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Dated: May 24, 2011.

Eric M. Bissonette,

Acting Director, Office of Ground Water and Drinking Water.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 170

RIN 0991-AB77

Permanent Certification Program for Health Information Technology; Revisions to ONC-Approved Accreditor Processes

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

ACTION: Proposed rule.

SUMMARY: Under the authority granted to the National Coordinator for Health Information Technology (the National Coordinator) by section 3001(c)(5) of the Public Health Service Act (PHSA) as added by the Health Information Technology for Economic and Clinical Health (HITECH) Act, this rule proposes a process for addressing instances where the ONC-Approved Accreditor (ONC-AA) engages in improper conduct or does not perform its responsibilities under the permanent certification program. This rule also proposes to address the status of ONC-Authorized Certification Bodies (ONC-ACBs) in instances where there may be a change in the accreditation organization serving as the ONC-AA and clarifies the responsibilities of the new ONC-AA.

DATES: To be assured consideration, written or electronic comments must be received at one of the addresses provided below, no later than 5 p.m. on August 1, 2011.

ADDRESSES: Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments, identified by RIN 0991-AB77, by any of the following methods (please do not submit duplicate comments).

- *Federal eRulemaking Portal:* Follow the instructions for submitting comments. Attachments should be in Microsoft Word or Excel, Adobe PDF; however, we prefer Microsoft Word. <http://www.regulations.gov>.

- *Regular, Express, or Overnight Mail:* Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Attention: Revisions to ONC-AA Processes Proposed Rule, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave., SW., Washington, DC 20201. Please submit one original and two copies.

- *Hand Delivery or Courier:* Office of the National Coordinator for Health Information Technology, Attention: Revisions to ONC-AA Processes Proposed Rule, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave., SW., Washington, DC 20201. Please submit one original and two copies. (Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the mail drop slots located in the main lobby of the building.)

Inspection of Public Comments: All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. Please do not include anything in your comment submission that you do not wish to share with the general public. Such information includes, but is not limited to: a person's social security number; date of birth; driver's license number; state identification number or foreign country equivalent; passport number; financial account number; credit or debit card number; any personal health information; or any business information that could be considered to be proprietary. We will post all comments received before the close of the comment period at <http://www.regulations.gov>.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> or the 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 the contact listed below to arrange for inspection).

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

EHR Electronic Health Record
 HHS Department of Health and Human Services
 HIT Health Information Technology
 HITECH Health Information Technology for Economic and Clinical Health
 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
 PHSA Public Health Service Act
 RFA Regulatory Flexibility Act
 SBA Small Business Administration

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I. Background

[If you choose to comment on the background section, please include at the beginning of your comment the caption "Background" and any additional information to clearly identify the information about which you are commenting.]

A. Statutory Basis for the Permanent Certification Program

The Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A

and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5), amended the Public Health Service Act (PHSA) to add a new “Title XXX—Health Information Technology and Quality.” Section 3001(c)(5) of the PHSA, as added by section 13101 of the HITECH Act, provides the National Coordinator for Health Information Technology (National Coordinator) with the authority to establish a certification program or programs for the voluntary certification of health information technology (HIT). Specifically, section 3001(c)(5)(A) states 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 [section 3004 of the PHSA].”

B. Regulatory Background of the Permanent Certification Program

1. Initial Set of Standards, Implementation Specifications, and Certification Criteria Interim Final and Final Rules

In accordance with section 3004(b)(1) of the PHSA, the Secretary issued an interim final rule with request for comments entitled “Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology” (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 Electronic Health Record (EHR) Technology must include in order to, at a minimum, support the achievement of meaningful use Stage 1 by eligible professionals and eligible hospitals¹ under the Medicare and Medicaid EHR Incentive Programs.

2. Medicare and Medicaid EHR Incentive Programs Proposed and Final Rules

Associated with the HIT Standards and Certification Criteria interim final rule, CMS concurrently published in the **Federal Register** (75 FR 1844, Jan. 13, 2010) 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.

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

Based on the authority provided in section 3001(c)(5) of the PHSA, 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). We proposed to use the certification programs for the purposes of testing and certifying HIT and specified the processes the National Coordinator would follow to authorize organizations to perform the testing and/or certification of HIT. Notably, we issued two final rules to implement our proposals. On June 24, 2010, a final rule was published in the **Federal Register** (75 FR 36158) to establish a temporary certification program (the “Temporary

Certification Program final rule”). On January 7, 2011, a final rule was published in the **Federal Register** (76 FR 1262) to establish the permanent certification program (the “Permanent Certification Program final rule”). The permanent certification program will eventually replace the temporary certification program, which will sunset on December 31, 2011, or on a subsequent date if the permanent certification program is not fully constituted at that time.

EHR technology that is tested and certified through the certification programs currently must be tested and certified in accordance with all applicable certification criteria adopted by the Secretary under section 3004(b)(1) of the PHSA and could potentially be used to satisfy the definition of Certified EHR Technology. Eligible professionals and eligible hospitals that successfully demonstrate meaningful use of Certified EHR Technology may receive incentive payments under the Medicare and Medicaid EHR Incentive Programs.

C. Overview of the Permanent Certification Program

Key facets of the permanent certification program are summarized as follows. The permanent certification program provides a process by which an organization or organizations may become an Office of the National Coordinator for Health Information Technology-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.

An organization that seeks to become an ONC-ACB must, among other requirements, successfully obtain accreditation from the accreditation organization that has been approved by the National Coordinator as the ONC-Approved Accreditor (ONC-AA). Only one accreditation organization at a time may be approved to serve as the ONC-AA. An accreditation organization that wishes to be considered for ONC-AA status must submit a written request to the National Coordinator during the specified submission period and

¹References to “eligible hospitals” in this rule shall mean “eligible hospitals and/or critical access hospitals, as defined in 42 CFR 495.4” unless otherwise indicated.

include certain information to demonstrate its ability to serve as the ONC-AA. The National Coordinator will determine which accreditation organization is best qualified to serve as the ONC-AA, and the organization that is approved on a final basis will be expected to serve a three-year term. The ONC-AA must fulfill certain on-going responsibilities for the permanent certification program, which include: maintaining conformance with ISO/IEC 17011:2004 (ISO 17011); in accrediting certification bodies, verifying that they conform to ISO/IEC Guide 65:1996 (Guide 65) at a minimum; and performing certain activities related to surveillance that will be conducted by ONC-ACBs.

The National Coordinator will accept applications for ONC-ACB status at any time, which must include the type of authorization sought, general identifying information, documentation that confirms that the applicant has been accredited by the ONC-AA, and an executed agreement that it will adhere to the Principles of Proper Conduct for ONC-ACBs. ONC-ACBs will be required to remain in good standing by, among other things, adhering to the Principles of Proper Conduct for ONC-ACBs, which include a requirement that an ONC-ACB must maintain its accreditation that was granted by the ONC-AA. An ONC-ACB's status will expire in three years, unless its status is renewed. The National Coordinator may revoke an ONC-ACB's status and/or suspend an ONC-ACB's operations under permanent certification program, based on Type-1 and Type-2 violations.

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.

II. Provisions of the Proposed Rule

[If you choose to comment on the provisions of the proposed rule section, please include at the beginning of your comment the section title to which your comments apply and any additional information to clearly identify the proposals about which you are commenting.]

A. Removal of the ONC-AA for Improper Conduct or Failure To Perform Its Responsibilities

In the proposed rule to establish the temporary and permanent certification programs (75 FR 11328), we did not propose a formal process for the

National Coordinator to remove or take other corrective action against an accreditation organization serving as the ONC-AA based on misconduct or failure to perform its responsibilities. We did propose and finalize a process through which the National Coordinator could revoke the status and/or suspend the operations of an ONC-Authorized Testing and Certification Body (ONC-ATCB) under the temporary certification program and an ONC-ACB under the permanent certification program. Some of the comments we received asked how we would address concerns with an ONC-AA's operations and remove or replace an ineffective ONC-AA. We responded to those comments in the Permanent Certification Program final rule (76 FR 1269) by stating our intentions to issue a notice of proposed rulemaking that would 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 recognized that an ONC-AA has significant responsibilities under the permanent certification program that are inextricably linked to the success of the program. We believe that a removal process, similar to the revocation and suspension processes we have established for ONC-ATCBs under the temporary certification program and ONC-ACBs under the permanent certification program, would protect the integrity of the permanent certification program and maintain public confidence in the program by removing an ONC-AA that engages in misconduct or fails to satisfy its performance obligations under the program.

To address improper conduct by the ONC-AA or its failure to perform its responsibilities under the permanent certification program, we are proposing a process for removing the ONC-AA that is similar to the process established in the Permanent Certification Program final rule for suspending and/or revoking an ONC-ACB's status. We propose that the National Coordinator may remove the ONC-AA under the permanent certification program based on either a conduct or performance violation by the ONC-AA. We describe these violations and the removal process below and in the provisions of proposed § 170.575. We welcome comments on our proposals discussed below.

1. Conduct Violations

The types of violations we would consider conduct violations include violations of law or permanent certification program policies that threaten or significantly undermine the

integrity of the permanent certification program. Conduct violations would include, but are not limited to, false, fraudulent, or abusive activities that affect: the permanent certification program; a program administered by the Department of Health and Human Services (HHS); or any program administered by the Federal government. These violations could jeopardize the integrity of the permanent certification program and would include examples such as: the ONC-AA, or a principal employee, owner, or agent of the ONC-AA, being charged with or convicted of fraud, embezzlement or extortion, or of violating similar Federal or State securities laws while participating in the permanent certification program; falsifying accreditations; or withholding, destroying, or altering information that would indicate false or fraudulent activity had occurred within the permanent certification program.

For the public to maintain faith in the integrity of permanent certification program, the program's participants must properly fulfill their responsibilities. Therefore, we propose that if the National Coordinator has reliable evidence that the ONC-AA committed one or more conduct violations, the National Coordinator may issue the ONC-AA a notice proposing to remove it as the ONC-AA under the permanent certification program.

2. Performance Violations

The types of violations we would consider performance violations include the ONC-AA failing to properly fulfill one or more of its responsibilities specified in § 170.503(e). These responsibilities include: maintaining conformance with ISO 17011; in accrediting certification bodies, verifying conformance to, at a minimum, Guide 65 and ensuring the surveillance approaches used by ONC-ACBs include the use of consistent, objective, valid, and reliable methods; verifying that ONC-ACBs are performing surveillance in accordance with their respective annual plans; and reviewing ONC-ACB surveillance results to determine if the results indicate any substantive non-conformance by the ONC-ACBs with the conditions of their respective accreditations.

Opportunities to assess an ONC-AA's performance of its responsibilities will be available at certain junctures during the permanent certification program. As an example in the Permanent Certification Program final rule (76 FR 1270), we noted that 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 noted that we expect that our review and analysis of surveillance plans and results will not only include feedback from the ONC-ACBs but also feedback from the ONC-AA. The ONC-AA feedback will provide us with additional information on the ONC-AA's performance of its responsibilities to monitor and review ONC-ACBs' surveillance activities.

The National Coordinator could obtain information about the ONC-AA from other sources as well. For example, we could potentially receive information from an organization that sought accreditation by the ONC-AA and was denied, or from an ONC-ACB that had its accreditation withdrawn by the ONC-AA. Such information could provide reliable evidence that the ONC-AA was not in compliance with ISO 17011, as required by § 170.503(e)(1). For example, section 7 (Accreditation process) of ISO 17011 requires the ONC-AA to establish a proper assessment process for accrediting conformance assessment bodies (*i.e.*, certification bodies or ONC-ACBs), which includes establishing procedures to address appeals by such bodies. Information from a certification body that sought accreditation or an ONC-ACB could indicate whether the ONC-AA had a sufficient assessment or appeals processes in place. We propose that if the National Coordinator obtains reliable evidence from fact-gathering, requesting information from the ONC-AA, contacting the ONC-AA's customer(s), and/or complaints that the ONC-AA is not properly performing its responsibilities under § 170.503(e), the National Coordinator would notify the ONC-AA of an alleged performance violation. The notification would include all pertinent information regarding the National Coordinator's assessment. Unless otherwise specified by the National Coordinator, the ONC-AA would be permitted up to 30 days from the date it is notified about the alleged performance violation(s) to submit a written response and any accompanying documentation that could demonstrate no violation(s) occurred or validate that violation(s)

occurred and were corrected. If the ONC-AA fails to submit a response to the National Coordinator within 30 days, the National Coordinator may issue the ONC-AA a notice proposing to remove it as the ONC-AA under the permanent certification program.

If the ONC-AA submits a response, the National Coordinator would be permitted up to 60 days to evaluate the ONC-AA's response (and request additional information, if necessary). If the National Coordinator determines that the ONC-AA did not commit a performance violation, or may have committed a performance violation but satisfactorily corrected any violation(s) that may have occurred, a memo will be issued to the ONC-AA to confirm this determination. If the National Coordinator determines that the ONC-AA's response is insufficient and that a performance violation had occurred and had not been adequately corrected, then the National Coordinator may propose to remove the ONC-AA.

3. Proposed Removal of the ONC-AA

Under our removal process, the National Coordinator may propose the removal of the ONC-AA for alleged conduct violations and for failing to respond to, or satisfactorily address, a notification related to a performance violation. Based on our assessment, the option to propose removal is more appropriate than the option to suspend the ONC-AA's activities under the permanent certification program. Any form of suspension would prevent the ONC-AA from performing its responsibilities under § 170.503(e), which would not benefit the permanent certification program because these ongoing responsibilities are an integral part of the program. We welcome comments on these options and whether certain circumstances may warrant the suspension of the ONC-AA.

4. Opportunity To Respond to a Proposed Removal Notice

If the National Coordinator issues a proposed removal notice to the ONC-AA, we propose that the ONC-AA must respond within 20 days of receipt of the removal notice in order to contest the proposed removal and must provide sufficient documentation to support its explanation for why it should not be removed. Upon receipt of the ONC-AA's response to a proposed removal notice, the National Coordinator would be permitted up to 60 days to review the information submitted by the ONC-AA and make a decision.

During the time period provided for the ONC-AA to respond to the proposed removal notice and the National

Coordinator's review period, we would expect that the ONC-AA would continue to perform its responsibilities under the permanent certification program and propose that the National Coordinator would consider the ONC-AA's performance of its duties during this timeframe as a factor in reaching any final decision to remove the ONC-AA. We welcome comments on this proposal and whether it would be more appropriate for the National Coordinator to proceed in a different manner, including providing less time for the ONC-AA to respond to a proposed removal notice based on a conduct violation.

5. Removal of the ONC-AA

According to our proposal, the ONC-AA may be removed by the National Coordinator if it is determined that removal is appropriate after considering the information provided by the ONC-AA in response to the proposed removal notice or if the ONC-AA does not respond to a proposed removal notice within the specified timeframe. We propose that a decision to remove the ONC-AA would be final and would not be subject to further review unless the National Coordinator chooses to reconsider the removal.

If the National Coordinator determines that the ONC-AA should not be removed, the National Coordinator would notify the ONC-AA in writing to express this determination.

6. Extent and Duration of Removal Under the Permanent Certification Program

We propose that the removal of the ONC-AA would become effective upon the date specified in the removal notice and that the affected accreditation organization would be required to cease all activities under the permanent certification program, including accepting new requests for accreditation associated with the permanent certification program. We propose that an accreditation organization that has been removed as the ONC-AA will be prohibited from being considered for ONC-AA status for a period of 1 year from the effective date of removal. Violation(s) committed by the accreditation organization serving as the ONC-AA that result in its removal demonstrate that it cannot conduct itself properly or perform its responsibilities under the permanent certification program. Accordingly, we believe that if an accreditation organization has its ONC-AA status removed, it would be inappropriate to permit the accreditation organization to immediately reapply to become the

ONC-AA. We therefore propose a 1-year waiting period to prevent the affected accreditation organization from being considered when ONC goes through the process in § 170.503 to approve its replacement. We request public comment on alternatives for the treatment of an accreditation organization that is removed as the ONC-AA under the permanent certification program.

B. Effects of Removing and/or Replacing the ONC-AA

1. ONC-ACB Status

In § 170.523(a) we require that an ONC-ACB “[m]aintain its accreditation.” During the course of an ONC-ACB’s three-year term, it is possible that there could be a change in accreditation organizations serving as the ONC-AA. In other words, the accreditation organization serving as the ONC-AA that initially accredited an ONC-ACB could be replaced by a different accreditation organization that is subsequently selected to serve as the ONC-AA. A change in ONC-AAs could occur under different scenarios, such as if the accreditation organization serving as the ONC-AA resigns before the end of its term, is replaced at the end of its term through the selection process under § 170.503, or is removed by the National Coordinator before the end of its term. If a different accreditation organization were to be approved as the ONC-AA, our primary goal would be to ensure stability among ONC-ACBs and within the HIT marketplace, which would include the uninterrupted certification of HIT. Therefore, we propose that if there is a change in accreditation organizations serving as the ONC-AA, such as in the scenarios described above, an ONC-ACB will retain its status under the permanent certification program, but only for a reasonable period of time to allow it to obtain accreditation from the accreditation organization that is approved as the new ONC-AA.

We propose that an ONC-ACB must obtain accreditation from the new ONC-AA within 12 months after the effective date of the new ONC-AA’s status or within a reasonable period specified by the National Coordinator. We use the term “effective date” because although an accreditation organization could be approved as the ONC-AA pursuant to the process in § 170.503, its status as the ONC-AA may not become effective until a later date (e.g., its status may not take effect until the then-current ONC-AA’s term expires). Based on our consultations with subject matter experts at the National Institute for

Standards and Technology (NIST), we believe that a new ONC-AA could complete the accreditation process for up to 6 ONC-ACBs within 6 to 9 months. We believe this could possibly be an appropriate timeframe and could be sufficient to meet the demand for accreditation considering that we estimated in the Permanent Certification Program final rule that only 6 ONC-ACBs will be operating under the permanent certification program and that only 6 ONC-Authorized Testing and Certification Bodies (ONC-ATCBs) are currently operating under the temporary certification program. However, considering that there may be more ONC-ACBs than we anticipate and that accreditation to the requirements of a new ONC-AA may require more time than anticipated, we believe 12 months would be a more reasonable timeframe for ONC-ACBs to obtain accreditation from the new ONC-AA. We believe the 12-month grace period provides for equitable treatment of ONC-ACBs, especially those that in good faith and without sufficient notice of a possible change in the ONC-AA recently paid for and obtained accreditation from an ONC-AA that is subsequently removed or replaced. We welcome comments on whether we should consider a shorter or longer period of time than 12 months.

Our proposal permits the National Coordinator to specify a reasonable period of time for ONC-ACBs to obtain accreditation from the new ONC-AA as an alternative to the 12-month timeframe. We believe this discretion is necessary to address unanticipated events, including but not limited to the following examples. For example, the new ONC-AA may be unable to offer accreditation within the 12-month timeframe for various reasons, such as unexpected demand for its accreditation services. It would be prudent for the National Coordinator to have the flexibility to grant an extension to an ONC-ACB if it had filed a request for accreditation with the new ONC-AA before the 12-month timeframe had elapsed and the new ONC-AA had not yet completed its accreditation of the ONC-ACB. Alternatively, there may be a need for the National Coordinator to require that ONC-ACBs obtain accreditation from the new ONC-AA in less than 12 months to protect the integrity of the permanent certification program. This situation could occur if the accreditation organization removed as the ONC-AA engaged in conduct that called into question the legitimacy of the accreditations granted to ONC-ACBs. We welcome comments on these examples and whether there may be

additional circumstances that would warrant the National Coordinator’s exercise of discretion to specify a different period of time for obtaining accreditation from the new ONC-AA. We also welcome comments on whether there should be a maximum period of time beyond 12 months in which an ONC-ACB must obtain accreditation from the new ONC-AA no matter the circumstances.

We propose to revise § 170.523(a) to state that an ONC-ACB shall “maintain its accreditation, or if a new ONC-AA is approved by the National Coordinator, obtain accreditation from the new ONC-AA within 12 months or a reasonable period specified by the National Coordinator and maintain such accreditation.”

2. New ONC-AA

As noted in our prior discussion, the National Coordinator may approve a new accreditation organization as the ONC-AA for reasons such as the former ONC-AA resigning, another accreditation organization being selected when the former ONC-AA’s term expires, or the former ONC-AA being removed for conduct or performance violations as described above. The selection and approval of the new ONC-AA will be conducted as soon as possible and consistent with the processes and timeframes outlined in § 170.503. Doing so permits the new ONC-AA to begin fulfilling its responsibilities as specified under § 170.503(e) when its status as the ONC-AA becomes effective. This means that the new ONC-AA will be expected to fulfill its responsibilities under § 170.503(e) with respect to the ONC-ACBs that it accredited, as well as those ONC-ACBs that were accredited by the former ONC-AA and are not yet accredited by the new ONC-AA. The new ONC-AA would be responsible for verifying that all ONC-ACBs are performing surveillance in accordance with their respective annual plans, as required by § 170.503(e)(3). In addition, consistent with § 170.503(e)(4), the new ONC-AA would review all ONC-ACB surveillance results to determine if the results indicate any substantive non-conformance by the ONC-ACBs with the conditions of their respective accreditations (even if an ONC-ACB was accredited by the former ONC-AA).

Section 170.503(e)(2) requires the ONC-AA, “[i]n accrediting certification bodies, [to] verify conformance to, at a minimum, [Guide 65] and ensure the surveillance approaches used by ONC-ACBs include the use of consistent, objective, valid, and reliable methods.” In the Permanent Certification Program

final rule (76 FR 1270), we explained this ongoing responsibility would require the ONC-AA to verify that ONC-ACBs continue to conform to the provisions of Guide 65 at a minimum as a condition of continued accreditation. Similar to 170.503(e)(3) and (e)(4), we expect the new ONC-AA to fulfill the responsibilities outlined in § 170.503(e)(2) for the certification bodies it accredits and all ONC-ACBs, including those ONC-ACBs it has not yet had an opportunity to accredit. To clarify this expectation, we propose to revise § 170.503(e)(2) to require the ONC-AA to ensure that all ONC-ACBs continue to conform to Guide 65 at a minimum, as indicated below. We made similar clarifying revisions to § 170.503(e)(4) in the Permanent Certification Program final rule. In that final rule (76 FR 1270), we explained that we were revising § 170.503(e)(4) to account for the possibility that different accreditation organizations may be approved to serve as the ONC-AA. Specifically, we revised that section to clarify that the ONC-AA would be responsible for reviewing ONC-ACB surveillance results to determine if the results indicated any substantive non-conformance by ONC-ACBs with the conditions of “their respective accreditations” rather than “with the terms set by the ONC-AA when it granted the ONC-ACB accreditation” as we had proposed.

We propose to revise § 170.503(e) as follows. Paragraphs (e)(3) and (e)(4) would be redesignated as paragraphs (e)(4) and (e)(5), respectively. Paragraph (e)(2) would be revised to state that the ONC-AA shall “[v]erify that the certification bodies it accredits and ONC-ACBs conform to, at a minimum, ISO/IEC Guide 65:1996 (incorporated by reference in § 170.599).” This revision removes the second part of paragraph (e)(2), which we propose to make a separate new paragraph. We propose to number this new paragraph as (e)(3) and for it to state that the ONC-AA shall “ensure that the surveillance approaches used by ONC-ACBs include the use of consistent, objective, valid, and reliable methods.”

Although these proposals will require the new ONC-AA to become familiar with the ONC-ACBs, many of which may not yet have been accredited by the new ONC-AA, we believe the proposed responsibilities are still achievable. With respect to the responsibilities under § 170.503(e)(3) and (4), ONC can make the ONC-ACBs’ surveillance plans available to the new ONC-AA and the former ONC-AA’s accreditation requirements should be publicly available, consistent with section 7.1.2

of ISO 17011, or they can be provided to the new ONC-AA by ONC. We expect that the new ONC-AA will fulfill these responsibilities in the manner we have described until it has the opportunity to accredit the ONC-ACBs according to its own accreditation requirements if applicable and to Guide 65 as required. As noted in the previous section’s discussion, we propose to give ONC-ACBs 12 months or another reasonable period to obtain accreditation from the new ONC-AA. In considering the appropriateness of our proposed timeframe for ONC-ACBs to be accredited by the new ONC-AA, we ask that commenters also consider our expectations for the new ONC-AA during this timeframe. We also welcome additional comments on our expectations and proposals.

III. Response to Comments

Because of the large number of public comments normally received in response to **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble of that document.

IV. Collection of Information Requirements

[If you choose to comment on the collection of information requirements section, please include at the beginning of your comment the caption “Collection of Information Requirements” and any additional information to clearly identify the information about which you are commenting.]

This proposed rule would only require the collection of information from the ONC-AA if we took an action against the ONC-AA under the provisions of this proposed rule and the ONC-AA submitted information to ONC in response to the action as provided for under the provisions of this proposed rule. The Paperwork Reduction Act of 1995, however, exempts the information collection activities referenced in this proposed rule. Specifically, 44 U.S.C. 3518(c)(1)(B)(ii) excludes collection activities during the conduct of administrative actions or investigations involving the agency against specific individuals or entities.

V. Regulatory Impact Statement

[If you choose to comment on the regulatory impact statement section, please include at the beginning of your

comment the caption “Regulatory Impact Statement” and any additional information to clearly identify the information about which you are commenting.]

We have examined the impact of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2011), the Regulatory Flexibility Act (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 Orders 12866 and 13563 direct 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 must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This proposed rule does not reach the economic threshold and thus is not considered a major rule. Therefore, a regulatory impact analysis has not been prepared.

The Regulatory Flexibility Act (RFA) requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the proposed rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, small organizations, and small governmental jurisdictions. Individuals and States are not included in the definition of a small entity. The entities that will be directly affected by this proposed rule are likely small businesses in the form of accreditation organizations interested in becoming the ONC-AA, the ONC-AA, potential applicants for ONC-ACB status, and ONC-ACBs. 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).² According to the NAICS codes identified above, this would mean Small Business Administration (SBA) size standards of \$12 million and \$7

² See 13 CFR 121.201.

million in annual receipts, respectively.³

We do not believe that this rule proposes requirements for the ONC-AA that would be unexpected by accreditation organizations interested in serving as the ONC-AA. An accreditation organization serving as the ONC-AA would expect to be required to properly fulfill its responsibilities and exhibit proper conduct or be subject to consequences. Moreover, as noted above, we indicated in prior rulemaking concerning the permanent certification program that we expected to issue this proposed rule and gave a general overview of the topics it would likely address. We believe the processes that we have proposed constitute 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 the ONC-AA. As for ONC-ACBs, this proposed rule mitigates any potential negative consequences of removing and replacing the ONC-AA if required. Should the ONC-AA be replaced, this proposed rule permits ONC-ACBs to retain their status and provides ONC-ACBs up to 12 months or a reasonable period specified by the National Coordinator to obtain accreditation from the new ONC-AA. Furthermore, the proposed process for addressing instances where the ONC-AA engages in improper conduct or fails to perform its responsibilities under the permanent certification program could create positive effects for program participants by increasing the accountability of the ONC-AA and protecting the integrity of the permanent certification program. We examined the implications of this proposed rule and have concluded, and the Secretary certifies, that this proposed rule will not have a significant economic impact on a substantial number of small entities.

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold level is approximately \$136 million. This proposed rule will not impose an unfunded mandate on State, local, and

Tribal governments or on the private sector of more than \$135 million annually.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this proposed rule does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this proposed rule was not reviewed by the Office of Management and Budget.

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. In § 170.503, revise paragraph (e)(2), redesignate and republish paragraphs (e)(3) and (e)(4) as paragraphs (e)(4) and (e)(5), and add new paragraph (e)(3) to read as follows:

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

* * * * *

(e) * * *

(2) Verify that the certification bodies it accredits and ONC-ACBs conform to, at a minimum, ISO/IEC Guide 65:1996 (incorporated by reference in § 170.599);

(3) Ensure the surveillance approaches used by ONC-ACBs include the use of consistent, objective, valid, and reliable methods;

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

(5) 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.

* * * * *

3. In § 170.523, republish the introductory text and revise paragraph (a) to read as follows:

§ 170.523 Principles of proper conduct for ONC-ACBs.

An ONC-ACB shall:

(a) Maintain its accreditation, or if a new ONC-AA is approved by the National Coordinator, obtain accreditation from the new ONC-AA within 12 months or a reasonable period specified by the National Coordinator and maintain such accreditation;

* * * * *

4. Add § 170.575 to read as follows:

§ 170.575 Removal of the ONC-AA.

(a) *Conduct violations.* The National Coordinator may remove the ONC-AA for committing a conduct violation. Conduct 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) *Performance violations.* The National Coordinator may remove the ONC-AA for failing to timely or adequately correct a performance violation. Performance violations constitute a failure to adequately perform the ONC-AA's responsibilities as specified in § 170.503(e).

(1) *Noncompliance notification.* If the National Coordinator obtains reliable evidence that the ONC-AA may no longer be adequately performing its responsibilities specified in § 170.503(e), the National Coordinator will issue a noncompliance notification with reasons for the notification to the ONC-AA requesting that the ONC-AA respond to the alleged violation and correct the violation, if applicable.

(2) *Opportunity to become compliant.* The ONC-AA is permitted up to 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 has been corrected.

(i) If the ONC-AA submits a response, the National Coordinator is permitted up to 60 days from the time the

³ 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. For more information on the SBA's size standards, see the SBA's Web site at: <http://www.sba.gov/content/small-business-size-regulations>.

response is received to evaluate the response and reach a decision. The National Coordinator may, if necessary, request additional information from the ONC-AA 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-AA confirming this determination. Otherwise, the National Coordinator may propose to remove the ONC-AA in accordance with paragraph (c) of this section.

(c) *Proposed removal.* (1) The National Coordinator may propose to remove the ONC-AA if the National Coordinator has reliable evidence that the ONC-AA has committed a conduct violation; or

(2) The National Coordinator may propose to remove the ONC-AA if, after the ONC-AA has been notified of an alleged performance violation, the ONC-AA fails to:

(i) Rebut the alleged 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) *Opportunity to respond to a proposed removal notice.* (1) The ONC-AA may respond to a proposed removal notice, but must do so within 20 days of receiving the proposed removal notice and include appropriate documentation explaining in writing why it should not be removed as the ONC-AA.

(2) Upon receipt of the ONC-AA's response to a proposed removal notice, the National Coordinator is permitted up to 60 days to review the information submitted by the ONC-AA and reach a decision.

(e) *Retention of ONC-AA status.* If the National Coordinator determines that the ONC-AA should not be removed, the National Coordinator will notify the ONC-AA in writing of this determination.

(f) *Removal.* (1) The National Coordinator may remove the ONC-AA if:

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

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

(2) A decision to remove the ONC-AA is final and not subject to further review unless the National Coordinator chooses to reconsider the removal.

(g) *Extent and duration of removal.* (1) The removal of the ONC-AA is effective upon the date specified in the removal notice provided to the ONC-AA.

(2) An accreditation organization that is removed as the ONC-AA must cease all activities under the permanent certification program, including accepting new requests for accreditation under the permanent certification program.

(3) An accreditation organization that is removed as the ONC-AA is prohibited from being considered for ONC-AA status for a period of 1 year from the effective date of its removal as the ONC-AA.

Dated: May 24, 2011.

Kathleen Sebelius,
Secretary.

[FR Doc. 2011-13372 Filed 5-27-11; 8:45 am]

BILLING CODE 4150-45-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Parts 383 and 390

[Docket No. FMCSA-2011-0146]

Regulatory Guidance: Applicability of the Federal Motor Carrier Safety Regulations to Operators of Certain Farm Vehicles and Off-Road Agricultural Equipment

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice; request for public comment.

SUMMARY: FMCSA requests public comment on: (1) Previously published regulatory guidance on the distinction between interstate and intrastate commerce in deciding whether operations of commercial motor vehicles within the boundaries of a single State are subject to the Federal Motor Carrier Safety Regulations (FMCSRs); (2) the factors the States are using in deciding whether farm vehicle drivers transporting agricultural commodities, farm supplies and equipment as part of a crop share agreement are subject to the commercial driver's license regulations; and (3) proposed guidance to determine whether off-road farm equipment or implements of husbandry operated on public roads for limited distances are considered commercial motor vehicles.

The guidance would be used to help ensure uniform application of the safety regulations by enforcement personnel, motor carriers and commercial motor vehicle drivers.

DATES: Comments must be received on or before June 30, 2011.

ADDRESSES: You may submit comments identified by Federal Docket Management System Number FMCSA-2011-0146 by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments.

- *Fax:* 1-202-493-2251.

- *Mail:* Docket Management Facility, (M-30), U.S. Department of Transportation (DOT), 1200 New Jersey Avenue, SE., West Building, Ground Floor, Room 12-140, Washington, DC 20590-0001.

- *Hand Delivery:* Same as mail address above, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

To avoid duplication, please use only one of these four methods. All submissions must include the Agency name and docket number for this notice. See the "Public Participation" heading below for instructions on submitting comments and additional information.

Note that all comments received, including any personal information provided, will be posted without change to <http://www.regulations.gov>. Please see the "Privacy Act" heading below.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> at any time or to Room W12-140 on the ground floor of the DOT Headquarters Building at 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act System of Records Notice for the DOT Federal Docket Management System published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit <http://edocket.access.gpo.gov/2008/pdf/E8-785.pdf>.

Public Participation: The <http://www.regulations.gov> Web site is generally available 24 hours each day, 365 days each year. You can get electronic submission and retrieval help