Office of the National Coordinator for Health IT
Proposed Rule Public Comment Template

ONC Health IT Certification Program:
Enhanced Oversight and Accountability

Preface

This document is meant to provide the public with a simple and organized way to submit comments on the "ONC Health IT Certification Program: Enhanced Oversight and Accountability" proposed rule, including responding to specific questions posed in the preamble of the proposed rule. The proposed rule is published in the *Federal Register* at 81 FR 11056. While use of this document is entirely voluntary, commenters may find it helpful to use the document in lieu of, or in addition to, submitting unstructured comments on the proposed rule or as an addendum to narrative cover pages.

This document alone does not provide a full and complete opportunity to comment on all of the provisions and questions included in the proposed rule. For example, while each of the comment tables below indicate whether specific questions related to a proposal are included in the proposed rule, the questions are not explicitly included in the tables to keep the size of this document to a minimum and because the preamble serves as the context for the questions.

The proposed rule introduces new requirements and modifications under the ONC Health IT Certification Program ("Program"), including provisions related to ONC's role in the Program. The proposed rule proposes to establish processes for ONC to directly review health IT certified under the Program and take action when necessary, including requiring the correction of non-conformities found in health IT certified under the Program and suspending and terminating certifications issued to Complete EHRs and Health IT Modules. In addition, the proposed rule includes processes for ONC to authorize and oversee accredited testing laboratories under the Program, similar to ONC's oversight over ONC-Authorized Certification Bodies (ONC-ACBs). It also includes a provision for the increased transparency and availability of surveillance results.

The following tables align with the presentation of the proposals in the preamble of the proposed rule. The tables note the page(s) of the *Federal Register* where we discuss the proposals and whether we ask specific questions about the proposals. The tables provide a field for submitting comments on the proposals, including responses to specific questions posed in the preamble. The field can be expanded as necessary for commenting.

To be considered, all comments (including comments provided using this document) must be submitted according to the instructions in the proposed rule. Electronic submissions are strongly encouraged and can be easily completed through the regulations.gov website and by clicking here: http://www.regulations.gov/#!documentDetail;D=HHS_FRDOC_0001-0620.

ONC Health IT Certification Program: Enhanced Oversight and Accountability

Provisions of the Proposed Rule

ONC Review of Certified Health IT – General Comments	
Preamble FR Citation: 81 FR 11060	**Specific questions in preamble?** *No*
Public Comment Field: Although the Pharmacy HIT Collaborative is supportive of enhanced oversight and accountability for the ONC Health IT Certification Program, we have a concern with the potential cost estimates to health providers if a certification termination is experienced as outlined in *C. Costs and Benefits*. ONC estimates "the cost of impact of certification termination on health care providers would range from $33,000 to $649,836,000 with a median cost of $792,000 and a mean cost of $6,270,000." As noted in the preamble, the proposal does not address remedies should a termination occur. Although remedies may be outside the scope of the proposal, we suggest that ONC look at possible remedies given the high costs that a health provider may incur that results from a termination. Such costs would be a financial burden, particularly to smaller health care providers and who use certified health IT but are not eligible to participate in the EHR Incentive Programs such as pharmacists. The proposal appears to focus on health care providers participating in the EHR Incentive Programs; it does not appear to recognize health care providers who are ineligible to participate in the EHR Incentive Programs but are users of the same certified health IT. Pharmacists are ineligible to participate in the EHR Incentive Programs; however, because they are part of integrated health care teams that include EPs, CAHs, and eligible hospitals, pharmacists are users of the same certified health IT.	

ONC Review of Certified Health IT – Authority and Scope (§ 170.580)	
(a) Direct review. ONC may directly review certified health IT whenever there is reason to believe that the certified health IT may not comply with requirements of the ONC Health IT Certification Program. (1) In determining whether to exercise such review, ONC shall consider: (i) The potential nature, severity, and extent of the suspected non-conformity(ies), including the likelihood of systemic or widespread issues and impact. (ii) The potential risk to public health or safety or other exigent circumstances. (iii) The need for an immediate and coordinated governmental response. (iv) Whether investigating, evaluating, or addressing the suspected non-conformity would: (A) Require access to confidential or other information that is unavailable to an ONC-ACB; (B) Present issues outside the scope of an ONC-ACB's accreditation; (C) Exceed the resources or capacity of an ONC-ACB; (D) Involve novel or complex interpretations or application of certification criteria or other requirements. (v) The potential for inconsistent application of certification requirements in the absence of direct review.	
Preamble FR Citation: 81 FR 11060 - 61	**Specific questions in preamble?** *Yes*
Public Comment Field: The Pharmacy HIT Collaborative supports the authority and scope as proposed.	

ONC Review of Certified Health IT - ONC-ACB's Role (§ 170.580)
(2) Relationship to ONC-ACB's oversight. (i) ONC's review of certified health IT is independent of, and may be in addition to, any review conducted by an ONC-ACB. (ii) ONC may assert exclusive review of certified health IT as to any matters under review by ONC and any other matters so intrinsically linked that divergent determinations between ONC and an ONC-ACB would be inconsistent with the effective administration or oversight of the ONC Health IT Certification Program.

(iii) ONC's determination on matters under its review is controlling and supersedes any determination by an ONC-ACB on the same matters.
(iv) An ONC-ACB shall provide ONC with any available information that ONC deems relevant to its review of certified health IT.
(v) ONC may end all or any part of its review of certified health IT under this section and refer the applicable part of the review to the relevant ONC-ACB(s) if ONC determines that doing so would be in the best interests of efficiency or the administration and oversight of the Program.

Preamble FR Citation: 81 FR 11061 - 62 **Specific questions in preamble?** *No*

Public Comment Field:
The Pharmacy HIT Collaborative supports the ONC-ACB's role as proposed.

Review Processes – General Comments

Preamble FR Citation: 81 FR 11062 **Specific questions in preamble?** *No*

Public Comment Field:
No comment.

Review Processes – Notice of Potential Non-Conformity or Non-Conformity (§ 170.580)

(b) Notice of potential non-conformity or non-conformity — (1) General. ONC will send a notice of potential non-conformity or notice of non-conformity to the health IT developer if it has information that certified health IT is not or may not be performing consistently with Program requirements.
(i) Potential non-conformity. ONC may require that the health IT developer respond in more or less time than 30 days based on factors such as, but not limited to:
(A) The type of certified health IT and certification in question;
(B) The type of potential non-conformity to be corrected;
(C) The time required to correct the potential non-conformity; and
(D) Issues of public health or safety or other exigent circumstances.
(ii) Non-conformity. ONC may require that the health IT developer respond and submit a proposed corrective action plan in more or less time than 30 days based on factors such as, but not limited to:
(A) The type of certified health IT and certification in question;
(B) The type of non-conformity to be corrected;
(C) The time required to correct the non-conformity; and
(D) Issues of public health or safety or other exigent circumstances.
(2) Records access. In response to a notice of potential non-conformity or notice of non-conformity, a health IT developer shall make available to ONC and for sharing within HHS, with other federal agencies, and with appropriate entities:
(i) All records related to the development, testing, certification, implementation, maintenance and use of its certified health IT; and
(ii) Any complaint records related to the certified health IT.
(3) Health IT developer response. The health IT developer must include in its response all appropriate documentation and explain in writing why the certified health IT is conformant.

Preamble FR Citation: 81 FR 11062 - 63 **Specific questions in preamble?** *Yes*

Public Comment Field:
The Pharmacy HIT Collaborative supports review process – notice of potential non-conformity or non-conformity as proposed. The Collaborative also supports an ONC-ACB being permitted to issue its own determination in matters where ONC does not assert direct or exclusive review.

Review Processes – Corrective Action (§ 170.580)
(c) Corrective action plan and procedures. (1) If ONC determines that certified health IT does not conform to Program requirements, ONC shall notify the health IT developer of the certified health IT of its findings and require the health IT developer to submit a proposed corrective action plan. (2) ONC shall provide direction to the health IT developer as to the required elements of the corrective action plan. ONC shall prescribe such corrective action as may be appropriate to fully address the identified non-conformity(ies). The corrective action plan is required to include, at a minimum, for each non-conformity: (i) A description of the identified non-conformity; (ii) An assessment of the nature, severity, and extent of the non-conformity, including how widespread they may be across all of the health IT developer's customers of the certified health IT; (iii) How the health IT developer will address the identified non-conformity, both at the locations where the non-conformity was identified and for all other potentially affected customers; (iv) A detailed description of how the health IT developer will assess the scope and impact of the non-conformity, including: (A) Identifying all potentially affected customers; (B) How the health IT developer will promptly ensure that all potentially affected customers are notified of the non-conformity and plan for resolution; (C) How and when the health IT developer will resolve issues for individual affected customers; and (D) How the health IT developer will ensure that all issues are in fact resolved; and (v) The timeframe under which corrective action will be completed. (3) When ONC receives a proposed corrective action plan (or a revised proposed corrective action plan), it shall either approve the proposed corrective action plan or, if the plan does not adequately address all required elements, instruct the developer to submit a revised proposed corrective action plan. (4) Upon fulfilling all of its obligations under the corrective action plan, the health IT developer must submit an attestation to ONC, which serves as a binding official statement by the health IT developer that it has fulfilled all of its obligations under the corrective action plan. (5) ONC may reinstitute a corrective action plan if it later determines that a health IT developer has not fulfilled all of its obligations under the corrective action plan as attested in accordance with paragraph (c)(4) of this section.
Preamble FR Citation: 81 FR 11063 - 64 **Specific questions in preamble?** *No*
Public Comment Field: The Pharmacy HIT Collaborative supports corrective action as proposed.

Review Processes – Suspension (§ 170.580)
(d) Suspension. (1) ONC may suspend the certification of a Complete EHR or Health IT Module at any time for any one of the following reasons: (i) Based on information it has obtained, ONC believes that the certified health IT poses a potential risk to public health or safety or other exigent circumstances exist. More specifically, ONC would suspend a certification issued to any encompassed Complete EHR or Health IT Module of the certified health IT if the certified health IT was, but not limited to: contributing to a patient's health information being unsecured and unprotected in violation of applicable law; increasing medical errors; decreasing the detection, prevention, and management of chronic diseases; worsening the identification and response to public health threats and emergencies; leading to inappropriate care; worsening health care outcomes; or undermining a more effective marketplace, greater competition, greater systems analysis, and increased consumer choice; (ii) The health IT developer fails to timely respond to any communication from ONC, including, but not limited to: (A) Fact-finding; (B) A notice of potential non-conformity within the timeframe established in accordance with paragraph (b)(1)(i) of this section; or (C) A notice of non-conformity within the timeframe established in accordance with paragraph (b)(1)(ii) of this section; (iii) The information provided by the health IT developer in response to any ONC communication, including, but not limited to: fact-finding, a notice of potential non-conformity, or a notice of non-conformity is insufficient or incomplete; (iv) The health IT developer fails to timely submit a proposed corrective action plan that adequately addresses the elements required by ONC as described in paragraph (c) of this section; (v) The health IT developer does not fulfill its obligations under the corrective action plan developed in accordance with paragraph (c) of this section. (2) When ONC decides to suspend a certification, ONC will notify the health IT developer of its determination through a notice of suspension. (i) The notice of suspension will include, but may not be limited to: (A) An explanation for the suspension; (B) The information ONC relied upon to reach its determination; (C) The consequences of suspension for the health IT developer and the Complete EHR or Health IT Module under the ONC Health IT Certification Program; and (D) Instructions for appealing the suspension. (ii) A suspension of a certification will become effective upon the health IT developer's receipt of a notice of suspension. (3) The health IT developer must notify all affected and potentially affected customers of the identified non-conformity(ies) and suspension of certification in a timely manner. (4) If a certification is suspended, the health IT developer must cease and desist from any marketing and sale of the suspended Complete EHR or Health IT Module as "certified" under the ONC Health IT Certification Program from that point forward until such time ONC may rescind the suspension. (5) Inherited certified status certification for a suspended Complete EHR or Health IT Module is not permitted until such time ONC rescinds the suspension. (6) ONC will rescind a suspension of certification if the health IT developer completes all elements of an approved corrective action plan and/or ONC confirms that all non-conformities have been corrected.
Preamble FR Citation: 81 FR 11064 - 65 **Specific questions in preamble?** *Yes*

Review Processes – Suspension (§ 170.580)

Public Comment Field:

The Pharmacy HIT Collaborative supports the suspension criteria as proposed. Regarding the question about how timely a health IT developer should notify affected and potentially affected customers of a suspension, the Collaborative recommends that affected customers be notified within a specified time after the health IT developer receives its suspension notification. Additionally, the Collaborative suggests that ONC, to the extent feasible, also consider sharing this notification responsibility with the health IT developer. ONC would be in a position to either send or post notices on its website, as other agencies do, alerting customers of pending suspensions. ONC could offer users the opportunity to sign up to receive notices from the ONC.

Review Processes – Termination (§ 170.580)

(e) Termination. (1) ONC may terminate a certification issued to a Complete EHR and/or Health IT Module if:
(i) The health IT developer fails to timely respond to any communication from ONC, including, but not limited to:
(A) Fact-finding;
(B) A notice of potential non-conformity within the timeframe established in accordance with paragraph (b)(1)(i) of this section; or
(C) A notice of non-conformity within the timeframe established in accordance with paragraph (b)(1)(ii) of this section;
(ii) The information provided by the health IT developer in response to any ONC communication, including, but not limited to: fact-finding, a notice of potential non-conformity, or a notice of non-conformity is insufficient or incomplete;
(iii) The health IT developer fails to timely submit a proposed corrective action plan that adequately addresses the elements required by ONC as described in paragraph (c) of this section;
(iv) The health IT developer does not fulfill its obligations under the corrective action plan developed in accordance with paragraph (c) of this section; or
(v) ONC concludes that a certified health IT's non-conformity(ies) cannot be cured.
(2) When ONC decides to terminate a certification, ONC will notify the health IT developer of its determination through a notice of termination.
(i) The notice of termination will include, but may not be limited to:
(A) An explanation for the termination;
(B) The information ONC relied upon to reach its determination;
(C) The consequences of termination for the health IT developer and the Complete EHR or Health IT Module under the ONC Health IT Certification Program; and
(D) Instructions for appealing the termination.
(ii) A termination of a certification will become effective either upon:
(A) The expiration of the 10-day period for filing an appeal in paragraph (f)(3) of this section if an appeal is not filed by the health IT developer; or
(B) A final determination to terminate the certification per paragraph (f)(7) of this section if a health IT developer files an appeal.
(3) The health IT developer must notify affected and potentially affected customers of the identified non-conformity(ies) and termination of certification in a timely manner.
(4) If ONC determines that a Complete EHR or Health IT Module certification should not be terminated, ONC will notify the health IT developer in writing of this determination.

Preamble FR Citation: 81 FR 11065 **Specific questions in preamble?** *Yes*

Public Comment Field:

The Pharmacy HIT Collaborative supports the termination criteria as proposed.

Review Processes – Appeal (§ 170.580)

(f) Appeal — (1) Basis for appeal. A health IT developer may appeal an ONC determination to suspend or terminate a certification issued to a Complete EHR or Health IT Module if the health IT developer asserts:
(i) ONC incorrectly applied Program methodology, standards, or requirements for suspension or termination; or
(ii) ONC's determination was not sufficiently supported by the information used by ONC to reach the determination.
(2) Method and place for filing an appeal. A request for appeal must be submitted to ONC in writing by an authorized representative of the health IT developer whose Complete EHR or Health IT Module was subject to the determination being appealed. The request for appeal must be filed in accordance with the requirements specified in the notice of termination or notice of suspension.
(3) Time for filing a request for appeal. An appeal must be filed within 10 calendar days of receipt of the notice of suspension or notice of termination.
(4) Effect of appeal on suspension and termination. (i) A request for appeal stays the termination of a certification issued to a Complete EHR or Health IT Module, but the Complete EHR or Health IT Module is prohibited from being marketed or sold as "certified" during the stay.
(ii) A request for appeal does not stay the suspension of a Complete EHR or Health IT Module.
(5) Appointment of a hearing officer. The National Coordinator will assign the case to a hearing officer to adjudicate the appeal on his or her behalf. The hearing officer may not review an appeal in which he or she participated in the initial suspension or termination determination or has a conflict of interest in the pending matter.
(6) Adjudication. (i) The hearing officer may make a determination based on:
(A) The written record as provided by the health IT developer with the appeal filed in accordance with paragraphs (f)(1) through (3) of this section and including any information ONC provides in accordance with paragraph (f)(6)(v) of this section; or
(B) All the information provided in accordance with paragraph (f)(6)(i)(A) and any additional information from a hearing conducted in-person, via telephone, or otherwise.
(ii) The hearing officer will have the discretion to conduct a hearing if he/she:
(A) Requires clarification by either party regarding the written record under paragraph (f)(6)(i)(A) of this section;
(B) Requires either party to answer questions regarding the written record under paragraph (f)(6)(i)(A) of this section; or
(C) Otherwise determines a hearing is necessary.
(iii) The hearing officer will neither receive testimony nor accept any new information that was not presented with the appeal request or was specifically and clearly relied upon to reach the determination issued by ONC under paragraph (d)(2) or (e)(2) of this section.
(iv) The default process will be a determination in accordance with paragraph (f)(6)(i)(A) of this section.
(v) ONC will have an opportunity to provide the hearing officer with a written statement and supporting documentation on its behalf that explains its determination to suspend or terminate the certification. The written statement and supporting documentation must be included as part of the written record. Failure of ONC to submit a written statement does not result in any adverse findings against ONC and may not in any way be taken into account by the hearing officer in reaching a determination.
(7) Determination by the hearing officer. (i) The hearing officer will issue a written determination to the health IT developer within 30 days of receipt of the appeal, unless the health IT developer and ONC agree to a finite extension approved by the hearing officer.
(ii) The National Coordinator's determination on appeal, as issued by the hearing officer, is final and not subject to further review.

Preamble FR Citation: 81 FR 11065 - 66 **Specific questions in preamble?** *Yes*

Public Comment Field:
The Pharmacy HIT Collaborative supports the appeal process as proposed.

Consequences of Certification Termination – General Comments	
Preamble FR Citation: 81 FR 11066	**Specific questions in preamble?** *No*

Public Comment Field:

Although the proposal does not address consequences of certification termination, the Pharmacy HIT Collaborative requests that ONC look at such consequences, including their impact on those health care providers who are not eligible for the EHR Incentive Programs but are using the same certified health IT as EPs. Pharmacists are currently ineligible to participate in the EHR Incentive Programs, but they are part of integrated health care teams that include EPs, and they use the same certified health IT as EPs. . Thus, in order to reach the goal of enhanced program oversight all users of certified health IT, not just those participating in the EHR Incentive Programs, needs to be taken into account.

Consequences of Certification Termination – Program Ban and Heightened Scrutiny (§ 170.581)	

(a) Testing and recertification. A Complete EHR or Health IT Module (or replacement version) that has had its certification terminated can be tested and recertified (certified) once all non-conformities have been adequately addressed.
(1) The recertified Complete EHR or Health IT Module (or replacement version) must maintain a scope of certification that, at a minimum, includes all the previous certified capabilities.
(2) The health IT developer must request, and have approved, permission to participate in the Program before testing and recertification (certification) may commence for the Complete EHR or Health IT Module (or replacement version).
(i) The request must include a written explanation of the steps taken to address the non-conformities that led to the termination.
(ii) ONC must approve the request to participate in the Program.
(b) Heightened scrutiny. Certified health IT that was previously the subject of a certification termination (or replacement version) shall be subject to heightened scrutiny for, at a minimum, one year.
(c) Program ban. The testing and certification of any health IT of a health IT developer that has the certification of one of its Complete EHRs or Health IT Modules terminated under the Program or withdrawn from the Program when the subject of a potential nonconformity or non-conformity is prohibited, unless:
(1) The non-conformity is corrected and implemented for all affected customers; or
(2) The certification and implementation of other health IT by the health IT developer would remedy the non-conformity for all affected customers.

Preamble FR Citation: 81 FR 11066 -67	**Specific questions in preamble?** *Yes*

Public Comment Field:

The Pharmacy HIT Collaborative supports the program ban and heightened security as proposed.

Consequences of Certification Termination - ONC-ACB Response to a Non-Conformity (§ 170.523) and (§ 170.581)
Principles of Proper Conduct for ONC-ACBs (§ 170.523) (o) Be prohibited from reducing the scope of a certification when the health IT is under surveillance or under a corrective action plan.
Consequences Due to the Termination of a Certification (§ 170.581) (a) Testing and recertification. A Complete EHR or Health IT Module (or replacement version) that has had its certification terminated can be tested and recertified (certified) once all non-conformities have been adequately addressed. (1) The recertified Complete EHR or Health IT Module (or replacement version) must maintain a scope of certification that, at a minimum, includes all the previous certified capabilities. (2) The health IT developer must request, and have approved, permission to participate in the Program before testing and recertification (certification) may commence for the Complete EHR or Health IT Module (or replacement version). (i) The request must include a written explanation of the steps taken to address the non-conformities that led to the termination. (ii) ONC must approve the request to participate in the Program. (b) Heightened scrutiny. Certified health IT that was previously the subject of a certification termination (or replacement version) shall be subject to heightened scrutiny for, at a minimum, one year. (c) Program ban. The testing and certification of any health IT of a health IT developer that has the certification of one of its Complete EHRs or Health IT Modules terminated under the Program or withdrawn from the Program when the subject of a potential nonconformity or non-conformity is prohibited, unless: (1) The non-conformity is corrected and implemented for all affected customers; or (2) The certification and implementation of other health IT by the health IT developer would remedy the non-conformity for all affected customers.
Preamble FR Citation: 81 FR 11067 **Specific questions in preamble?** *No*
Public Comment Field: The Pharmacy HIT Collaborative supports the ONC-ACB response to non-conformity as proposed.

Proposed Amendments to Include ONC-ATLs in the Program - General Comments
Preamble FR Citation: 81 FR 11068 **Specific questions in preamble?** *Yes*
Public Comment Field: No comment.

Proposed Amendments to Include ONC-ATLs in the Program – Applicability (§ 170.501)

(a) 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, Health IT Module(s), and other types of health IT in accordance with the applicable certification criteria adopted by the Secretary in subpart C of this part. It also establishes the processes that applicants for ONC-ATL status must follow to be granted ONC-ATL status by the National Coordinator; the processes the National Coordinator will follow when assessing applicants and granting ONC-ATL status; the requirements that ONC-ATLs must follow to maintain ONC-ATL status; and the requirements of ONC-ATLs for testing Complete EHRs and Health IT Modules in accordance with the applicable certification criteria adopted by the Secretary in subpart C of this part. Further, this subpart 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 ONC Health IT Certification Program as well as certain ongoing responsibilities for an ONC-AA.

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Preamble FR Citation: 81 FR 11068 **Specific questions in preamble?** *No*

Public Comment Field:

The Pharmacy HIT Collaborative supports the proposed amendments for applicability.

Proposed Amendments to Include ONC-ATLs in the Program – Definitions (§ 170.502)

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

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

(1) All applicable new and/or revised certification criteria adopted by the Secretary at subpart C of this part based on test results issued by a NVLAP-accredited testing laboratory under the ONC Health IT Certification Program or an ONC-ATL; 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 Health IT Module(s) under the ONC Health IT Certification Program.

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ONC-Authorized Testing Lab or ONC-ATL means an organization or a consortium of organizations that has applied to and been authorized by the National Coordinator pursuant to this subpart to perform the testing of Complete EHRs and Health IT Modules to certification criteria adopted by the Secretary at subpart C of this part.

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Preamble FR Citation: 81 FR 11068 **Specific questions in preamble?** *No*

Public Comment Field:

The Pharmacy HIT Collaborative supports the proposed amendments for definitions.

Proposed Amendments to Include ONC-ATLs in the Program – Correspondence (§ 170.505)

(a) Correspondence and communication with ONC or the National Coordinator shall be conducted by e-mail, unless otherwise necessary or specified. The official date of receipt of any e-mail between ONC or the National Coordinator and an accreditation organization requesting ONC-AA status, the ONC-AA, an applicant for ONC-ACB status, an applicant for ONC-ATL status, an ONC-ACB, an ONC-ATL, health IT developer, or a party to any proceeding under this subpart 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, an applicant for ONC-ATL status, an ONC-ACB, an ONC-ATL, health IT developer, or a party to any proceeding under this subpart to correspond or communicate with ONC or the National Coordinator by regular or express mail, the official date of receipt will be the date of the delivery confirmation.

Preamble FR Citation: 81 FR 11062 and 11068 **Specific questions in preamble?** *No*

Public Comment Field:

The Pharmacy HIT Collaborative supports the proposed amendments for correspondence.

Proposed Amendments to Include ONC-ATLs in the Program - Authorization Scope for ONC-ACB Status (§ 170.510)

Applicants for ONC-ACB status may seek authorization from the National Coordinator to perform the following types of certification:

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Preamble FR Citation: 81 FR 11068 **Specific questions in preamble?** *No*

Public Comment Field:

The Pharmacy HIT Collaborative supports the proposed amendments for authorization scope for ONC-ACB status.

Proposed Amendments to Include ONC-ATLs in the Program - Authorization Scope for ONC-ATL Status (§ 170.511)

Applicants may seek authorization from the National Coordinator to perform the testing of Complete EHRs or Health IT Modules to a portion of a certification criterion, one certification criterion, or many or all certification criteria adopted by the Secretary under subpart C of this part.

Preamble FR Citation: 81 FR 11068 **Specific questions in preamble?** *No*

Public Comment Field:

The Pharmacy HIT Collaborative supports the proposed amendments for authorization scope for ONC-ACB status.

Proposed Amendments to Include ONC-ATLs in the Program – Application (§ 170.520)

(a) ONC-ACB 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.

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

(2) General identifying, information including:

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

(ii) 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.

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

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

(b) ONC-ATL application. Applicants must include the following information in an application for ONC-ATL status and submit it to the National Coordinator for the application to be considered complete.

(1) The authorization scope sought pursuant to § 170.511.

(2) General identifying, information including:

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

(ii) 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.

(3) Documentation that confirms that the applicant has been accredited by NVLAP to ISO 17025.

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

Preamble FR Citation: 81 FR 11068 **Specific questions in preamble?** *No*

Public Comment Field:

The Pharmacy HIT Collaborative supports the proposed amendments for application.

Proposed Amendments to Include ONC-ATLs in the Program - Principles of Proper Conduct for ONC-ACBs (§ 170.523)

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(h) Only certify health IT (Complete EHRs and/or Health IT Modules) that has been tested, using test tools and test procedures approved by the National Coordinator, by a/an:

(1) ONC-ATL;

(2) NVLAP-accredited testing laboratory under the ONC Health IT Certification Program for no longer than six months from the authorization of the first ONC-ATL unless:

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

(ii) Performing gap certification.

Preamble FR Citation: 81 FR 11068 - 69 **Specific questions in preamble?** *Yes*

Public Comment Field:

The Pharmacy HIT Collaborative supports the proposed amendments for principles of proper conduct for ONC-ACBs.

Proposed Amendments to Include ONC-ATLs in the Program - Principles of Proper Conduct for ONC-ATLs (§ 170.524)

An ONC-ATL shall:

(a) Maintain its NVLAP accreditation to ISO 17025;

(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 test health IT;

(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 testing 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 test health IT.

(e) Allow ONC, or its authorized agent(s), to periodically observe on site (unannounced or scheduled), during normal business hours, any testing performed pursuant to the ONC Health IT Certification Program;

(f) Records retention. (1) Retain all records related to the testing of Complete EHRs and/or Health IT Modules to an edition of certification criteria for a minimum of 3 years from the effective date that removes the applicable edition from the Code of Federal Regulations; and

(2) Make the records available to HHS upon request during the retention period described in paragraph (f)(1) of this section;

(g) Only test health IT using test tools and test procedures approved by the National Coordinator; and

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

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

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

(3) Previous testing that it performed if its conduct necessitates the retesting of Complete EHRs and/or Health IT Modules.

Preamble FR Citation: 81 FR 11069 **Specific questions in preamble?** *No*

Public Comment Field:

The Pharmacy HIT Collaborative supports the proposed amendments for proper conduct for ONC-ATLs.

Proposed Amendments to Include ONC-ATLs in the Program - Application Submission (§ 170.525)

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

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

Preamble FR Citation: 81 FR 11069 **Specific questions in preamble?** *No*

Public Comment Field:

The Pharmacy HIT Collaborative supports the proposed amendments for application submission.

Proposed Amendments to Include ONC-ATLs in the Program -Review of Application (§ 170.530)

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(c) * * *

(2) In order for an applicant to continue to be considered for ONC-ACB or ONC-ATL 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.

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(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 or ONC-ATL 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) * * *

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

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

Preamble FR Citation: 81 FR 11069 **Specific questions in preamble?** *No*

Public Comment Field:

The Pharmacy HIT Collaborative supports the proposed amendments for review of application.

Proposed Amendments to Include ONC-ATLs in the Program - ONC-ACB and ONC-ATL Application Reconsideration (§ 170.535)

(a) Basis for reconsideration request. 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 or ONC-ATL status.

* * * * *

(d) * * *

(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 or ONC-ATL status.

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Preamble FR Citation: 81 FR 11069 **Specific questions in preamble?** *No*

Public Comment Field:

The Pharmacy HIT Collaborative supports the proposed amendments for ONC-ACB and ONC-ATL application reconsideration.

Proposed Amendments to Include ONC-ATLs in the Program - ONC-ACB and ONC-ATL Status (§ 170.540)

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

(b) Representation. Each ONC-ACB or ONC-ATL 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 ONC Health IT Certification Program.

(c) Renewal. An ONC-ACB or ONC-ATL is required to renew its status every three years. An ONC-ACB or ONC-ATL 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 or ONC-ATL'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.

Preamble FR Citation: 81 FR 11069 **Specific questions in preamble?** *No*

Public Comment Field:
The Pharmacy HIT Collaborative supports the proposed amendments for ONC-ACB and ONC-ATL status.

Proposed Amendments to Include ONC-ATLs in the Program - Authorized Testing and Certification Methods (§ 170.557)

(a) ONC-ATL applicability. An ONC-ATL must provide remote testing for both development and deployment sites.

(b) ONC-ACB applicability. An ONC-ACB must provide remote certification for both development and deployment sites.

Preamble FR Citation: 81 FR 11069 **Specific questions in preamble?** *No*

Public Comment Field:
The Pharmacy HIT Collaborative supports the proposed amendments for authorized testing and certification methods.

Proposed Amendments to Include ONC-ATLs in the Program - Good Standing as an ONC-ACB or ONC-ATL (§ 170.560)

(a) ONC-ACB good standing. An ONC-ACB must maintain good standing by:

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

(2) 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 Health IT Module(s) for which it does not have authorization; and

(3) Following all other applicable federal and state laws.

(b) ONC-ATL good standing. An ONC-ATL must maintain good standing by:

(1) Adhering to the Principles of Proper Conduct for ONC-ATLs;

(2) Refraining from engaging in other types of inappropriate behavior, including an ONC-ATL misrepresenting the scope of its authorization, as well as an ONC-ATL testing health IT for which it does not have authorization; and

(3) Following all other applicable federal and state laws.

Preamble FR Citation: 81 FR 11069 - 70 **Specific questions in preamble?** *No*

Public Comment Field:

The Pharmacy HIT Collaborative supports the proposed amendments for good standing as an ONC-ACB or ONC-ATL.

Proposed Amendments to Include ONC-ATLs in the Program - Revocation of ONC-ACB or ONC-ATL Status (§ 170.565)

(a) Type-1 violations. The National Coordinator may revoke an ONC-ATL or ONC-ACB's status for committing a Type-1 violation. Type-1 violations include violations of law or ONC Health IT Certification Program policies that threaten or significantly undermine the integrity of the ONC Health IT Certification Program. These violations include, but are not limited to: false, fraudulent, or abusive activities that affect the ONC Health IT 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-ATL or 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-ATL or 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-ATL or ONC-ACB requesting that the ONC-ATL or 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-ATL or 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-ATL or 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-ATL or 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-ATL or ONC-ACB confirming this determination.

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

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

(2) The National Coordinator may propose to revoke an ONC-ATL or ONC-ACB's status if, after the ONC-ATL or

ONC-ACB has been notified of a Type-2 violation, the ONC-ATL or ONC-ACB fails to:

(i) 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-ATL or ONC-ACB's operations. (1) The National Coordinator may suspend the operations of an ONC-ATL or ONC-ACB under the ONC Health IT Certification Program based on reliable evidence indicating that:

(i) Applicable to both ONC-ACBs and ONC-ATLs. The ONC-ATL or ONC-ACB committed a Type-1 or Type-2 violation;

(ii) Applicable to ONC-ACBs. The continued certification of Complete EHRs or Health IT Modules by the ONC-ACB could have an adverse impact on the health or safety of patients.

(iii) Applicable to ONC-ATLs. The continued testing of Complete EHRs or Health IT Modules by the ONC-ATL 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-ATL or ONC-ACB will be issued a notice of proposed suspension.

(3) Upon receipt of a notice of proposed suspension, an ONC-ATL or 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-ATL or 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-ATL or ONC-ACB's written response or if the ONC-ATL or 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-ATL or ONC-ACB's operations until it has adequately corrected a Type-2 violation; or

(iii) Propose revocation in accordance with paragraph (c) of this section and suspend the ONC-ATL or ONC-ACB's operations for the duration of the revocation process.

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

(e) Opportunity to respond to a proposed revocation notice. (1) An ONC-ATL or 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-ATL or 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-ATL or ONC-ACB's status should not be revoked, the National Coordinator will notify the ONC-ATL or ONC-ACB's authorized representative in writing of this determination.

(g) Revocation. (1) The National Coordinator may revoke an ONC-ATL or ONC-ACB's status if:

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

(ii) The ONC-ATL or 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-ATL or 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-ATL or ONC-ACB is effective as soon as the ONC-ATL or ONC-ACB receives the revocation notice.

(2) ONC-ACB provisions. (i) 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 ONC Health

IT Certification Program.

(ii) 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 ONC Health IT Certification Program for a period of 1 year.

(iii) 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 Health IT 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 ONC Health IT Certification Program.

(3) ONC-ATL provisions. (i) A testing lab that has had its ONC-ATL status revoked is prohibited from accepting new requests for testing and must cease its current testing operations under the ONC Health IT Certification Program.

(ii) A testing lab that has had its ONC-ATL status revoked for a Type-1 violation is not permitted to reapply for ONC-ATL status under the ONC Health IT Certification Program for a period of 1 year.

(iii) The failure of a testing lab that has had its ONC-ATL status revoked to promptly refund any and all fees for testing of health IT not completed will be considered a violation of the Principles of Proper Conduct for ONC-ATLs and will be taken into account by the National Coordinator if the testing lab reapplies for ONC-ATL status under the ONC Health IT Certification Program.

Preamble FR Citation: 81 FR 11070 **Specific questions in preamble?** *No*

Public Comment Field:

The Pharmacy HIT Collaborative supports the proposed amendments for revocation of an ONC-ACB or ONC-ATL status.

Request for Comment - In the Context of an ONC-ATL's Status Being Revoked (§ 170.570)

Preamble FR Citation: 81 FR 11070 **Specific questions in preamble?** *Yes*

Public Comment Field:

No comment.

Public Availability of Identifiable Surveillance Results (§170.523) and (§ 170.556)

Principles of Proper Conduct for ONC-ACBs (§170.523)

(i) Conduct surveillance as follows:

(1) Submit an annual surveillance plan to the National Coordinator.

(2) Report, at a minimum, on a quarterly basis to the National Coordinator the results of its surveillance.

(3) Publicly publish identifiable surveillance results on its website on a quarterly basis.

(4) Annually submit a summative report of surveillance results.

In-The-Field Surveillance and Maintenance of Certification for Health IT (§ 170.556)

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(e) * * *

(1) Rolling submission of in-the-field surveillance results. The results of in-the-field surveillance under this section must be submitted to the National Coordinator on an ongoing basis throughout the calendar year and, at a minimum, in accordance with § 170.523(i)(2).

Preamble FR Citation: 81 FR 11070 - 71 **Specific questions in preamble?** *Yes*

Public Availability of Identifiable Surveillance Results (§170.523) and (§ 170.556)
Public Comment Field: The Pharmacy HIT Collaborative supports the requirement for ONC-ACBs to publicly publish on their websites identifiable surveillance results, as required by the reporting requirement described in the 2015 Edition final rule, on a quarterly basis, especially as this information is already collected by the ONC-ACBs as part of their surveillance efforts under the program. We agree that publishing identifiable surveillance results would help hold health IT developers more accountable to the customers and users of certified health IT.

National Technology Transfer and Advancement Act (NTTAA)

ISO/IEC 17025:2005 (ISO 17025)	
Preamble FR Citation: 81 FR 11071	**Specific questions in preamble?** *No*
Public Comment Field: No comment.	

Incorporation by Reference (IBR)

ISO/IEC 17025:2005 (ISO 17025)	
Preamble FR Citation: 81 FR 11071	**Specific questions in preamble?** *No*
Public Comment Field: No comment.	

Collection of Information Requirements

Collection of Information Requirements	
Preamble FR Citation: 81 FR 11071 -72	**Specific questions in preamble?** *No*
Public Comment Field: No comment.	

Regulatory Impact Statement

Regulatory Impact Statement	
Preamble FR Citation: 81 FR 11072 -78	**Specific questions in preamble?** *Yes*
Public Comment Field: As noted previously, the Pharmacy HIT Collaborative is concerned about the potential cost estimates to health providers if a certification termination is experienced, particularly for health care providers who ineligible to participate in the EHR Incentive Programs and are users of certified health IT. The Collaborative believes ONC should explore and propose possible remedies before moving forward.	