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45 CFR Part 170  
Establishment of the Permanent Certification for Health Information  
Technology; Final Rule

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

#### 45 CFR Part 170

RIN 0991-AB59

### Establishment of the Permanent 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 permanent certification program for the purpose of certifying health information technology (HIT). This final rule is issued pursuant to 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 permanent certification program will eventually replace the temporary certification program that was previously established by a final rule. The National Coordinator will use the permanent certification program to authorize organizations to certify electronic health record (EHR) technology, such as Complete EHRs and/or EHR Modules. The permanent certification program could also be expanded to include the certification of other types of HIT.

**DATES:** These regulations are effective February 7, 2011. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of February 7, 2011.

**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®

CAQH Council for Affordable Quality Healthcare  
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 of 1996  
HIT Health Information Technology  
HITECH Health Information Technology for Economic and Clinical Health  
ILAC International Laboratory Accreditation Cooperation  
ISO International Organization for Standardization  
IT Information Technology  
LAP Laboratory Accreditation Program  
MA Medicare Advantage  
MRA Mutual/Multilateral Recognition Arrangement  
NIST National Institute of Standards and Technology  
NPRM Notice of Proposed Rulemaking  
NVCASE National Voluntary Conformity Assessment System Evaluation  
NVLAP National Voluntary Laboratory Accreditation Program  
OIG Office of Inspector General  
OMB Office of Management and Budget  
ONC Office of the National Coordinator for Health Information Technology  
ONC-AA ONC-Approved Accreditor  
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 the 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*
- *Day or days*
- *Disclosure*
- *EHR Module*
- *Implementation specification*
- *Qualified EHR*
- *Standard*

The definition of the term ONC-Authorized Testing and Certification Body (ONC-ATCB) can be found at 45 CFR 170.402.

## B. Legislative and Regulatory History

### 1. Legislative History

The 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 PHS Act and created “Title XXX—Health Information Technology and Quality” (Title XXX) to improve health care quality, safety, and efficiency through the promotion of HIT and electronic health information exchange. Section 3001 of the PHS Act establishes the Office of the National Coordinator for Health Information Technology (ONC). Title XXX of the PHS Act 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 Certified EHR Technology. References to “eligible hospitals” in this final rule shall mean “eligible hospitals and/or critical access hospitals” unless otherwise indicated.

#### 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 PHS Act, 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 PHS Act consistent with the ONC-coordinated Federal Health IT Strategic Plan.

Section 3004 of the PHS Act defines how the Secretary adopts standards, implementation specifications, and certification criteria. Section 3004(a) of the PHS Act 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 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. Eligible professionals for the Medicare EHR incentive program are physicians as defined in section 1861(r) of the SSA. A hospital-based eligible professional furnishes substantially all of his or her Medicare-covered professional services in a hospital inpatient or emergency room setting. Hospital-based eligible professionals are not eligible for the Medicare incentive payments. 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 critical access hospitals that meaningfully use Certified EHR Technology with an incentive payment 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) for States' expenditures for incentive payments to eligible health care providers participating in the Medicaid program to adopt, implement, or upgrade and meaningfully use Certified EHR Technology and 90 percent FFP for States' reasonable administrative expenses related to the administration of the incentive payments. For the Medicaid EHR incentive program, eligible professionals are physicians (primarily doctors of medicine and doctors of osteopathy), dentists, nurse practitioners, certified nurse midwives, and physician assistants practicing in a Federally Qualified Health Center led by a physician assistant or Rural Health Clinic that is so led. Eligible hospitals that can participate in the Medicaid EHR incentive program are acute care hospitals (including cancer and critical access hospitals) and children's hospitals.

#### c. HIT Certification Programs

Section 3001(c)(5) of the PHS Act 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 PHS Act). 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 and Final Rules

In accordance with section 3004(b)(1) of the PHS Act, 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" (75 FR 2014, Jan. 13, 2010) (the "HIT Standards and Certification Criteria interim final rule"), which adopted an initial set of standards, implementation specifications, and certification criteria. After consideration of the public comments received on the interim final rule, a final rule was issued to complete the adoption of the initial set of standards, implementation specifications, and certification criteria and realign them with the final objectives and measures established for meaningful use Stage 1. Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Final Rule, 75 FR 44590 (July 28, 2010) (the "HIT Standards and Certification Criteria final rule"). On October 13, 2010, an interim final rule was issued to remove certain

implementation specifications related to public health surveillance that had been previously adopted in the HIT Standards and Certification Criteria final rule (75 FR 62686).

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 meaningful use Stage 1 by eligible professionals and eligible hospitals under the Medicare and Medicaid EHR Incentive Programs final rule (*see* 75 FR 44314 for more information about meaningful use and the Stage 1 requirements).

##### b. Medicare and Medicaid EHR Incentive Programs Proposed and Final Rules

On January 13, 2010, CMS published in the **Federal Register** (75 FR 1844) the Medicare and Medicaid EHR Incentive Programs proposed rule. The rule proposed a definition for Stage 1 meaningful use of Certified EHR Technology and regulations associated with the incentive payments made available under Division B, Title IV of the HITECH Act.

Subsequently, CMS published a final rule for the Medicare and Medicaid EHR Incentive Programs in the **Federal Register** (75 FR 44314) on July 28, 2010 (the "Medicare and Medicaid EHR Incentive Programs final rule"), simultaneously with the publication of the HIT Standards and Certification Criteria final rule. The final rule published by CMS established the objectives and associated measures that eligible professionals and eligible hospitals must satisfy in order to demonstrate "meaningful use" during Stage 1.

##### c. HIT Certification Programs Proposed Rule and the Temporary and Permanent Certification Programs Final Rules

Section 3001(c)(5) of the PHS Act 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, Mar. 10, 2010) (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. Consistent with our proposal, we issued a final rule to establish a temporary certification program, which was published in the **Federal Register** (75 FR 36158) on June 24, 2010 (the "Temporary Certification Program final rule"). To conclude our proposed approach, we are issuing this final rule to establish a permanent certification program whereby the National Coordinator will authorize organizations to certify Complete EHRs, EHR Modules, and/or other types of HIT. As provided in the Temporary Certification Program final rule, the temporary certification program will sunset on December 31, 2011, or on a subsequent date if the permanent certification program is not fully constituted at that time.

#### **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, the Department of Health and Human Services (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 an organization for "recognized certification body" status. The CGD served as a guide for ONC to evaluate applications for "recognized certification body" status and provided the information an organization would need to apply for and obtain such status. Under the process specified in the CGD, the Certification Commission for Health Information Technology (CCHIT) was the only organization that both applied for and had been granted "recognized certification body" status.

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. After consideration of the public comments we received on this proposal, we determined that the ONC-ATCB and ONC-ACB "authorization" processes would constitute the Secretary's "recognition" of a certification body and finalized our proposal for both the temporary certification program and permanent certification program in the Temporary Certification Program final rule (75 FR 36186). Any questions regarding compliance with the exception or safe harbor should be directed to CMS and OIG, respectively.

#### **II. Overview of the Permanent Certification Program**

The permanent certification program provides a process by which an organization or organizations may become an ONC-Authorized Certification Body (ONC-ACB) authorized by the National Coordinator to perform the certification of Complete EHRs and/or EHR Modules. ONC-ACBs may also be authorized under the permanent certification program to perform the certification of other types of HIT in the event that applicable certification criteria are adopted by the Secretary. We note, however, that the certification of Complete EHRs, EHR Modules, or potentially other types of

HIT under the permanent certification program would not constitute a replacement or substitution for other Federal requirements that may be applicable.

Under the permanent certification program, the National Coordinator will accept applications for ONC-ACB status after the effective date of this final rule and at any time during the existence of the permanent certification program. In order to become an ONC-ACB, an organization or organizations must submit an application to the National Coordinator to demonstrate its competency and ability to certify Complete EHRs, EHR Modules, and/or potentially other types of HIT by documenting its accreditation by the ONC-Approved Accreditor (ONC-AA) and by meeting other specified application requirements. These organizations will be required to remain in good standing by adhering to the Principles of Proper Conduct for ONC-ACBs. ONC-ACBs will also be required to follow the conditions and requirements applicable to the certification of Complete EHRs, EHR Modules, and/or potentially other types of HIT as specified in this final rule. The permanent certification program will eventually replace the temporary certification program that was established previously by a final rule (75 FR 36158). Testing and certification under the permanent certification program is expected to begin on January 1, 2012, or upon a subsequent date when the National Coordinator determines that the permanent certification program is fully constituted. The permanent certification program has no anticipated sunset date. ONC-ACBs are required to renew their status every three years under the permanent certification program.

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

##### **A. Overview**

This section discusses and responds to the comments that were timely received on the proposed provisions of the permanent certification program that were set forth in the Proposed Rule. As explained in the Proposed Rule, we chose to propose both the temporary certification program and the permanent certification program in the same notice of proposed rulemaking in order to offer the public a broader context for each of the programs and an opportunity to make more informed comments on our proposals. We noted that we expected to receive public comments that were

applicable to both of the proposed certification programs due to the fact that we had proposed certain elements that were the same or similar for both programs. As anticipated, we received comments in response to the Proposed Rule that were applicable to both certification programs. In the Temporary Certification Program final rule, we discussed and responded to all of the comments that were applicable to the temporary certification program. Because some of those comments are also related to provisions of the permanent certification program, we discuss them again in this final rule and respond to them in the context of the permanent certification program. Many of the common elements that we proposed for both the temporary and the permanent certification programs are based on the same or similar underlying policy reasons or objectives. As a result, we often reach the same or similar conclusions in this final rule as we did in the Temporary Certification Program final rule. In responding to comments in this final rule, we often make reference to or restate parts of our responses to comments that we provided in the Temporary Certification Program final rule due to the various similarities that exist between the temporary and permanent certification programs.

We have structured this section of the final rule based on the proposed regulatory sections of the permanent certification program and discuss each regulatory section sequentially. For each discussion of a 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 and indicate whether we are finalizing the provision as proposed in the Proposed Rule or modifying the proposed provision in response to public comment, to provide clarification, or to correct inadvertent errors. Comments on dual-accredited testing and certification bodies, the concept of "self-developed," validity and expiration of certifications, differential or "gap" certification, barriers to entry for potential ONC-ACBs, an ONC-managed certification program, 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 § 170.500 that the permanent certification program would serve to implement section 3001(c)(5) of the

PHSA, and that subpart E would also set forth the rules and procedures related to the permanent certification program for HIT administered by the National Coordinator. Under § 170.501, we proposed that subpart E would establish the processes that applicants for ONC-ACB status must follow to be granted ONC-ACB status by the National Coordinator, the processes the National Coordinator would follow when assessing applicants and granting ONC-ACB status, and the requirements of ONC-ACBs for certifying Complete EHRs and/or EHR Modules in accordance with the applicable certification criteria adopted by the Secretary in subpart C of part 170. We also proposed that subpart E would establish the processes that accreditation organizations would follow to request approval from the National Coordinator, the processes the National Coordinator would follow to approve an accreditation organization under the permanent certification program, and the ongoing responsibilities of an ONC-AA.

*Comments.* We received comments that expressed general support for the permanent certification program. We also received a few comments regarding the extension of the scope of the permanent certification program to other types of HIT. One commenter asserted that there was a need for the permanent certification program to focus on the implementation of the nationwide health information network.

*Response.* We appreciate the comments expressing support for the permanent certification program. We intend to address the governance mechanisms for the nationwide health information network through a separate rulemaking. We will more specifically address the comments related to other types of HIT when we discuss proposed § 170.553 later in this preamble, but we note here that we are revising § 170.501 to acknowledge the possibility for ONC-ACBs to certify "other types of HIT" under the permanent certification program. We are also revising § 170.501 to clearly state that this subpart includes requirements that ONC-ACBs must follow to maintain their status as ONC-ACBs under the permanent certification program. These references were inadvertently left out of § 170.501 in the Proposed Rule although they were included elsewhere in the preamble discussion and regulation text.

#### C. Definitions

In the Proposed Rule, we proposed to define four terms related to the permanent certification program.

##### 1. Day or Days

We proposed to add the definition of "day or days" to § 170.102. We proposed to define "day or days" to mean a calendar day or calendar days. We added this definition to § 170.102 in the Temporary Certification Program final rule. Further, we did not receive any comments on this definition related to the permanent certification program. Therefore, references to "day" or "days" in provisions of subpart E have the meaning provided to them in § 170.102.

##### 2. Applicant

We proposed in § 170.502 to define "applicant" to mean a single organization or a consortium of organizations that seek to become an ONC-ACB by requesting and subsequently submitting an application for ONC-ACB status to the National Coordinator. We did not receive any comments on this proposed definition. We are, however, revising the definition of "applicant" by removing the condition that an "applicant" must "request" an application. We clearly indicated in the Proposed Rule preamble that, unlike under the temporary certification program, "applicants" for ONC-ACB status would no longer need to request an application.

##### 3. ONC-ACB

We proposed in § 170.502 to define an "ONC-Authorized Certification Body" or "ONC-ACB" to mean an organization or a consortium of organizations that has applied to and been authorized by the National Coordinator pursuant to subpart E to perform the certification of, at minimum, Complete EHRs and/or EHR Modules using the applicable certification criteria adopted by the Secretary.

*Comments.* A commenter noted that the proposed definition would not preclude an ONC-ACB from certifying other types of HIT, but would require an ONC-ACB to be able to certify Complete EHRs and/or EHR Modules. The commenter contended that this requirement will prevent organizations that may want to certify only other types of HIT (and not Complete EHRs or EHR Modules) from becoming ONC-ACBs.

*Response.* We did not intend to preclude an organization from seeking authorization to certify only other types of HIT besides Complete EHRs and EHR Modules, when and if the option becomes available. To the contrary, as noted in proposed § 170.510, we indicated that an applicant could seek authorization to certify Complete EHRs, EHR Modules, other types of HIT, or any

combination of the three. However, as we specified in the Proposed Rule preamble and in proposed § 170.510, the Secretary must first adopt applicable certification criteria under subpart C of part 170 before authorization to certify other types of HIT could be granted to ONC-ACBs.

In response to the comment and to be consistent with our intent as expressed in § 170.510, we are removing “at a minimum” from the definition of ONC-ACB. This will allow an organization or consortium of organizations to become an ONC-ACB that is authorized to certify only other types of HIT besides Complete EHRs and/or EHR Modules. We are also revising the definition by replacing “using the applicable certification criteria adopted by the Secretary” with “under the permanent certification program.” We believe this revision more clearly reflects the focus of an ONC-ACB and is more consistent with the definition of an ONC-ATCB that we finalized in the Temporary Certification Program final rule. We note that ONC-ACBs that are authorized to certify Complete EHRs and/or EHR Modules will be required to perform certifications using the applicable certification criteria adopted by the Secretary based on the provisions of §§ 170.545 and 170.550.

#### 4. ONC-AA

We proposed in § 170.502 to define the term “ONC-Approved Accreditor” or “ONC-AA” to mean an accreditation organization that the National Coordinator has approved to accredit certification bodies under the permanent certification program.

We did not receive any comments on this proposed definition. Therefore, we are finalizing this definition without modification.

#### *D. ONC-AA Status, On-going Responsibilities and Reconsideration of Request for ONC-AA Status*

In the Proposed Rule, we proposed processes for requesting ONC-AA status, the process for reviewing and approving an ONC-AA, the ongoing responsibilities of an ONC-AA, and the process for an accreditation organization to request reconsideration of its denied request for ONC-AA status.

##### 1. ONC-AA Status

We proposed in § 170.503 that the National Coordinator would approve only one ONC-AA at a time. We proposed that in order for an accreditation organization to become an ONC-AA, it would need to submit a request in writing to the National Coordinator along with certain

information to demonstrate its ability to serve as an ONC-AA. This information included: A detailed description of how the accreditation organization conforms to ISO/IEC17011:2004 (ISO 17011) and its experience evaluating the conformance of certification bodies to ISO/IEC Guide 65:1996 (Guide 65); a detailed description of the accreditation organization’s accreditation requirements and how the requirements complement the Principles of Proper Conduct for ONC-ACBs; detailed information about the accreditation organization’s procedures that would be used to monitor ONC-ACBs; detailed information, including education and experience, about the key personnel who would review organizations for accreditation; and the accreditation organization’s procedures for responding to, and investigating, complaints against ONC-ACBs.

We proposed that the National Coordinator would be permitted up to 30 days to review a request for ONC-AA status from an accreditation organization upon receipt and issue a determination on whether the organization is approved. We proposed that the National Coordinator’s determination would be based on the information and the completeness of the descriptions provided, as well as each accreditation organization’s overall accreditation experience. We proposed that the National Coordinator would review requests by accreditation organizations for ONC-AA status in the order they were received and would approve the first qualified accreditation organization based on the information required to be submitted with a request for ONC-AA status. We proposed that an ONC-AA’s status would expire not later than 3 years from the date its status was granted by the National Coordinator. We further proposed that beginning 120 days prior to the expiration of the then-current ONC-AA’s status, the National Coordinator would again accept requests for ONC-AA status.

We specifically requested comment on whether it would be in the best interest of the ONC-ACB applicants and Complete EHR and EHR Module developers to allow for more than one ONC-AA at a time and whether we should extend the duration of an ONC-AA’s term to 5 years, shorten it to 2 years, or identify a different period of time.

*Comments.* Commenters expressed support for an independent accreditation body, which they stated would provide an open and transparent process. One commenter, however, asked for clarification as to why we

proposed to have an accreditor independent of ONC. The commenter stated that the proposal seemed to introduce unnecessary overhead. A commenter also requested clarification of the requirement for an ONC-AA to conform to ISO 17011. Another commenter recommended that we require an ONC-AA to be recognized under the NIST National Voluntary Conformity Assessment Systems Evaluation, or “NVCASE” program. The commenter further recommended that the ONC-AA should demonstrate its ISO 17011 compliance for the ISO Guide 65 scope by being a signatory to the International Accreditation Forum’s Mutual/Multilateral Recognition Agreement (MRA) for product certification, which is verified by regular peer assessments. The commenter stated that such a requirement would mirror a benchmark set elsewhere for similar Federal agency program requirements for an accreditation body (*i.e.*, the U.S. EPA “WaterSense” program requirements).

Many commenters recommended that there be only one ONC-AA to ensure consistency, while only two commenters expressed openness to having more than one ONC-AA at a time. One of the commenters favoring more than one ONC-AA opined that the approval of more than one accreditor would ensure that all potential ONC-ACBs could be timely accredited and that the unique needs of potential ONC-ACBs would be adequately addressed, such as in the case of organizations that seek to certify other types of HIT besides Complete EHRs and EHR Modules. The other commenter suggested that we consider approving more than one ONC-AA if we anticipate a high volume of applicants for ONC-ACB status. One commenter stated that, given the importance of the ONC-AA in ensuring that the accredited certification bodies operate in a fair and effective manner, the ONC-AA should be chosen through an open competition that would allow for the comparison of the strengths and weaknesses of all interested accreditation organizations.

Commenters expressed support for either 3-year or 5-year terms for an ONC-AA. Some commenters suggested 5 years would provide more reliability and consistency. One commenter suggested an interim review of the ONC-AA after 3 years and granting an “extension” to 5 years based on the results of the review. One commenter suggested that an ONC-AA should not be allowed to “renew” its status at the end of the proposed 3-year term. The commenter contended that this would prevent an ONC-AA from overly

influencing how certification bodies are accredited. A commenter recommended that we begin accepting and reviewing requests for ONC-AA status sooner than 120 days prior to the expiration of the then-current ONC-AA's status and suggested 180 days as a possible alternative. The commenter reasoned that more time may be necessary to review and approve an ONC-AA. A couple of commenters requested clarification regarding how we would address concerns with an ONC-AA's operations and how we would remove or replace an ineffective ONC-AA.

*Response.* We do not believe that the use of an accreditor is unnecessary overhead. As stated in the Proposed Rule, we believe that accreditation (and the use of an accreditor) is the optimal and most practical approach for the long term because specialized accreditors in the private sector are better equipped to react effectively and efficiently to changes in the HIT market and to rigorously oversee the certification bodies they accredit. Further, the impartiality, knowledge, and experience of an accreditor will instill additional confidence in HIT developers, eligible professionals and eligible hospitals, and the general public regarding the ONC-ACB selection process. We believe that conformance to ISO 17011 is an appropriate measure to assess an accreditation organization's ability to perform accreditation under the permanent certification program, among the other submission requirements specified in § 170.503. ISO 17011 was developed by the International Organization for Standardization (ISO) and specifies the general requirements for accreditation bodies that accredit conformity assessment bodies. As noted in the Proposed Rule, an ONC-AA and the ONC-ACBs would be analogous to an accreditation body and the conformity assessment bodies, respectively, as referred to in ISO 17011. The introductory section of ISO 17011 explains that a system to accredit conformity assessment bodies is designed to provide confidence to the purchaser and the regulator through impartial verification that conformity assessment bodies are competent to perform their tasks. ISO 17011 and Guide 65 are standards that 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.

We appreciate the recommendations by the commenter, but we do not believe that it is necessary or appropriate to require an accreditation organization to be recognized under the NVCASE program or as a signatory to the International Accreditation Forum's MRA. It is our understanding that some of the requirements for recognition under the NVCASE program are similar to the requirements we have proposed for an accreditation organization to be approved as an ONC-AA. For example, the NVCASE Program Handbook states that the generic requirements for recognition as an accreditor are based on the ISO/IEC 17011 standard, and recognized accreditors of certification bodies must accredit those bodies to ISO/IEC Guide 65.<sup>1</sup> Therefore, we do not believe that a sufficient additional benefit would result from requiring accreditation organizations to be recognized under the NVCASE program. Adding such a requirement at this point may not provide sufficient notice and time for accreditation organizations that are not currently recognized by the NVCASE program to obtain NVCASE recognition in time to be eligible for approval as the ONC-AA at the start of the permanent certification program. Although we will not require an accreditation organization to be a signatory to the International Accreditation Forum's MRA, this information could be provided as part of an accreditation organization's detailed description of its accreditation experience to be included in its submitted request for ONC-AA status.

We agree with the commenters that, as proposed, granting ONC-AA status to only one accreditation body at a time is the best way to ensure consistency among ONC-ACBs. In addition, we believe that one ONC-AA will be able to address and support the needs of the market based on our projection of approximately 6 ONC-ACBs operating under the permanent certification program. We also agree with the commenter that suggested the ONC-AA should be chosen based on a competitive process that would allow us to evaluate all interested accreditation organizations in comparison to each other and select the organization that is best qualified to serve as the ONC-AA. Under the process we proposed, the National Coordinator would review requests for ONC-AA status in the order

they are received and select as the ONC-AA the first accreditation organization that is deemed to be qualified based on the factors specified in § 170.503(b). We recognize the limitations of this approach in that it would prevent the National Coordinator from considering all of the requests for ONC-AA status that are submitted and selecting the accreditation organization that is found to be the best qualified in comparison to the entire pool of organizations that submitted requests for ONC-AA status. We believe that the permanent certification program would benefit from a more competitive approach to selecting the ONC-AA. A competitive process will ensure the best qualified organization that submits a request is chosen as the ONC-AA, which will improve the overall quality of the program and instill confidence in the general public as well as industry stakeholders.

We are revising § 170.503 to eliminate the provision for the National Coordinator to review requests for ONC-AA status in order of receipt and approve the first qualified accreditation organization. Instead, under this revised § 170.503, the National Coordinator will review all timely requests for ONC-AA status in one batch and choose the best qualified accreditation organization to serve as the ONC-AA. We are revising § 170.503(b) to provide a 30-day period during which all interested accreditation organizations may submit requests for ONC-AA status. We will publish a notice in the **Federal Register** to announce this submission period. We are revising § 170.503(c) to permit the National Coordinator up to 60 days to review all timely submissions and determine which accreditation organization is best qualified to serve as the ONC-AA based on the information provided in the submissions and each organization's overall accreditation experience. We originally proposed to permit the National Coordinator up to 30 days to review a request for ONC-AA status and make a decision. Based on the changes to the ONC-AA approval process, the National Coordinator will likely need more time to review and compare all of the requests for ONC-AA status in one batch and determine which accreditation organization is best qualified to be the ONC-AA out of a potential pool of multiple organizations. The National Coordinator will select the best qualified accreditation organization as the ONC-AA on a preliminary basis and subject to the resolution of the reconsideration process in § 170.504. The accreditation organization that is selected on a preliminary basis is not

<sup>1</sup> National Institute of Standards and Technology, U.S. Dep't of Commerce, NVCASE Program Handbook, NISTIR 6440 2004 ED (Dec. 2004), available at <http://gsi.nist.gov/global/index.cfm/L1-4/L2-38>.



permitted to represent itself as the ONC-AA or perform any accreditation(s) under the permanent certification program, unless and until it is notified by the National Coordinator that it has been approved as the ONC-AA on a final basis. All other accreditation organizations will be notified that their requests for ONC-AA status have been denied.

Any accreditation organization that submits a timely request for ONC-AA status and is denied may request reconsideration of that decision pursuant to § 170.504. In order to request reconsideration under revised § 170.504(b), an accreditation organization must submit to the National Coordinator, within 15 days of its receipt of a denial notice, a written statement with supporting documentation contesting the decision to deny its request for ONC-AA status. The submission must demonstrate that clear, factual errors were made in the review of its request for ONC-AA status and that it would have been selected as the ONC-AA pursuant to § 170.503(c) if those errors had been corrected. Requests for reconsideration that are not received within the specified timeframe may be denied. We are revising § 170.504(c) such that the National Coordinator will have up to 30 days to review all timely submissions and determine whether an accreditation organization has met the standard specified in § 170.504(b) (*i.e.*, its submission has demonstrated that clear, factual errors were made in the review of its request for ONC-AA status and that it would have been selected as the ONC-AA pursuant to § 170.503(c) if those errors had been corrected). In determining whether an accreditation organization would have been selected as the ONC-AA, the National Coordinator will evaluate those accreditation organizations that demonstrate clear, factual errors, in comparison to each other as well as to the accreditation organization that was initially selected as the ONC-AA on a preliminary basis.

We are adding a new paragraph (d) to § 170.503 and revising § 170.504(d) such that if the National Coordinator determines that an accreditation organization has demonstrated that clear, factual errors were made in the review of its request for ONC-AA status and that it would have been selected as the ONC-AA pursuant to § 170.503(c) if those errors had been corrected, then that organization will be approved as the ONC-AA on a final basis. All other accreditation organizations will be notified that their requests for reconsideration have been denied.

Conversely, if the National Coordinator determines that no accreditation organization has met the standard specified in § 170.504(b), then the organization that was initially selected as the ONC-AA on a preliminary basis will be approved as the ONC-AA on a final basis. An accreditation organization has not been granted "ONC-AA status" unless and until it is notified by the National Coordinator that it has been approved as the ONC-AA on a final basis, as stated in revised paragraph (f) of § 170.503.

We believe that it is appropriate to provide a 3-year term for an ONC-AA. A 5-year term may provide more consistency and reliability, but we believe a 3-year term provides an appropriate interval to fully assess an ONC-AA's performance under the permanent certification program and provide an opportunity for other interested organizations to seek ONC-AA status. We believe all interested accreditation organizations should be given the opportunity to request ONC-AA status when the National Coordinator is seeking to approve an ONC-AA. An interested accreditation organization should not be barred from "reapplying" simply because it previously served as an ONC-AA. Such a preclusion could prevent the National Coordinator from approving the best qualified accreditation organization or the only interested organization.

We agree with the commenter that we should begin to accept requests for ONC-AA status sooner than 120 days prior to the expiration of the then-current ONC-AA's status as we originally proposed. Similar to the commenter's recommendation, the National Coordinator will begin to accept requests for ONC-AA status at least 180 days prior to the expiration of the then-current ONC-AA's status. We believe this will give the market more time to transition to a new ONC-AA if we were to approve a different accreditation organization as the ONC-AA. We note, however, that if we were to approve a different accreditation organization as the ONC-AA, its status would not become effective until after the end of the then-current ONC-AA's term. As with the approval of the first ONC-AA and in accordance with the revised § 170.503(b), we will notify the public of the 30-day period for requesting ONC-AA status by publishing a notice in the **Federal Register**. Consistent with this discussion, we are revising § 170.503(f)(3) to specify that the National Coordinator will accept requests for ONC-AA status, in accordance with paragraph (b), at least

180 days before the then-current ONC-AA's status is set to expire.

As pointed out by the commenters, we did not propose a formal process for the National Coordinator to remove or take other corrective action against an ONC-AA that is performing poorly. We recognize that an ONC-AA, like an ONC-ACB, has significant responsibilities under the permanent certification program that are inextricably linked to the success of the permanent certification program. We agree with the commenters that a specified process for the National Coordinator to address poor performance or inappropriate conduct by an ONC-AA would be beneficial for the permanent certification program and would ensure that an ONC-AA is held accountable for its actions. Accordingly, we intend to issue a notice of proposed rulemaking (NPRM) that will address improper conduct by an ONC-AA, the potential consequences for engaging in such conduct, and a process by which the National Coordinator may take corrective action against an ONC-AA. We expect to issue this NPRM in the near future and do not believe it will unnecessarily delay the implementation of the permanent certification program.

## 2. On-Going Responsibilities

We proposed in § 170.503(e) that an ONC-AA would be required to, at minimum: Maintain conformance with ISO 17011; in accrediting certification bodies, verify conformance to, at a minimum, Guide 65; verify that ONC-ACBs are performing surveillance in accordance with their respective annual plans; and review ONC-ACB surveillance results to determine if the results indicate any substantive non-conformance with the terms set by the ONC-AA when it granted the ONC-ACB accreditation. We specifically requested public comment on these proposed responsibilities and whether there are other responsibilities that we should require an ONC-AA to fulfill.

*Comments.* A couple of commenters expressed agreement with the outlined responsibilities. One commenter suggested that the ONC-AA should provide annual reports of the results of their responsibilities. The commenter also recommended that the ONC-AA should review and/or audit all ONC-ACB processes, such as bylaws and standard operating procedures, no less than annually.

*Response.* We appreciate the expression of confidence in the ongoing responsibilities we have proposed for an ONC-AA. We also appreciate the commenter's recommendations for annual reports on the ONC-AA's

responsibilities and annual reviews and/or audits by the ONC-AA of all ONC-ACBs' processes. We believe, however, that annual reports from the ONC-AA are unnecessary. As stated above, the approval of an ONC-AA every three years will serve as a sufficient periodic review of the ONC-AA. There will also be opportunities to assess an ONC-AA's performance of its responsibilities at other junctures during the permanent certification program. The Principles of Proper Conduct for ONC-ACBs require ONC-ACBs to submit annual surveillance plans and to annually report surveillance results to the National Coordinator. Our review of an ONC-ACB's surveillance results should give an indication of whether the ONC-AA is performing its responsibilities to review ONC-ACB surveillance results and verify that ONC-ACBs are performing surveillance in accordance with their surveillance plans. We also expect that our review and analysis of surveillance plans and results will not only include feedback from the ONC-ACBs but also from the ONC-AA. The ONC-AA feedback will provide us with additional information on the ONC-AA's performance of its monitoring and review responsibilities related to ONC-ACB surveillance activities.

ISO 17011 specifies that an accreditation body (*i.e.*, an ONC-AA) shall require a conformance assessment body (*i.e.*, an ONC-ACB) to commit to fulfill continually the requirements for accreditation set by the accreditation body, cooperate as is necessary to enable the accreditation body to verify fulfillment of requirements for accreditation, and report changes that may affect its accreditation to the accreditor. ISO 17011 also contains provisions that require an ONC-AA to review an ONC-ACB periodically, but no less than every two years, and to do so in a manner prescribed under ISO 17011. Moreover, as one of its ongoing responsibilities, the ONC-AA will be required to verify that ONC-ACBs continue to conform to the provisions of Guide 65 at a minimum as a condition of continued accreditation. We believe these provisions will enable the ONC-AA to sufficiently oversee (*i.e.*, review and/or audit) the ONC-ACBs for the purposes of the permanent certification program. For instance, if the ONC-AA finds that an ONC-ACB is not in compliance with its accreditation requirements, then the ONC-ACB may lose its accreditation and subsequently its ONC-ACB status. The Principles of Proper Conduct for ONC-ACBs will also provide additional assurance that ONC-

ACBs are operating in an acceptable manner under the permanent certification program.

We are revising § 170.503(e)(4) to state that the ONC-AA will be responsible for reviewing ONC-ACB surveillance results to determine if the results indicate any substantive non-conformance by ONC-ACBs "with the conditions of their respective accreditations." We believe this clarification more accurately accounts for the possibility that different accreditation organizations may be approved to serve as the ONC-AA.

### 3. Reconsideration of Request for ONC-AA Status

We proposed in § 170.503(d) that an accreditation organization could appeal a decision to deny its request for ONC-AA status in accordance with § 170.504, but only if no other accreditation organization had been granted ONC-AA status. We proposed in § 170.504 to use generally the same procedures for reconsideration of an accreditation organization's request for ONC-AA status as we did for reconsideration of applications for ONC-ACB status with a few substantive distinctions. We proposed that an accreditation organization could ask the National Coordinator to reconsider a decision to deny its request for ONC-AA status only if no other accreditation organization had been granted ONC-AA status and it could demonstrate that clear, factual errors were made in the review of its request for ONC-AA status and that the errors' correction could lead to the accreditation organization obtaining ONC-AA status. We proposed that an accreditation organization that wished to contest its denial would be 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 request for ONC-AA status and explaining with sufficient documentation what factual error(s) it believes can account for the denial. We proposed that if the National Coordinator did not receive the accreditation organization's written statement within the specified timeframe that its request for reconsideration could be rejected. 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, that correction of those factual errors would not remove all identified deficiencies, or that a

qualified ONC-AA had already been approved, the National Coordinator could reject the applicant's reconsideration request and that this decision would be final and not subject to further review.

We did not receive any comments on these provisions. We are, however, revising § 170.503(c) and (d) and § 170.504 consistent with the changes we discussed earlier in this section of the preamble.

### E. Correspondence

We proposed in § 170.505 to require applicants for ONC-ACB status and ONC-ACBs to correspond and communicate with the National Coordinator by e-mail, unless otherwise necessary. We proposed that the official date of receipt of any e-mail between the National Coordinator and an applicant for ONC-ACB status or an ONC-ACB would be the day the e-mail was sent. We further proposed that in circumstances where it was necessary for an applicant for ONC-ACB status or an ONC-ACB 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 § 170.505 to include "or an ONC-ACB" in paragraph (b) to clarify that either an applicant for ONC-ACB status or an ONC-ACB may, when necessary, utilize the specified correspondence methods. This reference was inadvertently left out of § 170.505(b) in the Proposed Rule. We are also revising this section to apply the correspondence requirements to accreditation organizations that submit requests for ONC-AA status and the ONC-AA. These organizations are similarly situated to applicants for ONC-ACB status and ONC-ACBs with respect to corresponding with ONC. In particular, with our revisions that establish a specific time period for submitting requests for ONC-AA status, application of § 170.505 to accreditation organizations requesting ONC-AA status will provide a clear understating of when a request will be deemed received by the National Coordinator. Overall, we believe that applying the correspondence requirements to accreditation organizations requesting ONC-AA status and the ONC-AA will increase the efficiencies of the permanent certification program and lessen the correspondence burden on these organizations.

## F. Certification Options for ONC-ACBs

### 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-ACBs would have too much discretion related to certification. The commenters asserted that ONC-ACBs 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 gives too much discretion to an ONC-ACB.

*Response.* Our response to these comments is similar to the response we provided in the Temporary Certification Program final rule due to similarities that exist between the two certification programs. We require as a Principle of Proper Conduct that ONC-ACBs shall maintain their accreditation, which will, at minimum, require ONC-ACBs to operate their certification programs in accordance with Guide 65. As noted above, the ONC-AA will be required to verify that ONC-ACBs continue to conform to Guide 65 at a minimum as a condition of maintaining their accreditation. 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-

ACB’s certification program operations. We understand the concerns expressed by commenters over our example of a “quality management system” as another factor that ONC-ACBs 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-ACBs related to certification and expressed concerns about the level of discretion afforded to ONC-ACBs, we agree that additional clarity is necessary regarding our intent and expectations of ONC-ACBs as initially expressed 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. We 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 requirements imposed on ONC-ACBs in subpart E of part 170.

We seek to make clear that the primary responsibility of ONC-ACBs under the permanent certification program is to certify Complete EHRs and EHR Modules, and potentially other types of HIT at some point in the future, in accordance with the certification criteria adopted by the Secretary. In consideration of the comments and the preceding discussion, we are adding new provisions to § 170.545 (paragraph (b)) and § 170.550 (paragraph (b)) to make it explicitly clear that an ONC-ACB must offer the option for a Complete EHR or EHR Module to be certified solely to the applicable certification criteria adopted by the Secretary and not to any additional certification criteria. In other words, if a developer makes a request for its Complete EHR or EHR Module to be certified solely to the applicable certification criteria adopted by the Secretary, an ONC-ACB cannot require the Complete EHR or EHR Module to be certified to any other certification criteria beyond those that have been adopted by the Secretary. In complying with such a request, the ONC-ACB would still be expected to issue

certifications in accordance with the requirements specified by subpart E of part 170 (for example, § 170.523(k)). As a matter of its own business practices, however, an ONC-ACB may decide to offer multiple options for the certification of HIT, some of which could potentially impose other requirements for certification or include additional certification criteria beyond what has been adopted by the Secretary. If an ONC-ACB chooses to offer multiple certification options for HIT, we expect it would be done consistent with the requirements of the ONC-ACB's accreditation. Additionally, in accordance with Guide 65, section 6, the ONC-ACB would be required to "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-ACB 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 would not be within the scope of an ONC-ACB's authority granted under the permanent certification program and should not be considered to be 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-ACBs (discussed in more detail in section O. *Validity of Complete EHR and EHR Module Certification and Expiration of Certified Status*) that any certifications that are based solely 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 that meets the definition of a Complete EHR or EHR Module and is certified to the certification criteria adopted by the Secretary as well as to an ONC-ACB's own additional certification criteria must have its certified status as a Complete EHR or EHR Module noted separately and distinctly from any other certification the ONC-ACB may issue based on its own certification criteria. For example, an ONC-ACB 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 Certification

We proposed in § 170.510 that applicants for ONC-ACB status may seek authorization from the National Coordinator to perform Complete EHR certification, EHR Module certification, and/or certification of other types of HIT for which the Secretary has adopted certification criteria under subpart C of this part.

We received multiple comments on the types of certification that ONC-ACBs can and should perform. These comments were in direct response to our requests for public comments on whether ONC-ACBs should certify the integration of EHR Modules and on whether applicants for ONC-ACB status should be permitted to apply to certify only Complete EHRs designed for an ambulatory setting or only Complete EHRs designed for an inpatient setting.

### a. Complete EHRs for Ambulatory or Inpatient Settings

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

*Comments.* We received comments ranging from support for providing the option for applicants to certify Complete EHRs for either ambulatory or inpatient settings to support for our proposal to require an ONC-ACB to perform 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 certification for both settings. These commenters stated that allowing for Complete EHR certification for either an ambulatory or inpatient setting could enhance 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-ACBs. One commenter also thought that the option may lead to applicants for ONC-ACB status competing for limited resources, such as specialized staff for conducting certification.

Some commenters expressed concern that if the National Coordinator were to allow applicants to certify Complete EHRs for either ambulatory or inpatient settings, there would not be enough ONC-ACBs to 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-ACBs for each setting. One commenter only supported giving ONC-ACBs an option to certify Complete EHRs for either ambulatory or inpatient settings if the option included 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-ACB status could seek authorization to 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-ACB status the option to seek authorization to certify Complete EHRs for either ambulatory or inpatient settings because an applicant for ONC-ACB status could essentially choose that option by seeking all the necessary EHR Module authorizations for either ambulatory or inpatient settings.

*Response.* In the Temporary Certification Program final rule, based on the concerns expressed by the commenters, we determined that it was inappropriate under the temporary certification program to allow applicants for ONC-ATCB status to seek authorization to test and certify Complete EHRs for either only ambulatory settings or only inpatient settings. We stated that we would reconsider the option for the permanent certification program based on any additional comments we received on the proposed permanent certification program.

The comments discussed above include comments we received that were applicable to both the temporary certification program and the permanent certification program as well as comments focused solely on the permanent certification program. As mentioned, we discussed the comments that were applicable to the temporary

certification program in the Temporary Certification Program final rule. The comments that were focused solely on the permanent certification program did not contain any additional information or rationale that would cause us to conclude that the option to allow applicants for ONC-ACB status to seek authorization to certify Complete EHRs for only ambulatory settings or only inpatient settings would be appropriate for the permanent certification program. Accordingly, we are not permitting this option in the permanent certification program.

To address the commenters' concerns about "almost complete" EHRs, we reiterate that for EHR technology to be considered a Complete EHR, it must have been developed to meet, at a minimum, *all* of the applicable certification criteria adopted by the Secretary. For example, a Complete EHR for an ambulatory setting must have been developed to meet all of the certification criteria adopted at § 170.302 and § 170.304. Therefore, if we were to provide the option for ONC-ACBs to seek authorization to certify Complete EHRs for only ambulatory settings or only inpatient settings, the Complete EHRs that they certify must have been developed to meet all of the applicable certification criteria adopted by the Secretary.

We agree with the commenter that an applicant for ONC-ACB status could seek authorization to certify certain types of EHR Modules that together could potentially include all of the capabilities required by the applicable certification criteria for an ambulatory setting. The important distinction between the commenter's suggested approach and the option we proposed is that under the commenter's approach the ONC-ACB would not be able to issue a "Complete EHR certification" for a combination of EHR Modules because the ONC-ACB had not received authorization to certify Complete EHRs. Consequently, if a Complete EHR developer wanted to obtain Complete EHR certification, they could not seek such certification from an ONC-ACB that did not have authorization to grant Complete EHR certifications. We would assume that a potential applicant for ONC-ACB status would consider this impact on its customer base when determining what type of authorization to seek.

Consistent with this discussion, we are finalizing proposed § 170.510 without modification.

#### b. Integrated Testing and Certification of EHR Modules

In the Proposed Rule, we requested public comment on whether ONC-ACBs should be required to 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 certifying EHR Modules based on their ability to integrate with one another is a worthwhile endeavor. These commenters stated that such 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 certified for compatibility and raised various concerns. Overall, these commenters asserted that it would be technically infeasible as well as both logistically (*e.g.*, multiple certification sites and multiple EHR Module developers) and financially impractical to attempt to certify whether two or more EHR Modules were compatible given the huge and shifting numbers of possible combinations. Another concern indicated that a mandatory requirement for ONC-ACBs to perform this type of certification would be challenging for ONC-ACBs because the EHR Module concept as defined in regulation is relatively new and because there is limited available guidance and mature testing and certification processes for this type of certification. One commenter opined that certification was not necessary because EHR Module developers would likely strive for integration on their own as a marketing tool for their EHR Modules.

Some commenters suggested that EHR Modules could be 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-ACBs be given the option, but not be required, to determine if EHR Modules are compatible.

*Response.* We believe that including a mandatory provision requiring ONC-

ACBs to certify whether two or more EHR Modules are compatible would not be prudent due to the various impracticalities that were raised by commenters. We arrived at the same conclusion for the temporary certification program as explained in the Temporary Certification Program final rule. We believe that requiring ONC-ACBs to certify 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. We also agree with the commenter who suggested that developers will choose, most likely selectively, to integrate their EHR Modules with other EHR Modules for the purposes of making their products more marketable. Consequently, we believe that the market through business decisions and agreements may work to achieve integration where necessary and beneficial.

An EHR Module developer or developers may present EHR Modules together as a pre-coordinated, integrated bundle for certification pursuant to § 170.550(e) for the purpose of satisfying the privacy and security certification criteria adopted at subpart C of part 170. An ONC-ACB, however, is only permitted to certify a pre-coordinated, integrated bundle of EHR Modules if it is capable of meeting all of the applicable certification criteria and would otherwise meet the definition of and constitute a Complete EHR. We assume that the EHR Module developer(s), for business and potentially other reasons, would have reconciled any compatibility issues among the constituent EHR Modules that make up the pre-coordinated, integrated bundle before the bundle is presented for testing and certification.

We note that nothing in this final rule precludes an ONC-ACB or other entity from offering a service to certify EHR Module-to-EHR Module integration. However, to be clear, although we do not require or specifically preclude an ONC-ACB from certifying EHR Module-to-EHR Module integration, any EHR Module-to-EHR Module certification performed by an ONC-ACB or other entity will be done without specific authorization from the National Coordinator and will not be considered part of the permanent certification program. We understand that certification for EHR Module-to-EHR Module integration may be advantageous in certain instances, but

we do not believe, based on the impracticalities discussed above, that we could set all the necessary parameters for certification of EHR Module-to-EHR Module integration.

Consistent with this discussion, we are finalizing proposed § 170.510 without modification.

### G. *ONC-ACB Application Process*

#### 1. Application

We proposed in § 170.520 that an application would need to be submitted to the National Coordinator and that the application would need to contain certain information to be considered complete. We also noted that applications would be made available on ONC's Web site and could be submitted by e-mail.

Similar to the temporary certification program, we proposed to require an applicant for ONC-ACB status to indicate on its application the type of certification it seeks authorization to perform under the permanent certification program. Consistent with proposed § 170.510, an applicant could indicate that it seeks authorization to certify Complete EHRs, EHR Module(s), and/or other types of HIT for which the Secretary has adopted certification criteria. If the applicant were to request authorization to certify EHR Module(s), we proposed to require the applicant to identify the type(s) of EHR Module(s) that it seeks to certify.

We proposed that an applicant must provide general identifying information, including the applicant's name, address, city, State, zip code, and Web site. We proposed that an applicant also must designate an authorized representative and provide the name, title, phone number, and e-mail address of the person who would serve as the applicant's point of contact. We proposed that an applicant must submit documentation confirming the applicant's accreditation by an ONC-AA. Lastly, we proposed that an applicant must submit an executed agreement to adhere to the "Principles of Proper Conduct for ONC-ACBs."

We proposed that if the Secretary adopts certification criteria for HIT other than Complete EHRs and EHR Modules, an ONC-ACB would be required to submit an addendum to its original application if it wished to request authorization to certify this other type of HIT. Additionally, we proposed that if a new organization wanted to be authorized to certify another type of HIT, it would need to follow the rules for becoming an ONC-ACB, including first receiving accreditation from an ONC-AA.

*Comments.* We received comments expressing agreement with the application requirements, including the need for an applicant to be accredited before it applies. One commenter suggested that if an organization fails to become accredited on the first attempt that the organization should be given another opportunity. Another commenter suggested that, similar to the temporary certification program, we institute a "proficiency examination" for "key personnel." The commenter stated that such a competency test, adherence to credentialing standards such as ASTM International 2659, or a more formal and ongoing personnel certification program in accordance with ISO 17024 may have long-term benefits for the permanent certification program. A commenter also requested clarification on what information the National Coordinator would deem sufficient to confirm the applicant's accreditation. The commenter suggested that a current letter of accreditation, as opposed to the re-submission of supporting documentation that was submitted previously to the ONC-AA, could fulfill the requirement to confirm an ONC-ACB's accreditation.

*Response.* We appreciate the support for the proposed application requirements. We wish to further clarify these requirements for applicants who seek authorization to certify EHR Modules. In addition to identifying the specific type(s) of EHR Module(s) that they wish to certify, these applicants are expected to identify as part of their application the certification criterion or criteria that they believe should be included within the scope of their authorization for the EHR Module(s) they have identified. We believe requiring applicants to provide this information will ensure that an applicant and the National Coordinator will have a shared understanding of the scope of the authorization requested by the applicant, which could otherwise be difficult to discern based solely on the name(s) or type(s) of EHR Module(s) that the applicant identifies in its application.

In response to the commenter, we note that the ONC-AA will develop and manage the accreditation process for organizations that intend to apply for ONC-ACB status, including the number of times an organization may attempt to become accredited. We appreciate the commenter's recommendation for ONC-ACB personnel to undergo competency testing and/or a formal credentialing program, and we understand the potential benefits associated with such requirements. We do not, however, believe that ONC should independently

require personnel of applicants for ONC-ACB status to pass a certain exam or possess certain credentials before the applicant applies ONC-ACB status. We believe that accreditation by the ONC-AA will be sufficient to ensure that an applicant for ONC-ACB status will have personnel who are qualified to perform certifications of Complete EHRs, EHR Modules, and/or other types of HIT. Further, we will require ONC-ACBs to attend ONC mandatory training and to maintain training programs for their own personnel, which we believe are adequate measures to ensure that ONC-ACB personnel will remain competent. Lastly, to properly document an ONC-ACB applicant's accreditation, the applicant should provide a copy of its accreditation record consistent with the accreditation record that the ONC-AA must keep in accordance with section 7.14 of ISO 17011. We believe that a copy of the record will allow the National Coordinator to properly confirm the extent of an applicant's accreditation.

In the Temporary Certification Program final rule, we noted a commenter's suggestion that we should establish a process that would enable ONC-ATCBs to apply for additional authorization to test and certify additional types of EHR Modules. We declined to establish a process separate from the application process that we had proposed for the temporary certification program, but we indicated that we would consider whether an alternative process would be appropriate for the permanent certification program. In other words, if an ONC-ACB is authorized to certify a certain type(s) of EHR Module(s) and wants to expand the scope of its current authorization so that it may certify other types of EHR Modules, should there be a way for it to obtain this authorization without following the application process outlined in § 170.520. After considering this possibility, we have decided to adopt a more streamlined process for ONC-ACBs that want to expand the scope of their current authorization to include Complete EHRs, other types of EHR Modules, and/or other types of HIT if it becomes an option. In order to request additional authorization under this process, an ONC-ACB must specify in writing the type of authorization it is seeking (including, for EHR Module(s) authorization, identification of the certification criterion or criteria that it believes should be included within the scope of its authorization) and provide documentation of its current accreditation that would support the

type of authorization it seeks, as described in § 170.520(a) and (c), respectively. The ONC-ACB would not be required to resubmit the other information specified in § 170.520, unless any of that information had changed since it was last provided to ONC. In deciding whether to grant an ONC-ACB's request to expand the scope of its current authorization, the National Coordinator may also consider whether the ONC-ACB has completed any mandatory training as may be required by § 170.523(b), which would confirm whether the ONC-ACB is competent to certify the specific type(s) of HIT for which it seeks authorization. For example, an ONC-ACB that is authorized to certify a certain type of EHR Module may request authorization to certify other types of EHR Modules that may include different capabilities and thus implicate different certification criteria adopted by the Secretary. The National Coordinator may require the ONC-ACB to complete mandatory training to ensure that the ONC-ACB understands the test tools and test procedures used for testing to the different certification criteria and can competently certify the other types of EHR Modules. We believe a more streamlined process will benefit both ONC-ACBs and developers of Complete EHRs, EHR Modules, and other types of HIT because it will enable ONC-ACBs to expand the scope of their authorization more efficiently and consequently provide additional certification services to developers. Overall, we believe this could potentially benefit the market for HIT by increasing the speed with which certified Complete EHRs, EHR Modules and potentially other types of HIT are available for purchase and/or implementation.

We are revising § 170.520(c) such that the documentation provided by the applicant must confirm that the applicant has been accredited by "the ONC-AA," instead of "an ONC-AA" as proposed. We believe the revision more clearly reflects that there will be only one ONC-AA at a time.

## 2. Principles of Proper Conduct for ONC-ACBs

We received multiple comments on the proposed Principles of Proper Conduct for ONC-ACBs. Many of those comments were also relevant to the proposed Principles of Proper Conduct for ONC-ATCBs because several identical Principles were proposed for both ONC-ACBs and ONC-ATCBs. As explained earlier in this preamble, given the similarities that exist between the temporary and permanent certification

programs, the responses we provide below are often similar or identical to our responses to comments on the proposed Principles of Proper Conduct for ONC-ATCBs that we provided in the Temporary Certification Program final rule.

We did not receive any comments on the Principles of Proper Conduct proposed in paragraphs (b), (c) and (d) of § 170.523. Therefore, we are finalizing these Principles of Proper Conduct without modification. While we received comments on all of the other proposed Principles of Proper Conduct for ONC-ACBs and suggestions for additional principles of proper conduct, the majority of the comments were focused on or related to the proposed Principles that would require ONC-ACBs to provide ONC, no less frequently than weekly, a current list of Complete EHRs and EHR Modules that have been certified; only certify HIT that has been tested by a NVLAP-accredited testing laboratory; and submit an annual surveillance plan and annually report surveillance results.

### a. Maintain Accreditation

We proposed in § 170.523(a) that an ONC-ACB would be required to maintain its accreditation. As discussed earlier, the ONC-AA will be required as part of its ongoing responsibilities to verify that ONC-ACBs are continuing to operate in accordance with Guide 65 at a minimum in order to maintain their accreditation.

*Comments.* A few commenters expressed opinions that accreditation was an appropriate requirement for ONC-ACBs. One commenter recommended that we review the processes of other accreditation organizations such as the American National Standards Institute, the Joint National Commission, and the ISO to assist in the development of the accreditation program for the permanent certification program, while another commenter recommended that we only require compliance with select, appropriate provisions of Guide 65 as part of accreditation instead of all of Guide 65.

*Response.* We have reviewed the processes of other accreditation organizations and have concluded, as proposed, that the standards developed by the ISO (specifically, ISO 17011 and Guide 65) should serve as the foundation for developing the accreditation element of the permanent certification program. In particular, we have stated that we expect the ONC-AA will accredit ONC-ACBs based on the guidelines specified in ISO 17011. Further, we believe that all of the provisions of Guide 65 would be

applicable to the accreditation program and thus we proposed that accreditation would include verification of a certification body's conformance, at minimum, to Guide 65. We believe that requiring ONC-ACBs to be accredited will ensure that ONC-ACBs are qualified to perform certifications and will continue to be capable of properly performing certifications.

### b. ONC Visits to ONC-ACB Sites

We proposed in § 170.523(e) to require an ONC-ACB to allow ONC, or its authorized agent(s), to periodically observe on site (unannounced or scheduled) any certifications performed to demonstrate compliance with the requirements of the permanent certification program.

*Comments.* A commenter expressed agreement with our proposal stating that both scheduled and unannounced visits are appropriate. Another commenter stated that if visits are unannounced, then there can be no assurance that a certification will actually be underway upon the arrival of an ONC representative. Therefore, the commenter recommended that we should revise the requirement to require an ONC-ACB to respond within 2 business days to an ONC request to observe certification by providing the date, time, and location of the next scheduled certification. Another commenter recommended that all visits should be planned because staff may not be available and "clearances" may need to be arranged well in advance of a site visit. A commenter also stated that ONC observers for site visits would likely need to execute confidentiality and/or business associate agreements because some HIT developers treat their software screens and other elements as trade secrets.

*Response.* Our proposal gave us the option to conduct either scheduled or unannounced visits. After considering the comments, we believe it is appropriate to maintain both options, as we did in the context of the temporary certification program. If we determine that there is a specific 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 permanent certification program and to maintain the integrity of the program, we believe that unannounced visits are appropriate. We anticipate that ONC "authorized agents" could potentially include individuals or entities under contract with ONC, personnel from an entity with which ONC has a regulatory relationship (e.g., personnel from the

ONC-AA), or personnel from other Federal agencies with certification expertise (e.g., NIST). We expect to establish ahead of time for ONC-ACBs the parameters around announced or unannounced on-site visits. In establishing these parameters, we expect ONC-ACBs to ensure that any "clearances" for ONC or its authorized agents are obtained in a timely manner given the possibility of an unannounced site visit. We also expect ONC-ACBs will take the necessary steps to address any potential confidentiality issues with their customers (for example, through a confidentiality agreement that would enable ONC and its authorized representatives to observe the certification of a customer's HIT). Therefore, we are finalizing this Principle of Proper Conduct with only a minor modification. We are revising § 170.523(e) to clarify that site visits will be conducted during normal business hours. This condition was inadvertently left out of the proposed provision, but is consistent with our original intent as shown in the proposed and final versions of the analogous provision for ONC-ATCBs.

### c. Lists of Certified Complete EHRs and EHR Modules

#### i. ONC-ACB Lists

We proposed in § 170.523(f) to require an ONC-ACB to provide ONC, no less frequently than weekly, a current list of Complete EHRs and/or EHR Modules that have been certified which includes, at a minimum, the vendor name (if applicable), the date certified, the 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 certified.

*Comments.* Many commenters expressed appreciation for the proposed requirement and the proposed frequency for which the lists were to be updated. In relation to the information ONC-ACBs must report, a commenter specifically expressed support for making timely, complete, and useful information available to eligible professionals and eligible hospitals as they purchase and implement Certified EHR Technology that will enable them to attempt 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-ACB to notify ONC within a week of successful certification

of new Complete EHRs and/or EHR Modules. Additionally, the commenter contended that the proposed provision was unclear as to whether an ONC-ACB was required to send a complete, current list or only new additions and whether the list could be sent via e-mail. Another commenter suggested revising the provision to require an ONC-ACB to also report a current list of "applicants" and their status in the certification queue.

*Response.* As proposed and as already finalized for the temporary certification program, we will require ONC-ACBs to provide the National Coordinator, no less frequently than weekly, with a current list of Complete EHRs and/or EHR Modules that have been certified. We anticipate only requiring weekly updates, but ONC-ACBs are free to provide more frequent updates. We believe weekly updates are sufficient for providing current information to the public on the status of certified Complete EHRs and EHR Modules without placing an administrative burden on ONC-ACBs. In this regard, we have previously stated and continue to expect that ONC-ACBs will provide the information electronically, such as through e-mail. We also agree with the commenter that it would be unnecessary for an ONC-ACB 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 any substantial benefit would result from requiring ONC-ACBs to report on the status of Complete EHRs and/or EHR Modules that are in the process of being certified. The time needed for the 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-ACB'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. We note that much of the information that will be reported by ONC-ACBs will also be included in the Certified HIT Products List (CHPL) that will be made publicly available on ONC's Web site. After consideration of the public comments received and our own programmatic objectives, we will require ONC-ACBs to report information related to the two

additional elements that we already finalized for ONC-ATCBs in the Temporary Certification Program final rule. Our intention in including these two additional elements is to make more information widely available about the technology that has been certified, which will benefit eligible professionals, eligible hospitals, and other interested parties who wish to adopt certified Complete EHRs and EHR Modules. The two additional elements that we will require ONC-ACBs to report are the clinical quality measures to which a Complete EHR or EHR Module has been certified and, where applicable, any additional software that a Complete EHR or EHR Module relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary. As with the other information that ONC-ACBs must report, these two additional elements will enable eligible professionals and eligible hospitals to make better informed purchasing decisions, consistent with the commenter's suggestion.

The reporting of clinical quality measures to which a Complete EHR or EHR Module has been 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. Eligible professionals and eligible hospitals could use this information 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, as with the temporary certification program, 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 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 certified using 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.

We are revising § 170.523(f) to correct an inadvertent reference to vendors of Complete EHRs or EHR Modules. As proposed, the section would require ONC-ACBs to report the names of certified Complete EHR or EHR Module vendors, if applicable. Our use of the word "vendor" was not intended to exclude information related to self-developers from the reporting requirements of § 170.523(f). Throughout the Proposed Rule and this final rule, we have collectively referred to self-developers and commercial vendors as "developers" of Complete EHRs and EHR Modules. Therefore, we are replacing "vendor" with "Complete EHR or EHR Module developer" in § 170.523(f)(1).

We also believe it would be helpful to clarify the specific information that should be reported with respect to pre-coordinated, integrated bundles of EHR Modules that are certified in accordance with § 170.550(e). ONC-ACBs are required by § 170.523(f)(4) to report the unique certification number or other specific product identification of Complete EHRs and EHR Modules that have been certified. They are also required by § 170.523(f)(7) to report, where applicable, the certification criterion or criteria to which each EHR Module has been certified. Based on these provisions, ONC-ACBs should identify and include in their reports to the National Coordinator: the pre-coordinated, integrated bundles of EHR Modules that they certify; the list of constituent EHR Modules that comprise each bundle; and, where applicable, identify for each constituent EHR Module the certification criterion or criteria to which that particular EHR Module has been certified.

Finally, as with the temporary certification program, we note that our required reporting elements constitute a minimum. We do not preclude ONC-ACBs 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-ACBs to consider making such information available on their own Web sites to better inform prospective purchasers and users of Complete EHRs and EHR Modules.

We are revising § 170.523(f) 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 certified by ONC-ACBs available on the ONC Web site. The CHPL would be a public service and would be a single, aggregate source of all the certified product information ONC-ACBs 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 Web site, which could include interactive functions to help eligible professionals and eligible hospitals determine whether a particular combination of certified EHR Modules could potentially qualify as 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 Web site. 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 types of 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-ACB 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-ACB should not maintain on its own Web site a current list of the Complete EHRs and/or EHR Modules that it has certified, but instead reference the CHPL on ONC's Web site 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. As previously explained in the Temporary Certification Program final rule, we intend for the CHPL to be a single, aggregate source of all certified Complete EHRs and EHR Modules reported by ONC-ACBs to the National Coordinator. The CHPL will include 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-ACBs 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 (e.g., an alphanumeric

identifier) for each certified Complete EHR and each combination of certified EHR Modules that meets the definition of Certified EHR Technology. The unique identifier provided by the CHPL webpage could subsequently be used to submit to CMS for attestation purposes.

Consistent with the temporary certification program, 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-ACB from maintaining on its own Web site a list of Complete EHRs and/or EHR Modules that it certified. An ONC-ACB's own list could have benefits for the market in identifying the specific ONC-ACB that certified a Complete EHR or EHR Module. The ONC-ACB may also create a link on its Web site to the CHPL, which conceivably would be a user-friendly feature.

#### d. Records Retention

We proposed in § 170.523(g) to require an ONC-ACB to retain all records related to the certification of Complete EHRs and/or EHR Modules for a minimum of 5 years.

*Comments.* Commenters recommended that our records retention requirement be consistent with CMS's requirement for eligible professionals and eligible hospitals who seek to qualify for Medicare or Medicaid incentive payments for meaningful use, plus an additional two years to ensure that records are available during an audit process.

*Response.* As stated in the Proposed Rule, the record retention requirement is based on our consultations with NIST regarding standard industry practice. As also stated in the Proposed Rule, the purpose of our records retention requirement is twofold. An ONC-ACB's records would be directly relevant to a determination by the National Coordinator that the ONC-ACB committed a Type-2 violation and/or to revoke the ONC-ACB's status. Second, ONC-ACBs' certification records will likely be necessary for ONC-ACBs to conduct surveillance under the permanent certification program. In addition to the records retention requirement of § 170.523(g), ONC-ACBs are expected to retain records consistent with the terms of their accreditation, which will include the requirements of Guide 65. Lastly, our records retention requirement should be construed as an independent requirement and is not intended to replace or supplant any other requirements imposed by law or otherwise agreed to by ONC-ACBs. Accordingly, we will, as proposed,

require ONC-ACBs to retain all records related to the certification of Complete EHRs and/or EHR Modules for a minimum of 5 years.

#### e. NVLAP-Accredited Testing Laboratory

In the Proposed Rule, we proposed to separate the responsibilities for testing and certification in the permanent certification program. We proposed that the National Coordinator's authorization granted to ONC-ACBs under the permanent certification program would not extend to the testing of Complete EHRs or EHR Modules. Instead, we proposed that the National Voluntary Laboratory Accreditation Program (NVLAP), as administered by NIST, would be responsible for accrediting testing laboratories and determining their competency. In this role, NVLAP would be solely responsible for overseeing accreditation activities related to testing laboratories for purposes of the permanent certification program. We mentioned NVLAP's experience with developing specific laboratory accreditation programs (LAPs) for testing and calibration laboratories in response to legislative or administrative actions, requests from government agencies or, in special circumstances, from private sector entities. We proposed that the National Coordinator would decide whether to issue a request to NVLAP to develop a LAP for testing laboratories after considering public comments on our proposals for the permanent certification program. To ensure that ONC-ACBs review test results from legitimate and competent testing laboratories, we further proposed in § 170.523(h) to require ONC-ACBs to only certify HIT, including Complete EHRs and/or EHR Modules, that has been tested by a NVLAP-accredited testing laboratory.

We received a number of comments on these proposals and have divided them into two categories: Separation of testing and certification; and accreditation, test tools and test procedures, and ONC-ACBs' permitted reliance on certain test results.

#### i. Separation of Testing and Certification

*Comments.* Commenters expressed general support for our proposal to establish a permanent certification program that includes the use of independent, accredited testing laboratories. Commenters stated that the separation of the testing and certification processes will provide more transparency and result in a more rigorous permanent certification program. Conversely, a few commenters

were not certain that separation or an accredited testing process were even necessary. One of these commenters was concerned that separation would lead to increased costs, particularly for self-developers that will require on-site testing and certification. Another commenter was concerned that separation, if not managed properly, could unintentionally result in confusion and delay the certification of HIT products. Although a commenter assumed that HIT products will be tested before they are certified, the commenter noted that we did not clearly delineate the order of testing and certification in the Proposed Rule.

*Response.* We appreciate the comments of support for our proposal to separate the testing process from the certification process in the permanent certification program. We believe that the separation of testing laboratories and certification bodies is appropriate because it will result in a more transparent and demanding permanent certification program, as the commenters noted. We also believe these program qualities will be enhanced by the use of specialized accreditation organizations from the private sector to accredit the certification bodies that ultimately will become ONC-ACBs. As discussed in the Proposed Rule, these accreditation organizations will be better equipped than ONC to react effectively and efficiently to changes in the HIT market and rigorously oversee the certification bodies they accredit. Additionally, as noted in the Proposed Rule, we have observed in other industries, such as the manufacturing of water-conserving products, that testing and certification processes are typically handled independently and separately.

We expect that the separation of testing and certification will be managed properly by accredited testing laboratories and ONC-ACBs, respectively, and will not lead to undue delays or confusion. If necessary, we may issue program guidance at some point in the future in order to address questions or confusion about the elements and processes of the permanent certification program as well as the eventual transition from testing and certification under the temporary certification program. As for possible delays, we believe that any customer and/or product could experience delays under a testing and certification program for various reasons, but we do not anticipate any undue delays that would be specifically attributable to the separation of testing and certification under the permanent certification program. We expect that the ONC-ACBs

and accredited testing laboratories, having achieved accreditation, will have the ability to manage requests for certification and testing, respectively, in a timely manner. We also expect that these bodies will be able to answer questions about requests for certification and/or testing, as applicable, and provide other guidance to HIT developers based on the training and instruction they receive from ONC and NVLAP.

We appreciate the commenter's concern about the potential costs of testing and certification. The commenter seems to suggest that the costs associated with the testing and certification of Complete EHRs and EHR Modules will be higher because of the separation of the testing and certification processes, particularly for self-developers. We agree that the costs to Complete EHR and EHR Module developers could potentially increase due to the separation of the testing and certification processes, but we believe that any potential increases will not be prohibitive for developers. Our Regulatory Impact Analysis (RIA) in both the Proposed Rule and this final rule accounts for potential cost increases due to the separation of the testing and certification processes. The RIA states that our estimated costs for the testing and certification of Complete EHRs and EHR Modules under the permanent certification program include the costs of separate testing and certification as well as on-site testing and certification. We have provided a range for the potential costs of testing and certification under the permanent certification program. We did not receive any comments demonstrating that the costs associated with testing and certification will be higher than our estimates in the Proposed Rule because of the separation of the testing and certification processes. In addition, the actual costs of testing and certification may be lower than our estimates due to factors such as competitive pricing and/or lower costs attributable to gap certification. We further discuss the processes and costs associated with gap certification in section *P. Differential or Gap Certification* and in the RIA. Lastly, we note that ONC-ACBs may also become accredited testing laboratories under the permanent certification program, which may result in cost savings for developers that choose to have their Complete EHR and/or EHR Module tested and certified by the same organization.

The commenter correctly assumed that Complete EHRs and EHR Modules must first be tested before they can be certified under the permanent

certification program. As we discussed in the Proposed Rule and this final rule, the concept of "certification" requires an ONC-ACB to analyze the quantitative results of testing and subsequently assess whether a Complete EHR or EHR Module has met all of the applicable certification criteria adopted by the Secretary. The chronological order of testing and certification is also addressed in § 170.523(h), which requires an ONC-ACB to only certify HIT that has been tested in accordance with the provisions of that section. For these reasons, it would be impracticable for a Complete EHR or EHR Module to be certified by an ONC-ACB before it undergoes testing.

#### ii. Accreditation, Test Tools and Test Procedures, and ONC-ACBs' Permitted Reliance on Certain Test Results

*Comments.* Commenters generally requested more information about the accreditation of testing laboratories under the permanent certification program. One commenter asked whether NVLAP will develop a specific field of accreditation for EHR technology and whether it will provide an application for entities interested in becoming an accredited testing laboratory. Another commenter supported our proposal to ask NVLAP to develop a LAP and requested that the LAP be designed specifically for Complete EHR and EHR Module testing. Commenters requested that we provide detailed information explaining how ONC and NIST will coordinate efforts to ensure that the accredited testing laboratories overseen by NVLAP are established within a timeframe that is consistent with ONC's efforts to authorize certification bodies. The commenters also requested information explaining how it will be determined whether testing laboratories have sufficient technical expertise and capacity to support the demand for testing in a timely manner. Many commenters recommended that testing laboratories be required to offer remote and on-site testing. Additionally, a commenter requested guidance as to how an ONC-ACB would know that a testing organization is NVLAP-accredited and suggested listing NVLAP-accredited testing laboratories on ONC's Web site as a reasonable solution.

*Response.* As discussed in the Proposed Rule, section 3001(c)(5) of the PHSA authorizes the National Coordinator, in consultation with the Director of NIST, to establish a program or programs for the voluntary certification of HIT, and such program(s) "shall include, as appropriate, testing of the technology in

accordance with section 13201(b) of the [HITECH] Act." Section 13201(b) of the HITECH Act provides that the Director of NIST, in coordination with the HIT Standards Committee, "shall support the establishment of a conformance testing infrastructure \* \* \*," the development of which "may include a program to accredit independent, non-Federal laboratories to perform testing." Consistent with this statutory authority, we are finalizing our proposal that NVLAP, as administered by NIST, will be responsible for establishing and managing a program for the accreditation of laboratories to perform HIT testing under the permanent certification program.

As noted in the Proposed Rule, we are confident that NVLAP has the necessary scientific staff with specialized technical capabilities to develop an accreditation program for the testing of HIT. NVLAP has been responsible for developing a biometrics LAP for the Department of Homeland Security, a program to accredit laboratories for conducting security evaluations for the National Security Agency, a program to accredit laboratories to test hardware and software for voting systems, as well as many other programs for accrediting testing laboratories in response to Federal agencies' requests. Additionally, NIST scientific staff has exhibited their expertise with HIT by developing the test tools and test procedures for the temporary certification program. Based on our discussions with NIST, these experts will also be involved in developing the LAP for the permanent certification program. Given the demonstrated scope of NVLAP's and NIST's technical expertise, the National Coordinator will request that NVLAP develop a LAP specifically for HIT and the permanent certification program. The National Coordinator anticipates that the LAP will align with the programmatic goals of the permanent certification program, including the program's current focus on EHR technology.

We are currently working closely with NIST to achieve programmatic objectives related to the testing of Complete EHRs and EHR Modules under the temporary certification program. We expect this close relationship and degree of coordination will extend into the permanent certification program as the HIT LAP is developed. To further align our efforts with NIST, we are issuing this final rule a year in advance of the anticipated sunset of the temporary certification program and the start of testing and certification under the permanent certification program. During this period

of time, we expect NVLAP will develop the HIT LAP for the permanent certification program after receiving the National Coordinator's request and will subsequently begin the accreditation of testing laboratories. We also expect to complete the process of approving the ONC-AA during this timeframe, which will enable certification bodies to attempt to become accredited and apply for ONC-ACB status.

We anticipate that NVLAP, based on their aforementioned experience in developing other LAPs, will develop a LAP for the permanent certification program that will ensure accredited testing laboratories have the necessary technical expertise and the capacity to support market demand. We also anticipate that NVLAP will take into account current HIT industry testing practices and market demands, such as the use of remote testing and the need for on-site testing in some instances, when developing the LAP for accrediting testing laboratories. Even if the LAP developed by NVLAP does not expressly address remote and/or on-site testing, we expect accredited testing laboratories would offer such testing options if there was market demand. Lastly, as the commenter recommended, we expect to coordinate efforts with NIST and NVLAP to ensure that the public is made aware of NVLAP-accredited testing laboratories by listing them on our respective Web sites and identifying them through other appropriate means.

*Comments.* Commenters requested more specificity about the development and implementation of test tools, test procedures, and test scripts. Commenters requested clarity as to whether NIST, the accredited testing laboratories, or another entity would be responsible for developing the test tools and test procedures. One commenter stated that if NIST would be responsible, then NIST should provide information on how it will address the testing of open source Complete EHRs and EHR Modules. Some commenters recommended that a collaborative process be used in the development and implementation of test tools and test procedures. A commenter suggested that we create an advisory body for the development of test tools and test procedures, while other commenters suggested that consultations with Standards Development Organizations (SDOs) should be a requirement. One commenter recommended the use of the EHR System Functional Model (EHR-S FM). Alternatively, most commenters simply requested an open, transparent and industry consensus-based approach to developing and implementing test

methods that allows for a user-friendly feedback process. Another commenter requested that we ensure that states be prohibited from requiring separate and additional testing processes.

*Response.* We can assure commenters that, as with the temporary certification program, only test tools and test procedures that have been approved by the National Coordinator can be used to test Complete EHRs, EHR Modules and potentially other types of HIT in order for them to be eligible for certification by an ONC-ACB under the permanent certification program. This requirement is imposed on ONC-ACBs under § 170.523(h). We believe by having the National Coordinator approve test tools and test procedures, we will ensure the best test tools and test procedures are utilized. We also believe the National Coordinator's approval will instill greater certainty and confidence in developers and users of Complete EHRs, EHR Modules and other types of HIT. Lastly, we believe that by having the National Coordinator approve the test tools and test procedures for the permanent certification program, we can provide greater consistency in the testing of Complete EHRs, EHR Modules and potentially other types of HIT.

In the Temporary Certification Program final rule, we adopted a process for approving test tools and test procedures, and we intend to use this same process for the permanent certification program. For the permanent certification program, 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 NVLAP-accredited testing laboratories. 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, EHR Module's, or if applicable, other type of HIT'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 for purposes of the permanent certification program, 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 (*i.e.*, assesses all required capabilities) for NVLAP-accredited testing laboratories to use in testing a Complete EHR's, EHR Module's, or other type of HIT'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 for purposes of the permanent certification program, we will publish a notice of availability in the **Federal Register** and identify the approved test tools and test procedures on the ONC Web site.

Once test tools and test procedures have been approved by the National Coordinator, we expect NVLAP-accredited testing laboratories will have some degree of responsibility and flexibility to configure their own test scripts (*i.e.*, specific scenarios using the approved test tools and test procedures). This could involve, for example, the creation of a testing sequence that a NVLAP-accredited testing laboratory believes is the most efficient way to test a certain suite of capabilities. Of course, this responsibility and flexibility may be constrained by the accreditation requirements applicable to the NVLAP-accredited testing laboratories. Given the level and types of adjustments that have been made by ONC-ATCBs for the temporary certification program, we do not believe that it will be possible for NVLAP-accredited testing laboratories to include significant variations in their test scripts such that a Complete EHR or EHR Module will pass a test administered by one laboratory but fail a test administered by a different laboratory.

Based on our stated approach to the development of test tools and test procedures under the permanent certification program, we do not believe that an advisory board will be necessary for the development of test tools and test procedures. In deciding whether to approve specific test tools and test procedures, the National Coordinator will consider whether public feedback was a part of the process for developing those tools and procedures. Although public feedback could take many different forms, we expect it might potentially include some or all of the methods that were mentioned by the commenters (*e.g.*, transparent processes, collaborative and HIT industry consensus-based approaches, consultations with SDOs, and/or utilization of EHR-S FM). In response to commenters' questions about NIST's

role in the development of test tools and test procedures, we anticipate that many of the test tools and test procedures that were developed by NIST and approved for the temporary certification program will likely be applicable to and may be approved for use in performing testing under the permanent certification program, particularly if the adopted certification criteria have not been revised when testing begins under the permanent certification program. As for the future development of test tools and test procedures, we expect to continue to consult with NIST in the development of test tools and test procedures as needed for the testing of HIT to new and/or revised certification criteria adopted by the Secretary. In addition, as previously discussed, any person or entity may submit test tools and test procedures for the National Coordinator's consideration for use in the permanent certification program. We expect that open source Complete EHRs and EHR Modules will be tested in the same manner as proprietary Complete EHRs and EHR Modules because we intend for them to be certified in the same manner as proprietary Complete EHRs and EHR Modules. Lastly, we are not familiar with State law requirements that may be applicable to testing laboratories and thus are unable to provide a fully informed response to the commenter's suggestion.

**Comments.** Commenters recommended that only one accreditor be permitted to accredit testing laboratories in order to ensure consistency in the accreditation process. Multiple commenters supported the recognition of NVLAP as the accreditor, pointing out that NVLAP is an internationally recognized testing laboratory accreditation program, while other commenters objected to the use of NVLAP as the sole accreditor. The commenters stated that there are at least 4 laboratory accreditation bodies in the United States that are considered equivalent to NVLAP under the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA). The commenters asserted that, as a signatory to the ILAC MRA, NVLAP is obligated to promote the acceptance of other signatories' accreditations as being equivalent to their own. Further, the commenters recommended that the current proposal for ONC-ACBs to certify only HIT that has been tested by a NVLAP-accredited testing laboratory should be rescinded and replaced with a principle of proper conduct that allows ONC-ACBs to certify HIT that has been tested by any

ILAC MRA signatory. Possibly as an alternative approach, one of these commenters suggested that NVLAP could validate and acknowledge the other accreditations by ILAC MRA signatories and thereby authorize those accredited testing laboratories to conduct the testing of Complete EHRs and/or EHR Modules under the permanent certification program. The commenter asserted that such an approach would be consistent with the ILAC MRA.

**Response.** We strongly believe, as supported by the commenters, that consistency in accreditation will be an important element of the permanent certification program. We have already demonstrated our commitment to such consistency by concluding that there should be only one ONC-AA at a time. Similarly, we believe that there should be only one accreditor for testing laboratories under the permanent certification program. We believe NVLAP is the best qualified accreditation organization to fill the role of the sole accreditor for testing laboratories based on the reasons we articulated above in support of our decision to ask NVLAP to develop a HIT LAP for the permanent certification program.

We disagree with the commenters' suggestion that ONC-ACBs should be allowed to rely on testing results from laboratories that have been accredited by any signatory to the ILAC MRA. Although commenters stated that other accreditation bodies are considered to be equivalent to NVLAP based on the ILAC MRA, we are unable to independently verify this assertion and thus cannot rely on it for purposes of assessing the competence of other accreditation bodies. More importantly, as previously discussed, the use of multiple accreditation bodies may undermine our programmatic goal of ensuring consistency in accreditation. Further, considering that the National Coordinator intends to ask NVLAP to develop a HIT LAP, requiring ONC-ACBs to use test results from NVLAP-accredited testing laboratories will ensure accreditation is performed according to a LAP that the National Coordinator believes is appropriate for the permanent certification program. As for the commenter's suggestion that NVLAP could validate and acknowledge the accreditations of testing laboratories by ILAC MRA signatories, we believe such a decision would be within the purview of NVLAP. Under § 170.523(h), ONC-ACBs are only permitted to certify HIT that was tested by a NVLAP-accredited testing laboratory or, in certain circumstances, by an ONC-

ATCB. For purposes of that section, a testing laboratory must be accredited by NVLAP in accordance with the HIT LAP that the National Coordinator will ask NVLAP to develop. NVLAP could decide to pursue the approach of validating or acknowledging the testing laboratory accreditations of ILAC MRA signatories. In order for an ONC-ACB to certify HIT that was tested by one of those testing laboratories, however, the testing laboratory must also receive a separate accreditation from NVLAP.

Consistent with this discussion, we are revising § 170.523(h) to state that an ONC-ACB may only certify HIT, including Complete EHRs and/or EHR Modules, that has been tested by a NVLAP-accredited testing laboratory using test tools and test procedures that have been approved by the National Coordinator. We are also revising § 170.523(h) to allow ONC-ACBs, under certain circumstances, to rely on testing that has been performed by ONC-ATCBs, which must also have been done using test tools and test procedures that have been approved by the National Coordinator. The circumstances when an ONC-ACB may rely on testing performed by an ONC-ATCB are more fully discussed under sections *O. Validity of Complete EHR and EHR Module Certification and Expiration of Certified Status* and *P. Differential or Gap Certification* of this preamble.

#### **f. Surveillance**

We proposed that ONC-ACBs would be required to conduct surveillance of Complete EHRs and/or EHR Modules that they had previously certified. As part of its surveillance efforts, we proposed in § 170.523(i) to require an ONC-ACB to submit an annual surveillance plan to the National Coordinator and annually report to the National Coordinator its surveillance results. Noting that ONC-ACBs will be accredited to the requirements of Guide 65 at a minimum, we stated that we expect ONC-ACBs to perform surveillance in accordance with Guide 65 at a minimum, which in section 13 provides that the "certification body [or 'ONC-ACB'] shall periodically evaluate the marked [or 'certified'] products to confirm that they continue to conform to the [adopted] standards." We further clarified that this would require ONC-ACBs to evaluate and reevaluate previously certified Complete EHRs and/or EHR Modules to determine whether the Complete EHRs and/or EHR Modules they had certified in a controlled environment also performed in an acceptable, if not the same, manner in the field.

We proposed that the ONC-AA must have processes in place to ensure that the certification bodies it accredits properly conduct surveillance. In this regard, we stated that ONC-ACBs should be given the flexibility to conduct surveillance in accordance with their accreditation. We acknowledged that the HIT industry could potentially benefit from the development of common elements of surveillance and requested comments on what those elements should include as well as specific approaches to surveillance that have been successful in other industries and should be replicated for HIT. We indicated that we expected to issue annual guidance for ONC-ACBs identifying ONC's priorities regarding certain elements of surveillance that could be considered for inclusion in their surveillance plans.

We noted that we expected to use the results of ONC-ACB surveillance as feedback on the operations of the permanent certification program and to make information publicly available regarding the implementation and performance of Complete EHRs and EHR Modules in the field. We further noted that surveillance results could also be used by prospective purchasers of Complete EHRs and/or EHR Modules as a tool for evaluating specific products. We emphasized that surveillance results obtained by ONC-ACBs and reported to the National Coordinator would not immediately affect a Complete EHR or EHR Module's certification. We stated that, if after an ONC-ACB reevaluated a Complete EHR it had previously certified and reported that the Complete EHR no longer met a certification criterion or criteria because, for example, an individual had taken actions to alter a capability provided by the Complete EHR such that it no longer performed according to its original design or improperly installed the Complete EHR, such a result would not automatically invalidate the Complete EHR's certification. We also stated that we would expect ONC-ACBs upon the identification of a pattern of poorly performing previously certified Complete EHRs and/or EHR Modules to determine whether they had properly certified the Complete EHR or EHR Module in the past. Further, we requested public comment on whether the National Coordinator should consider taking proactive steps to protect purchasers of Complete EHRs and/or EHRs Modules through actions such as "de-certifying" Complete EHRs and/or EHR Modules if a pattern of unsatisfactory surveillance results

emerges and the ONC-ACB has not taken any measures to evaluate the poor performance.

*Comments.* We received many comments related to surveillance with commenters supporting the concept of surveillance as well as offering recommendations for the focus/elements of surveillance plans. An overarching theme expressed in the comments was that surveillance conducted by ONC-ACBs under the permanent certification program should have uniform and consistent elements. Commenters expressed various opinions about the focus/elements of surveillance plans. One commenter noted that Guide 65, Section 13 does not specifically identify post-market surveillance of products that are being used by purchasers. This commenter also mentioned that Guide 65 is currently under review by ISO and requested clarification as to how the National Coordinator would address any changes to Guide 65. Another commenter expressed a concern that the term "surveillance" might be associated with FDA post-market activities of drugs and devices, which would suggest that surveillance involves the reporting of only adverse events. Therefore, the commenter suggested using the term "monitoring" to describe the surveillance process because the commenter asserted that "monitoring" better conveys the process of assessing the performance, and encouraging the adoption of, Certified EHR Technology. A commenter expressed concerns about surveillance from a practical perspective and gave the example that the surveillance of MRI or CT devices for radiation doses is of a different scope than overseeing the functionality of Certified EHR Technology. The commenter further asserted that, for clinical systems, it will be important that any type of surveillance activity to measure system safety not become overly prescriptive or stringent. Another commenter requested clarification of whether surveillance would be limited to the certified Complete EHR or EHR Module or extend to include the end user's use of the Complete EHR and EHR Module, including the assembly of certified EHR Modules into Certified EHR Technology.

Multiple commenters asserted that surveillance should focus only on adopted certification criteria and whether certified products meet the criteria in operation. Consistent with this position, commenters suggested that surveillance plans should contain elements such as testing whether certified Complete EHRs and EHR Modules are performing in "live"

environments as certified, ensuring that Complete EHR and EHR developers "label" certified Complete EHRs and EHR Modules according to their certifications, and monitoring that the versions of Complete EHRs and EHR Modules that are being used are certified versions. Some commenters suggested that surveillance could assess patient and/or provider satisfaction. More specifically, commenters suggested that surveillance could attempt to assess eligible professionals' and eligible hospitals' success in achieving meaningful use with the certified Complete EHRs and EHR Modules. However, many commenters recognized that surveillance of concepts such as satisfaction and success would implicate additional variables, such as training and implementation, as well as other factors such as subjective observations.

*Response.* Our proposed approach to surveillance was based on the concept that eligible professionals and eligible hospitals must be able to rely on the certifications that are issued by ONC-ACBs. ONC-ACBs have a responsibility to ensure that the certifications they issue serve as an indication of a Complete EHR and/or EHR Module's capabilities and compliance with the certification criteria adopted by the Secretary. We expect ONC-ACBs, consistent with their accreditation and Guide 65, to conduct surveillance of the Complete EHRs and/or EHR Modules they have previously certified. An ONC-ACB would focus its surveillance activities on whether the Complete EHRs and/or EHR Modules it has certified continue to perform "in the field" or in a "live" environment as they did when they were certified. Many commenters understood this to be the scope of our proposal and agreed with this approach. Other commenters, however, suggested that we consider other aspects of performance that are less directly related to whether a previously certified Complete EHR or EHR Module continues to perform in a manner consistent with its certification (e.g., the assessment of a provider's success in achieving meaningful use). While we appreciate these additional suggestions, we do not believe that they are appropriate to include as requirements for ONC-ACBs in this final rule because they would not accomplish our stated objective for surveillance, namely, to confirm that previously certified Complete EHRs and EHR Modules continue to perform "in the field" or in a "live" environment as they did when they were certified.

We believe the term "surveillance" was readily understood by commenters

and is a more appropriate term to use than “monitoring” as suggested by a commenter. As discussed here and noted in the Proposed Rule, we anticipate surveillance will involve the assessment of whether certified Complete EHRs and EHR Modules are continuing to function as intended when they are in operational settings (*i.e.*, “in the field” or in a “live” environment). We noted in the Proposed Rule that if a certified Complete EHR or EHR Module was not functioning in a manner consistent with its certification, we would expect the ONC-ACB to identify the reason(s) the Complete EHR or EHR Module was not functioning properly. We expect surveillance results will indicate the reason(s) behind a Complete EHR or EHR Module’s failure to function properly, such as an implementation error, a misapplication by a user, or other factors.

To further illustrate our expectations for surveillance, we offer the following examples based on the capabilities included in three certification criteria. When ONC-ACBs perform surveillance, we would expect them to verify that a certified Complete EHR or, if applicable, a certified EHR Module properly performs drug-drug, drug-allergy interaction checks in accordance with § 170.302(a) in an operational setting. This could include, for example, the use of scenarios or test data to determine whether the certified Complete EHR or EHR Module correctly generates automatic notifications of contraindications. If the certified Complete EHR or EHR Module does not correctly generate automatic notifications, we would expect the ONC-ACB to identify the cause of this problem, to the extent that the ONC-ACB is reasonably able to do so. The ONC-ACB might find, for example, that the notifications were turned off by a user or technician, or that the Complete EHR or EHR Module was improperly installed. As a similar example using the capabilities required by §§ 170.304(e)(2) and 170.306(c)(2), a certified Complete EHR or, if applicable, a certified EHR Module must correctly generate (based on the clinical decision support rules it includes) an automatic notification when a scenario or test data would cause such a notification to be triggered. If the certified Complete EHR or EHR Module does not correctly generate an automatic notification, we would expect the ONC-ACB to identify and the surveillance results to reflect the reason(s) why this failed to occur. As a final example, we would expect an ONC-ACB performing surveillance to verify whether a certified Complete EHR

or, if applicable, a certified EHR Module correctly generates patient reminder lists as required by § 170.304(d). If patient reminder lists are not correctly generated in an operational setting, then as with the preceding examples, we would expect the ONC-ACB to determine why the patient reminder lists are not being correctly generated to the extent it is reasonably able to do so. We believe these examples should clarify for commenters the extent to which ONC-ACBs will be expected to assess as part of surveillance an end user’s use of Certified EHR Technology and the “assembly” of Certified EHR Technology.

We appreciate the broad range of responses and opinions from commenters who suggested possible areas or topics that surveillance could address. As we indicated in the Proposed Rule, we anticipate that we will issue guidance on an annual basis in order to identify specific elements of surveillance that we consider to be a priority. For example, the guidance could specify as a priority specific capabilities required by an adopted certification criterion (*e.g.*, electronic prescribing) or categories of capabilities required by adopted certification criteria (*e.g.* “safety-related” capabilities, which could include computerized provider order entry (CPOE); clinical decision support (CDS); drug-drug, drug-allergy interaction checks; electronic prescribing; and other similar capabilities required by adopted certification criteria). The purpose of this guidance will be to assist ONC-ACBs as they develop their annual surveillance plans by providing them with information on topics that could be addressed in those plans. It will also convey information to other industry stakeholders, such as HIT developers and users, regarding ONC’s priorities for surveillance. We presume that this guidance could include topics that would be consistent from year to year, but that it might also include specific focus areas in certain cases, such as when a new certification criterion has been adopted that we believe is important to assess. In developing any future guidance regarding surveillance, we will consider the comments received in the course of this rulemaking, and we expect that the input provided by commenters will prospectively inform our thinking on this topic.

In response to our surveillance proposals, a commenter indicated that Guide 65 does not explicitly call for post-market surveillance. While the words “post-market surveillance” are not expressly included in Guide 65, we interpret Section 13.4 to include this

concept when it states that certification bodies “shall periodically evaluate the marked products to confirm that they continue to conform to the standards.” With respect to the comment regarding potential revisions to Guide 65, if such revisions were to occur and be finalized, the National Coordinator would evaluate the revised version in the context of the permanent certification program and determine what action to take based on that evaluation.

*Comments.* Commenters recommended that surveillance be consistent among ONC-ACBs and be conducted using reliable assessment measures that will produce valid and objective results. To ensure consistency, multiple commenters recommended a centralized approach to surveillance with one commenter recommending that the ONC-AA be responsible for ensuring a consistent approach to surveillance among the ONC-ACBs it accredits. Commenters suggested various methods for conducting surveillance, but generally agreed that the methods should meet scientific and industry best practices regarding sampling, statistical significance, independence and transparency of evaluation. One commenter suggested conducting surveys of Complete EHR and EHR Module purchasers. Another commenter recommended that surveillance be conducted through actual inspection and/or testing, rather than through a passive form of review. Some commenters contended that surveillance must be conducted at more than one individual site to ensure a statistically valid sample. To obtain a valid sample, commenters recommended using a representative sample, such as a percentage of a Complete EHR or EHR Module developer’s customer base or an assessment based on no less than five customer sites. A few commenters suggested that intervals of surveillance be clearly specified.

*Response.* Although we stated in the Proposed Rule that ONC-ACBs should have flexibility in developing their approaches to surveillance, we strongly agree with the commenters that there should be consistency among these surveillance approaches and that surveillance should be conducted through methods that meet scientific and industry best practices regarding sampling, statistical significance, independence and transparency of evaluation. To achieve a necessary degree of consistency, we believe and agree with the commenter who suggested that the ONC-AA should be responsible for ensuring that all of the certification bodies it accredits will use

similar and comparable surveillance approaches. Therefore, we are revising proposed paragraph (b)(2) of § 170.503 to require an accreditation organization that seeks to become the ONC-AA to submit a detailed description of how its accreditation requirements will ensure that the surveillance approaches employed by ONC-ACBs will include the use of consistent, objective, valid, and reliable methods. We are also revising paragraph (e)(2) of § 170.503 to state that an ONC-AA must, in accrediting certification bodies, not only verify conformance to, at minimum, Guide 65, but also ensure that the surveillance approaches across all of the certification bodies that it accredits include the use of consistent, objective, valid, and reliable methods. We believe that these parameters will still provide sufficient flexibility for ONC-ACBs to develop their surveillance plans and conduct surveillance, but also meet our programmatic goals and addresses concerns expressed by commenters, such as ensuring that the sampling mechanisms used by ONC-ACBs are appropriate and that one ONC-ACB will not use appreciably more stringent surveillance methods than another ONC-ACB.

*Comments.* A few commenters recommended that we should conduct and make publicly available a study and/or analysis to evaluate the options for surveillance, provide specific proposals for surveillance based on the results, and obtain feedback from stakeholders through a process of public notice and comment. Similarly, commenters asserted that if the National Coordinator intends to specify the elements of surveillance that will be required as part of ONC-ACBs' surveillance plans, then the public should have an opportunity to comment on the specific elements. A commenter requested that before ONC-ACBs are instructed to conduct surveillance, ONC should provide additional information and an opportunity for the industry to comment on ONC's positions, particularly with respect to various questions raised by the commenter. One commenter suggested that all ONC-ACB surveillance plans should be subject to review and public comment to allow input from technology vendors.

*Response.* We do not believe it is necessary at this time to conduct a study or analysis of potential approaches to surveillance because, as explained above, we have provided an approach to surveillance that we believe is appropriate for the permanent certification program. We did not intend to imply as some commenters may have interpreted that there would be a formal

opportunity for the public to comment on the surveillance plans that will be submitted by ONC-ACBs or ONC's recommendations on specific elements that could be addressed in those plans. In order to apply for ONC-ACB status, a certification body first must develop its surveillance approach in accordance with Guide 65 and then seek accreditation by the ONC-AA. The ONC-AA in turn will subsequently evaluate whether the certification body's proposed approach to surveillance is consistent with Guide 65 in general and more specifically with section 13 that addresses the concept of surveillance. As we explained in the Proposed Rule, Guide 65 constitutes a minimum threshold that certification bodies will need to meet in order to become accredited, and as such, the ONC-AA could specify additional requirements for surveillance as part of its program to accredit certification bodies. With respect to the annual surveillance plans submitted to the National Coordinator, we expect that these plans will be based on and consistent with the requirements of an ONC-ACB's accreditation. As we mentioned in the Proposed Rule and further discussed above, we expect to issue annual guidance to ONC-ACBs to inform their understanding of topics or elements that may be addressed in the surveillance plans. As we develop that guidance, we will take into account the comments discussed above and may seek additional input from the public if necessary, such as through the HIT Policy Committee.

*Comments.* Commenters suggested that surveillance should include the input of eligible professionals and eligible hospitals. These commenters suggested that efficient feedback could be achieved either through a feedback process incorporated into Certified EHR Technology or by requiring a "label" on Complete EHRs and EHR Modules that provides instructions for reporting complaints or concerns. One commenter suggested such a "complaint process" could be patterned after the Council for Affordable Quality Healthcare (CAQH's) Committee on Operating Rules for Information Exchange (CORE) policies and processes for documenting and correcting compliance violations. A commenter also stated that, to ensure objectivity and eliminate bias, Complete EHR and EHR Module developers should be prevented from influencing evaluations.

Commenters suggested that the publication of surveillance results would be a beneficial tool for eligible professionals and eligible hospitals seeking to purchase Certified EHR

Technology in an effort to qualify for incentive payments under the Medicare and Medicaid EHR Incentive Programs. Commenters expressed opinions, however, that Complete EHR and EHR Module developers should have an opportunity to respond to "negative input" before surveillance results are published and that surveillance results should not be used to influence specific purchasing decisions because this might implicate a conflict of interest in the role of an ONC-ACB.

*Response.* In general, eligible professionals and eligible hospitals should have the opportunity to provide feedback through a complaints process established by Complete EHR and EHR Module developers. Guide 65, Section 15 instructs an ONC-ACB to ensure that the developers of the HIT that it certifies have a process in place for receiving and addressing complaints related to certified products. Section 15 also requires that the HIT developers make complaint records available to the ONC-ACB upon request. We anticipate that eligible professionals and eligible hospitals may also have the opportunity to provide feedback about the capabilities of the Complete EHRs and EHR Modules that they possess in those cases where they are contacted by an ONC-ACB to participate in surveillance.

Because an ONC-ACB's accreditation and credibility is at stake with respect to the certifications it issues, we believe it will take the proper steps to prevent EHR technology developers from inappropriately influencing the outcomes of surveillance. However, we also expect that through the procedures developed by ONC-ACBs for performing surveillance, Complete EHR and EHR Module developers will be provided an opportunity to give input to an ONC-ACB, where appropriate, regarding the surveillance results obtained by the ONC-ACB prior to it reporting such results to the National Coordinator. Therefore, we do not expect it will be necessary to provide for any additional opportunity for input from Complete EHR and EHR Module developers after surveillance results have been submitted by an ONC-ACB to the National Coordinator. Lastly, although we indicated in the Proposed Rule that we expected to make the surveillance results that we receive from ONC-ACBs publicly available, we have not yet determined whether or in what form these results will be made available.

*Comments.* We received comments both supporting and opposing the option for the National Coordinator to take proactive steps to protect purchasers of certified technology (for



example, by “decertifying” the technology) if a pattern of unsatisfactory surveillance results emerges and an ONC-ACB has not taken any measures to evaluate the poor performance. Commenters expressed support for the idea of “decertification” if a pattern of unsatisfactory surveillance results emerged because it is important to protect purchasers of Complete EHRs and/or EHRs Modules. Alternatively, a commenter suggested that if the ONC-ACB in question does not take any measures to evaluate the poor performance of a certified Complete EHR or EHR Module, then the National Coordinator should have another ONC-ACB conduct the evaluation or the National Coordinator should conduct the evaluation before proceeding with decertification. Some commenters stated that any form of decertification should be left to the discretion of the ONC-ACBs. Other commenters asked us to explain how a decertification process would be conducted and to provide an opportunity for the public to comment on the process. Multiple commenters recommended that we should consider the impact decertification would have on eligible professionals and eligible hospitals that are using the affected certified Complete EHR or EHR Module to meet the requirements of the Medicare and Medicaid EHR Incentive Programs.

*Response.* We appreciate the thoughtful comments that were submitted on this matter, although we will not use this final rule to establish a process for the decertification of Complete EHRs and/or EHR Modules. After ONC-ACBs begin to conduct surveillance and submit the results to the National Coordinator, we will have an opportunity to assess the results and determine whether ONC-ACBs are taking appropriate action to address any patterns of unsatisfactory results. If we determine that unsatisfactory surveillance results are not being addressed, or if the results indicate certified Complete EHRs or EHR Modules are adversely affecting public health or safety or the programmatic goals of the permanent certification program, we will consider what steps are necessary to respond to the particular situation at issue at that time. In taking any action, commenters can be assured that the National Coordinator will consider the impact on eligible professionals and eligible hospitals who are using certified products to meet the requirements of the Medicare and Medicaid EHR Incentive Programs. We believe the potential consequences of failing to fulfill their responsibilities,

such as facing corrective action under the permanent certification program or losing reputational standing and business in the market, will sufficiently motivate the ONC-AA and the ONC-ACBs to take the necessary actions to ensure surveillance plans are followed and unsatisfactory surveillance results are properly addressed. We also believe that the potential for surveillance results to be made publicly available as we proposed will sufficiently motivate developers of Complete EHRs and/or EHR Modules to improve their products and address any shortcomings identified by the ONC-ACB surveillance process.

#### g. Refunds

We proposed in § 170.523(j) to require an ONC-ACB to promptly refund any and all fees received for certifications that will not be completed.

*Comments.* Commenters requested that we clarify that refunds would only be required where an ONC-ACB's conduct caused the certification to be incomplete as opposed to the failure of a developer of Complete EHRs, EHR Modules and/or other types of HIT to meet certification requirements. One commenter contended that this provision should only apply when an ONC-ACB has its accreditation status revoked. Another commenter suggested that our proposed requirement for ONC-ACBs to return funds should also apply to situations where developers are required to recertify their products because of misconduct by an ONC-ACB.

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

We are revising § 170.523(j) consistent with our discussion above.

#### h. Suggested New Principles of Proper Conduct

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

*Comments.* A commenter recommended that applicants for ONC-ACB status should be required not to have an interest, stake and/or conflict of interest in more than one entity receiving ONC-ACB status nor have any conflict of interest with EHR product companies actively promoting EHR products in the marketplace. Another commenter recommended that we adopt a principle of proper conduct that requires an ONC-ACB to establish, publish and adhere to a non-discriminatory protocol to ensure that requests for certification are processed in a timely manner beginning on the date the ONC-ACB sets for accepting requests for certification. One commenter recommended that all requests for certification be required to be processed within 6 months of receipt by an ONC-ACB.

*Response.* Applicants for ONC-ACB status and ONC-ACBs must be accredited, which requires adherence to the requirements of Guide 65 at a minimum. These requirements explicitly obligate certification bodies to conduct business in an impartial manner. For instance, an applicant for ONC-ACB status and/or an ONC-ACB must have a documented structure which safeguards impartiality, including provisions to ensure the impartiality of the operations of the certification body and that activities of related bodies do not affect the confidentiality, objectivity and impartiality of its certifications. Guide 65 also 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.” We believe these provisions as well as other impartiality provisions contained in Guide 65 will adequately address any potential conflicts of interest, potential discriminatory practices, or other situations that might jeopardize the integrity of the permanent certification program. We will not require requests for certification to be completed within six months as the commenter proposed. A predetermined timeframe is not realistic because the time it takes for a product to be certified will likely vary based on factors such as the current number of ONC-ACBs, the volume of

requests for certification, the type of product that is submitted for certification, and an ONC-ACB's specific business practices.

### 3. Application Submission

We proposed in § 170.525 to allow an applicant for ONC-ACB status to submit its application either electronically via e-mail (or web submission if available), or by regular or express mail at any time during the existence of the permanent certification program. We did not receive any comments on this proposal. We are, however, revising § 170.525 to clarify that an applicant for ONC-ACB status may submit its application at any time after the permanent certification program has been established by this final rule.

### 4. Overall Application Process

We received a few comments regarding the overall application process.

*Comment.* One commenter contended that there is an optimal number of ONC-ACBs that can effectively perform certification in both the near and long term. The commenter reasoned that if there are too few ONC-ACBs, then the ONC-ACBs will be unable to handle the demand for certifications that can be expected at the outset of the permanent certification program. Alternatively, the commenter reasoned that if there are too many ACBs, the demand for their services may not be sufficient for all of them to remain financially viable. The commenter believed the key to the appropriate number of ONC-ACBs is for ONC to determine the ONC-ACBs' ability to handle the needs of the market. Another commenter suggested that the number of ONC-ACBs be limited to 5. The commenter reasoned that there might be variances in certification processes if there are too many ONC-ACBs, while limiting the number of ONC-ACBs to 5 organizations will ensure that an ONC-AA will be able to effectively monitor the ONC-ACBs. One commenter suggested that applicants for ONC-ACB status preferably be not-for-profit organizations.

*Response.* We believe it is appropriate to allow all qualified applicants to apply and obtain ONC-ACB status and that organizations will determine whether pursuing ONC-ACB status can be a successful business venture. We believe that a greater number of successful applicants for ONC-ACB status will benefit the market in terms of increased competition and more options for the certification of Complete EHRs, EHR Modules, and/or other types of HIT. Restricting the number of ONC-ACBs or

imposing arbitrary eligibility requirements on applicants, such as requiring an applicant to be a not-for-profit organization, will only limit these potential benefits. Further, we believe that the requirements of the permanent certification program, including requiring accreditation from a sole ONC-AA and adherence to the Principles of Proper Conduct for ONC-ACBs, will ensure the necessary consistency in certifications granted by ONC-ACBs.

*Comments.* A commenter recommended that we provide for "provisional acceptance" of an organization before requiring an organization to go through full accreditation to become an ONC-ACB. The commenter believed this would lessen the risk for organizations in pursuing ONC-ACB status.

*Response.* Based on the structure of the permanent certification program and the important role played by the ONC-AA, we do not believe that we could properly evaluate the qualifications of an organization until after it had obtained the appropriate accreditation. Therefore, we do not believe we could offer any form of "provisional acceptance" without fundamentally altering the permanent certification program's structure.

### H. ONC-ACB Application Review, Reconsideration, and ONC-ACB Status

In the Proposed Rule, we proposed to review an application for ONC-ACB status and issue a decision within 30 days in most cases. We proposed that if an applicant was issued a denial notice and certain criteria were met, an applicant could seek reconsideration of the denied application. We proposed that if an applicant's application were deemed satisfactory, we would make it publicly known that the applicant had achieved ONC-ACB status and that the ONC-ACB would be able to begin certifying consistent with the authorization granted by the National Coordinator. We further proposed that an ONC-ACB's status would expire two years from the date it was granted unless it was renewed.

#### 1. Application Review

We proposed in § 170.530 that we would review completed applications in the order in which we received them 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. In these cases, before issuing a formal deficiency notice, we proposed that the National Coordinator may request such information from the applicant's authorized representative as an addendum to its application. We further proposed that if the applicant failed to provide such information to the National Coordinator within the timeframe specified, which would not be less than 5 days, the National Coordinator could issue a formal deficiency notice. In other circumstances, the National Coordinator could immediately send a formal deficiency notice if it was determined that significant deficiencies existed which could not be addressed by a clarification or correction of a minor omission.

We proposed that the National Coordinator would identify any deficiencies in an application and provide an applicant with an opportunity to correct any deficiencies by submitting a revised application in response to a deficiency notice. We proposed that an applicant would have 15 days to submit a revised application in response to a deficiency notice and that the National Coordinator would be permitted up to 15 days to review a revised application once it has been received. We further proposed that if the National Coordinator determined that a revised application still contained deficiencies, the applicant would be issued a denial notice indicating that the applicant would no longer be considered for authorization under the permanent certification program.

We proposed that an applicant could request reconsideration of the decision in accordance with § 170.535. We proposed that an application would be deemed satisfactory if it met all of 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-ACB and begin certifying Complete EHRs, EHR Modules and/or other types of HIT consistent with its authorization.

*Comments.* We did not receive any comments specific to § 170.530. We did, however, receive two comments on the temporary certification program application review provisions during the permanent certification program public comment period that are equally applicable to § 170.530. 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 15 days to respond to a formal deficiency notice. The commenter suggested, however, that considering our position that not many organizations will be capable of obtaining authorization under the certification programs, the National Coordinator should have the discretion to grant an extension beyond the 15-day response period upon a showing of good cause by the applicant.

*Response.* Based on the comments received, we believe that certain modifications to the ONC-ACB application review process would be beneficial for ONC-ACB applicants as well as the permanent certification program as a whole. We made similar modifications to the ONC-ATCB application review process in the Temporary Certification Program final rule.

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 § 170.530(b)(1). Although we anticipate that the National Coordinator would likely seek correction of only minor errors or omissions (e.g., missing contact information of an authorized representative as opposed to a more significant deficiency such as not providing sufficient documentation that confirms that the applicant has been accredited by the ONC-AA), these revisions will provide the National Coordinator with more flexibility to allow an applicant to correct an error or omission instead of issuing a deficiency notice to the applicant. This flexibility will be beneficial for applicants and the permanent certification program itself considering the limited opportunities and short timeframes for correcting applications. Similarly, we believe that the application review process would be improved if the National Coordinator could also request the clarification of statements and the correction of errors or omissions in a revised application. This change will make the application review process more collaborative as suggested by the commenter. Therefore, we are also revising § 170.530 to allow the National Coordinator to request

clarification of statements and the correction of errors or omissions during the 15-day period provided for review of a revised application.

We are making additional revisions to § 170.530 in response to the commenter's recommendation 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 § 170.530 to allow an applicant for ONC-ACB status to request an extension of the 15-day period for submitting 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 period of time for a good cause extension. Instead, the duration of an extension will be determined based on an applicant's particular circumstances that constitute good cause for the extension. For example, if an applicant is accredited but fails to submit sufficient documentation of its accreditation, a good cause extension could be granted for a period of time that would allow the applicant to obtain and submit the appropriate documentation.

We proposed in § 170.530(c)(4) that 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 permanent certification program. We believe this section should be modified in order to allow unsuccessful applicants to reapply for ONC-ACB status after a period of time has passed. Although we proposed in § 170.535 that applicants could submit a request for the National Coordinator to reconsider a denial notice, this reconsideration process is only applicable to an application that is the subject of a denial

notice and only in limited circumstances. We believe revisions to § 170.530(c)(4) are necessary because, as discussed below, it could significantly compromise the quality of the permanent certification program if qualified applicants are unable to reapply for ONC-ACB status because they were previously issued a denial notice. Consequently, we are revising this section to state that a denial notice will indicate that the applicant cannot reapply for ONC-ACB status for a period of six months from the date of the denial notice.

As proposed, § 170.530(c)(4) would prevent applicants from reapplying and being considered for ONC-ACB status if they have been issued a denial notice for the permanent certification program. Once a denial notice has been issued, the unsuccessful applicant would be permanently barred from submitting any subsequent applications for ONC-ACB status. We believe that a permanent bar on reapplying for ONC-ACB status could potentially have detrimental effects on the permanent certification program. Unlike the temporary certification program, the permanent certification program has no anticipated sunset date and is expected to continue indefinitely. We believe an applicant for ONC-ACB status that receives a denial notice should be given an opportunity to correct the deficiency or deficiencies on which the denial notice was based. For example, an applicant that is otherwise qualified to serve as an ONC-ACB could be issued a denial notice if its accreditation is suspended or revoked while its ONC-ACB application is under review. The application review process finalized in this rule is intended to provide applicants with multiple opportunities to correct problems with their applications. We recognize, however, that an applicant may need more time to have its accreditation reinstated than would be possible within the timeframe for application review, even if the applicant could show good cause for an extension. We believe it would be unfair and contrary to the program's best interests not to allow such an applicant to reapply for ONC-ACB status. As another example, an otherwise qualified applicant may be barred from reapplying if it receives a denial notice because it unintentionally missed an established deadline for responding to a deficiency notice and did not request a good cause extension for submitting a revised application. As previously noted, we expect that only a limited number of organizations will possess the requisite qualifications that would enable them to become ONC-

ACBs. Permanently barring qualified applicants from reapplying solely because they had been issued a denial notice would unnecessarily restrict the limited supply of organizations that are qualified to serve as ONC-ACBs. We believe such a restriction would not be in the best interest of the permanent certification program and would undermine our objective to encourage a competitive market for the certification of HIT. Moreover, an applicant that is denied authorization to certify Complete EHRs and/or EHR Modules may still be qualified to certify other types of HIT. We believe such organizations should be given a chance to apply for ONC-ACB status in the event that other types of HIT are included in the permanent certification program after the Secretary adopts applicable certification criteria.

We believe that 6 months is a reasonable period of time for an applicant to wait before it may reapply. By way of comparison, an organization that has had its ONC-ACB status revoked for a Type-1 violation must wait 1 year in accordance with § 170.565(h)(3) before it may reapply for ONC-ACB status. It would be inequitable as well as inconsistent with our program goals to permanently bar an organization from reapplying because it received a denial notice, while allowing an organization that had its ONC-ACB status revoked to reapply after a year. In light of the fact that Type-1 violations include violations of law or permanent certification program policies that threaten or significantly undermine the integrity of the permanent certification program, we believe that an organization's inability to meet the application requirements of § 170.520 deserves a far lesser consequence than a permanent bar on reapplying for ONC-ACB status. We believe that a 6-month waiting period will in many cases provide sufficient time for an applicant to evaluate and correct the deficiencies with its application (assuming the deficiencies are capable of correction) and will deter unqualified applicants from repeatedly applying. Accordingly, we are revising paragraph (c)(4) of § 170.530 consistent with the preceding discussion.

We proposed an identical provision in § 170.430(c)(4) for the temporary certification program, which we finalized in the Temporary Certification Program final rule. Under that provision, an applicant that is issued a denial notice cannot reapply and be considered for ONC-ATCB status, which we believe is appropriate for the temporary certification program. We anticipate that the temporary certification program will only remain

in existence for a short period of time and expect that it will sunset on December 31, 2011. We expect that a vast majority of certifications will be conducted early in the temporary certification program based on the associated meaningful use requirements and reporting periods of the Medicare and Medicaid EHR Incentive Programs. Further, any applicant that is permanently barred from reapplying for ONC-ATCB status will still be able to apply for ONC-ACB status under the permanent certification program. Therefore, due to the short duration of the temporary certification program and the fact that an unsuccessful applicant for ONC-ATCB status may apply for ONC-ACB status under the permanent certification program, the consequences of a permanent bar on reapplication are not nearly as severe as they would have been under the permanent certification program had we not revised our proposal.

We state in § 170.530(d) that the National Coordinator will notify the applicant's authorized representative of its satisfactory application and its successful achievement of ONC-ACB status and that once notified, the applicant may represent itself as an ONC-ACB and begin certifying HIT consistent with its authorization. We believe it is important to clarify that there is a distinction between the point at which an organization is notified that it has been granted ONC-ACB status and the point when it may begin to perform certifications consistent with the authorization that it has been granted. To illustrate this distinction with an example, an applicant may be notified in October 2011 that it has been granted ONC-ACB status, although the permanent certification program is not scheduled to begin until at least January 1, 2012. After receiving notice, the ONC-ACB may begin to represent and market itself as ONC-ACB and participate in mandatory ONC training for ONC-ACBs, but its authorization to perform certifications would not become effective until the commencement of the permanent certification program on January 1, 2012 or on a subsequent date when the National Coordinator determines that the permanent certification program is fully constituted. At that time, the ONC-ACB may begin to certify the type(s) of HIT that fall within the scope of its authorization. Similarly, after the ONC-ACB has participated in the permanent certification program for a period of time, it may choose to submit a request to the National Coordinator to expand the current scope of its

authorization (for example, to include other types of EHR Modules or Complete EHRs). If the National Coordinator grants its request based on the information it submits and the completion of any applicable mandatory ONC training, then the ONC-ACB's authorization would be expanded effective as of the date specified by the National Coordinator. In both cases (the initial granting of ONC-ACB status and the subsequent expansion of the ONC-ACB's authorization), the National Coordinator would make publicly available the date of the ONC-ACB's authorization and the type(s) of certification included within its authorization, pursuant to § 170.540(a).

## 2. Application Reconsideration

We proposed in § 170.535 that an applicant after receiving a denial notice may request that the National Coordinator reconsider the denied application only if the applicant can demonstrate that clear, factual errors were made in the review of the application and that their correction could lead to the applicant obtaining ONC-ACB status. We proposed that an applicant would be 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 request for ONC-ACB status and explaining with sufficient documentation what factual errors it believes can account for the denial. We proposed that if the National Coordinator did not receive the applicant's submission within the specified timeframe that its request could be rejected. We proposed that the National Coordinator would have up to 15 days to consider and issue a decision on 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.

*Comments.* A commenter expressed agreement with our proposed ONC-ACB application reconsideration process. Another commenter stated, however, that the National Coordinator should have discretion to reconsider an application for reasons besides clear factual errors that could lead to the applicant receiving ONC-ACB status. The commenter suggested that the National Coordinator should consider

several factors in determining whether to reconsider an application, 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.

*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 applications for any reason. Rather, as we determined for the temporary certification program in the Temporary Certification Program final rule, we believe that the National Coordinator should only reconsider an application if the applicant for ONC-ACB status can demonstrate that there were clear factual errors in the review of its application that could lead to the applicant obtaining ONC-ACB 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-ACBs. The application requirements proposed, particularly the requirement that an applicant be accredited by an ONC-AA, are designed to ensure that applicants are qualified. Our review process is designed to ensure the veracity of an application and to confirm that an applicant has the necessary capabilities to be authorized to conduct the certification sought by the applicant. Our review process is also designed to reach final decisions in a timely manner. Overall, we believe the application review process is efficient yet fair by providing opportunities 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 are clear, factual errors that, if corrected, could lead to the applicant obtaining ONC-ACB status. We also note that if an applicant is unable to demonstrate that clear, factual errors were made in the review of its application, it still would have the ability to reapply for ONC-ACB status after waiting a period of six months. Accordingly, we are finalizing § 170.535 without modification.

### 3. ONC-ACB Status

We proposed in § 170.540 that the National Coordinator will acknowledge and make publicly available the names of ONC-ACBs, including the date each was authorized and the type(s) of certification each has been authorized to perform. We proposed that each ONC-

ACB would be required to prominently and unambiguously identify on its Web site and in all marketing and communications statements (written and oral) the scope of its authorization. We also proposed that an ONC-ACB's status would expire two years from the date it was granted by the National Coordinator unless it was renewed. To renew its status, we proposed that an ONC-ACB submit a renewal request (*i.e.*, an updated application) to the National Coordinator 60 days prior to the expiration of its status.

In association with these proposals, we specifically requested that the public comment on whether there was any additional information an ONC-ACB should provide the National Coordinator in order to have its status renewed, such as documentation of the ONC-ACB's current accreditation status and any additional information or updates to the original application that would aid in the National Coordinator's review of the renewal request.

*Comments.* A commenter expressed an opinion that it is important to the industry that the National Coordinator makes distinctions as to what a certifying body is authorized to certify. One commenter recommended that our requirements related to marketing and communications be limited to the ONC-ACB's Web site and all marketing and communications pertaining to its role in the certification of Complete EHRs, EHR Modules and/or other types of HIT under the permanent certification program. 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-ACB status.

Commenters expressed agreement with having an ONC-ACB's status expire after two years, while others suggested 3-year and 4-year terms. The commenters requesting longer terms stated that a longer term would promote more stability and lessen overhead costs for ONC-ACBs. A commenter that suggested a 3-year term reasoned that a 3-year term could run concurrent with the ONC-AA's term. The commenter also requested that in cases where the ONC-AA has its status revoked or not renewed, ONC-ACBs should be allowed to retain their status with ONC until at least 12 months after a new ONC-AA has been appointed by ONC. The commenter reasoned that this would allow time for "reaccreditation" by the approved accreditation organization.

In terms of what information we should consider for the renewal of an ONC-ACB's status, commenters generally agreed that an ONC-ACB

should provide updated accreditation information and demonstrate compliance with the Principles of Proper Conduct for ONC-ACBs. Commenters also suggested that ONC request and consider Complete EHR and EHR Module developers' evaluations of ONC-ACBs' performance, documentation regarding the handling of customer complaints by ONC-ACBs, the percentage of certifications in relation to requests for certification, the total number of previous certifications granted, the number of certifications granted after two or more attempts, and surveillance results.

*Response.* We appreciate the support for our proposals and reiterate that, as proposed, an ONC-ACB will only be able to certify Complete EHRs, EHR Modules and/or other types of HIT consistent with the scope of authorization granted by the National Coordinator. Additionally, as proposed, the ONC-ACB 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-ACB "identify on its Web site 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-ACB under the permanent certification program. Specifically, we have revised the provision to state, in relevant part, "each ONC-ACB must prominently and unambiguously identify the scope of its authorization on its Web site, and in all marketing and communications statements (written and oral) pertaining to its activities under the permanent certification program."

We believe, after consideration of public comments, that an ONC-ACB should be allowed to maintain its status for three years, instead of the proposed two years, from the date it is granted before being required to renew its status. Considering that an applicant could obtain ONC-ACB status at any time during the permanent certification program, it would be impossible to align the tenure of the ONC-AA with that of the ONC-ACBs. However, a three-year term for ONC-ACBs will offer additional stability for those HIT developers seeking certification under the permanent certification program as well as for ONC-ACBs. It will also lessen the reapplication burden for ONC-ACBs. We anticipate by beginning the process to approve an ONC-AA at least 180 days prior to the end of the then-current ONC-AA's term, there will

be minimal disruption in the accreditation processes if we were to select a different ONC-AA. As previously noted in this final rule, we intend to issue an NPRM that will address improper conduct by an ONC-AA and propose a corrective action process. At that time, we will consider the implications for ONC-ACBs if an ONC-AA's status is revoked or other corrective action is taken.

We do not believe that there is a need to require an ONC-ACB to provide any of the information suggested by the commenters for ONC to consider in determining whether to renew an ONC-ACB's status. The Principles of Proper Conduct for ONC-ACBs require an ONC-ACB to submit a weekly list of certified Complete EHRs, EHR Modules, and/or other types of HIT, attend mandatory training, and submit an annual surveillance plan and annually report surveillance results.

Accreditation requires an ONC-ACB to be compliant with Guide 65 at a minimum, which requires an ONC-ACB to have a complaints process that includes documentation of the resolution of complaints. Accreditation also involves a regular review of an ONC-ACB's processes and performance. Consequently, we believe that by maintaining its accreditation and adhering to the Principles of Proper Conduct for ONC-ACBs, an ONC-ACB will be more than adequately situated to pursue renewal.

To renew its status, an ONC-ACB must submit to the National Coordinator the information specified in § 170.520(a) and (c) that would otherwise be required to apply for ONC-ACB status and, if applicable, include any requests to expand the current scope of its authorization. We expect that an ONC-ACB will be providing updates to the information specified in § 170.520(b) as part of its compliance with the Principles of Proper Conduct for ONC-ACBs. Therefore, we do not expect an ONC-ACB to submit its "general identifying information" unless the information that is on record with ONC is outdated or otherwise incorrect. Lastly, we do not believe it will be necessary for an ONC-ACB to execute and submit a new agreement to adhere to the Principles of Proper Conduct for ONC-ACBs because the initial agreement that was executed when the organization obtained ONC-ACB status will remain valid as long as the organization maintains its ONC-ACB status.

We are revising § 170.540 consistent with this discussion, including clarifying the representation requirements of ONC-ACBs, extending

the term of ONC-ACB status to 3 years and clarifying that a renewal request must include any updates to the information specified in § 170.520.

### **I. Certification of Complete EHRs, EHR Modules and Other Types of HIT**

In the Proposed Rule, we described the scope of authority that would be granted to certification bodies that become ONC-ACBs. We also specified which certification criterion or criteria ONC-ACBs would be required to use to certify Complete EHRs, EHR Modules and/or other types of HIT. As discussed below, the comments we received on these proposed provisions were in many cases also applicable to analogous provisions of the temporary certification program. As a result of the similarities that exist between the temporary and permanent certification programs, our responses to the comments below are often similar or identical to responses we provided in the Temporary Certification Program final rule.

#### **1. Complete EHRs**

We proposed in § 170.545 that to be authorized to certify Complete EHRs under the permanent certification program, an ONC-ACB would need to be capable of certifying Complete EHRs to all applicable certification criteria adopted by the Secretary at subpart C of part 170. We further proposed that an ONC-ACB that had been authorized to certify Complete EHRs would also be authorized to certify all EHR Modules under the permanent certification program.

*Comments.* Commenters expressed agreement with our proposals that, in order to be authorized to certify Complete EHRs under the permanent certification program, an ONC-ACB must be capable of certifying Complete EHRs to all applicable certification criteria and that such an ONC-ACB would also be authorized to certify all EHR Modules under the permanent certification program. One commenter recommended that we *require* ONC-ACBs authorized to certify Complete EHRs to also 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-ACB that is authorized to certify Complete EHRs to also certify EHR Modules. We clearly acknowledged in the preamble of the Proposed Rule and in our proposed regulatory provision that an ONC-ACB authorized to certify Complete EHRs would also have the capability and, more importantly, the authorization from the National Coordinator to certify EHR

Modules. We do not, however, believe that we should require an ONC-ACB that is authorized to certify Complete EHRs to also certify EHR Modules. An ONC-ACB, despite its authorization to do so, might have multiple business justifications for choosing not to certify EHR Modules, such as an insufficient number of qualified employees to conduct the certification of EHR Modules in addition to conducting 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 § 170.545(a) to state that "When certifying Complete EHRs, an ONC-ACB must certify Complete EHRs in accordance with all applicable certification criteria adopted by the Secretary at subpart C of this part." This revision is consistent with our description of certification of Complete EHRs in the Proposed Rule preamble, as well as the approach we finalized for the temporary certification program. It also makes explicit that ONC-ACBs must not only be capable, but as with EHR Modules, are required to certify Complete EHRs to all of the applicable certification criteria adopted by the Secretary under subpart C of part 170. We are also redesignating proposed paragraph (b) as paragraph (e) because of additional revisions we are making to § 170.545. These revisions are discussed in sections *F. Certification Options for ONC-ACBs*, *O. Validity of Complete EHR and EHR Module Certification and Expiration of Certified Status* and *P. Differential or Gap Certification* of this preamble.

#### **2. EHR Modules**

##### **a. Applicable Certification Criterion or Criteria**

We proposed in § 170.550(a) and (b) that an ONC-ACB must 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 "(f)" (the first paragraph level) identifies that this certification criterion relates to recording and charting vital signs. It includes three specific capabilities at (f)(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 “(f)” (namely, (f)(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 certification at a lower level (subparagraph) would result in a very large number of EHR 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 criteria within a single objective. In that case, the commenter asserted that the EHR 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 an EHR Module to perform all of the listed functions or capabilities associated with a specific certification criterion would create a problem. In particular, the commenter stated that for the “drug-drug, drug-allergy, drug-formulary checks” certification criterion specified in the HIT Standards and Certification Criteria interim final rule, 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. Therefore, the commenter recommended that we narrow the scope of EHR Module certification to one of the capabilities or functions (subparagraphs) of a criterion. The commenter stated that this solution would necessitate that the ONC–ACB provide EHR Modules that only perform such discrete functions with a “conditional certification” that carries the caveat that the EHR Module must be used in conjunction with other certified EHR 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 certified to the first paragraph level of a certification criterion, as described in our example

above. We believe that this is the most appropriate level for 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 addressed the concern expressed by the other commenter about the “drug-drug, drug-allergy, drug-formulary checks” certification criterion by adopting separate certification criteria in the HIT Standards and Certification Criteria final rule.

We are modifying § 170.550 to remove proposed paragraph (b) because it is repetitive of the requirements set forth in paragraph (a). We made a similar modification to § 170.450 in the Temporary Certification Program final rule.

#### **b. Privacy and Security Certification**

With respect to EHR Modules, we discussed in the Proposed Rule when ONC–ACBs would be required to certify EHR Modules to the privacy and security certification criteria adopted by the Secretary. We proposed in § 170.550(c) that EHR Modules must be certified to all privacy and security certification criteria adopted by the Secretary unless the EHR Module(s) is/are presented for certification in one of the following manners:

- The EHR Module(s) are presented for 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 certified in the same manner as a Complete EHR. Pre-coordinated, integrated 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 a pre-coordinated, integrated bundle must be separately certified to all privacy and security certification criteria;
- An EHR Module is presented for certification, and the presenter can demonstrate to the ONC–ACB that it would be technically infeasible for the EHR Module to be certified in accordance with some or all of the privacy and security certification criteria; or
- An EHR Module is presented for certification, and the presenter can demonstrate to the ONC–ACB that the EHR Module is designed to perform a specific privacy and security capability. In such instances, the EHR Module may only be 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 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 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.

One commenter noted that, under the permanent certification program, an EHR Module developer would first be required to demonstrate to a testing laboratory that it is technically infeasible to certify an EHR Module to a particular privacy and security certification criterion, which would require the testing laboratory to make an independent subjective decision on technical feasibility. The commenter recommended that ONC and/or NIST develop an “applicability matrix” to reduce subjectivity and ensure consistent determinations among testing laboratories and ONC–ACBs related to the applicability of privacy and security certification criteria to EHR Modules. Another commenter expressed an understanding of our privacy and security certification approach to EHR Modules, but cautioned that to ensure the privacy and security of an EHR system in its entirety, that the entire combination needs to be tested for privacy and security due to variances that can occur in how EHR Modules perform once they are “linked.” The commenter suggested that an EHR Module developer should be required to

explain how the EHR Module will be “securely” assembled.

*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 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 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 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 and as we concluded in the Temporary Certification Program final rule, we believe that the proposed standard of “technically infeasible” is more appropriate than the HIPAA Security Rule’s “addressable” concept for the purposes of 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.

In response to the comment regarding the assessment of privacy and security certification criteria by testing labs, we anticipate that an EHR Module developer would request a testing lab to only test the privacy and security certification criteria to which the EHR Module developer believes are appropriate for its EHR Module. In other words, a testing lab would test what is requested by an EHR Module developer and not be responsible for determining whether other privacy and security certification criteria (not requested for testing) may in fact be applicable or technically feasible for the EHR Module developer to implement. This responsibility would be an ONC-ACB’s and, for the purposes of certification, we require that an individual or entity that presents an EHR Module for certification must provide sufficient documentation to the ONC-ACB to support its assertion 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-ACB shall independently assess and make a reasonable determination as to whether the EHR Module should be exempt from having to satisfy particular privacy or security certification criteria. As a result, there could be situations where despite an EHR Module developer’s belief that a privacy and security certification criterion is inapplicable or technically infeasible an ONC-ACB makes a determination to the contrary. We believe that these instances would be the exception and not the rule but, nonetheless, we encourage EHR Module developers to carefully consider those privacy and security certification criteria they believe are inapplicable or technically infeasible prior to seeking testing. Finally, we recognize that this approach provides a certain amount of

discretion among the ONC-ACBs, but we believe that any inconsistent application that emerges could be mitigated by guidance from the National Coordinator.

A commenter expressed a concern about the overall privacy and security of a combination of EHR Modules. As we stated in the Proposed Rule and the HIT Standards and Certification Criteria interim final rule, it is incumbent on the eligible professional or eligible hospital to ensure that a combination of EHR Modules properly work together to meet all of the required capabilities necessary to meet the definition of Certified EHR Technology. Thus, the flexibility and customization provided through the use of EHR Modules may also include some additional work on the part of an eligible professional or eligible hospital to ensure that adopted EHR Modules properly work together. Alternatives to this custom approach, as we have discussed, include the adoption of Complete EHRs and pre-coordinated, integrated bundles of EHR Modules.

We also agree with the commenter who stated that we should remove the third exception and simply require all EHR Modules, if not included in a pre-coordinated integrated bundle, to follow the same approach. As a result, and as we did in the context of the temporary certification program, only the first and second exception of proposed § 170.550(c) will be finalized. 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 of 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 omit the general requirement that each individual EHR Module must be certified to all of the adopted privacy and security criteria. We believe it would be pragmatic to eliminate 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-ACB for



certification. In these circumstances, the pre-coordinated, integrated bundle of EHR Modules would otherwise meet the definition of and constitute a Complete EHR. Therefore, consistent with our approach in the Temporary Certification Program final rule, we clarify that in the circumstances where a pre-coordinated, integrated bundle of EHR Modules is presented for 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 certified to the 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 certification as a pre-coordinated, 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 certified to the adopted privacy and security certification criteria.

With respect to the proposed carve out to this exception related to EHR Modules that would "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 a "pre-coordinated, 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 "pre-coordinated, 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. We are redesignating proposed § 170.550(c) as § 170.550(e). The entire provision at § 170.550(e), including the changes from both of our responses above, will read:

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

(1) The EHR Modules are presented for certification as a pre-coordinated, integrated bundle of EHR Modules, which would otherwise meet the definition of and constitute a Complete EHR, and one or more of the constituent EHR Modules is demonstrably responsible for providing all of the privacy and security capabilities for the entire bundle of EHR Modules; or

(2) An EHR Module is presented for certification, and the presenter can demonstrate and provide documentation to the ONC-ACB that a privacy and security certification criterion is inapplicable or that it would be technically infeasible for the EHR Module to be certified in accordance with such certification criterion. We made similar modifications to § 170.450(c) in the Temporary Certification Program final rule.

We would like to clarify a few points related to pre-coordinated, integrated bundles of EHR Modules. First, a pre-coordinated, integrated bundle of EHR Modules will qualify for the exception at § 170.550(e)(1) if, and only if, the bundle would otherwise meet the definition of and constitute a Complete EHR. In other words, the pre-coordinated, integrated bundle of EHR Modules must meet, at a minimum, all of the applicable certification criteria adopted by the Secretary in subpart C of part 170, even though the bundle and its constituent EHR Modules would not have been developed as a Complete EHR. For example, three EHR Modules may be integrated and "bundled" together, but if the bundle does not satisfy all of the applicable certification criteria that have been adopted, it will not qualify for this specific exception. In those cases, we would view such a bundle as an EHR Module that provides multiple capabilities. Second, because a pre-coordinated, integrated bundle of

EHR Modules would otherwise meet the definition of and constitute a Complete EHR, we expect to list it as a "Complete EHR" and not an "EHR Module" on the CHPL, but would provide a designation noting that it is a pre-coordinated, integrated bundle of EHR Modules. Based on experience, we may determine that a more effective method for listing pre-coordinated, integrated bundles of EHR Modules on the CHPL would be appropriate and will periodically evaluate if another method would be beneficial. As previously discussed in this preamble, we expect ONC-ACBs will specifically identify pre-coordinated, integrated bundles of EHR Modules as part of their reporting obligations under § 170.523(f). Finally, in case it is unclear from the context, we clarify that references to EHR Module(s) in other provisions of § 170.550 are intended to include pre-coordinated, integrated bundles 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, as we stated in the Temporary Certification Program final rule, 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 direct another service or function to do it.

#### c. Identification of Certified Status

We proposed in § 170.550(d) to require ONC-ACBs authorized to certify EHR Modules to clearly indicate the certification criterion or criteria to which an EHR Module has been 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-ACBs, 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-ACBs regarding the proper identification of Complete EHRs and EHR Modules, similar to the new Principle of Proper Conduct for ONC-ATCBs we finalized in the Temporary Certification Program final rule. We further discuss the basis for this new Principle of Proper Conduct for ONC-ACBs under the heading titled “O. Validity of Complete EHR and EHR Module Certification and Expiration of Certified Status” later in this preamble. Consistent with this decision, we are modifying § 170.550 to remove proposed 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.

### 3. Other Types of HIT

We proposed in § 170.553 that an ONC-ACB could be authorized to certify HIT, other than Complete EHRs and/or EHR Modules, in accordance with the applicable certification criterion or criteria adopted by the Secretary at subpart C of part 170. In association with this proposed provision, we invited public comment on the need for additional HIT certifications, the types of HIT that would be appropriate for certification, and on any of the potential benefits or challenges associated with certifying other types of HIT.

*Comments.* We received numerous comments on our proposal to utilize the permanent certification program for the certification of other types of HIT, with commenters overwhelmingly in favor of this proposal. Commenters also made suggestions of other types of HIT that could be certified, such as personal health records, health information organizations, pharmacy and laboratory

systems, ancillary clinical systems including radiology information systems, picture archiving and communication systems, cardiology systems, vital signs and point-of-care medical devices, and telehealth and remote patient care solutions. Conversely, a few commenters did not believe that there was a current need for the certification of other types of HIT and suggested that we should first determine whether a private market would develop for the certification of other types of HIT. A few other commenters suggested that the permanent certification program should first focus on the certification of Complete EHRs and EHR Modules and that further certification of other types of HIT should be done with the intent of supporting meaningful use efforts.

*Response.* We appreciate the support for the certification of other types of HIT under the permanent certification program. Consistent with our discussion in the Proposed Rule, we maintain that section 3001(c)(5) of the PHSA provides the National Coordinator with the authority to establish a voluntary certification program or programs for other types of HIT besides Complete EHRs and EHR Modules. We agree with the commenters, however, that the initial focus of the permanent certification program should be on the certification of Complete EHRs and EHR Modules in support of efforts by eligible professionals and eligible hospitals who seek to demonstrate meaningful use under the Medicare and Medicaid EHR Incentive Programs. Moreover, as we stated in the Proposed Rule, the Secretary must first adopt certification criteria applicable to other types of HIT before the National Coordinator could subsequently authorize an ONC-ACB to certify such HIT under the permanent certification program. In the event that the Secretary adopts such applicable certification criteria and future circumstances suggest the need or demand for the certification of other types of HIT, we will further consider the comments received in determining how to proceed, including those comments suggesting specific types of other HIT that would be appropriate for certification. As previously noted in this preamble, if the scope of the permanent certification program is eventually expanded to include other types of HIT, certification would not constitute a replacement or substitution for other Federal requirements that may be applicable to those other types of HIT. Consistent with this discussion, we are finalizing § 170.553 without modification.

### J. 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 to the adopted code set and consequently may be permitted for use in certification. We proposed, as described in § 170.555, that once the Secretary has accepted a new version of an adopted “minimum standard” code set that:

- (1) Any ONC-ACB 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-ACBs 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 Web site, 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. We first note that we inadvertently referenced “testing” in proposed § 170.555. As specified in this final rule, the National Coordinator will authorize ONC-ACBs to perform certifications and not testing under the permanent certification program. Therefore, we are removing references to “testing” in § 170.555. Second, based on the commenters’ feedback, we have decided to adopt both of the proposed approaches for the permanent certification program, as we did for the temporary certification program. 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-ACBs 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 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 commenter 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 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-ACBs, Complete EHR or EHR Module developers, or the eligible professionals and eligible hospitals who have implemented Certified EHR Technology. We provided similar clarification for the temporary certification program in the final rule establishing that program. 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-ACBs to use an accepted newer version of a “minimum standard” code set to 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-ACB 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. Accordingly, except for removing references to “testing,” we are finalizing § 170.555 without modification.

*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, including specifying the timeframes for publication.

*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 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.

#### **K. Authorized Certification Methods**

We proposed in § 170.557 that, as a primary method, an ONC-ACB would be required to be capable of certifying Complete EHRs and/or EHR Modules at its facility. We also proposed that an ONC-ACB would be required to have the capacity to 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-ACB's facility).

*Comments.* We received many comments on our proposal. We received varying recommendations and proposals, but the majority of commenters did not agree with certification at an ONC-ACB'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 certification would not only be burdensome but in many cases impossible. Instead, many commenters recommended that we require ONC-ACBs 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-ACBs to offer remote certification as the primary method because of its efficiency and low cost to Complete EHR and EHR Module developers. Commenters also noted that ONC-ACBs could offer other methods, including performing certification at an ONC-ACB's facility. One commenter recommended that, as the primary method, ONC-ACBs should be required to support 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 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-ACB must have the capacity to provide remote certification for both development and deployment sites. For the purposes of the permanent certification program, a development site is the physical location where a Complete EHR, EHR Module or other type of HIT was developed. For the purposes of the permanent certification program, a deployment site is the physical location where a Complete EHR, EHR Module or other type of HIT resides or is being or has been implemented. As discussed in the Proposed Rule, remote certification would include the use of methods that do not require the ONC-ACB 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 certification, an ONC-ACB may also offer certification at its facility or at the physical location of a development or deployment site, but we are not requiring that an ONC-ACB offer such certification. As indicated by commenters and our own additional research, the market currently utilizes predominantly remote methods for the certification of HIT. On-site certification was cited as costly and inefficient. Therefore, consistent with our requirements of ONC-ATCBs under the temporary certification program, we are not requiring ONC-ACBs to offer such certification, but anticipate that some ONC-ACBs will offer on-site certification if there is a market demand. In response to those commenters who requested clarification regarding "live" certification, we want to make clear that we do not believe that a Complete EHR, EHR Module or other type of HIT must be "live at a customer's site" in order to qualify for certification by an ONC-ACB. As stated above, a Complete EHR, EHR Module or other type of HIT could be certified at the development site of a developer of Complete EHRs, EHR Modules or other types of HIT. Consistent with this discussion, we are revising § 170.557 to require an ONC-

ACB to provide remote certification for both development and deployment sites and have included the definitions of "development site," "deployment site," and "remote certification" in § 170.502.

#### **L. Good Standing as an ONC-ACB, Revocation of ONC-ACB Status, and Effect of Revocation on Certifications Issued by a Former ONC-ACB**

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

##### **1. Good Standing as an ONC-ACB**

We proposed in § 170.560 that, in order to maintain good standing, an ONC-ACB would be required to adhere to the Principles of Proper Conduct for ONC-ACBs; refrain from engaging in other types of inappropriate behavior, including misrepresenting the scope of its authorization or certifying Complete EHRs and/or EHR Modules for which it was not given authorization; and follow all applicable Federal and State laws.

*Comments.* Commenters expressed appreciation for our proposed standards of conduct for ONC-ACBs. One commenter encouraged us to evaluate 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-ACBs are essential to maintaining the integrity of the permanent certification program, as well as ensuring public confidence in the program and the Complete EHRs, EHR Modules, and other types of HIT that may be certified under the program. We intend to monitor compliance with the Principles of Proper Conduct for ONC-ACBs on an ongoing basis by, among other means, ensuring that ONC-ACBs are attending all mandatory ONC training. It is also expected that ONC-ACBs will maintain relevant documentation of their compliance with the Principles of Proper Conduct for ONC-ACBs 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 under § 170.565. At the time of renewal, an ONC-ACB will be assessed based on the updated

application it provides in accordance with § 170.540, which would entail reviewing an ONC-ACB's current accreditation and adherence to the Principles of Proper Conduct. Accordingly, we are finalizing § 170.560 without modification.

## 2. Revocation of ONC-ACB Status

We proposed in § 170.565 that the National Coordinator could revoke an ONC-ACB'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 permanent certification program policies that threaten or significantly undermine the integrity of the permanent certification program. These violations include, but are not limited to: false, fraudulent, or abusive activities that affect the permanent certification program, a program administered by HHS or any program administered by the Federal government.

We defined Type-2 violations as noncompliance with § 170.560, which would include without limitation, failure to adhere to the Principles of Proper Conduct for ONC-ACBs, engaging in other types of inappropriate behavior, or failing to follow other applicable laws. We proposed that if the National Coordinator were to obtain reliable evidence that an ONC-ACB may no longer be in compliance with § 170.560, the National Coordinator would issue a noncompliance notification. We proposed that an ONC-ACB would have 30 days from receipt of a noncompliance notification to submit a written response and accompanying documentation that demonstrates that no violation occurred or that the alleged violation had been corrected. We further proposed that the National Coordinator would have up to 30 days from the time the response is received to evaluate 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-ACB's status if the ONC-ACB committed a Type-1 violation. We proposed that the National Coordinator could propose to revoke an ONC-ACB's status if, after an ONC-ACB has been notified of a Type-2 violation, the ONC-ACB fails 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-ACB did not submit a written response to a Type-2 noncompliance notification within the specified timeframe. We proposed that

an ONC-ACB would have up to 10 days from receipt of the proposed revocation notice to submit a written response explaining why its status should not be revoked. We proposed that the National Coordinator would have up to 30 days from the time the response is received to review the information submitted by the ONC-ACB and reach a decision. We further proposed that an ONC-ACB would be able to continue its operations under the permanent certification program during the time periods provided for the ONC-ACB to respond to a proposed revocation notice and the National Coordinator to review the response.

We proposed that if the National Coordinator determined that an ONC-ACB's status should not be revoked, the National Coordinator would notify the ONC-ACB's authorized representative in writing of the determination. We also proposed that the National Coordinator could revoke an ONC-ACB's status if it is determined that revocation is appropriate after considering the ONC-ACB's response to the proposed revocation notice or if the ONC-ACB did not respond to a proposed revocation notice within the specified timeframe. We further proposed that a decision to revoke an ONC-ACB'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-ACB received the revocation notice. We proposed that a certification body that had its ONC-ACB status revoked would be prohibited from accepting new requests for certification and would be required to cease its current certification operations under the permanent certification program. We further proposed that if a certification body had its ONC-ACB status revoked for a Type-1 violation, it would be prohibited from reapplying for ONC-ACB status under the permanent certification program for one year.

We proposed that failure to promptly refund any and all fees for uncompleted certifications of Complete EHRs and EHR Modules after the revocation of ONC-ACB status would be considered a violation of the Principles of Proper Conduct for ONC-ACBs. We proposed that the National Coordinator would consider such violations in the event that a certification body reapplied for ONC-ACB status under the permanent certification program.

In association with these proposals, we specifically requested that the public comment on three additional proposals. First, we requested that the public comment on whether the National

Coordinator should consider proposing the revocation of an ONC-ACB's status for repeatedly committing Type-2 violations even if the ONC-ACB 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-ACB and to what extent the frequency of these violations should be a consideration. Second, we requested that the public comment on whether the proposed 1-year bar on reapplying for ONC-ACB status imposed on a revoked certification body should be shortened or lengthened and whether alternative sanctions should be considered. In addition we noted that, depending on the type of violation that led to the former ONC-ACB's status being revoked, it was possible that the former ONC-ACB would also lose its accreditation. Third, we requested that the public comment on whether the National Coordinator should also include a process to suspend an ONC-ACB'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 concern that a lack of confidence in the qualifications or integrity of an ONC-ACB could seriously undermine the permanent certification program's objectives. Commenters requested that developers of HIT and eligible professionals and eligible hospitals be notified if an ONC-ACB is suspended, the National Coordinator proposes to revoke an ONC-ACB's status, and/or an ONC-ACB's status is revoked.

A commenter recommended that there not be a "broad" categorical Type-1 violation bar on reapplying for ONC-ACBs that had their status revoked. A few commenters suggested a shorter bar on reapplying could be possible if the organization demonstrated good faith and timely addressed the reasons for revocation, while other commenters supported the proposed 1-year bar or extending the bar to at least three years. Commenters recommending a longer bar on reapplying reasoned that a longer bar would be a stronger deterrent and provide sufficient time for a certification body to "re-organize" itself. These commenters also recommended that a "re-authorized" former ONC-ACB serve a probationary period. A commenter recommended that an ONC-ACB should have its accreditation permanently revoked if it commits three Type-1 violations. The commenter also noted that it was unlikely that the market

would support an ONC-ACB that committed repeated violations.

We received a few comments on whether we should revoke an ONC-ACB's status for committing multiple Type-2 violations even if the violations were corrected. A couple of commenters suggested that an ONC-ACB should have its status revoked for committing multiple violations. One 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-ACB be allowed to continue operations during a suspension or be provided "due process" rights before being suspended, while other commenters suggested that allowing an ONC-ACB 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-ACB be allowed to continue operations unless the alleged violation would or could adversely impact patient safety and/or quality of care. Some commenters also requested that the fees paid by a Complete EHR and/or EHR Module developer for certification be refunded if the ONC-ACB is suspended.

*Response.* 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 permanent certification program." As noted in the Proposed Rule, we believe such a violation could significantly undermine the public's faith in our permanent certification program. Therefore, we believe that revocation and barring a former ONC-ACB from reapplying for ONC-ACB status is an appropriate remedy. In reaching any conclusion to revoke an ONC-ACB's status, we believe that we have provided appropriate due process (*i.e.*, an appropriate appeals process).

We noted in the Temporary Certification Program final rule that we believed a 1-year bar on reapplying for ONC-ACB status was appropriate for

the temporary certification program, but we would reconsider the appropriate length of the bar and whether a probationary period would be appropriate for the permanent certification program. Having considered these issues in the context of the permanent certification program, we continue to believe that a 1-year bar on reapplying is appropriate and have adopted this position for the permanent certification program. We believe that the 1-year bar on reapplying will allow the former ONC-ACB a sufficient amount of time to address the reasons for the Type-1 violation before reapplying. In addition, when assessing a former ONC-ACB's application for "reinstatement," we will be able to determine if the applicant is accredited by the ONC-AA. The accreditation process, itself, will be managed by the ONC-AA in accordance with ISO 17011. The ONC-AA will be responsible for determining appropriate sanctions for non-conformance with accreditation requirements in accordance with ISO 17011 and its accreditation program. However, considering accreditation is a requirement to become an ONC-ACB, we believe that accreditation will be another means of ensuring that a former ONC-ACB has fully addressed the reasons for revocation and, therefore, do not believe that a "probationary period" will be necessary. Once "re-authorized," an ONC-ACB will be subject to the same requirements for maintaining its status and consequences for not adhering to those requirements.

We do not believe that it is appropriate to initiate revocation proceedings against an ONC-ACB for any amount of corrected Type-2 violations under the permanent 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-ACB 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-ACB. 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-ACB

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-ACB 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-ACB should remain in good standing if it sufficiently corrects a Type-2 violation, no matter how many times an ONC-ACB commits a Type-2 violation. Violations will be a matter of public record that, as noted by a commenter, may influence Complete EHR, EHR Module and HIT developers' decisions on which ONC-ACB to select for the certification of their Complete EHRs, EHR Modules and/or other types of HIT.

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-ACB's operations under the permanent certification program when there is reliable evidence indicating that the ONC-ACB committed a Type-1 or Type-2 violation and that the continued certification of Complete EHRs, EHR Modules and/or other types of HIT 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-ACB; contacting an ONC-ACB's customers; witnessing an ONC-ACB perform certification; and/or reviewing substantiated complaints.

Due to the disruption a suspension may cause for an ONC-ACB, and more so for the market, we believe that suspension is appropriate in only the limited circumstances described above and have revised § 170.565 to provide the National Coordinator with the discretion to suspend an ONC-ACB's operations accordingly. An ONC-ACB would first be issued a notice of proposed suspension. Upon receipt of a notice of proposed suspension, an ONC-ACB 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-ACB's response and issue a determination. In the determination, the National Coordinator will either rescind the proposed suspension, suspend the ONC-ACB's operations until it has adequately corrected a Type-2 violation, or propose revocation in accordance with § 170.565(c) and suspend the ONC-ACB's operations for the duration of the revocation process. The National Coordinator may also make any one of the above determinations if an ONC-ACB fails to submit a timely response to a notice of proposed suspension. A suspension will become effective upon an ONC-ACB's receipt of a notice of suspension. We believe that this process addresses both the commenters' concerns about due process and about maintaining the industry's confidence in the permanent certification program by not allowing an ONC-ACB to continue operations while an investigation is ongoing and/or violations are being resolved related to patient health or safety.

We are designating the new suspension provision as paragraph (d) of § 170.565. Proposed paragraphs (d) through (g) are being redesignated as paragraphs (e) through (h), respectively. As discussed in a previous section of this preamble, we are revising § 170.523(j) to clarify that an ONC-ACB 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-ACB is suspended.

We intend to provide public notification via our Web site and list serve if an ONC-ACB is suspended, issued a notice proposing its revocation, and/or has its status revoked. We also note that we are revising § 170.565(c)(1) to state that "[t]he National Coordinator may propose to revoke an ONC-ACB's status if the National Coordinator has reliable evidence that the ONC-ACB committed a Type-1 violation." The term "reliable" was inadvertently left out of the provision in the Proposed Rule.

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

We proposed in § 170.570 to allow the certified status of Complete EHRs and/or EHR Modules certified by an ONC-ACB 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-ACB. In such circumstances, we proposed that the National Coordinator would review the facts surrounding the revocation of the ONC-ACB's status and publish a notice on ONC's Web site if the National Coordinator believed that Complete EHRs and/or EHR Modules were fraudulently certified by a former ONC-ACB 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 recertification.

*Comments.* Multiple commenters expressed agreement and understanding with the need to protect the integrity of the permanent certification program by ensuring the legitimacy of certifications issued by a former ONC-ACB 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 only require recertification of the affected areas and elements and/or 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 wait and 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. Some 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 6 ONC-ACBs at the time of decertification, which is the number of ONC-ACBs we estimate will exist 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 permanent 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 permanent 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-ACB 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 certified by the former ONC-ACB.

In this regard, the National Coordinator has a statutory responsibility to ensure that Complete EHRs and EHR Modules certified under the permanent 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 recertification by an ONC-ACB is 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 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 eligible professionals and eligible hospitals attesting to the use of Certified EHR Technology, and the perceived insufficient amount of time to have a Complete EHR and/or EHR Module 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 Web site and list serve, which we believe will help eligible professionals and/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-ACB(s) that could be used for 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 § 170.570 without modification.

#### **M. Dual-Accredited Testing and Certification Bodies**

In the Proposed Rule, we explained that the authorization given to ONC-ACBs by the National Coordinator would be valid only for performing certifications under the permanent certification program. We noted that this limitation was not intended to preclude an organization from also performing testing. In fact, we clarified that in order for a single organization (which may include subsidiaries or components) to perform both testing and certification under the permanent certification program it would need to be: 1) accredited by an ONC-AA and subsequently become an ONC-ACB; and 2) accredited under the NVLAP. We requested public comment on whether we should give organizations who are "dual accredited" and also become an

ONC-ACB a special designation to indicate to the public that such an organization would be capable of performing both testing and certification under the permanent certification program.

*Comments.* We received a few comments expressing support for the concept of allowing organizations to conduct both testing and certification under the permanent certification program and giving a special designation to such organizations. Commenters stated that it would be convenient and efficient for Complete EHR and EHR Module developers if organizations are permitted to conduct both testing and certification. A commenter also noted that a special designation would provide clarity for the market.

*Response.* We agree with the commenters that organizations that are accredited and authorized to perform both testing and certification under the permanent certification program may be able to offer convenience and efficiencies as well as other benefits to HIT developers. We do note, however, that these types of organizations must adhere to the respective requirements of their accreditations. For instance, under the permanent certification program, ONC-ACBs must maintain their accreditation, which requires them to conform to Guide 65 at a minimum. Several different sections of Guide 65 require certification bodies to maintain impartiality in their organizational structure and practices. The impartiality requirement will safeguard against the risk that the certification component of an organization will be improperly influenced to certify HIT that has been tested by the testing component of that same organization.

We also agree with the commenters that a unique designation for organizations that are both ONC-ACBs and NVLAP-accredited testing labs is appropriate and will provide clarity to the market. We will indicate on our Web site those organizations that are both ONC-ACBs and NVLAP-accredited testing labs. We also suspect that such an organization will publicize its status as an ONC-ACB and NVLAP-accredited testing lab in an effort to increase market share.

#### **N. Concept of "Self-Developed"**

In the Proposed Rule, 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 "self-developed" could also include a previously purchased Complete EHR or EHR Module that 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 may be made to previously certified Complete EHRs or EHR Modules without requiring a Complete EHR or EHR Module 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 be permitted to make necessary modifications to certified EHR Modules in order to fulfill that responsibility. 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 Complete EHR or EHR Module can still perform the function(s) for which it was originally certified, such modifications should not trigger a



requirement for the Complete EHR or EHR Module to be certified as self-developed, even if the changes affect the capabilities addressed by the certification criteria.

The commenters stated that 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 enable providers to be confident in the attestations they submit to Federal and State agencies regarding the certification status of the EHR technology they use.

*Response.* As we stated in the Temporary Certification Program final rule, we understand the unique needs and requirements of eligible professionals and eligible hospitals with respect to the successful implementation and integration of HIT into operational environments. We provided a description of the term “self-developed” in the Proposed Rule’s preamble for two main reasons. First, in order to provide greater clarity for stakeholders regarding who would be responsible for the costs associated with certification, and second, to clearly differentiate in our regulatory 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 testing and 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 certified. Rather, it appeared that commenters were concerned about whether any modification to a Complete EHR or EHR Module that had been certified already, including those modifications that would be enhancements or required to integrate several EHR Modules, would compromise the technology’s certification or certifications and consequently require the eligible professional or eligible hospital to seek a new certification because the EHR technology 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 offer further clarification of the intent of our statements. We agree with commenters that not every modification would or should require a previously certified Complete EHR or EHR Module to be certified again as self-developed. We provided an example in the Proposed Rule, quoted above, regarding modifications that would not affect any of the capabilities addressed by the certification criteria adopted by the Secretary. In the Temporary Certification Program final rule, we acknowledged that a certified Complete EHR or EHR Module may not automatically meet a health care provider’s needs when 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 choose to use EHR Modules to meet the definition of Certified EHR Technology, they alone would be responsible for properly configuring multiple EHR Modules in order to make them work together. 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., multiple rules could be added to the clinical decision support capability), we believe it is unrealistic to expect that the capabilities included within adopted certification criteria applicable to a Complete EHR or EHR Module will not be modified in some 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 capabilities for which certification criteria have been adopted without compromising the Complete EHR or EHR Module’s certification. Stated differently, an eligible professional or eligible hospital’s modifications to a certified Complete EHR or EHR Module would not automatically make the Complete EHR or EHR Module “self-developed” and consequently require the eligible professional or eligible hospital to obtain a new certification for the modified product. While we cannot review or address in this final rule every

potential modification to determine whether it could possibly compromise 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 Module will perform according to the certification criteria to which it was tested and certified. Any modification to a Complete EHR or EHR Module after it has been certified has the potential to adversely affect the capabilities for which certification criteria have been adopted such that the Complete EHR or EHR Module no longer performs as it did when it was tested and certified, which in turn may compromise an eligible professional or eligible hospital’s ability to achieve meaningful use. If an eligible professional or eligible hospital wants complete assurance that a Complete EHR or EHR Module’s capabilities for which certification criteria have been adopted were not adversely affected by modifications that were made post-certification, they may choose to have the Complete EHR or EHR Module retested and recertified. Additionally, any post-certification modifications that adversely affect a Complete EHR or EHR Module’s capabilities for which certification criteria have been adopted may be identified through surveillance conducted by an ONC-ACB.

#### ***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 recertified in order to continue to qualify as Certified EHR Technology.

With respect to EHR Modules, we noted that there could be situations where measures associated with a meaningful use objective may change, but the capability a certified EHR Module would need to provide would not change. As a result, we stated that it may be impracticable or unnecessary for the EHR Module to be re-certified. Therefore, we requested public comment on whether there should be circumstances where EHR Modules should not have to be re-certified.

We clarified that regardless of the year and meaningful use stage at which an eligible professional or eligible hospital enters the Medicare or Medicaid EHR Incentive Programs, the Certified EHR Technology that would need to be used must include the capabilities necessary to meet the most current set of certification criteria adopted by the Secretary at 45 CFR 170 subpart C in order to satisfy the definition of Certified EHR Technology. Finally, we asked for public comment on the best way to assist eligible professionals and eligible hospitals that 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 that Complete EHRs and EHR Modules need to include the capabilities necessary to meet the most current set of certification criteria adopted by the Secretary at 45 CFR 170 subpart C in order to satisfy the

definition of Certified EHR Technology. 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 the effect on 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.

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 has 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.

A number of commenters expressed concerns about our position and contended that it would require eligible professionals and eligible hospitals who adopt Certified EHR Technology in 2012 (and attempt meaningful use Stage 1 in 2012) to upgrade their Certified EHR Technology twice in two years in order to continue to be eligible for meaningful use incentives during 2013 when they would still only have to meet meaningful use Stage 1 (according to the staggered approach for meaningful use stages that was proposed by CMS). Some of these commenters viewed this as a penalty and disagreed with our position that eligible professionals and eligible hospitals should be required to use Certified EHR Technology that had been certified to the most recently adopted certification criteria. Additionally, these commenters stated 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.* In the Temporary Certification Program final rule, we discussed the concept of validity as it relates to the definition of Certified EHR Technology and the certifications that are issued to Complete EHRs and EHR Modules. We believe it is necessary to clarify that discussion in this final rule. We explained that an eligible professional or eligible hospital cannot

assert that a certification issued to a particular Complete EHR or EHR Module is valid for purposes of satisfying the definition of Certified EHR Technology if the certification criteria (including the standards and implementation specifications referenced by the criteria) that are related to a particular capability have been modified. In other words, if the applicable certification criteria have been altered or changed, then an eligible professional or eligible hospital can no longer represent that a certified Complete EHR or combination of certified EHR Modules continues to constitute Certified EHR Technology based on the certifications that were previously issued.

As mentioned in both the HIT Standards and Certification Criteria final rule and the Medicare and Medicaid EHR Incentive Programs final rule, it is anticipated that the requirements for meaningful use will be adjusted every two years. We expect the Secretary will adopt certification criteria through rulemaking every two years in correlation with the changes to the meaningful use requirements. We also recognize, however, that circumstances may necessitate a deviation from the expected two-year rulemaking cycle, such as with the interim final rule published on October 13, 2010 (75 FR 62686) to remove the previously adopted implementation specifications related to public health surveillance. Future rulemakings could potentially include the adoption of new and revised certification criteria in addition to those already adopted. We consider new certification criteria to be those that specify capabilities for which the Secretary has not previously adopted certification criteria. New certification criteria would also include certification criteria that were previously adopted for Complete EHRs or EHR Modules designed for a specific setting and are subsequently adopted for Complete EHRs or EHR Modules designed for a different setting (for example, if the Secretary previously adopted a certification criterion at § 170.304 only for Complete EHRs or EHR Modules designed for an ambulatory setting and then subsequently adopts that certification criterion at § 170.306 for Complete EHRs or EHR Modules designed for an inpatient setting). We consider revised certification criteria to be certification criteria previously adopted by the Secretary that are modified to add, remove, or otherwise alter the specified capabilities and/or the standard(s) or implementation specification(s) referred to by the

certification criteria. Revised certification criteria would also include certification criteria that were previously adopted as optional but are subsequently adopted as mandatory (for example, if the optional criterion at § 170.302(w) is subsequently adopted as a mandatory criterion).

Only when eligible professionals or eligible hospitals are in possession of a Complete EHR or EHR Module that has been certified to all of the applicable certification criteria, including new and revised certification criteria, that have been adopted by the Secretary at subpart C of part 170, will they be able to assert that they possess a Complete EHR or EHR Module with a certification that would be considered valid for purposes of satisfying the definition of Certified EHR Technology. For example, based on our expectation that the meaningful use requirements will be modified every two years, we anticipate that the Secretary will adopt certification criteria during 2012 for the 2013 and 2014 payment years of the Medicare and Medicaid EHR Incentive Programs (referenced in Table 1 below). A Complete EHR that was previously certified in 2010 to the certification criteria adopted for the 2011 and 2012 payment years must be certified again as compliant with all of the applicable certification criteria adopted for the 2013 and 2014 payment years in order for that Complete EHR to continue to meet the definition of Certified EHR Technology. As we discuss in the next section of this preamble (*P. Differential or Gap Certification*), the permanent certification program will include the option of “gap certification” in an effort to provide a more efficient and streamlined process for the certification of previously certified Complete EHRs and EHR Modules.

We explained in the HIT Standards and Certification Criteria final rule that additional flexibility and specificity can be introduced into future cycles of rulemaking through the adoption and designation of “optional” standards, implementation specifications, and certification criteria. We acknowledged that these would be voluntary and would not be required for testing and certifying a Complete EHR or EHR Module, although they could help to prepare the HIT industry for future mandatory certification requirements. Thus, in certain instances, the Secretary may adopt through rulemaking additional standards and/or implementation specifications that would be referenced as optional by a previously adopted certification criterion or criteria, in an effort to provide EHR technology developers

more flexibility with respect to what is permitted to achieve certification for a Complete EHR or EHR Module. We emphasize that this would not affect the validity of certifications that were previously issued to Complete EHRs and EHR Modules. In other words, a previously certified Complete EHR or EHR Module would not be required to be certified according to new optional standard(s) or implementation specifications in order for it to continue to be used to meet the definition of Certified EHR Technology.

As we stated in the Proposed Rule, if a previously certified Complete EHR is not tested and certified as compliant with all of the applicable certification criteria adopted by the Secretary, it would not lose its certification, but it also would no longer satisfy the definition of Certified EHR Technology. Many commenters acknowledged that especially in situations where certification criteria have been adopted to improve the interoperability of EHR technology, certification to new and revised certification criteria would be needed and justified in order to meet the definition of Certified EHR Technology. 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 the requirements of 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 or revised certification criteria, Complete EHRs and likely many EHR Modules may no longer provide all of the capabilities that would be necessary to support an eligible professional’s or eligible hospital’s attempt to meet the requirements of a particular stage of meaningful use.

In its final rule, CMS indicated that “[t]he stages of criteria of meaningful use and how they are demonstrated are described further in this final rule and will be updated in subsequent rulemaking to reflect advances in HIT products and infrastructure. *We note that such future rulemaking might also include updates to the Stage 1 criteria.*” 75 FR 44323 (emphasis added). We believe that the 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 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 and consistent with the statement by CMS quoted above, it is possible that in a subsequent rulemaking to establish the objectives and measures for meaningful use Stage 2, CMS could change what is required to successfully demonstrate meaningful use Stage 1 in 2013. Consequently, such changes could include additional requirements that are based on advances in HIT and go beyond the requirements that have been finalized by CMS for meaningful use Stage 1 in 2011 and 2012. Therefore, an eligible professional or eligible hospital who demonstrates meaningful use for the first time in 2012 may potentially need Certified EHR Technology with new or additional capabilities in order to satisfy the meaningful use Stage 1 requirements in 2013.

Because the HITECH Act requires eligible professionals and eligible hospitals to use Certified EHR Technology in order to qualify for incentive payments under the Medicare and Medicaid EHR Incentive Programs, we reaffirm our position expressed in the Proposed Rule. Regardless of the year and meaningful use stage at which eligible professionals or eligible hospitals enter the Medicare or Medicaid EHR Incentive Programs, they must use Certified EHR Technology that has been certified to all of the applicable certification criteria adopted by the Secretary at subpart C of part 170, which includes new and revised certification criteria that have been adopted since their EHR technology was previously certified. We believe this position takes into account the best interests of eligible professionals and eligible hospitals because those who implement EHR technology that meets the definition of Certified EHR Technology will have the assurance that their EHR technology includes the requisite capabilities to support their attempts to demonstrate meaningful use. Moreover, our 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 as we did in the Temporary Certification Program final rule 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 certification criteria adopted by the Secretary for the 2011/2012 payment years will not need to be recertified as having met the certification criteria for those years. In other words, the fact that the permanent certification program has replaced the temporary certification program will not automatically render certifications that were issued by ONC-ATCBs pursuant to the certification

criteria adopted for the 2011/2012 payment years invalid for the purpose of meeting the definition of Certified EHR Technology. However, once the permanent certification program is fully constituted and after the Secretary has adopted new or revised certification criteria (which we expect will occur in 2012, based on the two-year rulemaking cycle), Complete EHRs and EHR Modules that were previously certified under the temporary certification

program by ONC-ATCBs must be certified by an ONC-ACB.

We provide the following illustration overlaid on “Table 1—Stage of Meaningful Use Criteria by Payment Year” from the Medicare and Medicaid EHR Incentive Programs final rule (75 FR 44323) to more clearly convey the discussion above. This illustration would also be applicable to the Medicaid program.

TABLE 1—STAGE OF MEANINGFUL USE CRITERIA BY PAYMENT YEAR

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 1.
2014 .....	.....	.....	.....	Stage 1.
	Complete EHRs and EHR Modules certified by ONC-ATCBs or ONC-ACBs <sup>2</sup> to all of the applicable certification criteria adopted for the 2011 & 2012 payment years meet the definition of Certified EHR Technology.		Complete EHRs and EHR Modules certified by ONC-ACBs to all of the applicable certification criteria adopted for the 2013 & 2014 payment years meet the definition of Certified EHR Technology.	

*Comments.* In response to our question about how to identify those Complete EHRs and/or EHR Modules that have been certified to the most current set of adopted certification criteria (and thus would constitute 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 whether a Complete EHR or EHR Module’s certification is current. 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 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 “pre-coordinated, integrated bundle” concept we proposed with respect to the certification of EHR Modules to the adopted privacy and security certification 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 certified 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. We believe more specificity will assist eligible professionals and eligible hospitals with their purchasing decisions by helping them to identify those Complete EHRs and EHR Modules that have a current and valid certification issued by an ONC-ACB. As previously discussed, the ONC-AA must verify that ONC-ACBs conform to Guide 65 at a minimum, which includes in section 14 a requirement that certification bodies (i.e., ONC-ACBs) exercise control over the use and display of “certificates” and marks of conformity. To ensure consistency in how the certified status of a Complete EHR or EHR Module is represented and communicated, and in response to those comments, we are adding a new principle to the Principles of Proper Conduct for ONC-ACBs at

§ 170.523(k). We added a similar new Principle of Proper Conduct for ONC-ATCBs in the Temporary Certification Program final rule. The new Principle of Proper Conduct requires ONC-ACBs to ensure adherence to the following requirements when issuing a certification to Complete EHRs and/or EHR Modules:

(1) A Complete EHR or EHR Module developer must conspicuously include the following on its Web site 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 20[XX]/20[XX] compliant and has been certified by an ONC-ACB in accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services. This certification does not represent an endorsement by the U.S. Department of Health and Human Services or guarantee the receipt of incentive payments.”; and

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

(2) A certification issued to a pre-coordinated, integrated bundle of EHR

<sup>2</sup> If the permanent certification program is fully constituted and the temporary certification program sunsets on December 31, 2011, all new requests

made after that date for certification of Complete EHRs or EHR Modules to the 2011/2012

certification criteria will be processed by ONC-ACBs.

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 the certification must also indicate each EHR Module that is included in the bundle; and

(3) A certification issued to a Complete EHR or EHR Module based solely on the 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.

This new Principle of Proper Conduct is based on our assumption that the Secretary will adopt certification criteria through rulemaking every two years in correlation with the expected modifications to the meaningful use requirements. With respect to the requirement in § 170.523(k)(1)(i) regarding “20[XX]/20[XX] compliant,” we expect ONC-ACBs will indicate the years “2011/2012 compliant” for all Complete EHRs and EHR Modules that are certified to the certification criteria adopted by the Secretary for the 2011 and 2012 payment years of the Medicare and Medicaid EHR Incentive Programs. Continuing our assumption of a two-year rulemaking cycle, we expect ONC-ACBs to follow this convention as the Secretary adopts certification criteria for subsequent payment years. For example, if the Secretary adopts certification criteria as expected in 2012 for the 2013 and 2014 payment years, ONC-ACBs would indicate “2013/2014 compliant.”

Given the clarification we provided as to when a Complete EHR or EHR Module’s certification will be considered valid for purposes of meeting the definition of Certified EHR Technology, we believe it would be inappropriate and misleading to adopt an identification requirement that is solely associated with the meaningful use stages. We also believe it would be inappropriate to identify a Complete EHR or EHR Module based on whether its 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 not be useful to another eligible professional or eligible hospital.

We do, however, agree with the commenter who suggested the specific constraint for a pre-coordinated, integrated bundle of EHR Modules. As we explained, we would expect that EHR Module developer(s) will have addressed any issues related to the compatibility of EHR Modules that make up a pre-coordinated, integrated bundle before the bundle is presented for certification pursuant to

§ 170.550(e)(1). The pre-coordinated, integrated bundle of EHR Modules is greater than the sum of the individual EHR Modules that make up the bundle, and for that reason, we clarify that individual EHR Modules that are certified as part of a pre-coordinated, integrated bundle would not each separately inherit a certification just because they had been certified as part of a bundle. For example, if EHR Modules A, B, C, and D are certified as a pre-coordinated, 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 pre-coordinated, integrated bundle. If an EHR Module developer wanted to make EHR Module C available for use by eligible professionals and eligible hospitals as a single certified EHR Module independent of and separate from the bundle, then it must have EHR Module C separately certified by an ONC-ACB.

As we discussed in the Proposed Rule, there may be situations where the measures associated with a meaningful use objective may change as a result of subsequent rulemaking, but the capability a certified EHR Module would need to provide would not change. As a hypothetical example, during the expected 2012 rulemaking cycle, the threshold of the meaningful use Stage 1 measure associated with the “record patient demographics” objective could be increased from 50% to 75%. When the Secretary adopts certification criteria for the 2013/2014 payment years, however, the certification criterion or criteria that are applicable to an EHR Module designed to record patient demographics could potentially remain unchanged.

We recognize it may not be practical or beneficial for the EHR Module in this example to be certified again, where the certification criterion or criteria to which it was previously certified have not been revised and no new certification criteria have been adopted that are applicable to it. However, in accordance with § 170.423(k)(1) or § 170.523(k)(1), the ONC-ATCB or ONC-ACB that certified the EHR Module would have required the EHR Module developer to include certain information on its Web site and in other materials related to the payment years associated with the certification criteria to which the EHR Module was previously certified. To ensure that the information required by § 170.523(k)(1)(i) remains accurate and reflects the correct payment years, we will permit ONC-ACBs to provide updated certifications to previously certified EHR Modules.

We define “providing or provide an updated certification” as the action taken by an ONC-ACB to ensure that the developer of a previously certified EHR Module shall update the information required by § 170.523(k)(1)(i), after the ONC-ACB has verified that the certification criterion or criteria to which the EHR Module was previously certified have not been revised and that no new certification criteria adopted for privacy and security are applicable to the EHR Module. To verify that the certification criterion or criteria have not been revised, an ONC-ACB would compare the certification criterion or criteria to which the EHR Module was previously certified with all of the certification criteria adopted by the Secretary for the relevant payment years (in the example above, the 2013/2014 payment years). To verify whether new certification criteria adopted for privacy and security are applicable to the EHR Module, an ONC-ACB would complete the analysis described in § 170.550(e)(2) to determine, upon a request to provide an updated certification, whether the EHR Module developer has demonstrated and provided documentation that such certification criteria are inapplicable or that it would be technically infeasible for the EHR Module to be certified in accordance with such certification criteria.

We believe that providing updated certifications is a pragmatic approach for the treatment of previously certified EHR Modules and that it is consistent with requirements specified in Guide 65, section 12 (Decision on certification), which requires certification bodies to issue certifications specifying the scope of the certification, the effective date of the certification, and any applicable terms. We also believe that this approach is consistent with Guide 65, section 14 (Use of licenses, certificates and marks of conformity), which requires the certification body to exercise proper control over the use and display of certificates and marks of conformity, including addressing incorrect references to the certification system or misleading use of certificates or marks. The information required by § 170.523(k)(1) is intended to assist eligible professionals and eligible hospitals in identifying specific EHR technology that could be purchased and adopted for the purpose of meeting the definition of Certified EHR Technology and attempting to demonstrate meaningful use. ONC-ACBs must be able to ensure that this information is kept current and accurate if it is to be

helpful to prospective purchasers of EHR technology and to instill confidence in the certifications issued under the permanent certification program. We are defining “providing or provide an updated certification” in § 170.502 and are adding a new provision to § 170.550, designated as paragraph (d), to permit ONC-ACBs to provide updated certifications to previously certified EHR Module(s).

ONC-ACBs may choose to provide updated certifications but are not required to do so, because we recognize situations could exist where an ONC-ACB is not comfortable providing an updated certification. For instance, an ONC-ACB may not want to provide an updated certification if it did not issue the original certification to the EHR Module or if there has been an extended period of time since the EHR Module was tested and/or certified. If an ONC-ACB elects not to provide updated certifications, an EHR Module developer may choose to have its EHR Module recertified and/or retested, even though the certification criterion or criteria to which the EHR Module was previously certified have not been revised and no new certification criteria have been adopted that are applicable to the EHR Module. In order to make the certification process as efficient as possible in this scenario, we will permit ONC-ACBs to rely on prior testing completed by an ONC-ATCB. Accordingly, we are revising § 170.523(h) to permit ONC-ACBs to rely on the results of testing performed by ONC-ATCBs for the purpose of certifying a previously certified EHR Module(s) if the certification criterion or criteria to which the EHR Module(s) was previously certified have not been revised and no new certification criteria are applicable to the EHR Module(s).

*Comments.* Several commenters requested that we clarify whether each updated version of a Complete EHR or EHR Module would need to be recertified in order for its certification to remain valid, and whether there would be a mechanism available to accommodate routine changes and product maintenance without the need for full recertification of each updated version 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). Another commenter requested that we consider the impact of potentially more dynamic software development/release models,

such as those related to cloud computing and software-as-a-service, that may not fit a traditional (major/minor/maintenance) release schedule. The commenter indicated that there may be more frequent software updates for these types of EHR technologies.

*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 either to 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 is whether these changes adversely affect the capabilities of a Complete EHR or EHR Module that has already been certified and whether the 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 or modified capabilities without the need for recertification, and such changes may affect capabilities that are related or unrelated to the certification criteria adopted by the Secretary.<sup>3</sup> 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 newer version do not adversely affect the proper functioning of the capabilities for which certification was previously granted. An ONC-ACB should, at a minimum, review an attestation submitted by a Complete EHR or EHR Module developer explaining the changes that were made and the reasons for those changes, as well as other information and supporting documentation that would be necessary for the ONC-ACB to evaluate the potential effects of the changes on previously certified capabilities. We believe this process is

<sup>3</sup> 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-ACB for a Complete EHR or EHR Module whose version number may represent a minor or major version change.

consistent with the requirements placed on certification bodies by Guide 65, sections 4.6.2 (related to conditions and procedures for granting, maintaining, extending, suspending and withdrawing certification) and 12.4 (related to decisions on certifications).

As a result, we are adding a new provision to § 170.545, designated as paragraph (d), that requires an ONC-ACB to accept requests for a newer version of a previously certified Complete EHR to inherit the certified status of the previously certified Complete EHR without requiring the newer version to be recertified. We are also adding a similar provision to § 170.550, designated as paragraph (f), that requires an ONC-ACB to accept requests for a newer version of a previously certified EHR Module(s) to inherit the certified status of the previously certified EHR Module(s) without requiring the newer version to be recertified. However, consistent with both of these new provisions, the developer of the Complete EHR or EHR Module(s), must submit an attestation as described above in the form and format specified by the ONC-ACB that the newer version does not adversely affect any capabilities for which certification criteria have been adopted. After reviewing the attestation, the ONC-ACB must determine whether the Complete EHR’s or EHR Module’s capabilities, for which certification criteria have been adopted, have been adversely affected (which would consequently require the newer version to be recertified), or whether to grant a certification to the newer version of the previously certified Complete EHR or EHR Module that is based on the previous certification. In determining whether the newer version should be recertified, the ONC-ACB may also determine whether retesting is necessary.

If the ONC-ACB issues a certification to a newer version of a previously certified Complete EHR or EHR Module, the ONC-ACB must include this certification in its weekly report to the National Coordinator. We believe that for the purposes of associating a certification with a given EHR technology, this policy is appropriate regardless of the software development/release approach employed by an EHR technology developer. As we have stated before, certification represents a snapshot, a fixed point in time, where it has been confirmed (in this case by an ONC-ACB) that a Complete EHR or EHR Module has met all applicable certification criteria adopted by the Secretary. Thus, if a different version of a Complete EHR or EHR Module is made available and the EHR technology

developer seeks to have this version inherit a prior version's certification, the prior version's certification needs to be formally associated with this newer version and subsequently reported to the National Coordinator. Without this association, an EHR technology developer would not be able to assert that the updated or modified EHR technology was "certified," nor would eligible professionals or eligible hospitals be able to verify on ONC's Certified HIT Products List (CHPL) that the EHR technology is certified.

Aside from the requirements discussed above, we do not specify the fees or any other processes that an ONC-ACB must follow before granting certified status to a newer version of a previously certified Complete EHR or EHR Module based on the submitted attestation. We encourage ONC-ACBs to develop streamlined approaches for attestations in order to accommodate different software release models and schedules.

#### **P. Differential or Gap Certification**

We stated in the Proposed Rule that, after Complete EHRs and EHR Modules have been certified as being in compliance with the certification criteria associated with meaningful use Stage 1, it may benefit both Complete EHR and EHR Module developers as well as eligible professionals and eligible hospitals if some form of differential certification were available. We described differential certification as the certification of Complete EHRs and/or EHR Modules to the differences between the certification criteria adopted by the Secretary associated with one stage of meaningful use and a subsequent stage of meaningful use. As an example, we stated that if the Secretary were to adopt 5 new certification criteria to support meaningful use Stage 2 and those were the only additional capabilities that needed to be certified in order for a Complete EHR's certification to be valid again (*i.e.*, all other certification criteria remained the same) for the purposes of meaningful use Stage 2, then the Complete EHR would only have to be tested and certified to those 5 criteria rather than the entire set of certification criteria again.

We noted that differential certification could be a valuable and pragmatic approach for the future and that it may further reduce costs for certification and expedite the certification process. Accordingly, we requested public comments on whether we should require ONC-ACBs to offer differential certification, what factors we should consider in determining when

differential certification would be appropriate and when it would not, and when differential certification should begin. To further clarify these requests and inform commenters, we noted the factors we thought were appropriate for consideration in determining when to allow for differential certification. These factors included whether the standard(s) associated with a certification criterion or criteria changed and whether additional certification criteria changed in such a way that they affected other previously certified capabilities of a Complete EHR or EHR Module. We specifically asked whether differential certification should be permitted to begin with Complete EHRs and EHR Modules certified under the temporary certification program (*i.e.*, the differences between 2011 and 2013) or after all Complete EHRs and EHR Modules had been certified once under the permanent certification program (*i.e.*, the differences between 2013 and 2015). Regarding these options, we asked commenters to consider the differences in rigor that we expect Complete EHRs and EHR Modules will go through to get certified under the permanent certification program.

*Comments.* Commenters overwhelmingly supported some form of differential certification based on, as we noted, the potential for efficiencies and lower certification costs. These commenters expressed general agreement with the factors we specified for determining when differential certification would be appropriate. That is, they stated that testing and certifying a Complete EHR or EHR Module to only new or revised certification criteria would be appropriate as long as other required capabilities (as specified in other adopted certification criteria) of a Complete EHR or other EHR Modules were not also affected by the new or revised certification criteria. Conversely, a few commenters did not believe that differential certification would be appropriate based on various concerns. One commenter suggested that testing to only new or revised certification criteria could be time consuming and cost prohibitive. Another commenter contended that differential certification will create "tiers" in the market of fully certified versus differentially certified Complete EHRs and EHR Modules, which could lead to confusion among purchasers. A couple of commenters expressed concern about ONC-ACBs guaranteeing the compliance of all capabilities required by adopted certification criteria of a Complete EHR without testing all of the components. A couple of commenters also noted that if

differential certification is allowed, ONC-ACBs should not be required to offer it as an option for certification. Rather, it should be up to each ONC-ACB to decide whether to conduct differential certification.

Commenters who were in favor of differential certification indicated strong support for beginning differential certification with the differences between the 2011 and 2013 certification criteria adopted by the Secretary. These commenters reasoned that the potential for lower certification costs and reduced certification times should be made available to the market as soon as possible, particularly if the separate testing and certification processes of the permanent certification program could increase the time for certified Complete EHRs and EHR Modules to reach the market. Alternatively, a few commenters stated that it would be more appropriate for Complete EHRs and EHR Modules to be tested and certified at least once under the proposed more rigorous permanent certification program before they would be considered eligible for differential certification.

*Response.* We understand based on our research that the term "gap certification" is commonly used by the HIT industry to refer to the concept we have described as "differential certification." As a result, for consistency and ease of reference, we will use the term "gap certification" instead of "differential certification" for purposes of the permanent certification program. The description of "differential certification" that we gave in the Proposed Rule focused on the differences between adopted certification criteria as related to the stages of meaningful use. As noted earlier in this final rule, however, the Medicare and Medicaid EHR Incentive Programs final rule indicated that the meaningful use Stage 1 requirements may be updated in future rulemaking, such as when the requirements for Stage 2 are established. As a result, the concept of gap certification must allow for the possibility that the Secretary may adopt certification criteria through future rulemaking that would encompass and be associated with both the revised Stage 1 requirements and newly established Stage 2 requirements. This possibility is consistent with our position that, regardless of the year and meaningful use stage at which an eligible professional or eligible hospital enters the Medicare or Medicaid EHR Incentive Programs, they must use Certified EHR Technology that has been certified to all of the applicable certification criteria adopted by the Secretary at subpart C of part 170. Thus,

gap certification must focus on the differences between certification criteria that are adopted through rulemaking at different points in time rather than the differences between the stages of meaningful use.

We define and will use the term gap certification to mean the certification of a previously certified Complete EHR or EHR Module to: (1) All applicable new and/or revised certification criteria adopted by the Secretary at subpart C of this part based on the test results of a NVLAP-accredited testing laboratory; and (2) all other applicable certification criteria adopted by the Secretary at subpart C of this part based on the test results used previously to certify the Complete EHR or EHR Module. We believe this definition of gap certification is conceptually analogous to the description of differential certification in the Proposed Rule as well as common industry usage of the term.

While a commenter asserted that testing to only new or revised certification criteria could be more time consuming and cost prohibitive, commenters overwhelmingly agreed with our premise that gap certification would likely be a less costly and time-consuming certification option for Complete EHR and EHR Module developers. Further, we believe that the potential lower costs and expedited certification timeframes that gap certification will presumably offer outweigh the concerns some commenters raised about the reliability of testing under the temporary certification program. As previously stated in this final rule, the testing and certification performed under the temporary certification program is conducted by testing and certification bodies that are determined to be qualified and have been authorized by the National Coordinator. Complete EHRs and EHR Modules are tested by ONC-ATCBs using test tools and test procedures approved by the National Coordinator and should be expected to perform consistent with their certifications. Therefore, ONC-ACBs should be confident in relying upon the test results provided by ONC-ATCBs when performing gap certification under the permanent certification program. Accordingly, gap certification will be available as an option for ONC-ACBs to offer as soon as ONC-ACBs are authorized to begin performing certifications under the permanent certification program.

A few commenters suggested that gap certification would lead to “tiers” in the market of “fully tested and certified” Complete EHRs and EHR Modules and

“partially tested and certified” Complete EHRs and EHR Modules, while a couple of other commenters expressed concern about ONC-ACBs guaranteeing the compliance of all capabilities of a Complete EHR without testing all of the components. We believe, as suggested by commenters, that the decision on whether to conduct gap certification is best left to each ONC-ACB. However, as discussed above, we believe that the testing performed by ONC-ATCBs or by any NVLAP-accredited testing laboratory will be valid and reliable. Therefore, when gap certifying a Complete EHR or EHR Module, an ONC-ACB will be expected to issue a certification for the entire Complete EHR or EHR Module that it gap certifies. For these reasons, the HIT market should consider a Complete EHR or EHR Module that has been gap certified to be equal to a Complete EHR or EHR Module that has been fully tested and certified to all applicable certification criteria adopted by the Secretary. In addition, as discussed earlier in this preamble, ONC-ACBs will be expected to conduct annual surveillance of the Complete EHRs and/or EHR Modules that they certify under the permanent certification program. Surveillance should provide additional assurances to the HIT market that Complete EHRs and EHR Modules will continue to perform in an operational setting or “live” environment as they did when they were certified.

Consistent with this discussion, we are adding the definition of gap certification to § 170.502 and adding new provisions to § 170.545 (paragraph (c)) and § 170.550 (paragraph (c)) to permit ONC-ACBs to provide the option of and to perform gap certification under the permanent certification program. In addition to these revisions, we are revising § 170.523(h) to permit ONC-ACBs to accept the results of testing performed on Complete EHRs and EHR Modules by ONC-ATCBs under the temporary certification program for the purpose of gap certification. These testing results may be necessary for conducting gap certification under the permanent certification program when previously certified Complete EHRs and EHR Modules were last tested under the temporary certification program.

#### **Q. Barriers to Entry for Potential ONC-ACBs and an ONC-Managed Certification Process**

We noted in the Proposed Rule that the overall success of the Medicare and Medicaid EHR Incentive Programs could be jeopardized if the certification program for EHR technology fails to

operate properly. We requested public comment on specific issues related to the proposed permanent certification program that could adversely affect the operation of that program. First, we asked whether the proposed provisions of the permanent certification program created high barriers to market entry for potential ONC-ACBs and, if so, how we could revise the proposed requirements to lower those barriers and encourage participation. Second, we expressed concern about the potential risks to the permanent certification program if no ONC-ACBs were authorized or only one ONC-ACB was authorized and engaged in monopolistic behavior. We requested public comment on potential approaches that could be pursued to stimulate market involvement or remedy these situations if they were to develop, including the possibility of the National Coordinator establishing a temporary ONC-managed certification process that would include some type of certification review board. We noted that this option was not preferred and would come with significant limitations. In particular, section 3001(c)(5) of the PHSA does not expressly authorize the National Coordinator or the Secretary to assess and collect fees related to the certification of HIT and subsequently retain and use those fees to administer an ONC-managed certification process if it were established.

*Comments.* Commenters stated that the proposed provisions of the permanent certification program did not present high barriers to entry for potential ONC-ACBs. Commenters also generally agreed that we should eliminate any identified barriers to entry with one commenter specifically suggesting that the National Coordinator could waive certain conditions that are creating barriers to entry as long as it would not adversely impact patient safety or quality of care. Another commenter noted that the proposed permanent certification program permits multiple entry points for organizations to pursue ONC-ACB status, allowing the market to decide how many ONC-ACBs are acceptable.

Most commenters expressed agreement with our proposal for a temporary ONC-managed certification process to stimulate market involvement or remedy the situations described above and in the Proposed Rule. Some commenters suggested that if there were fewer than two ONC-ACBs at the start of the permanent certification program we should continue the temporary certification program or allow ONC-ATCBs in good standing under the temporary certification program to



become ONC-ACBs under the permanent certification program without having to meet any of the application requirements of the permanent certification program. Another commenter suggested that if these options were not immediately viable then we should allow for self-attestation by Complete EHR and EHR Module developers to the certification criteria until there are a sufficient number of ONC-ACBs. Conversely, some commenters contended that if there was only one ONC-ACB it would not necessarily be the result of the permanent certification program requirements. Although these commenters stated that the authorization of more than one ONC-ACB would be preferable to handle requests for certification, they asserted that one ONC-ACB could be a good starting point for the permanent certification program, at least until other ONC-ACBs became operational. A commenter reasoned that the accreditation guidelines that ONC-ACBs must adhere to should be sufficient to preclude a single ONC-ACB from acting in a monopolistic or other improper manner.

*Response.* We agree with many of the sentiments expressed by the commenters. We agree that there are multiple entry points for qualified organizations who seek to become ONC-ACBs, such as applying to become an ONC-ACB for only Complete EHRs, only EHR Modules, or only limited types of EHR Modules. We also agree that the market will likely determine the appropriate number of ONC-ACBs and that only one ONC-ACB may be sufficient for starting (and potentially operating long term) the permanent certification program. For comparison, consistent with our estimate, there are currently 5 ONC-ATCBs under the temporary certification program. We acknowledge, however, that there remains the remote possibility that there may be no ONC-ACBs under the permanent certification program, that one ONC-ACB will not be sufficient to meet demand, or that only one ONC-ACB will be authorized and could engage in conduct that is detrimental to the permanent certification program.

To begin the permanent certification program, we believe that we have established an approach that addresses the concerns expressed by some commenters and is consistent with the solutions they offered. Section 170.490 provides 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 stated in the Temporary Certification Program final rule that in determining whether the permanent certification program is fully constituted, the National Coordinator would consider whether there are a sufficient number of ONC-ACBs and accredited testing laboratories to address the current market demand. We believe this approach will ensure that the permanent certification program functions properly at the outset. If we determine at a later time under the permanent certification program that an insufficient number of ONC-ACBs exists, we will consider what steps may be taken to remedy the situation. This may include implementing a temporary ONC-managed certification process and/or evaluating other means for stimulating the market, such as revising or waiving certain ONC-ACB requirements or taking other actions as suggested by the commenters.

#### **R. General Comments**

We received comments that were not attributable to a specific provision of the permanent certification program, but were still reasonably within the scope of the program. These comments addressed the timing of the permanent certification program; “grandfathering” of previously certified technology; the potential for a backlog of requests for certification; the costs of certification; and the safety of Complete EHRs, EHR Modules and other types of HIT.

*Comments.* Although we did not propose or discuss the concept of “grandfathering” in the Proposed Rule, several commenters made recommendations on the subject. To summarize the discussion of comments in the Temporary Certification Program final rule, in general, the concept of grandfathering would allow technology that had been certified prior to the inception of the temporary and/or permanent certification programs to be deemed Certified EHR Technology.

*Response.* In the Temporary Certification Program final rule, we responded to comments on the concept of grandfathering and concluded that any form of grandfathering would be inappropriate for purposes of our certification programs and inconsistent with the statutory requirements for Certified EHR Technology set forth in the PHSA. 75 FR 36186–36187. Our position on grandfathering as stated in the Temporary Certification Program final rule remains valid.

*Comments.* Commenters requested that we take action to prevent testing and certification monopolies and backlogs of requests for testing and

certification. Commenters also requested that we mandate pricing for certification or at least establish a reasonable fee requirement.

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

*Comments.* A commenter requested that the National Coordinator establish a single application process for the testing and certification of developers’ HIT. By doing so, the commenter contended that this would alert accredited testing laboratories and ONC-ACBs of a developer’s readiness and intent to apply for testing and/or certification.

*Response.* We do not believe it is necessary or appropriate to create such an “application process.” Each accredited testing laboratory and ONC-ACB is capable of establishing their own customer base based on a multitude of factors including pricing, efficiency, services offered, and prior relationships. Further, we assume that a HIT developer’s readiness and “intent” to apply may fluctuate based on multiple factors, including whether their Complete EHR and/or EHR Module successfully passed testing or whether they determine testing and/or certification of their HIT should be delayed. Accordingly, we believe it is appropriate for each accredited testing laboratory and ONC-ACB to establish its own process for soliciting and accepting requests for testing and certification, as applicable.

*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 development and implementation of the permanent 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 permanent certification program has been sufficiently constituted to ensure that ONC-ACBs will competently certify Complete EHRs, EHR Modules and potentially other types of HIT. We have established a process in the permanent certification program that the National Coordinator could use to immediately suspend an ONC-ACB's authority to issue certifications if there is reliable evidence indicating that allowing the ONC-ACB to continue issuing certifications would pose an adverse risk to patient health and safety. The permanent certification program also includes a post-market surveillance program that is designed to ensure that certified Complete EHRs and EHR Modules perform in the market as certified and may also shed light on any safety concerns reported by eligible professionals and eligible hospitals.

#### **S. 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 later rulemakings or through guidance 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 § 170.501, we added language, based on our proposal and public comments, that expands the scope of the permanent certification program to "other types of HIT." We also added "the requirements that ONC-ACBs must follow to maintain their status" to properly identify that this subpart contains requirements that ONC-ACBs must follow to maintain their status under the permanent certification program.

- In § 170.502, we revised the definition of applicant by removing the condition that an applicant must "request" an application. We revised the

definition of ONC-ACB by removing "at a minimum" from the definition to allow an organization or consortium of organizations to become an ONC-ACB that is authorized to certify only types of HIT besides Complete EHRs and/or EHR Modules. We also revised this definition by replacing "using the applicable certification criteria adopted by the Secretary" with "under the permanent certification program." In addition to revising the definitions of applicant and ONC-ACB, we added the definitions of "deployment site," "development site," "gap certification," "providing or provide an updated certification," and "remote certification" to this section.

- In § 170.503, we revised paragraph (b) to provide for a 30-day time period in which all interested accredited organizations may submit requests for ONC-AA status. We revised (b)(2) to specify that a request for ONC-AA status must include a detailed description of how the accreditation organization will ensure that the surveillance approaches used by ONC-ACBs include the use of consistent, objective, valid, and reliable methods. We revised paragraph (c) to permit the National Coordinator up to 60 days to review all timely submissions and determine which accreditation organization is best qualified to serve as the ONC-AA. We revised paragraph (c) to provide for the selection of an ONC-AA on a preliminary basis and subject to the resolution of the reconsideration process in § 170.504. We included in paragraph (c) the option, originally specified in proposed paragraph (d), for an accreditation organization to request reconsideration of the National Coordinator's decision to deny an accreditation organization ONC-AA status. We established a new provision, designated as paragraph (d), that specifies the final approval process for ONC-AA status. We revised paragraph (e)(2) to require an ONC-AA, in accrediting certification bodies, to ensure that surveillance approaches include the use of consistent, objective, valid and reliable methods. We revised paragraph (e)(4) to state that the ONC-AA will be required to review ONC-ACB surveillance results to determine if the results indicate any substantive non-conformance by ONC-ACBs "with the conditions of their respective accreditations." We revised paragraph (f) to specify that an accreditation organization has not been granted ONC-AA status unless and until it is notified by the National Coordinator that it has been approved as the ONC-AA on a final basis pursuant to paragraph (d) of

this section. We also revised paragraph (f) to specify that the National Coordinator will accept requests for ONC-AA status, in accordance with paragraph (b), at least 180 days before the then current ONC-AA's status is set to expire.

- In § 170.504, consistent with our revisions to § 170.503, we revised paragraph (a) to state that an accreditation organization that submits a timely request for ONC-AA status in accordance with § 170.503 and is denied may ask the National Coordinator to reconsider the decision to deny its request for ONC-AA status. We revised paragraph (b) to state that the accreditation organization's request for reconsideration must demonstrate that clear, factual errors were made in the review of its request for ONC-AA status and that the accreditation organization would have been selected as the ONC-AA pursuant to § 170.503(c) if those errors had been corrected. We revised paragraph (c) to permit the National Coordinator up to 30 days to review all timely received reconsideration requests and determine whether an accreditation organization has met the standard specified in paragraph (b) of this section. We revised paragraph (d) to state that if the National Coordinator determines that an accreditation organization has met the standard specified in paragraph (b) of this section, then that organization will be approved as the ONC-AA on a final basis and all other accreditation organizations will be notified that their requests for reconsideration have been denied.

- In § 170.505, we revised paragraph (b) by adding "or ONC-ACB" to clarify that either an applicant for ONC-ACB status or an ONC-ACB may, when necessary, utilize the specified correspondence methods. We also revised this section to apply its correspondence requirements to accreditation organizations that submit requests for ONC-AA status and the ONC-AA.

- In § 170.520, we revised paragraph (c) such that the documentation provided by the applicant must confirm that the applicant has been accredited by "the ONC-AA," instead of "an ONC-AA" as proposed.

- In § 170.523, we revised paragraph (e) by clarifying that site visits will be conducted during normal business hours. We revised paragraph (f) by replacing "vendor" with "Complete EHR or EHR Module developer." We also revised paragraph (f) by specifying that an ONC-ACB will be required to additionally report the clinical quality measures to which a Complete EHR or

EHR Module has been 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. We revised paragraph (h) to require ONC-ACBs to only certify HIT, including Complete EHRs and/or EHR Module(s), that has been tested by a NVLAP-accredited testing laboratory using test tools and test procedures that have been approved by the National Coordinator. We also revised paragraph (h) to allow ONC-ACBs, under certain circumstances, to rely on testing that has been performed by ONC-ATCBs, which must also have been done using test tools and test procedures that have been approved by the National Coordinator. We revised paragraph (j) to clarify that an ONC-ACB will only be responsible for issuing refunds in situations where the ONC-ACB's conduct caused certification to be suspended and a request for certification is withdrawn, and in instances where the ONC-ACB's conduct caused the certification not to be completed or necessitated the recertification of Complete EHRs and/or EHR Module(s) that had been previously certified. Lastly, we added a new Principle of Proper Conduct for ONC-ACBs and designated it as paragraph (k). The new Principle of Proper Conduct will require ONC-ACBs to ensure that all Complete EHRs and EHR Modules are properly identified and marketed.

- In § 170.525, we revised paragraph (b) by removing “during the existence of the permanent certification program.”

- In § 170.530, in response to public comment, we revised paragraph (b)(1) by removing the terms “inadvertent” and “minor.” We revised paragraph (c)(1), also in response to public comment, to allow an applicant for ONC-ACB status to request an extension of the 15-day period provided to submit a revised application in response to a deficiency notice. We 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 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. Finally, we revised paragraph (c)(4) to state that a denial notice issued to an applicant will indicate that the applicant cannot reapply for ONC-ACB status for a period of six months from the date of the denial notice.

- In § 170.540, we revised paragraph (b) to state, in relevant part, “Each ONC-ACB must prominently and unambiguously identify the scope of its authorization on its Web site, and in all marketing and communications statements (written and oral) pertaining to its activities under the permanent certification program.” We clarified in paragraph (c) that an ONC-ACB must include any updates to the information required to be provided under § 170.520 when requesting to have its status renewed. We also revised paragraph (c) to state that an ONC-ACB will need to have its status renewed every three years instead of every two years. We similarly revised paragraph (d) to state that an ONC-ACB's status will expire three years from the date it was granted by the National Coordinator unless it is renewed.

- In § 170.545, we revised paragraph (a) to state that “When certifying Complete EHRs, an ONC-ACB must certify Complete EHRs in accordance with all applicable certification criteria adopted by the Secretary at subpart C of this part.” We redesignated proposed paragraph (b) as paragraph (e). We added three new provisions. We added a new provision, designated as paragraph (b), which states that an ONC-ACB must provide the option for a Complete EHR to be certified solely to the applicable certification criteria adopted by the Secretary at subpart C of this part. We added a new provision, designated as paragraph (c), to permit ONC-ACBs to provide the option for and perform gap certification. Finally, we added a new provision, designated as paragraph (d), which requires an ONC-ACB to accept requests for a newer version of a previously certified Complete EHR to inherit the certified status of the previously certified Complete EHR without requiring the newer version to be recertified.

- In § 170.550, we removed proposed paragraphs (b) and (d) because they were redundant of other regulatory requirements within this subpart. We redesignated proposed paragraph (c) as paragraph (e) and revised it to state that EHR Modules shall be certified to all privacy and security certification criteria adopted by the Secretary unless the EHR Module(s) is presented for certification in one of the following manners: (1) The EHR Modules are presented for certification as a pre-coordinated, integrated bundle of EHR Modules, which would otherwise meet the definition of and constitute a Complete EHR, and one or more of the constituent EHR Modules is demonstrably responsible for providing all of the privacy and security

capabilities for the entire bundle of EHR Modules; or (2) An EHR Module is presented for certification, and the presenter can demonstrate and provide documentation to the ONC-ACB that a privacy and security certification criterion is inapplicable or that it would be technically infeasible for the EHR Module to be certified in accordance with such certification criterion. We added four new provisions. We added a new provision, designated as paragraph (b), which states that an ONC-ACB must provide the option for an EHR Module(s) to be certified solely to the applicable certification criteria adopted by the Secretary at subpart C of this part. We added a new provision, designated as paragraph (c), to permit ONC-ACBs to provide the option for and perform gap certification. We added a new provision, designated as paragraph (d), which permits an ONC-ACB to provide an updated certification to a previously certified EHR Module(s). Finally, we added a new provision, designated as paragraph (f), which requires an ONC-ACB to accept requests for a newer version of a previously certified EHR Module(s) to inherit the certified status of the previously certified EHR Module(s) without requiring the newer version to be recertified.

- In § 170.555, we removed inadvertent references to testing under the permanent certification program.

- In § 170.557, we revised the section to require that an ONC-ACB provide remote certification for both development and deployment sites.

- In § 170.565, we revised paragraph (c)(1) to state that “[t]he National Coordinator may propose to revoke an ONC-ACB's status if the National Coordinator has reliable evidence that the ONC-ACB committed a Type-1 violation.” The term “reliable” was inadvertently left out of the Proposed Rule. We also established a new provision. We designated this provision as paragraph (d) and redesignated proposed paragraphs (d) through (g) as paragraphs (e) through (h), respectively. Paragraph (d) provides the National Coordinator with the discretion to suspend an ONC-ACB's operations if there is reliable evidence indicating that the ONC-ACB has committed a Type-1 or Type-2 violation and that the continued certification of Complete EHRs, EHR Modules and/or other types of HIT by the ONC-ACB could have an adverse impact on patient health or safety. An ONC-ACB 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-ACB. The National Coordinator will make a determination to either rescind the proposed suspension, suspend the ONC-ACB until it has adequately corrected a Type-2 violation, or propose revocation in accordance with § 170.565(c) and suspend the ONC-ACB's operations for the duration of the revocation process. The National Coordinator may also make any one of the above determinations if an ONC-ACB fails to submit a timely response to a notice of proposed suspension. A suspension will become effective upon an ONC-ACB's receipt of a notice of suspension.

- We added § 170.599 to incorporate by reference ISO 17011 and Guide 65.

**V. Collection of Information Requirements**

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to provide 60-day notice in the **Federal Register** and solicit public comment on a proposed collection of information before it is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

1. Whether the information collection is necessary and useful to carry out the proper functions of the agency;
2. The accuracy of the agency's estimate of the information collection burden;
3. The quality, utility, and clarity of the information to be collected; and
4. Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the Proposed Rule, we solicited public comment on each of these issues for the information collections set forth in 45 CFR §§ 170.503(b), 170.520, and 170.523(f) and (g). The final rule also specifies another information collection requirement pertaining to the annual submission by an ONC-ACB of a surveillance plan and surveillance results to the National Coordinator as required by § 170.523(i). The information collection requirement of § 170.523(i) was not specifically identified in the Proposed Rule, but was available for comment during the 60-day public comment period for the Proposed Rule and included in our request to OMB. Please refer to section E below for this information collection.

**A. Collection of Information: Required Documentation for Requesting ONC-Approved Accreditor Status Under the Permanent Certification Program**

Section 170.503(b) requires an accreditation organization to submit specific information to the National Coordinator to be considered for ONC-AA status under the permanent certification program. We estimated in the Proposed Rule that there will only be two accreditation organizations that will prepare and submit the information sought by the National Coordinator to be considered for ONC-AA status. We also provided estimates for the amount of time we believe will be necessary to collect and provide the information requested by the National Coordinator in § 170.503(b). Specifically, we estimated that it will take approximately:

- 20 minutes for an accreditation organization to provide a detailed description of the accreditation organization's conformance to ISO 17011 and experience evaluating the

conformance of certification bodies to Guide 65;

- 20 minutes for an accreditation organization to provide a detailed description of the accreditation organization's accreditation requirements and how the requirements complement the Principles of Proper Conduct for ONC-ACBs;
- 5 minutes for an accreditation organization to provide a copy of the procedures that would be used to monitor ONC-ACBs;
- 10 minutes for an accreditation organization to provide detailed information, including education and experience, about the key personnel who review certification bodies for accreditation; and
- 5 minutes for an accreditation organization to provide a copy of the procedures for responding to, and investigating, complaints against ONC-ACBs.

We did not receive any comments on our estimates for the burden associated with § 170.503(b). We added the requirement that accreditation organizations specify how their accreditation requirements will ensure the surveillance approaches used by ONC-ACBs include the use of consistent, objective, valid, and reliable methods. We do not believe that this additional requirement will appreciably increase the burden for accreditation organizations requesting ONC-AA status and that any potential increase in the burden can be accounted for in the 20 minutes allotted for providing a detailed description of the accreditation organization's accreditation requirements and how the requirements complement the Principles of Proper Conduct for ONC-ACBs. Therefore, we have maintained the same burden estimates we provided in the Proposed Rule.

Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Accreditation Organization .....	2	1	1	2

**B. Collection of Information: Application for ONC-ACB Status Under the Permanent Certification Program**

Section 170.520 requires an organization to submit specific information to the National Coordinator to be considered for ONC-ACB status under the permanent certification program. We estimated in the Proposed Rule that there would be no more than 6 applicants for ONC-ACB status under the permanent certification program. We

also provided estimates for the amount of time we believe will be necessary to complete an application for ONC-ACB status, *i.e.*, meet the requirements of § 170.520. Specifically, we estimated that it will take approximately:

- 10 minutes to provide the general identifying information requested in the application;
- 30 minutes to assemble the information necessary to provide

documentation of accreditation by an ONC-AA; and

- 20 minutes to review and agree to the "Principles of Proper Conduct for ONC-ACBs."

Our burden estimates were based on the assumption that potential applicants will be familiar with many of the application requirements and will, for example, already have a majority—if not all—of the documentation requested

already developed and available before applying for ONC-ACB status.

*Comments.* We received one comment expressing agreement that most potential applicants would likely have a majority of the necessary documentation available when applying for ONC-ACB status. The commenter contended, however, that we should add a minimum of an additional 200 hours of staff time in consideration of the effort that will be required by an organization to become accredited, which the commenter noted is a prerequisite for applying for ONC-ACB status.

*Response.* We believe that the commenter's concerns related to the effort to become accredited are best addressed in our discussion of accreditation costs for potential ONC-ACB applicants under the regulatory impact analysis section of this final rule. The burden described under this section is for PRA purposes and is confined to the actual collection and submission of information required to apply for ONC-ACB status as specified in § 170.520. We note, however, that in the Proposed Rule we did not specifically attribute an amount of time (*i.e.*, burden) to

identifying the type of authorization sought by a potential applicant. Although identifying the type of authorization sought is a requirement of § 170.520, we believe any time utilized to provide this information can be accounted for within the 10 minutes we have allotted for providing the requested general identifying information. Accordingly, our estimate of the burden for an applicant to collect and submit the information necessary to apply for ONC-ACB status remains the same as specified in the Proposed Rule.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Burden hours per response	Total burden hours
Applicant .....	6	1	1	6

**C. Collection of Information: ONC-ACB Collection and Reporting of Information Related to Complete EHR and/or EHR Module Certifications**

Section 170.523(f) requires an ONC-ACB to provide ONC, no less frequently than weekly, a current list of Complete EHRs and/or EHR Modules that have been 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, as we did for the related temporary certification program provision, specified in this final rule

two additional reporting elements that must be submitted by ONC-ACBs on a weekly basis (*i.e.*, clinical quality measures to which a Complete EHR or EHR Module has been 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-ACBs 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 not believe that the reporting of these two additional elements will increase the reporting burden for ONC-ACBs.

For the purposes of estimating the potential burden, we have maintained our prior assumptions. We assume that all of the estimated applicants will apply and become ONC-ACBs (*i.e.*, 6 applicants). We also assume that ONC-ACBs 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-ACBs. 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-ACB Certification Results .....	6	52	1	312

**D. Collection of Information: Records Retention Requirements**

Section 170.523(g) requires ONC-ACBs to retain certification records for 5 years. In the Proposed Rule, we stated our belief, based on our consultations with NIST, that the 5-year requirement was in line with common industry practice and, consequently, would not represent an additional cost to ONC-ACBs. We did not receive any comments related to our assertion and, therefore, maintain our belief that the 5-year record retention requirement will not create a burden or additional cost for ONC-ACBs.

**E. Collection of Information: Submission of Surveillance Plan and Surveillance Results**

Section 170.523(i) requires an ONC-ACB to submit an annual surveillance plan to the National Coordinator and annually report to the National Coordinator its surveillance results.

For the purposes of estimating the potential burden, we assume that all of the estimated number of applicants for the permanent certification program (*i.e.*, six) will become ONC-ACBs. We anticipate that the burden for each ONC-ACB will be the same based on the following assumptions. We assume

that all surveillance plans will be fairly comparable. We also assume that all ONC-ACBs will, on average, have a similar burden in submitting results. Finally, we assume that an ONC-ACB will submit a copy of their annual surveillance plan and annually report surveillance results by either electronic transmission or paper submission. In either instance, we believe that an ONC-ACB will spend a similar amount of time and effort in organizing, categorizing and submitting the requested information. Therefore, we estimate that an ONC-ACB will annually allocate 1 hour to submit the

plan (response #1) and 1 hour to report the results (response #2). 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-ACB Surveillance Plan and Results .....	6	2	1	12

As required by section 3504(h) of the PRA, we have submitted a copy of this document to OMB for its review of these information collection requirements.

**VI. 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 permanent certification program is not an economically significant rule because we estimate that the overall costs and benefits associated with the permanent 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 certify Complete EHRs, EHR Modules, and/or other types of HIT. As to Complete EHRs and EHR Modules, once certified, they 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.* As recited in the Temporary Certification Program final rule, we received a few comments that 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 EHR technology.

*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-ACB should be able to charge for certifying a Complete EHR or EHR Module. Based on the number of applicants we have granted ONC-ATCB status, we anticipate that we will there will be multiple ONC-ACBs that will compete for market share under the permanent certification program. As a result of this expected competition, we believe that 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.* We received one comment expressing agreement that most potential applicants would likely have a majority of the necessary documentation available when applying for ONC-ACB status. The commenter contended, however, that we should add a minimum of an additional 200 hours of staff time in consideration of the effort that will be required by an organization to become accredited.

*Response.* We believe that attributing 200 hours of staff time for preparing and participating in the accreditation process is reasonable. We also believe that it is appropriate to calculate the cost of the staff time at a position equivalent to a Federal GS-15, Step 1 employee. Accordingly, we have supplemented our original cost estimates to account for this staff time and have provided revised total cost estimates for accreditation and the ONC-ACB application process under the section titled "Application Process for ONC-ACB Status" in this RIA.

*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. One commenter suggested that if our estimates of the number of EHR Modules and Complete EHRs that will be tested and certified and the costs for testing and certification are accurate, then the commenter contended that there will not be a sufficient market for sustaining ONC-ACBs and, therefore, ONC should assume all costs for testing and certification.

*Response.* As discussed in the Temporary Certification Program final rule (75 FR 36197), the certification programs final rules are part of a coordinated rulemaking effort. Each rule accounts for its specific effects. In the "Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology" 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-ACB status and the costs for Complete EHRs and EHR Modules to be tested and certified by ONC-ACBs. The HIT Standards and Certification Criteria final rule (75 FR 44590) provides our final analysis of the estimated 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, while the Medicare and Medicaid EHR Incentive Programs final rule (75 FR 44314) provides a final analysis of 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.

As we stated in the Temporary Certification Program final rule, 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 under the permanent certification program. We believe that our new estimates indicate that there will be a sufficient market to sustain an appropriate amount of ONC-ACBs necessary for the success of the permanent certification program. Further, we do not believe that it is appropriate for ONC to enter the market where private entities have concluded that there is a sufficient market for the testing and certification of HIT to be willing to perform the testing and certification of HIT. This conclusion has arguably been validated by the fact that 5 private entities have already become ONC-ATCBs under the temporary certification program.

## 2. Executive Order 12866 Final Analysis

As required by Executive Order 12866, we have examined the economic implications of this final rule as it

relates to the permanent 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 final rule is therefore not "economically significant," as defined by Executive Order 12866, OMB has determined that this final rule constitutes a "significant regulatory action" as defined by Executive Order 12866 because it raises novel legal and policy issues.

### a. Permanent Certification Program Estimated Costs

#### i. Request for ONC-AA Status

#### Costs for Accreditation Organizations

We believe that at most two accreditation organizations will prepare and submit the information sought by the National Coordinator. Additionally, we estimate that it will take 1 hour to prepare and submit a request for ONC-AA status. We believe that an employee equivalent to the Federal Salary Classification of GS-15 Step 1 would be responsible for preparing and submitting the required information. We have utilized the corresponding employee hourly rate for the locality pay area of Washington, DC, as published by the OPM, to calculate our cost estimates. We have also calculated the costs of an employee's benefits while preparing and submitting the required information to be considered for ONC-AA status. We have calculated these costs by assuming that an accreditation organization 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 2 below.

TABLE 2—PERMANENT CERTIFICATION PROGRAM: COST TO ACCREDITATION ORGANIZATIONS TO SUBMIT THE INFORMATION REQUIRED TO BECOME AN ONC-AA

Requirement	Employee equivalent	Burden hours	Employee hourly wage rate	Cost of employee benefits per hour	Total cost per applicant
Submission of Request for ONC-AA Status .....	GS-15 Step 1 .....	1	\$59.30	\$21.35	\$80.65

Using our estimates above, we believe that the cost to submit the information required to become an ONC-AA will be \$81 and the total cost for the two accreditation organizations that we estimate will submit requests for ONC-AA status will be \$161. Based on our estimate of two accreditation organizations submitting the required documentation to be considered for ONC-AA status and on the requirement that an ONC-AA be selected every three years, we estimate the annualized cost of requesting ONC-AA status to be \$54.

**Costs to the Federal Government**

We anticipate that there will be costs associated with reviewing the information provided by accreditation organizations requesting to become an ONC-AA under the permanent certification program. We believe that a GS-15 Step 1 employee will review the submissions and the National Coordinator (or designated representative) will issue final decisions on all submissions. We anticipate that it will take 40 hours to review all submissions and reach a final decision on the best qualified accreditation organization. This estimate includes the time necessary to review the additional documentation that is now required to be submitted related to an accreditation organization's proposed administration of surveillance by ONC-ACBs and to prepare a briefing for the National Coordinator on approving the best qualified ONC-AA. This estimate also includes the time of the National Coordinator and other senior executive officials devoted to reaching a decision on the best qualified ONC-AA. Their time has been included in the 40 hour estimate at the GS-15 cost level. We estimate the Federal government's overall cost to review the submissions and approve an ONC-AA to be \$3,226. Based on our estimate of two accreditation organizations submitting the required documentation to be considered for ONC-AA status and on the requirement that an ONC-AA be selected every three years, the annualized cost to the Federal government for reviewing the submissions for ONC-AA status will be \$1,075. If we notify the public of the selection of the ONC-AA by posting the

information on our Web site and/or by issuing a press release, we believe that we will incur negligible costs from these actions.

**ii. Application Process for ONC-ACB Status**

**Costs for Applicant**

Similar to the temporary certification program, an applicant for ONC-ACB status will be required to submit an application. However, unlike the temporary certification program, an applicant for ONC-ACB status must be accredited in order to be a qualified ONC-ACB applicant. As specified in the Proposed Rule, we estimate that there will be 6 applicants for ONC-ACB status under the permanent certification program and that those 6 applicants will first seek and become accredited by an ONC-AA. Because accreditation will include a demonstration of conformance to Guide 65 for all organizations that seek to be accredited, we do not believe that there will be a difference in the cost of accreditation for organizations who seek to become ONC-ACBs for EHR Modules versus ONC-ACBs for Complete EHRs.

Based on our consultations with NIST, we estimate that it will take approximately 2 to 5 days for an ONC-AA to complete the accreditation process. We anticipate that accreditation applicants will incur an estimated \$5,000 administrative fee and the cost of the accreditation assessment will be approximately \$15,000. In response to public comment, we have calculated a cost for the staff time necessary to prepare and participate in the accreditation assessment. We have accepted the commenter's suggestion that 200 hours of staff time is appropriate to attribute to preparation and participation in the accreditation assessment and have calculated the corresponding cost for this time based on the assumption that an employee equivalent to a Federal GS-15 employee would be responsible for preparation and participation in the accreditation assessment. A GS-15 employee's hourly wage with benefits is approximately \$80.65. Therefore, the estimated staff cost for accreditation is \$16,130.

We expect that the accreditation renewal process will occur once between 2012 and 2016 for each ONC-ACB and assume that the accreditation renewal process will be less onerous than the initial accreditation process because an ONC-ACB will be able to rely on the information it previously prepared for its initial accreditation as well as any such information it has produced during the ongoing maintenance of its accreditation. Additionally, because the estimated number of organizations that could become an ONC-AA is small, we believe that it is reasonable to assume that the ONC-ACB would be accredited by the same ONC-AA and thus a completely new review of the ONC-ACB may not be necessary. We believe a completely new review would likely not be necessary because the ONC-AA will already be familiar with the ONC-ACB and have its documentation on file, and we do not expect that an ONC-ACB will make such drastic changes to its policies or procedures which will necessitate a lengthy assessment of their competency by an ONC-AA.

We estimate that it will take no more than 3 days to conduct the accreditation renewal process and that the accreditation assessment will cost \$10,000. In addition, we have similarly added a cost estimate to account for staff time to prepare and participate in the accreditation renewal process. As with our other renewal cost estimates, we anticipate that a reduced amount of staff time will be required. We have estimated that an employee equivalent to a GS-15 Federal employee will be responsible for preparation and participation in the accreditation renewal process and that no more than 100 hours of the employee's time will be required. As noted, a GS-15 employee's hourly wage with benefits is approximately \$80.65. Therefore, the estimated staff cost for an accreditation renewal assessment is \$8,065.

The total estimated cost for an ONC-ACB to become accredited is \$36,130 and the total estimated cost for it to renew its accreditation is \$18,065. These estimated costs are expressed in Table 4 below.

After becoming accredited by an ONC-AA, an applicant for ONC-ACB



status will incur minimal costs to prepare and submit an application to the National Coordinator. As noted in the collection of information section, we believe that it will take 10 minutes to provide the general information requested in the application, 30 minutes to assemble the information necessary to provide documentation of accreditation by an ONC-AA, and 20 minutes to review and agree to the "Principles of Proper Conduct for ONC-ACBs." We believe that these time estimates will also hold true when applying to renew ONC-ACB status.

Based on our consultations with NIST, we believe that an employee equivalent to the Federal Salary Classification of GS-9 Step 1 could provide the required general identifying information and documentation of accreditation status. We believe that an employee equivalent to the Federal Salary Classification of GS-15 Step 1 would be responsible for reviewing and agreeing to the "Principles of Proper Conduct for ONC-ACBs." We have taken these employee assumptions and utilized the corresponding employee hourly rates for the locality pay area of Washington, DC, as published by the

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. We believe that these same assumptions hold true for applying to renew ONC-ACB status. Our cost estimates are expressed in Table 3 below.

TABLE 3—PERMANENT CERTIFICATION PROGRAM: COST TO APPLICANTS TO APPLY TO BECOME ONC-ACBs AND COST FOR ONC-ACBs TO APPLY FOR STATUS RENEWAL

Requirement	Employee equivalent	Burden hours	Employee hourly wage rate	Cost of employee benefits per hour	Cost per applicant
General Identifying Information .....	GS-9 Step 1 .....	10/60	\$22.39	\$8.06	\$5.07
Documentation of Accreditation .....	GS-9 Step 1 .....	30/60	22.39	8.06	15.23
Principles of Proper Conduct .....	GS-15 Step 1 .....	20/60	59.30	21.35	26.88
Total Cost per Applicant .....					\$47.18

We have estimated the applicant costs and ONC-ACB renewal costs through 2016, but no further, because we believe that it is premature to assume how the meaningful use requirements will change when incentive payments are no longer available for eligible professionals and eligible hospitals under the Medicare EHR incentive program and what impact, if any, those potential changes will have on the permanent certification program. Using our estimates above, we believe that the average initial cost for an applicant to

become accredited and apply to be an ONC-ACB will be approximately \$36,177 and the total cost for all 6 applicants will be approximately \$217,062. We estimate that between 2012 and 2016 that all applicants will renew their accreditation and ONC-ACB status once. As noted, we assume that the costs for an ONC-ACB to renew its status with the National Coordinator will be similar in burden to its initial application. We believe that the average cost for an ONC-ACB to renew its accreditation and ONC-ACB status will

be approximately \$18,112 and the total renewal costs for all ONC-ACBs will be approximately \$108,672. We estimate that the total costs of the accreditation, application and renewal processes under the proposed permanent certification program between 2012 and 2016 would be approximately \$54,289 per applicant/ONC-ACB and approximately \$325,734 for all applicants/ONC-ACBs. Based on our cost estimate timeframe of 5 years (2012 through 2016), the annualized cost would be \$65,147.

TABLE 4—PERMANENT CERTIFICATION PROGRAM: TOTAL COSTS OF CERTIFICATION ACCREDITATION, APPLYING FOR ONC CERTIFICATION AUTHORIZATION, AND ACCREDITATION AND AUTHORIZATION RENEWAL BETWEEN 2012 AND 2016

Anticipated number of applicants	Cost of accreditation per applicant	Cost to apply for certification authorization per applicant	Cost to renew accreditation per applicant	Cost to renew ONC-ACB status	Total cost estimate per applicant/ ONC-ACB
6 .....	\$36,130	\$47	\$18,065	\$47	\$54,289
Total Cost of Accreditation, Application and Renewal .....					\$325,734

**Costs to the Federal Government**

We estimate the cost to develop the ONC-ACB application to be \$350 based on the 5 hours of work we believe it will take a Federal Salary Classification GS-14 Step 1 employee located in Washington, DC to develop an application form. We also anticipate that there will be costs associated with reviewing applications under the permanent 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 20 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 and prepare a briefing for the National Coordinator. We estimate the cost for the application review process to be \$10,392. As a result, we estimate the Federal government's overall cost of administering the entire application process at approximately \$10,742. Based on our cost estimate timeframe of 5 years (2012 through 2016), the

annualized cost to the Federal government will be \$2,148.

As previously noted, we will also post the names of applicants granted ONC-ACB status on our Web site. We believe that there will be minimal cost associated with this action and have calculated the potential cost to be approximately \$312 on an annual basis for posting and maintaining the information on our Web site (a maximum of 6 hours of work for a Federal Salary Classification GS-12 Step 1 employee located in Washington, DC).

### iii. 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 Complete EHR and EHR Module developers will seek to have their HIT tested and certified under the permanent certification program.

As previously stated in our discussion of the appropriate timeframe for estimating costs for the ONC-ACB application process, we estimate costs through 2016, but no further, because we believe that it is premature to assume how the meaningful use requirements will change when incentive payments are no longer available for eligible professionals and eligible hospitals under the Medicare EHR incentive program. Although CMS intends to promulgate updates to the meaningful use stages every 2 years, we assume that there could be more time between stages (*i.e.*, greater than 2 years) in years when incentive payments are no longer available under the Medicare EHR incentive program based on evaluations of earlier meaningful use stages, public feedback, and other factors, which could affect when Complete EHRs and/or EHR Modules would need to be recertified. However, we do expect meaningful use requirements between 2012 and 2016 to become more demanding and iterate every 2 years. Therefore, we can assume that Complete EHRs and EHR Modules will need to be tested and certified twice during this time period.

As specified in the Temporary Certification Program final rule, we believe that approximately 93 commercial/open source Complete EHRs and 50 EHR Modules will be tested and certified to the 2011/2012 certification criteria adopted by the Secretary. In addition to the testing and

certification of these Complete EHRs and EHR Modules, we anticipate that a percentage of eligible professionals and eligible hospitals will themselves incur the costs associated with the testing and certification of their self-developed Complete EHR or EHR Module(s) to the 2011/2012 certification criteria adopted by the Secretary.

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.<sup>4</sup> 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 have developed an 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 of approximately 550,000 eligible professionals (75 FR 44548) we multiply through by the numbers above ( $550,000 \times .05 \times .17 \times .10$ ) and then divide by a practice size of at least 50 which yields approximately 9 self-developed Complete EHRs designed for an ambulatory setting that could be submitted for testing and certification to the 2011/2012 certification criteria adopted by the Secretary. 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 (~94). We then assume an average number (1.25) 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

possesses a self-developed EHR Module that they would seek to have tested and certified. Our calculations produce a minimum estimate of 12 and a maximum estimate of 82 EHR Modules that may be presented for testing and certification to the 2011/2012 certification criteria adopted by the Secretary. 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 have developed estimates based on currently available data. We have based our calculations on the Medicare eligible hospital table CMS provided in its final rule (Table 25) (75 FR 44553) which conveys hospital IT capabilities according to three levels of adoption by hospital size according to the 2008 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 25 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

<sup>4</sup> 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.

Complete EHR. CMS estimated that 379 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. This equals about 38 self-developed Complete EHRs that we could expect to be tested and certified to the 2011/2012 certification criteria adopted by the Secretary. We believe that this estimate is generous and that a good portion of the eligible hospitals that 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 hospitals that 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 hospital 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, we have estimated a

minimum and a maximum number of EHR Modules that we could expect to be self-developed and presented for testing and certification to the 2011/2012 certification criteria adopted by the Secretary. For CAHs, we estimate a minimum of 7 and a maximum of 68 EHR Modules. For small and medium hospitals, we estimate a minimum of 163 and a maximum of 488. For large hospitals, we estimate a minimum of 190 and a maximum of 531. Again, we believe that our maximum estimates of self-developed EHR Modules are generous; however, to examine how we reached our estimates, please review our calculations specified in Table 5 below.

TABLE 5—ESTIMATED NUMBER OF SELF-DEVELOPED EHR MODULES DESIGNED FOR AN INPATIENT SETTING STRATIFIED BY TYPE OF ELIGIBLE HOSPITAL FOR TESTING AND CERTIFICATION TO THE 2011/2012 CERTIFICATION CRITERIA ADOPTED BY THE SECRETARY

Type of eligible hospital	Number of EHRs	Percent with EHR Module (low)	Percent with EHR Module (high)	Average number of EHR Modules, if any	Minimum number of EHR Modules	Maximum number of EHR Modules
CAH .....	616	1	10	1.1	7	68
S/M .....	2169	5	15	1.5	163	488
Large .....	379	25	70	2.0	190	531
Total .....	3164	.....	.....	.....	360	1087

Even though under the permanent certification program the costs for testing and certification could presumably be attributed to different entities (*i.e.*, testing costs to a NVLAP-accredited testing laboratory and certification costs to an ONC-ACB), we have included them together in an effort to reflect the overall effect of this final rule. In addition, 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).

As recited in the Proposed Rule, CCHIT testified on July 19, 2009 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 for the temporary certification program and as the basis for estimating costs for the permanent certification program. However, we assume that competition in the testing and certification markets 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.

In creating tables 6 through 13 below, we made the following assumptions:

- The cost for testing and certification will remain the same in the permanent certification program as they were in the temporary certification program even with the additional requirement of surveillance on the part of ONC-ACBs (which we would expect to be included in the cost they charge Complete EHR and/or EHR Module developers). We believe this is a reasonable assumption because of the low and high cost ranges we have estimated.
- That testing and certification costs will be unevenly distributed across subsequent years. We assume that there will be an increase in the year preceding the next stage of meaningful use and a decline between stages because Complete EHR and EHR Module developers will likely want to have their products certified as soon as possible to new standards and certification criteria

so that they can be available to eligible professionals and hospitals for meaningful use purposes. With respect to the peak years for when testing and certification costs would most likely occur, we assume that those peak years will be 2012 and 2014, the years preceding the proposed start dates of meaningful use Stages 2 and 3, respectively. We assume that an increase would encompass 85% of the Complete EHRs and EHR Modules to be certified, which would represent most, if not all, Complete EHRs and EHR Modules previously certified to the 2011/2012 certification criteria adopted by the Secretary and that the remaining 15% of testing and certification costs for 2013 would likely represent new EHR Module entrants to the HIT marketplace and Complete EHR or EHR Module developers who were late to get certified.

- We assume that commercial/open source Complete EHR developers will continue to consolidate due to mergers and acquisitions and that this consolidation would occur at a rate of 5% between meaningful use stages. Therefore, we believe that fewer commercial/open source Complete EHRs will need to be tested and certified prior to each meaningful use stage.

• Conversely, we assume that the number of commercial/open source-developed EHR Modules that would need to be tested and certified to meet associated meaningful use Stage 2 (2013/2014) certification criteria and beyond will grow at a rate of 20% between meaningful use stages (*i.e.*, based on our prior estimate of 50 EHR Modules between 2010 and 2012, there would be 10 new modules developed during 2012 and during meaningful use Stage 2 to meet certification criteria associated with meaningful use Stage 2). We believe our growth rate is reasonable because the cost barrier for EHR Modules to enter the market will be much less than a Complete EHR. Coupled with the ability of small or start-up HIT developers to enter the market we believe that the potential of EHR Modules will lead to a constant stream of new entrants year after year.

• The number of eligible professionals and eligible hospitals that incur the testing and certification costs for their self-developed Complete EHRs for meaningful use Stage 2 will drop by 50% in 2012 and another 25% in 2014 and level out after 2014 due to our assumption, that by 2014, and the proposed start of meaningful use Stage 3, all of the eligible professionals and eligible hospitals who still have a self-developed Complete EHR are likely to maintain their HIT rather than switch to a commercial product.

• The number of eligible professionals and eligible hospitals that incur the testing and certification costs for their self-developed EHR Modules will remain in the range we have provided for testing and certification to the 2011/2012 certification criteria

adopted by the Secretary. We believe this is the most reliable estimate at this time for a couple of reasons. First, we have provided a generous maximum estimate of EHR Modules that we believe will be self developed and should account for any potential increase in self-developed EHR Modules during future meaningful use stages. Second, and most importantly, we have no information that would suggest a particular direction for the market. We see the potential for a variety of ways that the market could progress, some of which include multiple self-developed EHR Modules being replaced by one commercial/open source EHR Module, more self-developed EHR Modules being created, or an equilibrium being created by eligible professionals and eligible hospitals switching from commercial to self-developed EHR Modules and vice versa. Without knowing the direction of the market, we believe that our estimated range of EHR Modules for testing and certification to the 2011/2012 certification criteria adopted by the Secretary is the most appropriate and reliable estimate to use for establishing projected testing and certification costs for meaningful use Stages 2 and 3.

• We assume that gap certification, as described in this final rule, will likely reduce the costs of certification. However, because of unknown variables such as the number of Complete EHRs and EHR Modules that will be eligible for gap certification and how readily ONC-ACBs will use gap certification, our cost estimates may vary from the actual costs for testing and certification to certification criteria associated with later stages of meaningful use.

As previously mentioned, we anticipate that the temporary certification program will sunset on December 31, 2011, or on a subsequent date that is determined to be appropriate by the National Coordinator. Therefore, it is quite possible that the permanent certification program could commence at the start of 2012 and ONC-ACBs would begin conducting certifications at that time. Taking this into consideration, as similarly calculated for the temporary certification program costs (75 FR 36201), we have estimated and attributed to the permanent certification program's costs the 2012 costs for testing and certifying 15% of the overall number of Complete EHRs and EHR Modules that could potentially be tested and certified to the 2011/2012 certification criteria adopted by the Secretary. This 15% 2012 cost for testing and certification is represented by 15% of the number of each type of Complete EHR and EHR Module we have estimated would be tested and certified to the 2011/2012 certification criteria adopted by the Secretary multiplied by the appropriate estimated costs for testing and certification. The overall cost is expressed in Table 6 below. It should be noted that the cost estimates are different than the cost estimates expressed in the Temporary Certification Program final rule for 2012 because they are based on an increased number of large practice groups and eligible hospitals that may self-develop a Complete EHR and/or EHR Module as specified in the Medicare and Medicaid EHR Incentive Programs final rule (75 FR 44548, 44553).

TABLE 6—DISTRIBUTED TOTAL COSTS FOR THE TESTING AND CERTIFICATION OF COMPLETE EHRs AND EHR MODULES TO THE 2011/2012 CERTIFICATION CRITERIA ADOPTED BY THE SECRETARY UNDER THE PERMANENT CERTIFICATION PROGRAM

Year	Ratio	Total low cost estimate (\$M)	Total high cost estimate (\$M)	Total average cost estimate (\$M)
2012	15%	\$ .95	\$ 7.46	\$ 3.30

The following tables represent estimated permanent certification program costs for the testing and certification of Complete EHRs and EHR Modules to meaningful use (MU) Stages 2 and 3 and include:

- MU Stage 2: Commercial/Open Source Complete EHRs and EHR Modules—Table 7;
- MU Stage 2: Self-developed Complete EHRs—Table 8;

- MU Stage 2: Self-developed EHR Modules—Table 9;
- MU Stage 3: Commercial/Open Source Complete EHRs and EHR Modules—Table 10;
- MU Stage 3: Self-developed Complete EHRs—Table 11;
- MU Stage 3: Self-developed EHR Modules—Table 12.

Table 7 illustrates the costs for testing and certification of commercial/open source Complete EHRs and EHR

Modules to meaningful use Stage 2. We have factored in the assumed 5% reduction in the estimated number of Complete EHRs presented for meaningful use Stage 1 and 20% increase of the estimated number of EHR Modules presented for meaningful use Stage 1. That is, we believe there will be approximately 88 commercial/open source Complete EHRs and 60 EHR Modules that will be tested and certified to meaningful use Stage 2.

TABLE 7—MU STAGE 2: COSTS FOR TESTING AND CERTIFICATION OF COMMERCIAL/OPEN SOURCE COMPLETE EHR AND EHR MODULE UNDER THE PERMANENT CERTIFICATION PROGRAM

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
Commercial/Open Source Complete EHR .....	88	\$0.03	\$0.05	\$0.04	\$2.64	\$4.40	\$3.52
Commercial/Open Source EHR Module .....	60	0.005	0.035	0.02	0.30	2.10	1.20
Total .....	148	.....	.....	.....	2.94	6.55	4.72

Table 8 illustrates the costs for testing and certification of eligible professional and eligible hospital self-developed Complete EHRs to meaningful use Stage 2. We have factored in the assumed 50% reduction of the estimated number of Complete EHRs presented for meaningful use Stage 1. That is, we believe there will be approximately 5 self-developed Complete EHRs for an ambulatory setting and 19 self-developed Complete EHRs for an inpatient setting that will be tested and certified to meaningful use Stage 2.

TABLE 8—MU STAGE 2: COSTS FOR TESTING AND CERTIFICATION OF SELF-DEVELOPED COMPLETE EHRs UNDER THE PERMANENT CERTIFICATION PROGRAM

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 .....	5	\$0.03	\$0.05	\$0.04	\$0.15	\$0.25	\$0.20
Self-Developed Complete EHRs Inpatient Setting .....	19	0.03	0.05	0.04	0.57	0.95	0.76
Total .....	23	.....	.....	.....	0.72	1.20	0.96

Table 9 illustrates the costs for testing and certification of eligible professional and eligible hospital self-developed EHR Modules to meaningful use Stage 2. Based on our assumption, the estimated range of EHR Modules that will be presented for testing and certification to meaningful use Stage 2 will remain the same as for meaningful use Stage 1. That is, we believe there will be between 12 and 82 self-developed EHR Modules for an ambulatory setting attributable to large eligible professional practice groups that will be tested and certified to meaningful use Stage 2. In addition, we believe there will be between 360 and 1087 self-developed Complete EHRs for an inpatient setting attributable to CAHs, small/medium hospitals, and large hospitals that will be tested and certified to meaningful use Stage 2. In total, we believe there will be a minimum of 372 and a maximum of 1,169 self-developed EHR Modules that will be tested and certified to meaningful use Stage 2.

TABLE 9—MU STAGE 2: COSTS FOR TESTING AND CERTIFICATION OF SELF-DEVELOPED EHR MODULES UNDER THE PERMANENT CERTIFICATION PROGRAM

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 number of EHR Modules .....	372	\$0.005	\$0.035	\$0.02	\$1.86	\$13.02	\$7.44
Max number of EHR Modules .....	1,169	0.005	0.035	0.02	5.85	40.92	23.38

Table 10 illustrates the costs for testing and certification of commercial/open source Complete EHRs and EHR Modules to meaningful use Stage 3. We have factored in the assumed 5% reduction in the estimated number of Complete EHRs presented for meaningful use Stage 2 and 20% increase in the estimated number of EHR Modules presented for meaningful use Stage 2. That is, we believe there will be approximately 84 commercial/open source Complete EHRs and 72 EHR Modules that will be tested and certified to meaningful use Stage 3.

TABLE 10—MU STAGE 3: COSTS FOR TESTING AND CERTIFICATION OF COMMERCIAL/OPEN SOURCE COMPLETE EHRs AND EHR MODULES UNDER THE PERMANENT CERTIFICATION PROGRAM

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
Commercial/Open Source Complete EHR .....	84	\$0.03	\$0.05	\$0.04	\$2.52	\$4.20	\$3.36
Commercial/Open Source EHR Module ..	72	0.005	0.035	0.02	0.36	2.52	1.44
Total .....	156	.....	.....	.....	2.88	6.72	4.80

Table 11 illustrates the costs for testing and certification of eligible professional and eligible hospital self-developed Complete EHRs to meaningful use Stage 3. We have

factored in the assumed 25% reduction in the estimated number of Complete EHRs presented for meaningful use Stage 2. That is, we believe there will be approximately 4 self-developed

Complete EHRs for an ambulatory setting and 14 self-developed Complete EHRs for an inpatient setting that will be tested and certified to meaningful use Stage 3.

TABLE 11—MU STAGE 3: COSTS FOR TESTING AND CERTIFICATION OF SELF-DEVELOPED COMPLETE EHRs UNDER THE PERMANENT CERTIFICATION PROGRAM

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 .....	4	\$0.03	\$0.05	\$0.04	\$0.12	\$0.20	\$0.16
Self-Developed Complete EHRs Inpatient Setting .....	14	0.03	0.05	0.04	0.42	.70	.56
Total .....	18	.....	.....	.....	0.54	.90	0.72

Table 12 illustrates the costs for testing and certification of eligible professional and eligible hospital self-developed EHR Modules to meaningful use Stage 3. Based on our assumption, the estimated range of EHR Modules that will be presented for testing and certification to meaningful use Stage 3 will remain the same as it did for

meaningful use Stages 1 and 2. That is, we believe there will be between 12 and 82 self-developed EHR Modules for an ambulatory setting attributable to large eligible professional practice groups that will be tested and certified to meaningful use Stage 3. In addition, we believe there will be between 360 and 1087 self-developed Complete EHRs for

an inpatient setting attributable to CAHs, small/medium hospitals, and large hospitals that will be tested and certified to meaningful use Stage 3. In total, we believe there will be a minimum of 372 and a maximum of 1,169 minimum self-developed EHR Modules that will be tested and certified to meaningful use Stage 3.

TABLE 12—MU STAGE 3: COSTS FOR TESTING AND CERTIFICATION OF SELF-DEVELOPED EHR MODULES UNDER THE PERMANENT CERTIFICATION PROGRAM

Self-developed EHR Modules	Number tested and certified	Cost per complete EHR Module (\$M)			Total cost for all EHR Modules over 3-year period (\$M)		
		Low	High	Mid-point	Low	High	Mid-point
Min number of EHR Modules .....	372	\$0.005	\$0.035	\$0.02	\$1.86	\$13.02	\$7.44
Max number of EHR Modules .....	1,169	0.005	0.035	0.02	5.85	40.92	23.38

Table 13 illustrates the 85% and 15% testing and certification cost distributions we estimate would be attributable to meaningful use Stages 2 and 3 (i.e., between 2012 and 2016) under the permanent certification program. Additionally, we assume that 100% of self-developed Complete EHRs and EHR Modules would be certified in

year that precedes the next meaningful use stage (i.e., 2012 and 2014) because eligible professionals and eligible hospitals who remain self-developers will be motivated to ensure that their HIT can meet the definition of Certified EHR Technology prior to the beginning of a new meaningful use stage in order to avoid missing out on the incentives

or being subject to downward payment adjustments. As a result, the costs for self-developers to get their Complete EHRs or EHR Modules are only attributed in Table 13 to the years 2012 and 2014. The totals multiplied by their respective percentages are derived from the tables above.

TABLE 13—ESTIMATED DISTRIBUTED YEARLY COSTS FOR THE TESTING AND CERTIFICATION OF COMPLETE EHRs AND EHR MODULES ASSOCIATED WITH MEANINGFUL USE STAGES 2 AND 3 UNDER THE PERMANENT CERTIFICATION PROGRAM

Meaningful Use State and Year(s)	Percentage	Type	Low (\$M)	High (\$M)	Mid-point (\$M)
Stage 2: 2012 .....	85	Commercial/	\$2.50 .....	\$5.57	\$4.01
	100	Open Source	2.58 .....	42.12	16.37
		Self-Developed			
2013/2014 .....	15	Commercial/	0.44 .....	0.98	.71
	0	Open Source	0 .....	0	0
		Self-Developed			
Stage 3: 2014 .....	85	Commercial/	2.45 .....	5.71	4.08
	100	Open Source	2.40 .....	41.82	16.13
		Self-Developed			
2015/2016 .....	15	Commercial/	0.43 .....	1.01	0.72
	0	OpenSource	0 .....	0	0
		Self-Developed			

iv. Costs for Collecting, Storing, and Reporting Certification Results  
Costs to ONC-ACBs

Under the permanent certification program, ONC-ACBs 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-ACBs 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 and consistent with the

Temporary Certification Program final rule, we have specified in this final rule two additional reporting elements that must be submitted by ONC-ACBs 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-ACBs 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 not believe that the reporting of these two additional elements will increase the reporting burden or costs for ONC-ACBs.

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, DC, 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-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 14 below.

TABLE 14—ANNUAL COSTS FOR AN ONC-ACB TO REPORT CERTIFICATIONS TO ONC

Program requirement	Employee equivalent	Annual burden hours per ONC-ACB	Employee hourly wage rate	Employee benefits hourly cost	Total cost per ONC-ACB
ONC-ACB 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., six) that we anticipate will apply under the permanent certification program will become ONC-ACBs. Therefore, we estimate the total annual reporting cost under the

permanent certification program to be \$9,500.40.

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 Web site. We believe

that there will be minimal cost associated with this action and have calculated the potential cost, including weekly updates, to be \$10,784 on an annualized basis. This amount is based on 208 hours of yearly work of a Federal Salary Classification GS-12 Step 1 employee located in Washington, DC

v. Costs for Retaining Certification Records

We stated in the Proposed Rule that we believe that the requirement for ONC-ACBs to retain certification records for five years, as specified in § 170.523(g), is in line with common industry practices and, consequently, does not represent additional costs to ONC-ACBs. This determination was based on our consultations with NIST. We did not receive any public comments contrary to our determination and continue to adhere to our determination.

vi. Submission of Surveillance Plan and Surveillance Results Costs to ONC-ACBs

Under the permanent certification program, ONC-ACBs will be required to submit an annual surveillance plan to the National Coordinator and annually

report to the National Coordinator their surveillance results.

As stated in the collection of information section, we anticipate that the burden for each ONC-ACB will be the same based on the following assumptions. We assume that all surveillance plans will be fairly comparable. We also assume that all ONC-ACBs will, on average, have a similar burden in submitting results. Finally, we assume that an ONC-ACB will submit a copy of their annual surveillance plan and surveillance results by either electronic transmission or paper submission. In either instance, we believe that an ONC-ACB will spend a similar amount of time and effort in organizing, categorizing and submitting the requested information. Therefore, we estimate that an ONC-ACB will annually allocate 1 hour to submit the surveillance plan and 1 hour to submit the surveillance results.

We believe that an employee equivalent to the Federal Classification of GS-9 Step 1 could complete the transmissions of the surveillance plan and surveillance results to ONC. We have utilized the corresponding employee hourly rate for the locality pay area of Washington, DC 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 surveillance plan and surveillance results. We have calculated these costs by assuming that an 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 15 below.

TABLE 15—ANNUAL COSTS FOR AN ONC-ACB TO SUBMIT A SURVEILLANCE PLAN AND SURVEILLANCE RESULTS

Program requirement	Employee equivalent	Annual burden hours per ONC-ACB	Employee hourly wage rate	Employee benefits hourly cost	Total cost per ONC-ACB
ONC-ACB Surveillance Plan and Surveillance Results.	GS-9 Step 1 .....	2	\$22.39	\$8.06	\$60.90

To estimate the highest possible cost, we assume that all of the estimated applicants (*i.e.*, six) that we anticipate will apply under the permanent certification program will become ONC-ACBs. Therefore, we estimate the total annual costs for submitting surveillance plans and surveillance results will be \$365.40.

Costs to the Federal Government

We believe that we will incur negligible costs in receiving ONC-ACBs' transmissions of surveillance plans and surveillance results.

vii. Overall Average Annual Costs by Entity

The following table provides a summary of our overall estimated

annual costs for the entities that we project will incur costs under the permanent certification program (as specified in the RIA of this final rule). For ONC-AA applicants, we have averaged the application costs over a 3-year period because the duration of an ONC-AA's term is 3 years. For ONC-ACB applicants, we have averaged the application costs over a 5-year period to coincide with the timeframe used to estimate testing and certification costs for this final rule. In estimating the overall annual costs for an ONC-ACB, we averaged the estimated costs of ONC-ACB status renewal over a 3-year period because the duration of an ONC-ACB's term is 3 years. For commercial, open source and self-developers, we

have provided the average of the mid-point estimated costs for the testing and certification of Complete EHRs and EHR Modules to certification criteria associated with meaningful use stages 2 and 3 over a 5-year period (*see also* Table 13). Estimated annual costs for the Federal government are averaged over the appropriate timeframe. For example, costs for reviewing and approving an ONC-AA are averaged over a 3-year period, while costs for reviewing ONC-ACB applications are averaged over a 5-year period. Table 16 is expressed in thousands of dollars (\$1,000). To illustrate, \$27 is expressed as .027 and \$6.5 million is expressed as \$6,500.00.

TABLE 16—OVERALL AVERAGE ANNUAL COSTS FOR ENTITIES UNDER THE PERMANENT CERTIFICATION PROGRAM

ONC-AA applicant	ONC-AA	ONC-ACB applicant	ONC-ACB	Commercial/open source developers	Self-developers	Federal Government
.027	N/A	7.24	7.68	1,900.00	6,500.00	14.32

\* Costs are expressed in thousands of dollars (\$1,000).

b. Permanent Certification Program Benefits

We believe that several benefits will accrue from the establishment of the

permanent certification program. The permanent certification program will provide a stable, consistent and reliable program for the certification of Complete EHRs, EHR Modules and

potentially other types of HIT. The permanent certification program will allow eligible professionals and eligible hospitals to adopt and implement Certified EHR Technology for future



meaningful use stages, such as Stages 2 and 3, and thus potentially qualify for incentive payments under the CMS Medicare and Medicaid EHR Incentive Programs. We further believe that the permanent 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 Web site.<sup>5</sup> 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-ACB 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).<sup>6</sup> We believe that there will be up to 6 applicants for ONC-ACB status. According to the NAICS codes identified above, this would mean SBA size standards of \$12 million and \$7 million in annual receipts, respectively.<sup>7</sup> 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-

ACB could be in the low millions of dollars. Moreover, it is unclear, whether these entities may be 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-ACB status as well as ONC-ACBs 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-ACB status will permit them to test and certify Complete EHRs, EHR Modules, and/or possibly other types of HIT. Thus, we expect that their annual receipts will increase as a result of becoming an ONC-ACB.

We did not receive any comments related to our RFA analysis on the permanent 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 permanent 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 \$135 million. We did not receive any comments related to the permanent 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 in 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 continues to read as follows:

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

■ 2. Add a new subpart E to part 170 to read as follows:

#### **Subpart E—Permanent Certification Program for HIT**

Sec.	
170.500	Basis and scope.
170.501	Applicability.
170.502	Definitions.
170.503	Requests for ONC-AA status and ONC-AA ongoing responsibilities.
170.504	Reconsideration process for requests for ONC-AA status.
170.505	Correspondence.
170.510	Types of certification.
170.520	Application.
170.523	Principles of proper conduct for ONC-ACBs.
170.525	Application submission.
170.530	Review of application.
170.535	ONC-ACB application reconsideration.
170.540	ONC-ACB status.
170.545	Complete EHR certification.
170.550	EHR Module certification.
170.553	Certification of health information technology other than Complete EHRs and EHR Modules.
170.555	Certification to newer versions of certain standards.
170.557	Authorized certification methods.
170.560	Good standing as an ONC-ACB.

<sup>5</sup> [http://sba.gov/idc/groups/public/documents/sba\\_homepage/serv\\_std\\_tablepdf.pdf](http://sba.gov/idc/groups/public/documents/sba_homepage/serv_std_tablepdf.pdf).

<sup>6</sup> See 13 CFR 121.201.

<sup>7</sup> 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](http://www.sba.gov/idc/groups/public/documents/sba_homepage/guide_to_size_standards.pdf).

- 170.565 Revocation of ONC-ACB status.  
 170.570 Effect of revocation on the certifications issued to Complete EHRs and EHR Modules.  
 170.599 Incorporation by reference.

### Subpart E—Permanent Certification Program for HIT

#### § 170.500 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 permanent certification program for health information technology (HIT) administered by the National Coordinator for Health Information Technology.

#### § 170.501 Applicability.

This subpart establishes the processes that applicants for ONC-ACB status must follow to be granted ONC-ACB status by the National Coordinator; the processes the National Coordinator will follow when assessing applicants and granting ONC-ACB status; the requirements that ONC-ACBs must follow to maintain ONC-ACB status; and the requirements of ONC-ACBs for certifying Complete EHRs, EHR Module(s), and other types of HIT in accordance with the applicable certification criteria adopted by the Secretary in subpart C of this part. It also establishes the processes accreditation organizations must follow to request approval from the National Coordinator and that the National Coordinator in turn will follow to approve an accreditation organization under the permanent certification program as well as certain ongoing responsibilities for an ONC-AA.

#### § 170.502 Definitions.

For the purposes of this subpart:

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

*Deployment site* means the physical location where a Complete EHR, EHR Module(s) or other type of HIT resides or is being or has been implemented.

*Development site* means the physical location where a Complete EHR, EHR Module(s) or other type of HIT was developed.

*Gap certification* means the certification of a previously certified Complete EHR or EHR Module(s) to:

(1) All applicable new and/or revised certification criteria adopted by the Secretary at subpart C of this part based on the test results of a NVLAP-accredited testing laboratory; and

(2) All other applicable certification criteria adopted by the Secretary at subpart C of this part based on the test results used to previously certify the Complete EHR or EHR Module(s).

*ONC-Approved Accreditor or ONC-AA* means an accreditation organization that the National Coordinator has approved to accredit certification bodies under the permanent certification program.

*ONC-Authorized Certification Body or ONC-ACB* 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 certification of Complete EHRs, EHR Module(s), and/or other types of HIT under the permanent certification program.

*Providing or provide an updated certification* means the action taken by an ONC-ACB to ensure that the developer of a previously certified EHR Module(s) shall update the information required by § 170.523(k)(1)(i), after the ONC-ACB has verified that the certification criterion or criteria to which the EHR Module(s) was previously certified have not been revised and that no new certification criteria adopted for privacy and security are applicable to the EHR Module(s).

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

#### § 170.503 Requests for ONC-AA status and ONC-AA ongoing responsibilities.

(a) The National Coordinator may approve only one ONC-AA at a time.

(b) *Submission.* The National Coordinator will publish a notice in the **Federal Register** to announce the 30-day period during which requests for ONC-AA status may be submitted. In order to be considered for ONC-AA status, an accreditation organization must submit a timely request in writing to the National Coordinator along with the following information to demonstrate its ability to serve as an ONC-AA:

(1) A detailed description of the accreditation organization's conformance to ISO/IEC17011:2004 (incorporated by reference in § 170.599) and experience evaluating the conformance of certification bodies to ISO/IEC Guide 65:1996 (incorporated by reference in § 170.599);

(2) A detailed description of the accreditation organization's accreditation, requirements as well as how those requirements would complement the Principles of Proper

Conduct for ONC-ACBs and ensure the surveillance approaches used by ONC-ACBs include the use of consistent, objective, valid, and reliable methods;

(3) Detailed information on the accreditation organization's procedures that would be used to monitor ONC-ACBs;

(4) Detailed information, including education and experience, about the key personnel who review organizations for accreditation; and

(5) Procedures for responding to, and investigating, complaints against ONC-ACBs.

#### (c) Preliminary selection.

(1) The National Coordinator is permitted up to 60 days from the end of the submission period to review all timely submissions that were received and determine which accreditation organization is best qualified to serve as the ONC-AA.

(2) The National Coordinator's determination will be based on the information provided, the completeness of an accreditation organization's description of the elements listed in paragraph (b) of this section, and each accreditation organization's overall accreditation experience.

(3) The accreditation organization that is determined to be the best qualified will be notified that it has been selected as the ONC-AA on a preliminary basis, subject to the resolution of the reconsideration process in § 170.504. All other accreditation organizations will be notified that their requests for ONC-AA status have been denied. The accreditation organization that is selected on a preliminary basis shall not represent itself as the ONC-AA or perform accreditation(s) under the permanent certification program unless and until it receives written notice from the National Coordinator that it has been approved as the ONC-AA on a final basis pursuant to paragraph (d) of this section.

(4) Any accreditation organization that submits a timely request for ONC-AA status and is denied may request reconsideration in accordance with § 170.504.

#### (d) Final approval.

(1) If the National Coordinator determines that an accreditation organization has met the standard specified in § 170.504(b), then that organization will be approved as the ONC-AA on a final basis. The accreditation organization that was selected as the ONC-AA on a preliminary basis pursuant to paragraph (c) of this section will be notified of this final decision and cannot request reconsideration or further review.

(2) If the National Coordinator determines that no accreditation organization has met the standard specified in § 170.504(b), then the organization that was selected as the ONC-AA on a preliminary basis pursuant to paragraph (c) of this section will be approved as the ONC-AA on a final basis.

(e) *ONC-AA ongoing responsibilities.* An ONC-AA must:

(1) Maintain conformance with ISO/IEC 17011:2004 (incorporated by reference in § 170.599);

(2) In accrediting certification bodies, verify conformance to, at a minimum, ISO/IEC Guide 65:1996 (incorporated by reference in § 170.599) and ensure the surveillance approaches used by ONC-ACBs include the use of consistent, objective, valid, and reliable methods;

(3) Verify that ONC-ACBs are performing surveillance in accordance with their respective annual plans; and

(4) Review ONC-ACB surveillance results to determine if the results indicate any substantive non-conformance by ONC-ACBs with the conditions of their respective accreditations.

(f) *ONC-AA status.*

(1) An accreditation organization has not been granted ONC-AA status unless and until it is notified by the National Coordinator that it has been approved as the ONC-AA on a final basis pursuant to paragraph (d) of this section.

(2) An ONC-AA's status will expire not later than 3 years from the date its status was granted by the National Coordinator.

(3) The National Coordinator will accept requests for ONC-AA status, in accordance with paragraph (b) of this section, at least 180 days before the current ONC-AA's status is set to expire.

#### **§ 170.504 Reconsideration process for requests for ONC-AA status.**

(a) An accreditation organization that submits a timely request for ONC-AA status in accordance with § 170.503 and is denied may request reconsideration of the decision to deny its request for ONC-AA status.

(b) *Submission requirement.* To request reconsideration, an accreditation organization is required to submit to the National Coordinator, within 15 days of receipt of a denial notice, a written statement with supporting documentation contesting the decision to deny its request for ONC-AA status. The submission must demonstrate that clear, factual errors were made in the review of its request for ONC-AA status and that the accreditation organization would have

been selected as the ONC-AA pursuant to § 170.503(c) if those errors had been corrected. If the National Coordinator does not receive an accreditation organization's submission within the specified timeframe, then its request for reconsideration may be denied.

(c) *Review of submissions.* The National Coordinator is permitted up to 30 days to review all timely submissions that were received and determine whether an accreditation organization has met the standard specified in paragraph (b) of this section.

(d) *Decision.*

(1) If the National Coordinator determines that an accreditation organization has met the standard specified in paragraph (b) of this section, then that organization will be approved as the ONC-AA on a final basis. All other accreditation organizations will be notified that their requests for reconsideration have been denied.

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

#### **§ 170.505 Correspondence.**

(a) Correspondence and communication with the National Coordinator shall be conducted by e-mail, unless otherwise necessary. The official date of receipt of any e-mail between the National Coordinator and an accreditation organization requesting ONC-AA status, the ONC-AA, an applicant for ONC-ACB status, or an ONC-ACB is the date on which the e-mail was sent.

(b) In circumstances where it is necessary for an accreditation organization requesting ONC-AA status, the ONC-AA, an applicant for ONC-ACB status, or an ONC-ACB 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.

#### **§ 170.510 Types of certification.**

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

(a) Complete EHR certification; and/or

(b) EHR Module certification; and/or

(c) Certification of other types of HIT for which the Secretary has adopted certification criteria under subpart C of this part.

#### **§ 170.520 Application.**

Applicants must include the following information in an application for ONC-ACB status and submit it to the

National Coordinator for the application to be considered complete.

(a) The type of authorization sought pursuant to § 170.510. For authorization to perform EHR Module certification, applicants must indicate the specific type(s) of EHR Module(s) they seek authorization to certify. If qualified, applicants will only be granted authorization to certify the type(s) of EHR Module(s) for which they seek authorization.

(b) General identifying information including:

(1) Name, address, city, state, zip code, and Web site of applicant; and

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

(c) Documentation that confirms that the applicant has been accredited by the ONC-AA.

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

#### **§ 170.523 Principles of proper conduct for ONC-ACBs.**

An ONC-ACB shall:

(a) Maintain its accreditation;

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

(c) Maintain a training program that includes documented procedures and training requirements to ensure its personnel are competent to certify HIT;

(d) 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 certification personnel;

(3) Policies or procedures;

(4) Location;

(5) Personnel, 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 certify HIT.

(e) Allow ONC, or its authorized agent(s), to periodically observe on site (unannounced or scheduled), during normal business hours, any certifications performed to demonstrate compliance with the requirements of the permanent certification program;

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

(1) The Complete EHR or EHR Module developer 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 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 certified.

(g) Retain all records related to the certification of Complete EHRs and/or EHR Module(s) for a minimum of 5 years;

(h) Only certify HIT, including Complete EHRs and/or EHR Module(s), that has been tested, using test tools and test procedures approved by the National Coordinator, by a/an:

(1) NVLAP-accredited testing laboratory; or

(2) ONC-ATCB when:

(i) Certifying previously certified EHR Module(s) if the certification criterion or criteria to which the EHR Module(s) was previously certified have not been revised and no new certification criteria are applicable to the EHR Module(s); or

(ii) Performing gap certification.

(i) Submit an annual surveillance plan to the National Coordinator and annually report to the National Coordinator its surveillance results; and

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

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

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

(3) Previous certifications that it performed if its conduct necessitates the recertification of Complete EHRs and/or EHR Module(s);

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

(1) A Complete EHR or EHR Module developer must conspicuously include the following on its Web site 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 20[XX]/20[XX] compliant and has been certified by an ONC-ACB in accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services. This certification does not represent an endorsement by the U.S. Department of Health and Human

Services or guarantee the receipt of incentive payments."; and

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

(2) A certification issued to a pre-coordinated, 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 the certification must also indicate each EHR Module that is included in the bundle; and

(3) A certification issued to a Complete EHR or EHR Module based solely on the 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.

#### **§ 170.525 Application submission.**

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

(b) An application for ONC-ACB status may be submitted to the National Coordinator at any time.

#### **§ 170.530 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 is permitted up to 30 days from receipt to review an application that is submitted for the first time.

(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 National Coordinator may issue a deficiency notice to the applicant.

(2) If the National Coordinator determines that deficiencies in 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 from the National Coordinator an extension for good cause of the 15-day period provided in paragraph (c)(2) of this section to submit a revised application.

(2) In order for an applicant to continue to be considered for ONC-ACB status, the 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 cannot reapply for ONC-ACB status for a period of six months from the date of the denial notice. An applicant may request reconsideration of this decision in accordance with § 170.535.

(d) *Satisfactory application.*

(1) An application will be deemed satisfactory if it meets all the application requirements, as determined by the National Coordinator.

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

(3) Once notified by the National Coordinator of its successful achievement of ONC-ACB status, the applicant may represent itself as an ONC-ACB and begin certifying health information technology consistent with its authorization.

#### **§ 170.535 ONC-ACB application reconsideration.**

(a) An applicant may request that the National Coordinator reconsider a denial notice only if the applicant can demonstrate that clear, factual errors were made in the review of its application and that the errors' correction could lead to the applicant obtaining ONC-ACB 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 error(s) it believes can account for the denial. If the National Coordinator does not receive the applicant's reconsideration request 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 determination and the applicant's successful achievement of ONC-ACB status.

(2) If, after reviewing an applicant's reconsideration request, the National Coordinator determines that the applicant did not identify factual errors or that the correction of the 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.

#### **§ 170.540 ONC-ACB status.**

(a) *Acknowledgement and publication.* The National Coordinator will acknowledge and make publicly available the names of ONC-ACBs, including the date each was authorized and the type(s) of certification each has been authorized to perform.

(b) *Representation.* Each ONC-ACB must prominently and unambiguously identify the scope of its authorization on its Web site and in all marketing and communications statements (written and oral) pertaining to its activities under the permanent certification program.

(c) *Renewal.* An ONC-ACB is required to renew its status every three years. An ONC-ACB is required to submit a renewal request, containing any updates to the information requested in § 170.520, to the National Coordinator 60 days prior to the expiration of its status.

(d) *Expiration.* An ONC-ACB's status will expire three years from the date it was granted by the National Coordinator

unless it is renewed in accordance with paragraph (c) of this section.

#### **§ 170.545 Complete EHR certification.**

(a) When certifying Complete EHRs, an ONC-ACB must certify in accordance with all applicable certification criteria adopted by the Secretary at subpart C of this part.

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

(c) *Gap certification.* An ONC-ACB may provide the option for and perform gap certification of previously certified Complete EHRs.

(d) *Inherited certified status.* An ONC-ACB must accept requests for a newer version of a previously certified Complete EHR to inherit the certified status of the previously certified Complete EHR without requiring the newer version to be recertified.

(1) Before granting certified status to a newer version of a previously certified Complete EHR, an ONC-ACB must review an attestation submitted by the developer of the Complete EHR to determine whether any change in the newer version has adversely affected the Complete EHR's capabilities for which certification criteria have been adopted.

(2) An ONC-ACB may grant certified status to a newer version of a previously certified Complete EHR if it determines that the capabilities for which certification criteria have been adopted have not been adversely affected.

(e) An ONC-ACB that has been authorized to certify Complete EHRs is also authorized to certify all EHR Modules under the permanent certification program.

#### **§ 170.550 EHR Module certification.**

(a) When certifying EHR Module(s), an ONC-ACB must certify in accordance with the applicable certification criteria adopted by the Secretary at subpart C of this part.

(b) An ONC-ACB must provide the option for an EHR Module(s) to be certified solely to the applicable certification criteria adopted by the Secretary at subpart C of this part.

(c) *Gap certification.* An ONC-ACB may provide the option for and perform gap certification of previously certified EHR Module(s).

(d) An ONC-ACB may provide an updated certification to a previously certified EHR Module(s).

(e) *Privacy and security certification.* EHR Module(s) shall be certified to all privacy and security certification criteria adopted by the Secretary, unless the EHR Module(s) is presented for

certification in one of the following manners:

(1) The EHR Modules are presented for certification as a pre-coordinated, integrated bundle of EHR Modules, which would otherwise meet the definition of and constitute a Complete EHR, and one or more of the constituent EHR Modules is demonstrably responsible for providing all of the privacy and security capabilities for the entire bundle of EHR Modules; or

(2) An EHR Module is presented for certification, and the presenter can demonstrate and provide documentation to the ONC-ACB that a privacy and security certification criterion is inapplicable or that it would be technically infeasible for the EHR Module to be certified in accordance with such certification criterion.

(f) *Inherited certified status.* An ONC-ACB must accept requests for a newer version of a previously certified EHR Module(s) to inherit the certified status of the previously certified EHR Module(s) without requiring the newer version to be recertified.

(1) Before granting certified status to a newer version of a previously certified EHR Module(s), an ONC-ACB must review an attestation submitted by the developer(s) of the EHR Module(s) to determine whether any change in the newer version has adversely affected the EHR Module(s)' capabilities for which certification criteria have been adopted.

(2) An ONC-ACB may grant certified status to a newer version of a previously certified EHR Module(s) if it determines that the capabilities for which certification criteria have been adopted have not been adversely affected.

#### **§ 170.553 Certification of health information technology other than Complete EHRs and EHR Modules.**

An ONC-ACB authorized to certify health information technology other than Complete EHRs and/or EHR Modules must certify such health information technology in accordance with the applicable certification criterion or certification criteria adopted by the Secretary at subpart C of this part.

#### **§ 170.555 Certification to newer versions of certain standards.**

(a) ONC-ACBs may certify Complete EHRs and/or EHR Module(s) 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 newer version of an adopted minimum standard.*

(1) ONC-ACBs are not required to certify Complete EHRs and/or EHR Module(s) 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.

**§ 170.557 Authorized certification methods.**

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

**§ 170.560 Good standing as an ONC-ACB.**

An ONC-ACB must maintain good standing by:

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

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

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

**§ 170.565 Revocation of ONC-ACB status.**

(a) *Type-1 violations.* The National Coordinator may revoke an ONC-ACB's status for committing a Type-1 violation. Type-1 violations include violations of law or permanent certification program policies that threaten or significantly undermine the integrity of the permanent certification program. These violations include, but are not limited to: False, fraudulent, or abusive activities that affect the permanent 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-ACB's status for failing to timely or adequately correct a Type-2 violation. Type-2 violations constitute noncompliance with § 170.560.

(1) *Noncompliance notification.* If the National Coordinator obtains reliable evidence that an ONC-ACB may no longer be in compliance with § 170.560, the National Coordinator will issue a noncompliance notification with reasons for the notification to the ONC-ACB requesting that the ONC-ACB respond to the alleged violation and correct the violation, if applicable.

(2) *Opportunity to become compliant.* After receipt of a noncompliance notification, an ONC-ACB 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-ACB 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-ACB 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-ACB confirming this determination.

(iii) If the National Coordinator determines that the ONC-ACB 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-ACB's status.

(c) *Proposed revocation.*

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

(2) The National Coordinator may propose to revoke an ONC-ACB's status if, after the ONC-ACB has been notified of a Type-2 violation, the ONC-ACB 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) of this section.

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

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

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

(ii) The continued certification of Complete EHRs, EHR Module(s), and/or other types of HIT by the ONC-ACB 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) of this section have

been met, an ONC-ACB will be issued a notice of proposed suspension.

(3) Upon receipt of a notice of proposed suspension, an ONC-ACB 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-ACB'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-ACB's written response or if the ONC-ACB fails to submit a written response within the timeframe specified in paragraph (d)(3) of this section:

(i) Rescind the proposed suspension; or

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

(iii) Propose revocation in accordance with § 170.565(c) and suspend the ONC-ACB's operations for the duration of the revocation process.

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

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

(1) An ONC-ACB 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-ACB's response to a proposed revocation notice, the National Coordinator is permitted up to 30 days to review the information submitted by the ONC-ACB and reach a decision.

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

(g) *Revocation.*

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

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

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

(2) A decision to revoke an ONC-ACB's status is final and not subject to further review unless the National

Coordinator chooses to reconsider the revocation.

(h) *Extent and duration of revocation.*

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

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

(3) A certification body that has had its ONC-ACB status revoked for a Type-1 violation, is not permitted to reapply for ONC-ACB status under the permanent certification program for a period of 1 year.

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

**§ 170.570 Effect of revocation on the certifications issued to Complete EHRs and EHR Module(s).**

(a) The certified status of Complete EHRs and/or EHR Module(s) certified by an ONC-ACB that had its 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-ACB.

(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-ACB, then the National Coordinator would:

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

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

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

**§ 170.599 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](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, <http://www.iso.org>.

(1) ISO/IEC 17011:2004 Conformity Assessment—General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies (Corrected Version), February 15, 2005, IBR approved for § 170.503.

(2) ISO/IEC GUIDE 65:1996—General Requirements for Bodies Operating Product Certification Systems (First Edition), 1996, IBR approved for § 170.503.

(3) [Reserved]

Dated: December 14, 2010.

**Kathleen Sebelius,**  
*Secretary.*

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