apply and become ONC-

ATCBs. We also assume that ONC-ATCBs will report weekly (i.e., respondents will respond 52 times per year). Finally, we assume that the information collections will be accomplished through electronic data collection and storage, which will be part of the normal course of business for ONC-ATCBs. Therefore, with respect to this proposed collection of information, the estimated burden is limited to the actual electronic reporting of the information to ONC.

Estimated Annualized Burden Hours

Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Hours per Response	Total Burden Hours
ONC-ATCB Testing and Certification Results	5	52	1	260

C. Collection of Information: ONC-ATCB Retention of Testing and Certification Records and the Submission of Copies of Records to ONC

Section 170.423(i) requires ONC-ATCBs to retain all records related to tests and certifications according to Guide 65 and ISO 17025 for the duration of the temporary certification program and provide copies of the final results of all completed tests and certifications to ONC at the conclusion of testing and certification activities under the temporary certification program.

We do not believe that there are any specific recordkeeping burdens associated with this requirement. Based on our consultations with NIST, we understand that it is standard industry practice to retain records related to testing and certification. Therefore, we believe that the only burden attributable to our requirement is associated with the submission of copies to ONC of the final results of all completed tests and certifications.

For the purposes of estimating the potential burden, we assume that all of the estimated number of applicants for the temporary certification program (i.e., five) will become ONC-ATCBs. For calculation purposes, we also assume that each ONC-ATCB will incur the same burden. We assume that on average each ONC-ATCB will test and certify an equal amount of ONC's estimate of the maximum amount of Complete EHRs and EHR Modules that will be tested and certified under the temporary certification program as specified in the regulatory impact analysis of this final rule. We estimate the equal amount of Complete EHRs and/or EHR Modules that will be tested and certified by each of the 5 estimated ONC-ATCBs to be approximately 205. Finally, we assume that an ONC-ATCB will submit copies of the final results of all completed tests and certifications to ONC by either electronic transmission or paper submission. In either instance, we believe that an ONC-ATCB will spend a similar amount of time and effort in organizing, categorizing and submitting the requested information. We estimate that this amount of time will be approximately 8 hours for each ONC-ATCB. Our estimates are expressed in the table below.

Estimated Annualized Burden Hours

Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Hours per Response	Total Burden Hours
ONC-ATCB Testing and Certification Records	5	1	8	40

VIII. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993, as further amended),

the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), section 202 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year). Based on the analysis of costs and benefits that follows, we have determined that this final rule covering the temporary certification program is not an economically significant rule because we estimate that the overall costs and benefits associated with the temporary certification program, including the costs associated with the testing and certification of Complete EHRs and EHR Modules, to be less than $100 million per year. Nevertheless, because of the public interest in this final rule, we have prepared an RIA that to the best of our ability presents the costs and benefits of the final rule.

B. Why is this Rule Needed?

As stated in earlier sections of this final rule, section 3001(c)(5) of the PHSA provides the National Coordinator with the authority to establish a certification program or programs for the voluntary certification of HIT. This final rule is needed to outline the processes by which the National Coordinator would exercise this authority to authorize certain organizations to test and certify Complete EHRs and/or EHR Modules. Once certified, Complete EHRs and EHR Modules will be able to be used by eligible

professionals and eligible hospitals as, or be combined to create, Certified EHR Technology. Eligible professionals and eligible hospitals who seek to qualify for incentive payments under the Medicare and Medicaid EHR Incentive Programs are required by statute to use Certified EHR Technology.

C. Executive Order 12866 – Regulatory Planning and Review Analysis

1. Comment and Response

Comments. A few commenters expressed concerns that the costs we attributed in the Proposed Rule related to the testing and certification of Complete EHRs and EHR Modules were too high, unrealistic, and unreliable. One commenter requested that we remove our cost estimates because they believed they were based on a monopolistic pricing structure. Other commenters indicated that we should regulate the pricing related to testing and certification in order to ensure that prices were not exorbitant and did not preclude smaller Complete EHR and EHR Module developers from being able to attain certification for their product.

Response. We understand the commenters' concerns; however, we have a responsibility to put forth a good faith effort to estimate the potential costs associated with this final rule. Part of that effort includes using the best available data to inform our assumptions and estimates. While we were open to revising our cost estimates in response to public comment, in no instance did a commenter provide alternative estimates or reference additional information from which we could base revisions. Conversely, we believe that commenters who expressed concerns about the potential costs, largely did so from the perspective of stating a request that we ensure the costs for testing and certification were not prohibitively high.

While we understand these commenters' perspectives, we do not believe that it is appropriate to dictate the minimum or maximum amount an ONC-ATCB should be able to charge for testing and certifying a Complete EHR or EHR Module. However, as evidenced by the increase in our estimate of the number of ONC-ATCB applicants under the temporary certification program, it is our hope that multiple ONC-ATCBs will be authorized and will compete for market share. As a result of expected increased competition among ONC-ATCBs, we believe there could also be increased downward pressure on the costs associated with testing and certification. If that cost pressure occurs, we believe that the upper ranges of the cost estimates we provide in this final rule could be overestimates.

Comments. Some commenters questioned our estimates related to the number of EHR Modules we expected to be tested and certified. One commenter suggested that the number of self-developed EHR Modules should be much higher than we estimated. Other commenters expressed that this rule needed to account for other costs associated with testing and certification (e.g., reprogramming a Complete EHR or EHR Module) and not just the costs associated with the application process and for Complete EHRs and EHR Modules to be tested and certified.

Response. This final rule is one of three coordinated rulemakings. Each of these rulemakings accounts for its specific effects. In the HIT Standards and Certification Criteria interim final rule (75 FR 2038), we summarized these effects as follows:

> While there is no bright line that divides the effects of this interim final rule and the other two noted above, we believe that each analysis properly focuses on the direct effects of the provisions it creates. This interim final rule estimates the costs commercial vendors, open source developers, and relevant Federal agencies will incur to prepare Complete EHRs and EHR Modules to be tested and certified to adopted standards, implementation specifications, and certification criteria. The

> Medicare and Medicaid EHR Incentive Programs proposed rule estimates the impacts related to the actions taken by eligible professionals or eligible hospitals to become meaningful users, including purchasing or self-developing Complete EHRs or EHR Modules. The HIT Certification Programs proposed rule estimates the testing and certification costs for Complete EHRs and EHR Modules.

As result, we estimate in this final rule, as we had before, the effects of the application process for ONC-ATCB status and the costs for Complete EHRs and EHR Modules to be tested and certified by ONC-ATCBs. With respect to EHR Modules, especially self-developed EHR Modules, we agree with those commenters regarding our estimates and have provided revised estimates that factor in a potential larger number of self-developed EHR Modules. While neither commenter who offered this concern related to EHR Modules provided any data to substantiate their claims, we determined that this revision was necessary because we had previously grouped self-developed Complete EHRs and EHR Modules together. Upon further review and other comments addressed above regarding EHR Modules, we believe that in order to provide a more accurate estimate, self-developed Complete EHRs and EHR Modules should be separately accounted for. We believe our prior estimates related to self-developed Complete EHRs and EHR Modules are more appropriately attributable to the number of self-developed Complete EHRs. Accordingly, we have developed new estimates (captured in the discussion and tables below) for the number of self-developed EHR Modules that we believe will be presented for testing and certification.

2. Executive Order 12866 Final Analysis

As required by Executive Order 12866, we have examined the economic implications of this rule as it relates to the temporary certification program. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory

alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a regulation as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million, or in a material way adversely affecting the economy, a sector of the economy, competition, or jobs. While this rule is therefore not "economically significant," as defined by Executive Order 12866, OMB has determined that this rule constitutes a "significant regulatory action" as defined by Executive Order 12866 because it raises novel legal and policy issues.

a. Temporary Certification Program Estimated Costs

i . Application Process for ONC-ATCB Status

Applicant Costs

As discussed under the collection of information section, we have increased our estimate of the number of applicants we expect will apply for ONC-ATCB status. In the Proposed Rule, we stated that we anticipated that there would be no more than 3 applicants for ONC-ATCB status. Based on the comments received, we now believe that there may be up to 5 applicants for ONC-ATCB status. In addition, we believe that up to 2 of these applicants will not have the level of preparedness that we originally estimated for all potential applicants for ONC-ATCB status.

As part of the temporary certification program, an applicant will be required to submit an application and complete a proficiency exam. We do not believe that there will be an appreciable difference in the time commitment an applicant for ONC-ATCB status

will have to make based on the type of authorization it seeks (i.e., we believe the application process and time commitment will be the same for applicants seeking authorization to conduct the testing and certification of either Complete EHRs or EHR Modules). We do, however, believe that there will be a distinction between applicants based on their level of preparedness. For the purposes of estimating applicant costs, we have divided applicants into two categories, "conformant applicants" and "partially conformant applicants." We still believe, after reviewing comments, that there will be three "conformant applicants" and that these applicants will have reviewed the relevant requirements found in the ISO/IEC standards and will have a majority, if not all, of the documentation requested in the application already developed and available before applying for ONC-ATCB status. Therefore, with the exception of completing a proficiency examination, we believe "conformant applicants" will only spend time collecting and assembling already developed information to submit with their application. Conversely, we believe that there will be up to two "partially conformant applicants" and that these applicants will spend significantly more time establishing their compliance with Guide 65 and ISO 17025. Based on our assumptions, review of comments, and consultations with NIST, we anticipate that it will take a "conformant applicant" approximately 28.5 hours and a "partially conformant applicant" approximately 424.5 hours to complete the application and submit the requested documentation. Our estimates include the time discussed above in our collection of information section and approximately up to 24 hours for all applicants to complete the proficiency examination – 8 hours (1 full work day) to complete section 1 (demonstration of technical expertise related to Complete EHRs and/or EHR Modules); 6 hours to complete section 2

(demonstration of test tool identification); and 10 hours to complete section 3 (demonstration of proper use of test tools and understanding of test results). Moreover, after consulting with NIST we assume that:

- an employee equivalent to the Federal Salary Classification of GS-9 Step 1 could provide the general information requested in the application and accomplish the paperwork duties associated with the application;
- an employee equivalent to the Federal Salary Classification of GS-15 Step 1 would be responsible for conducting the self audits and agreeing to the "Principles of Proper Conduct for ONC-ATCBs"; and
- an employee or employees equivalent to the Federal Salary Classification of GS-15 Step 1 would be responsible for completing the proficiency examination.

We have taken these employee assumptions and utilized the corresponding employee hourly rates for the locality pay area of Washington, D.C. as published by the U.S. Office of Personnel Management (OPM), to calculate our cost estimates. We have also calculated the costs of an employee's benefits while completing the application. We have calculated these costs by assuming that an applicant expends thirty-six percent (36%) of an employee's hourly wage on benefits for the employee. We have concluded that a 36% expenditure on benefits is an appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. Our calculations are expressed in Tables 1 and 2 below.

Table 1. Temporary Certification Program: Cost to Applicants to Apply to Become an ONC-ATCB

Application Requirement	Employee Equivalent	Burden Hours	Employee	Cost of Employee	Cost Per Applicant

		Conformant Applicant	Partially Conformant Applicant	Hourly Wage Rate	Benefits Per Hour	Conformant Applicant	Partially Conformant Applicant
General Identifying Information	GS-9 Step 1	10/60	10/60	$22.39	$8.06	$5.07	$5.07
Self Audits and Documentation	GS-15 Step 1	4	400	$59.30	$21.35	$322.60	$32,260.00
Principles of Proper Conduct	GS-15 Step 1	20/60	20/60	$59.30	$21.35	$26.89	$26.89
Proficiency Examination	GS-15 Step 1	24	24	$59.30	$21.35	$1,935.60	$1,935.60
Total Cost Per Application						$2,290.16	$34,227.56

Table 2. Temporary Certification Program: Total Applicant Cost

Type of Applicant	Anticipated Number of Applicants	Cost of Application Per Applicant ($)	Total Cost Estimate ($)
Conformant Applicant	3	$2,290.16	$6,870.48
Partially Conformant Applicant	2	$34,227.56	$68,455.12
Total Cost of Application Process			$75,325.60

We based our cost estimates on the amount of applicants that we believe will apply over the life of the temporary certification program. We assume that all applicants will apply during the first year of the program and thus all application costs should be attributed to the first year of the program. However, based on our projection that the temporary certification program will last approximately two years and that one or two applicants may choose to apply in the second year, the annualized cost of the application process will be $37,663.

Costs to the Federal Government

We have estimated the cost to develop the ONC-ATCB application, including the development and administration of the proficiency examination to be $34,618 based on the 495 hours we believe it will take to develop the application, prepare standard operating procedures as well as create the requisite pools of questions for the proficiency examinations. More specifically, we believe it will take 360 hours of work of a Federal Salary Classification GS-14 Step 1 employee located in Washington, D.C. to develop the proficiency examination, 80 hours of work by the same employee to develop the standard operation procedures and the actual application, and 55 hours to score all the exams and handle related administrative tasks.

We also anticipate that there will be costs associated with reviewing applications under the temporary certification program. We expect that a GS-15 Step 1 employee will review the applications and the National Coordinator (or designated representative) will issue final decisions on all applications. We anticipate that it will take approximately 40 hours to review and reach a final decision on each application. This estimate assumes a satisfactory application (i.e., no formal deficiency notifications) and includes the time necessary to verify the information in each application, assess the results of the proficiency examination, and prepare a briefing for the National Coordinator. We estimate the cost for the application review process, which we anticipate will include the review of 5 applications, to be $16,900.

As a result, we estimate the Federal government's overall cost of administering the entire application process, for the length of the temporary certification program, at approximately $51,518. Based on our projection that the temporary certification program will last approximately two years and that one or two applicants may choose to apply in

the second year, the annualized cost to the Federal government for administering the entire application process will be $25,759.

As previously noted, we will also post the names of applicants granted ONC-ATCB status on our website. We believe that there will be minimal cost associated with this action and have calculated the potential cost to be approximately $260 on an annual basis for posting and maintaining the information on our website (a maximum of 5 hours of work for a Federal Salary Classification GS-12 Step 1 employee located in Washington, D.C.).

ii. Testing and Certification of Complete EHRs and EHR Modules

Section 3001(c)(5)(A) of the PHSA indicates that certification is a voluntary act; however, due to the fact that the Medicare and Medicaid EHR Incentive Programs require eligible professionals and eligible hospitals to use Certified EHR Technology in order to qualify for incentive payments, we anticipate that a significant portion of Complete EHR and EHR Module developers will seek to have their HIT tested and certified.

In Tables 3 through 8 below, we estimate the costs for Complete EHRs and EHR Modules to be tested and certified under the temporary certification program. As discussed in the HIT Standards and Certification Criteria interim final rule, and to remain consistent with our previous estimates (75 FR 2039), we believe that approximately 93 commercial/open source Complete EHRs and 50 EHR Modules will be tested and certified under our proposed temporary certification program. In addition to these costs, we also take into account what we believe will be the costs incurred by a percentage of eligible professionals and eligible hospitals who themselves will incur the costs

associated with the testing and certification of their self-developed Complete EHR or EHR Module(s).

With respect to the potential for eligible professionals to seek testing and certification for a self-developed Complete EHR, DesRoches found that only 5% of physicians are in large practices of over 50 doctors.[3] Of these large practices, 17% use an "advanced EHR system" that could potentially be tested and certified if it were self-developed (we assume that smaller physician practices do not have the resources to self-develop a Complete EHR). We are unaware of any reliable data on the number of large practices who may have a self-developed Complete EHR for which they would seek to be tested and certified. As a result, we offer the following estimate based on currently available data. We believe that the total number of eligible professionals in large practices who both possess an IT staff with the resources to develop and support a Complete EHR and would seek to have such a self-developed Complete EHR tested and certified will be low – no more than 10%. By taking CMS's estimate in its proposed rule of approximately 450,000 eligible professionals (75 FR 1960) we multiply through by the numbers above (450,000 x .05 x .17 x .10) and then divide by a practice size of at least 50 which yields approximately 8 self-developed Complete EHRs designed for an ambulatory setting that could be submitted for testing and certification. Additionally, we believe that a reasonable estimate for the number of large practices with the IT staff and resources to self-develop an EHR Module and that would seek to have such an EHR Module tested and certified can also be derived from the calculation above but with a few differences. We start with the total number of large practices from the calculation above (~77). We

[3] DesRoches, CM et al. Electronic Health Records in Ambulatory Care — A National Survey of Physicians New England Journal of Medicine July 2008; 359:50-60

then assume an average number (1.1) of self-developed EHR Modules for this group of large practices and further refine this estimate by providing low and high probability assumptions (10% and 70%, respectively) to represent the likelihood that any one of these large practices possess a self-developed EHR Module that they would seek to have tested and certified. Given that no commenter provided data to further support this estimate, we believe that our maximum number of self-developed EHR Modules estimate is generous. While we do not dispute that practice sizes smaller than 50 could also possess self-developed EHR Modules, we believe those smaller practices will be the exception, not the rule, and that separately calculating a total for these smaller practices would produce a negligible amount of EHR Modules to add to our overall range.

With respect to eligible hospitals, similar to eligible professionals, we believe that only large eligible hospitals would have the IT staff and resources available to possess a self-developed Complete EHR that they would seek to have tested and certified. Again, we are unaware of any reliable data on the number of eligible hospitals who may have a self-developed Complete EHR for which they would seek to be tested and certified. Further, we believe that with respect to EHR Modules the probability varies across different types of eligible hospitals regarding their IT staff resources and ability to self-develop an EHR Module and seek to have it tested and certified. As a result, we offer the following estimates based on currently available data. We have based our calculations on the Medicare eligible hospital table CMS provided in its proposed rule (Table 38) (75 FR 1980) which conveys hospital IT capabilities according to three levels of adoption by hospital size according to the 2007 AHA annual survey. These three levels included: (1) Hospitals which had already implemented relatively advanced

systems that included CPOE systems for medications; (2) hospitals which had implemented more basic systems through which lab results could be shared, but not CPOE for medications; and (3) hospitals starting from a base level either neither CPOE or lab reporting. CMS indicated that CPOE for medication standard was chosen because expert input indicated that the CPOE standard in the proposed meaningful use definition will be the hardest one for hospitals to meet.

As stated above, we believe that only large hospitals (defined in Table 38 as those with 400+ beds) would have the IT staff and resources to develop, support, and seek the testing and certification of a self-developed Complete EHR. CMS indicated that 331 large hospitals had met either "level 1" or "level 2." As a result, we estimate that approximately 10% of these large eligible hospitals have a self-developed Complete EHR and would seek to have it tested and certified. We believe that this estimate is generous and that a good portion of the eligible professionals and eligible hospitals who would likely seek to qualify for incentive payments with self-developed Complete EHRs would only do so for meaningful use Stage 1. After meaningful use Stage 1 we anticipate that the number of eligible professionals and eligible hospitals who would incur the costs of testing and certification themselves will go down because the effort involved to maintain a Complete EHR may be time and cost prohibitive as the Secretary continues to adopt additional certification criteria to support future stages of meaningful use.

With respect to self-developed EHR Modules, we believe the probability varies across different types of eligible hospitals (CAHs, Small/Medium, and Large) regarding their IT staff resources and ability to self-develop EHR Modules. For each hospital type (identified in Table 38) we provide an estimate of the average number of self-developed

EHR Modules we believe each type of eligible hospital would seek to have tested and certified. Again, we believe that our high average number of self-developed EHR Modules is generous.

Due to the fact that an ONC-ATCB will be responsible for testing and certifying Complete EHRs and/or EHR Modules, we have combined the costs for testing and certification because we believe they would be difficult to independently estimate. Our cost range for the testing and certification of Complete EHRs and EHR Modules includes consideration of how the testing and certification will be conducted (i.e., by remote testing and certification, on-site testing and certification, or at the ONC-ATCB and for the complexity of an EHR Module).

On July 14, 2009, CCHIT testified in front of the HIT Policy Committee on the topic of EHR certification, including the certification of EHR Modules. CCHIT estimated that "EHR-comprehensive" according to CCHIT certification criteria would have testing and certification costs that would range from approximately $30,000 to $50,000. CCHIT also estimated that the testing and certification of EHR Modules would range from approximately $5,000 to $35,000 depending on the scope of the testing and certification. We believe that these estimates provide a reasonable foundation and have used them for our cost estimates. However, we assume that competition in the testing and certification market will reduce the costs of testing and certification as estimated by CCHIT but we are unable to provide a reliable estimate at this time of what the potential reduction in costs might be. The following tables represent our cost estimates for the preceding discussion and include:

- Commercial/Open Source Complete EHRs and EHR Modules - Table 3;

- Self-developed Complete EHRs - Table 4;
- Number of Self-developed EHR Modules by eligible professionals in large practices - Table 5;
- Number of Self-developed EHR Modules by type of eligible hospital – Table 6; and
- Total costs associated with self-developed EHR Modules – Table 7

Table 3. Temporary Certification Program: Estimated Costs for Testing & Certification of Commercial/Open Source Complete EHRs and EHR Modules							
Type	Number Tested and Certified	Cost Per Complete EHR/EHR Module ($M)			Total Cost for All Complete EHRs/EHR Modules over 3-year Period ($M)		
		Low	High	Mid-point	Low	High	Mid-point
Complete EHR	93	$0.03	$0.05	$0.04	$2.79	$4.65	$3.72
EHR Module	50	$0.005	$0.035	$0.02	$0.25	$1.75	$1.0
Total	143				$3.04	$6.4	$4.72

Table 4. Temporary Certification Program: Estimated Costs for Testing & Certification of Self-Developed Complete EHRs							
Type	Number Tested and Certified	Cost Per Complete EHR ($M)			Total Cost for All Complete EHRs over 3-year Period ($M)		
		Low	High	Mid-point	Low	High	Mid-point
Self Developed Complete EHRs Ambulatory Setting	8	$0.03	$0.05	$0.04	$0.24	$0.4	$0.32
Self-Developed Complete EHRs Inpatient Setting	30	$0.03	$0.05	$0.04	$0.9	$1.5	$1.2
Total	38				$1.14	$1.9	$1.52

In Table 5 below, we provide our estimate for the number of potential self-developed EHR Modules large practices of eligible professionals could seek to have tested and certified.

Table 5. Temporary Certification Program: Estimated Number of Self-Developed EHR Modules Designed for an Ambulatory Setting by Eligible Professionals in Large Practices						
Eligible Professional Practice Type	# of Large practices	% with EHR Module (Low)	% with EHR Module (High)	Average # of EHR Modules, if any	Min # of EHR Modules	Max # EHR Modules
Large	77	10%	70%	1.25	10	67

In Table 6 below, we provide our estimate for the number of potential self-developed EHR Modules varied by hospital type that eligible hospitals could seek to have tested and certified.

Table 6. Temporary Certification Program: Estimated Number of Self-Developed EHR Modules Designed for an Inpatient Setting Stratified by Type of Eligible Hospital						
Type of Eligible Hospital	# of EHs	% with EHR Module (Low)	% with EHR Module (High)	Average # of EHR Modules, if any	Min # of EHR Modules	Max # EHR Modules
CAH	518	1%	10%	1.1	6	57
S/M	1951	5%	15%	1.5	146	439
Large	331	25%	70%	2.0	166	463
Total	2800				318	959

In Table 7 below, we provide our estimate for the total testing and certification costs associated with the minimum and maximum number of self-developed EHR Modules from Table 5 and Table 6.

Table 7. Temporary Certification Program: Estimated Costs for Testing & Certification of All Self-Developed EHR Modules							
Self-Developed EHR Modules	Number Tested and Certified	Cost Per EHR Module ($M)			Total Cost for All EHR Modules over 3-year Period ($M)		
		Low	High	Mid-point	Low	High	Mid-point
Min # of EHR Modules	328	$0.005	$0.035	$0.02	$1.64	$11.5	$6.56
Max # of EHR Modules	1026	$0.005	$0.035	$0.02	$5.13	$35.9	$20.52
Total					$6.77	$47.4	$27.1

Our estimates cover anticipated testing and certification costs under the temporary certification program from 2010 through some portion of 2012 as we expect the permanent certification program to be operational by 2012. However, because we cannot predict the exact date at which ONC-ATCBs will finish any remaining tests and certifications in their queue, we believe that it is reasonable to assume the possibility that 2012 costs for testing and certification could be considered as part of the temporary certification program.

Consistent with our estimates in the HIT Standards and Certification Criteria interim final rule (75 FR 2041) about when Complete EHRs and EHR Modules will be prepared for testing and certification to the certification criteria adopted by the Secretary for meaningful use Stage 1, we anticipate that they will be tested and certified in the same proportions. Therefore, we believe that of the total number of Complete EHRs and EHR Modules that we have estimated (commercial, open source, and self-developed), 45% will be tested and certified in 2010, 40% will be tested and certified in 2011, and 15% will be tested and certified in 2012. Table 8 below represents this proportional distribution of the estimated costs we calculated for the testing and certification of Complete EHRs and EHR Modules to the certification criteria adopted to support meaningful use Stage 1 under the temporary certification program as expressed in Table 3 above.

Table 8. Distributed Total Costs for the Testing and Certification of Complete EHRs and EHR Modules to Stage 1 MU by Year (3 year period) – Totals Rounded

Year	Ratio	Total Low Cost Estimate ($M)	Total High Cost Estimate ($M)	Total Average Cost Estimate ($M)
2010	45%	$4.93	$25.07	$15.00
2011	40%	$4.38	$22.28	$13.34
2012	15%	$1.64	$8.36	$5.00

3-Year Totals		$10.95	$55.7	$33.34

iii. Costs for Collecting, Storing, and Reporting Certification Results

Costs to ONC-ATCBs

Under the temporary certification program, ONC-ATCBs will be required to provide ONC, no less frequently than weekly, an up-to-date list of Complete EHRs and/or EHR Modules that have been tested and certified as well as certain minimum information about each certified Complete EHR and/or EHR Module.

As stated in the collection of information section, we will require the reporting of this information on a weekly basis and that it will take ONC-ATCBs about an hour to prepare and electronically transmit the information to ONC each week (i.e., respondents will respond 52 times per year). As also noted in the collection of information section, we have specified in this final rule two additional reporting elements that must be submitted by ONC-ATCBs on a weekly basis (i.e., clinical quality measures to which a Complete EHR or EHR Module has been tested and certified and, where applicable, any additional software a Complete EHR or EHR Module relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary). ONC-ATCBs will be capturing these additional reporting elements in conjunction with the other information we request that they report on a weekly basis. Consequently, we do no believe that the reporting of these two additional elements will increase the reporting burden or costs for ONC-ATCBs.

We believe that an employee equivalent to the Federal Classification of GS-9 Step 1 could complete the transmissions of the requested information to ONC. We have utilized the corresponding employee hourly rate for the locality pay area of Washington,

D.C., as published by OPM, to calculate our cost estimates. We have also calculated the costs of the employee's benefits while completing the transmissions of the requested information. We have calculated these costs by assuming that an ONC-ATCB or ONC-ACB expends thirty-six percent (36%) of an employee's hourly wage on benefits for the employee. We have concluded that a 36% expenditure on benefits is an appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. Our cost estimates are expressed in Table 9 below.

Table 9. Annual Costs for an ONC-ATCB to Report Certifications to ONC

Program Requirement	Employee Equivalent	Annual Burden Hours Per ONC-ATCB	Employee Hourly Wage Rate	Employee Benefits Hourly Cost	Total Cost Per ONC-ATCB
ONC-ATCB Certification Results	GS-9 Step 1	52	$22.39	$8.06	$1,583.40

To estimate the highest possible cost, we assume that all of the estimated applicants (i.e., five) that we anticipate will apply under the temporary certification program will become ONC-ATCBs. Therefore, we estimate the total annual reporting cost under the temporary certification program to be $7,917.

We believe that the requirement for ONC-ATCBs to retain certification records for the length of the temporary certification program is in line with common industry practices and, consequently, does not represent additional costs to ONC-ATCBs as a result of this final rule.

Costs to the Federal Government

As stated previously in this final rule, we will post a comprehensive list of all certified Complete EHRs and EHR Modules on our website. We believe that there will

be minimal cost associated with this action and have calculated the potential cost, including weekly updates, to be $8,969 on an annualized basis. This amount is based on 173 hours of yearly work of a Federal Salary Classification GS-12 Step 1 employee located in Washington, D.C.

iv. Costs for Retaining Records and Providing Copies to ONC

Costs to ONC-ATCBs

Under the temporary certification program, ONC-ATCBs will be required to retain all records related to tests and certifications according to Guide 65 and ISO 17025 for the duration of the temporary certification program and provide copies of the final results of all completed tests and certifications to ONC at the conclusion of testing and certification activities under the temporary certification program.

We do not believe that there are any specific recordkeeping or capital costs associated with this requirement. Based on our consultations with NIST, we understand that it is standard industry practice to retain records related to testing and certification. Therefore, we believe that the only costs attributable to our requirement are those associated with the submission of copies to ONC of the final results of all completed tests and certifications.

As stated in the collection of information section, we estimate that each ONC-ATCB will incur the same burden and, assuming that there are 5 ONC-ATCBs, will test and certify, at most, approximately 205 Complete EHRs and/or EHR Modules under the temporary certification program. We also assume that an ONC-ATCB will submit copies of the final results of all completed tests and certifications to ONC by either electronic transmission or paper submission. In either instance, we believe that an ONC-ATCB will

spend a similar amount of time and effort in organizing, categorizing and submitting the requested information. We estimate that this amount of time will be approximately 8 hours for each ONC-ATCB.

Based on our own assumptions and consultations with NIST, we believe that an employee equivalent to the Federal Classification of GS-9 Step 1 could organize, categorize, and submit the final results of all completed tests and certifications either by electronic transmission or through paper submission of photocopies to ONC. We have taken this employee assumption and utilized the corresponding employee hourly rate for the locality pay area of Washington, D.C., as published by the U.S. Office of Personnel Management, to calculate the cost estimates. We have also calculated the costs of the employee's benefits while organizing, categorizing, and submitting the final results. We have calculated these costs by assuming that an ONC-ATCB will expend thirty-six percent (36%) of an employee's hourly wage on benefits for the employee. We have concluded that a 36% expenditure on benefits is an appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. Our calculations are expressed in the table below.

Table 10. Costs for an ONC-ATCB to Submit Copies of Records to ONC

Program Requirement	Employee Equivalent	Burden Hours Per ONC-ATCB	Employee Hourly Wage Rate	Employee Benefits Hourly Cost	Total Cost Per ONC-ATCB
Submission of Testing and Certification Records	GS-9 Step 1	8	$22.39	$8.06	$243.60

To estimate the highest possible cost, we assume that all of the estimated applicants (i.e., five) that we anticipate will apply under the temporary certification program will become ONC-ATCBs. Therefore, we estimate the total cost for submitting

the requested records at the conclusion of testing and certification activities under the temporary certification program to be $1,218.00.

Costs to the Federal Government

We anticipate that ONC will simply receive copies of the final results of all completed tests and certifications. Therefore, we believe the Federal government will only incur negligible costs.

b. Temporary Certification Program Benefits

We believe that several benefits will accrue from the establishment of the temporary certification program. The temporary certification program will allow for the rapid influx of Complete EHRs and EHR Modules to be tested and certified at a sufficient pace for eligible professionals and eligible hospitals to adopt and implement Certified EHR Technology for meaningful use Stage 1 and thus potentially qualify for incentive payments under the CMS Medicare and Medicaid EHR Incentive Programs proposed rule. The time between the temporary certification program and the permanent certification program will permit the HIT industry the time it needs for accredited testing laboratories to come forward, for an ONC-authorized accreditor to be approved and for additional applicants for ONC-ACB status to come forward. We further believe that the temporary certification program will meet our overall goals of accelerating health IT adoption and increasing levels of interoperability. At this time, we cannot predict how fast all of these savings will occur or their precise magnitude as they are partly dependent on future final rules for meaningful use and the subsequent standards and certification criteria adopted by the Secretary.

D. Regulatory Flexibility Act

The RFA requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For more information on the Small Business Administration's (SBA's) size standards, see the SBA's website.[4] For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. When conducting a RFA we are required to assess the potential effects of our rule on small entities and to make every effort to minimize the regulatory burden that might be imposed on small entities. We believe that the entities that are likely to be directly affected by this final rule are applicants for ONC-ATCB status. Furthermore, we believe that these entities would either be classified under the North American Industry Classification System (NAICS) codes 541380 (Testing Laboratories) or 541990 (Professional, Scientific and Technical Services).[5] We believe that there will be up to 5 applicants for ONC-ATCB status. According to the NAICS codes identified above, this would mean SBA size standards of $12 million and $7 million in annual receipts, respectively.[6] Because this segment of the HIT industry is in a nascent stage and is comprised of very few entities, we have been unable to find reliable data from which to determine what realistic annual receipts would be. However, based on our total estimates for Complete EHRs and EHR Modules to be tested and certified, we assume that the annual receipts of any one ONC-ATCB could be in the low millions of dollars. Moreover, it is unclear, whether these entities may be

[4] http://sba.gov/idc/groups/public/documents/sba_homepage/serv_sstd_tablepdf.pdf
[5] See 13 CFR 121.201
[6] The SBA references that annual receipts means "total income" (or in the case of a sole proprietorship, "gross income") plus "cost of goods sold" as these terms are defined and reported on Internal Revenue Service tax return forms.
http://www.sba.gov/idc/groups/public/documents/sba_homepage/guide_to_size_standards.pdf

involved in other testing and certification programs which would increase their annual receipts and potentially place them outside the SBA's size standards.

We believe that we have established the minimum amount of requirements necessary to accomplish our policy goals and that no appropriate regulatory alternatives could be developed to lessen the compliance burden for applicants for ONC-ATCB status as well as ONC-ATCBs once they have been granted such status by the National Coordinator. Moreover, we believe that this final rule will create direct positive effects for entities because their attainment of ONC-ATCB status will permit them to test and certify Complete EHRs and/or EHR Modules. Thus, we expect that their annual receipts will increase as a result of becoming an ONC-ATCB.

We did not receive any comments related to our RFA analysis during the comment period available for the temporary certification program. As a result, we examined the economic implications of this final rule and have concluded that it will not have a significant impact on a substantial number of small entities. The Secretary certifies that this final rule will not have a significant impact on a substantial number of small entities.

E. Executive Order 13132--Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications.

Nothing in this final rule imposes substantial direct requirement costs on State and local governments, preempts State law or otherwise has federalism implications. We are not aware of any State laws or regulations that conflict with or are impeded by our

temporary certification program, and we did not receive any comments to the contrary in response to the Proposed Rule.

F. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) requires cost-benefit and other analyses before any rulemaking if the rule includes a "Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year." The current inflation-adjusted statutory threshold is approximately $133 million. We did not receive any comments related to the temporary certification program on our analysis presented in the Proposed Rule. Therefore, we have determined that this final rule will not constitute a significant rule under the Unfunded Mandates Reform Act, because it imposes no mandates.

OMB reviewed this final rule.

List of Subjects

45 CFR Part 170

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Health care, Health information technology, Health insurance, Health records, Hospitals, Incorporation by reference, Laboratories, Medicaid, Medicare, Privacy, Reporting and recordkeeping requirements, Public health, Security.

- For the reasons set forth in the preamble, 45 CFR subtitle A, subchapter D, part 170, is amended as follows:

PART 170 – HEALTH INFORMATION TECHNOLOGY STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA

AND CERTIFICATION PROGRAMS FOR HEALTH INFORMATION TECHNOLOGY

▪ 1. The authority citation for part 170 is revised to read as follows:

Authority: 42 U.S.C. 300jj–11; 42 U.S.C 300jj–14; 5 U.S.C. 552.

▪ 2. Revise §170.100 to read as follows:

The provisions of this subchapter implement sections 3001(c)(5) and 3004 of the Public Health Service Act.

▪ 3. In §170.102, add in alphabetical order the definition of "Day or Day(s)" to read as follows:

§170.102 Definitions.

* * * * *

Day or Days means a calendar day or calendar days.

* * * * *

▪ 4. Add a new subpart D to part 170 to read as follows:

Subpart D – Temporary Certification Program for HIT

Sec.

Subpart D – Temporary Certification Program for HIT

§170.400 Basis and scope.

This subpart implements section 3001(c)(5) of the Public Health Service Act, and sets forth the rules and procedures related to the temporary certification program for health information technology administered by the National Coordinator for Health Information Technology.

§170.401 Applicability.

This subpart establishes the processes that applicants for ONC-ATCB status must follow to be granted ONC-ATCB status by the National Coordinator, the processes the National Coordinator will follow when assessing applicants and granting ONC-ATCB status, the requirements that ONC-ATCBs must follow to remain in good standing, and the requirements of ONC-ATCBs for testing and certifying Complete EHRs and/or EHR Modules in accordance with the applicable certification criteria adopted by the Secretary in subpart C of this part.

§170.402 Definitions.

For the purposes of this subpart:

Applicant means a single organization or a consortium of organizations that seeks to become an ONC-ATCB by requesting and subsequently submitting an application for ONC-ATCB status to the National Coordinator.

Deployment site means the physical location where a Complete EHR or EHR Module resides or is being or has been implemented.

Development site means the physical location where a Complete EHR or EHR Module was developed.

ONC-ATCB or ONC-Authorized Testing and Certification Body means an organization or a consortium of organizations that has applied to and been authorized by the National Coordinator pursuant to this subpart to perform the testing and certification of Complete EHRs and/or EHR Modules under the temporary certification program.

Remote testing and certification means the use of methods, including the use of web-based tools or secured electronic transmissions, that do not require an ONC-ATCB to be physically present at the development or deployment site to conduct testing and certification.

§170.405 Correspondence.

(a) Correspondence and communication with the National Coordinator shall be conducted by email, unless otherwise necessary. The official date of receipt of any email between the National Coordinator and an applicant for ONC-ATCB status or an ONC-ATCB is the day the email was sent.

(b) In circumstances where it is necessary for an applicant for ONC-ATCB status or an ONC-ATCB to correspond or communicate with the National Coordinator by regular or express mail, the official date of receipt will be the date of the delivery confirmation.

§170.410 Types of testing and certification.

Applicants may seek authorization from the National Coordinator to perform the following types of testing and certification:

(a) Complete EHR testing and certification; and/or

(b) EHR Module testing and certification.

§170.415 Application prerequisite.

Applicants must request in writing an application for ONC-ATCB status from the National Coordinator. Applicants must indicate:

(a) The type of authorization sought pursuant to §170.410; and

(b) If seeking authorization to perform EHR Module testing and certification, the specific type(s) of EHR Module(s) they seek authorization to test and certify. If qualified, applicants will only be granted authorization to test and certify the types of EHR Modules for which they seek authorization.

§170.420 Application.

The application for ONC-ATCB status consists of two parts. Applicants must complete both parts of the application in their entirety and submit them to the National Coordinator for the application to be considered complete.

(a) Part 1. An applicant must provide all of the following:

(1) General identifying information including:

(i) Name, address, city, state, zip code, and website of applicant; and

(ii) Designation of an authorized representative, including name, title, phone number, and email address of the person who will serve as the applicant's point of contact.

(2) Documentation of the completion and results of a self-audit against all sections of ISO/IEC Guide 65:1996 (incorporated by reference in §170.499), and the following:

(i) A description of the applicant's management structure according to section 4.2 of ISO/IEC Guide 65:1996;

(ii) A copy of the applicant's quality manual that has been developed according to section 4.5.3 of ISO/IEC Guide 65:1996;

(iii) A copy of the applicant's policies and approach to confidentiality according to section 4.10 of ISO/IEC Guide 65:1996;

(iv) A copy of the qualifications of each of the applicant's personnel who oversee or perform certification according to section 5.2 of ISO/IEC Guide 65:1996;

(v) A copy of the applicant's evaluation reporting procedures according to section 11 of ISO/IEC Guide 65:1996; and

(vi) A copy of the applicant's policies for use and display of certificates according to section 14 of ISO/IEC Guide 65:1996.

(3) Documentation of the completion and results of a self-audit against all sections of ISO/IEC 17025:2005 (incorporated by reference in §170.499), and the following:

(i) A copy of the applicant's quality system document according to section 4.2.2 of ISO/IEC 17025:2005;

(ii) A copy of the applicant's policies and procedures for handling testing nonconformities according to section 4.9.1 of ISO/IEC 17025:2005; and

(iii) The qualifications of each of the applicant's personnel who oversee or conduct testing according to section 5.2 of ISO/IEC 17025:2005.

(4) An agreement, properly executed by the applicant's authorized representative, that it will adhere to the Principles of Proper Conduct for ONC-ATCBs.

(b) Part 2. An applicant must submit a completed proficiency examination.

§170.423 Principles of proper conduct for ONC-ATCBs.

An ONC-ATCB shall:

(a) Operate its certification program in accordance with ISO/IEC Guide 65:1996 (incorporated by reference in §170.499) and testing program in accordance with ISO/IEC 17025:2005 (incorporated by reference in §170.499);

(b) Maintain an effective quality management system which addresses all requirements of ISO/IEC 17025:2005 (incorporated by reference in §170.499);

(c) Attend all mandatory ONC training and program update sessions;

(d) Maintain a training program that includes documented procedures and training requirements to ensure its personnel are competent to test and certify Complete EHRs and/or EHR Modules;

(e) Use test tools and test procedures approved by the National Coordinator for the purposes of assessing Complete EHRs and/or EHR Modules compliance with the certification criteria adopted by the Secretary;

(f) Report to ONC within 15 days any changes that materially affect its:

(1) Legal, commercial, organizational, or ownership status;

(2) Organization and management, including key testing and certification personnel;

(3) Policies or procedures;

(4) Location;

(5) Facilities, working environment or other resources;

(6) ONC authorized representative (point of contact); or

(7) Other such matters that may otherwise materially affect its ability to test and certify Complete EHRs and/or EHR Modules;

(g) Allow ONC, or its authorized agents(s), to periodically observe on site (unannounced or scheduled) during normal business hours, any testing and/or certification performed to demonstrate compliance with the requirements of the temporary certification program;

(h) Provide ONC, no less frequently than weekly, a current list of Complete EHRs and/or EHR Modules that have been tested and certified which includes, at a minimum:

(1) The vendor name (if applicable);

(2) The date certified;

(3) The product version;

(4) The unique certification number or other specific product identification;

(5) The clinical quality measures to which a Complete EHR or EHR Module has been tested and certified;

(6) Where applicable, any additional software a Complete EHR or EHR Module relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary; and

(7) Where applicable, the certification criterion or criteria to which each EHR Module has been tested and certified.

(i) Retain all records related to tests and certifications according to ISO/IEC Guide 65:1996 (incorporated by reference in §170.499) and ISO/IEC 17025:2005 (incorporated by reference in §170.499) for the duration of the temporary certification

program and provide copies of the final results of all completed tests and certifications to ONC at the conclusion of testing and certification activities under the temporary certification program;

(j) Promptly refund any and all fees received for:

(1) Requests for testing and certification that are withdrawn while its operations are suspended by the National Coordinator;

(2) Testing and certification that will not be completed as a result of its conduct; and

(3) Previous testing and certification that it performed if its conduct necessitates the recertification of Complete EHRs and/or EHR Modules;

(k) Ensure adherence to the following requirements when issuing a certification to Complete EHRs and/or EHR Modules:

(1) All certifications must 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 Complete EHR or EHR Module's certification:

(i) "This [Complete EHR or EHR Module] is 201[X]/201[X] compliant 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

(ii) The information an ONC-ATCB is required to report to the National Coordinator under paragraph (h) of this section for the specific Complete EHR or EHR Module at issue;

(2) A certification issued to an integrated bundle of EHR Modules shall be treated the same as a certification issued to a Complete EHR for the purposes of paragraph (k)(1) of this section except that it must also indicate each EHR Module that comprises the bundle; and

(3) A certification issued to a Complete EHR or EHR Module based on applicable certification criteria adopted by the Secretary at subpart C of this part must be separate and distinct from any other certification(s) based on other criteria or requirements.

§170.425 Application submission.

(a) An applicant for ONC-ATCB status must submit its application either electronically via email (or web submission if available), or by regular or express mail.

(b) An application for ONC-ATCB status may be submitted to the National Coordinator at any time during the existence of the temporary certification program.

§170.430 Review of application.

(a) Method of review and review timeframe.

(1) Applications will be reviewed in the order they are received.

(2) The National Coordinator will review Part 1 of the application in its entirety and determine whether Part 1 of the application is complete and satisfactory before proceeding to review Part 2 of the application in its entirety.

(3) The National Coordinator is permitted up to 30 days to review an application (submitted for the first time) upon receipt.

(b) Application deficiencies.

(1) If the National Coordinator identifies an area in an application that requires the applicant to clarify a statement or correct an error or omission, the National Coordinator may contact the applicant to make such clarification or correction without issuing a deficiency notice. If the National Coordinator has not received the requested information after five days, the applicant may be issued a deficiency notice specifying the error, omission, or deficient statement.

(2) If the National Coordinator determines that deficiencies in either part of the application exist, the National Coordinator will issue a deficiency notice to the applicant and return the application. The deficiency notice will identify the areas of the application that require additional information or correction.

(c) Revised application.

(1) An applicant is permitted to submit a revised application in response to a deficiency notice. An applicant may request an extension for good cause from the National Coordinator of the 15-day period provided in paragraph (c)(2) of this section to submit a revised application.

(2) In order to continue to be considered for ONC-ATCB status, an applicant's revised application must address the specified deficiencies and be received by the National Coordinator within 15 days of the applicant's receipt of the deficiency notice unless the National Coordinator grants an applicant's request for an extension of the 15-day period based on a finding of good cause. If a good cause

extension is granted, then the revised application must be received by the end of the extension period.

(3) The National Coordinator is permitted up to 15 days to review a revised application once it has been received and may request clarification of statements and the correction of errors or omissions in a revised application during this time period.

(4) If the National Coordinator determines that a revised application still contains deficiencies, the applicant will be issued a denial notice indicating that the applicant will no longer be considered for authorization under the temporary certification program. An applicant may request reconsideration of a denial in accordance with §170.435.

(d) Satisfactory application.

(1) An application will be deemed satisfactory if it meets all application requirements, including a passing score on the proficiency examination.

(2) The National Coordinator will notify the applicant's authorized representative of its satisfactory application and its successful achievement of ONC-ATCB status.

(3) Once notified by the National Coordinator of its successful achievement of ONC-ATCB status, the applicant may represent itself as an ONC-ATCB and begin testing and certifying Complete EHRs and/or EHR Modules consistent with its authorization.

§170.435 ONC-ATCB application reconsideration.

(a) An applicant may request that the National Coordinator reconsider a denial notice issued for each part of an application only if the applicant can demonstrate that clear,

factual errors were made in the review of the applicable part of the application and that the errors' correction could lead to the applicant obtaining ONC-ATCB status.

(b) Submission requirement. An applicant is required to submit, within 15 days of receipt of a denial notice, a written statement to the National Coordinator contesting the decision to deny its application and explaining with sufficient documentation what factual errors it believes can account for the denial. If the National Coordinator does not receive the applicant's submission within the specified timeframe, its reconsideration request may be rejected.

(c) Reconsideration request review. If the National Coordinator receives a timely reconsideration request, the National Coordinator is permitted up to 15 days from the date of receipt to review the information submitted by the applicant and issue a decision.

(d) Decision.

(1) If the National Coordinator determines that clear, factual errors were made during the review of the application and that correction of the errors would remove all identified deficiencies, the applicant's authorized representative will be notified of the National Coordinator's decision to reverse the previous decision(s) not to approve part of the applicant's application or the entire application.

(i) If the National Coordinator's decision to reverse the previous decision(s) affected part 1 of an application, the National Coordinator will subsequently review part 2 of the application.

(ii) If the National Coordinator's decision to reverse the previous decision(s) affected part 2 of an application, the applicant's authorized representative

will be notified of the National Coordinator's decision as well as the applicant's successful achievement of ONC-ATCB status.

(2) If, after reviewing an applicant's reconsideration request, the National Coordinator determines that the applicant did not identify any factual errors or that correction of those factual errors would not remove all identified deficiencies in the application, the National Coordinator may reject the applicant's reconsideration request.

(3) Final decision. A reconsideration decision issued by the National Coordinator is final and not subject to further review.

§170.440 ONC-ATCB status.

(a) Acknowledgement and publication. The National Coordinator will acknowledge and 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.

(b) Representation. Each ONC-ATCB must prominently and unambiguously identify the scope of its authorization on its website, and in all marketing and communications statements (written and oral) pertaining to its activities under the temporary certification program.

(c) Renewal. ONC-ATCB status does not need to be renewed during the temporary certification program.

(d) Expiration. The status of all ONC-ATCBs will expire upon the sunset of the temporary certification program in accordance with §170.490.

§170.445 Complete EHR testing and certification.

(a) An ONC-ATCB must test and certify Complete EHRs to all applicable certification criteria adopted by the Secretary at subpart C of this part.

(b) An ONC-ATCB must provide the option for a Complete EHR to be tested and certified solely to the applicable certification criteria adopted by the Secretary at subpart C of this part.

(c) Inherited certified status. An ONC-ATCB must accept requests for a newer version of a previously certified Complete EHR to inherit the previously certified Complete EHR's certified status without requiring the newer version to be retested and recertified.

(1) Before granting certified status to a newer version of a previously certified Complete EHR, an ONC-ATCB must review an attestation submitted by the developer of the Complete EHR to determine whether the newer version has adversely affected any previously certified capabilities.

(2) An ONC-ATCB may grant certified status to a newer version of a previously certified Complete EHR if it determines that previously certified capabilities have not been adversely affected.

(d) An ONC-ATCB that has been authorized to test and certify Complete EHRs is also authorized to test and certify all EHR Modules under the temporary certification program.

§170.450 EHR module testing and certification.

(a) When testing and certifying EHR Modules, an ONC-ATCB must test and certify in accordance with the applicable certification criterion or certification criteria adopted by the Secretary at subpart C of this part.

(b) An ONC-ATCB must provide the option for an EHR Module or a bundle of EHR Modules to be tested and certified solely to the applicable certification criteria adopted by the Secretary at subpart C of this part.

(c) Privacy and security testing and certification. 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 (as defined in 45 CFR 170.102), 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 and provide documentation 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.

(d) Inherited certified status. An ONC-ATCB must accept requests for a newer version of a previously certified EHR Module or bundle of EHR Modules to inherit the previously certified EHR Module's or bundle of EHR Modules certified status without requiring the newer version to be retested and recertified.

(1) Before granting certified status to a newer version of a previously certified EHR Module or bundle of EHR Modules, an ONC-ATCB must review an attestation submitted by the developer of the EHR Module or presenter of the bundle of EHR Modules to determine whether the newer version has adversely affected any previously certified capabilities.

(2) An ONC-ATCB may grant certified status to a newer version of a previously certified EHR Module or bundle of EHR Modules if it determines that previously certified capabilities have not been adversely affected.

§170.455 Testing and certification to newer versions of certain standards.

(a) ONC-ATCBs may test and certify Complete EHRs and EHR Module to a newer version of certain identified minimum standards specified at subpart B of this part if the Secretary has accepted a newer version of an adopted minimum standard.

(b) Applicability of an accepted new version of an adopted minimum standard.

(1) ONC-ATCBs are not required to test and certify Complete EHRs and/or EHR Modules according to newer versions of an adopted minimum standard accepted by the Secretary until the incorporation by reference provision of the adopted version is updated in the Federal Register with a newer version.

(2) Certified EHR Technology may be upgraded to comply with newer versions of an adopted minimum standard accepted by the Secretary without adversely affecting the certification status of the Certified EHR Technology.

§170.457 Authorized testing and certification methods.

An ONC-ATCB must provide remote testing and certification for both development and deployment sites.

§170.460 Good standing as an ONC-ATCB.

An ONC-ATCB must maintain good standing by:

(a) Adhering to the Principles of Proper Conduct for ONC-ATCBs;

(b) Refraining from engaging in other types of inappropriate behavior, including an ONC-ATCB misrepresenting the scope of its authorization as well as an ONC-ATCB testing and certifying Complete EHRs and/or EHR Modules for which it does not have authorization; and

(c) Following all other applicable Federal and state laws.

§170.465 Revocation of authorized testing and certification body status.

(a) Type-1 violations. The National Coordinator may revoke an ONC-ATCB's status for committing a Type-1 violation. Type-1 violations include violations of law or temporary certification program policies that threaten or significantly undermine the integrity of the temporary certification program. These violations include, but are not limited to: false, fraudulent, or abusive activities that affect the temporary certification program, a program administered by HHS or any program administered by the Federal government.

(b) Type-2 violations. The National Coordinator may revoke an ONC-ATCB's status for failing to timely or adequately correct a Type-2 violation. Type-2 violations constitute noncompliance with §170.460.

(1) Noncompliance notification. If the National Coordinator obtains reliable evidence that an ONC-ATCB may no longer be in compliance with §170.460, the National Coordinator will issue a noncompliance notification with reasons for the

notification to the ONC-ATCB requesting that the ONC-ATCB respond to the alleged violation and correct the violation, if applicable.

(2) Opportunity to become compliant. After receipt of a noncompliance notification, an ONC-ATCB is permitted up to 30 days to submit a written response and accompanying documentation that demonstrates that no violation occurred or that the alleged violation has been corrected.

(i) If the ONC-ATCB submits a response, the National Coordinator is permitted up to 30 days from the time the response is received to evaluate the response and reach a decision. The National Coordinator may, if necessary, request additional information from the ONC-ATCB during this time period.

(ii) If the National Coordinator determines that no violation occurred or that the violation has been sufficiently corrected, the National Coordinator will issue a memo to the ONC-ATCB confirming this determination.

(iii) If the National Coordinator determines that the ONC-ATCB failed to demonstrate that no violation occurred or to correct the area(s) of non-compliance identified under paragraph (b)(1) of this section within 30 days of receipt of the noncompliance notification, then the National Coordinator may propose to revoke the ONC-ATCB's status.

(c) Proposed revocation.

(1) The National Coordinator may propose to revoke an ONC-ATCB's status if the National Coordinator has reliable evidence that the ONC-ATCB committed a Type-1 violation; or

(2) The National Coordinator may propose to revoke an ONC-ATCB's status if, after the ONC-ATCB has been notified of a Type-2 violation, the ONC-ATCB fails to:

(i) To rebut the finding of a violation with sufficient evidence showing that the violation did not occur or that the violation has been corrected; or

(ii) Submit to the National Coordinator a written response to the noncompliance notification within the specified timeframe under paragraph (b)(2).

(d) Suspension of an ONC-ATCB's operations.

(1) The National Coordinator may suspend the operations of an ONC-ATCB under the temporary certification program based on reliable evidence indicating that:

(i) The ONC-ATCB committed a Type-1 or Type-2 violation; and

(ii) The continued testing and certification of Complete EHRs and/or EHR Modules by the ONC-ATCB could have an adverse impact on the health or safety of patients.

(2) If the National Coordinator determines that the conditions of paragraph (d)(1) have been met, an ONC-ATCB will be issued a notice of proposed suspension.

(3) Upon receipt of a notice of proposed suspension, an ONC-ATCB will be permitted up to 3 days to submit a written response to the National Coordinator explaining why its operations should not be suspended.

(4) The National Coordinator is permitted up to 5 days from receipt of an ONC-ATCB's written response to a notice of proposed suspension to review the response and make a determination.

(5) The National Coordinator may make one of the following determinations in response to the ONC-ATCB's written response or if the ONC-ATCB fails to submit a written response within the timeframe specified in paragraph (d)(3):

(i) Rescind the proposed suspension; or

(ii) Suspend the ONC-ATCB's operations until it has adequately corrected a Type-2 violation; or

(iii) Propose revocation in accordance with §170.465(c) and suspend the ONC-ATCB's operations for the duration of the revocation process.

(6) A suspension will become effective upon an ONC-ATCB's receipt of a notice of suspension.

(e) Opportunity to respond to a proposed revocation notice.

(1) An ONC-ATCB may respond to a proposed revocation notice, but must do so within 10 days of receiving the proposed revocation notice and include appropriate documentation explaining in writing why its status should not be revoked.

(2) Upon receipt of an ONC-ATCB's response to a proposed revocation notice, the National Coordinator is permitted up to 30 days to review the information submitted by the ONC-ATCB and reach a decision.

(3) Unless suspended, an ONC-ATCB will be permitted to continue its operations under the temporary certification program during the time period provided for the ONC-ATCB to respond to the proposed revocation notice and the National Coordinator to review the response.

(f) Good standing determination. If the National Coordinator determines that an ONC-ATCB's status should not be revoked, the National Coordinator will notify the ONC-ATCB's authorized representative in writing of this determination.

(g) Revocation.

(1) The National Coordinator may revoke an ONC-ATCB's status if:

(i) A determination is made that revocation is appropriate after considering the information provided by the ONC-ATCB in response to the proposed revocation notice; or

(ii) The ONC-ATCB does not respond to a proposed revocation notice within the specified timeframe in paragraph (d)(1) of this section.

(2) A decision to revoke an ONC-ATCB's status is final and not subject to further review unless the National Coordinator chooses to reconsider the revocation.

(h) Extent and duration of revocation.

(1) The revocation of an ONC-ATCB is effective as soon as the ONC-ATCB receives the revocation notice.

(2) A testing and certification body that has had its ONC-ATCB status revoked is prohibited from accepting new requests for testing and certification and must cease its current testing and certification operations under the temporary certification program.

(3) A testing and certification body that has had its ONC-ATCB status revoked for a Type-1 violation is prohibited from reapplying for ONC-ATCB status under the temporary certification program for one year. If the temporary certification program sunsets during this time, the testing and certification body is prohibited

from applying for ONC-ACB status under the permanent certification program for the time that remains within the one year prohibition.

(4) The failure of a testing and certification body that has had its ONC-ATCB status revoked, to promptly refund any and all fees for tests and/or certifications of Complete EHRs and EHR Modules not completed will be considered a violation of the Principles of Proper Conduct for ONC-ATCBs and will be taken into account by the National Coordinator if the testing and certification body reapplies for ONC-ATCB status under the temporary certification program or applies for ONC-ACB status under the permanent certification program.

§170.470 Effect of revocation on the certifications issued to complete EHRs and EHR Modules.

(a) The certified status of Complete EHRs and/or EHR Modules certified by an ONC-ATCB that had it status revoked will remain intact unless a Type-1 violation was committed that calls into question the legitimacy of the certifications issued by the former ONC-ATCB.

(b) If the National Coordinator determines that a Type-1 violation occurred that called into question the legitimacy of certifications conducted by the former ONC-ATCB, then the National Coordinator would:

(1) Review the facts surrounding the revocation of the ONC-ATCB's status; and

(2) Publish a notice on ONC's website if the National Coordinator believes that Complete EHRs and/or EHR Modules were improperly certified by the former ONC-ATCB.

(c) If the National Coordinator determines that Complete EHRs and/or EHR Modules were improperly certified, the certification status of affected Complete EHRs and/or EHR Modules would only remain intact for 120 days after the National Coordinator publishes the notice. The certification status of the Complete EHR and/or EHR Module can only be maintained thereafter by being re-certified by an ONC-ATCB in good standing.

§170.490 Sunset of the temporary certification program.

(a) 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 temporary certification program sunset date, ONC-ATCBs will be prohibited from accepting new requests to test and certify Complete EHRs or EHR Modules.

(b) ONC-ATCBs are permitted up to six months after the sunset date to complete all testing and certification activities associated with requests for testing and certification of Complete EHRs and/or EHR Modules received prior to the sunset date.

§170.499 Incorporation by reference.

(a) Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Department of Health and Human Services must publish notice of change in the Federal Register and the material must be available to the public. All approved material is available for inspection at the National Archives and Records Administration (NARA). For

information on the availability of this material at NARA, call 202–741–6030 or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Also, it is available for inspection at U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave, SW., Washington, DC 20201, call ahead to arrange for inspection at 202–690–7151, and is available from the source listed below.

(b) International Organization for Standardization, Case postale 56, CH·1211, Geneve 20, Switzerland, telephone +41-22-749-01-11, www.iso.org.

(1) ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories (Second Edition), May 15, 2005, IBR approved for §170.420 and §170.423.

(2) ISO/IEC GUIDE 65 General Requirements for Bodies Operating Product Certification Systems (First Edition), 1996, IBR approved for §170.420 and §170.423.

(3) [Reserved]

Dated: ____June 8, 2010_____

Kathleen Sebelius,

Secretary.

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