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May 2, 2016

Karen DeSalvo, MD, MPH, MSc
National Coordinator for Health Information Technology
Acting Assistant Secretary for Health
U.S. Department of Health and Human Services

Dear Dr. DeSalvo,

On behalf of the members of the Electronic Health Record (EHR) Association, we submit the attached detailed response to the Office of the National Coordinator for Health IT's (ONC's) Notice of Proposed Rulemaking (NPRM) for the ONC Health IT Certification Program: Enhanced Oversight and Accountability. More than 30 organizations that develop and support the vast majority of operational EHRs in hospitals and ambulatory care environments in the US have collaborated to develop this response.

We are generally positive on the proposals regarding Accredited Testing Labs (ATLs) and broader release of surveillance results (with specific recommendation and some concerns in our detailed comments), but the Association believes strongly that this ONC proposal for direct review of certified health IT inappropriately expands ONC's role in certification far beyond its current scope. ONC's claimed authority for this expansion is inappropriate, counter to what we believe to be Congressional intent in HITECH, and inconsistent with how that intent has been interpreted by ONC for more than six years. We are specifically very concerned with and opposed to the proposal to extend certification authority to non-certified capabilities, as this would require new and complex processes to assess such capabilities where there are no criteria against which to evaluate conformance.

We feel strongly that any oversight should be limited to certified functionality where there are clearly communicated and properly adopted criteria. Without specific criteria and a definition of conformance for non-certified functionality, it is not possible to define non-conformance in such a way as to be predictable for participating technology companies. Any direct review by ONC should be limited to exigent (that is, requiring immediate attention) patient safety issues regarding certified capabilities, which is a capability the Association believes ONC already has. Unfortunately, the proposed scope for engaging in such review is overly broad.

In addition, it is important to keep in mind, as ONC has recognized numerous times previously, that organizations purchasing EHRs and EHR users within those organizations do not always follow the implementation recommendations of EHR product developers. The concepts and repercussions within this proposed rule would potentially put developers in the awkward position of attempting to enforce regulations with their customers to avoid sanctions themselves.

We also note that there appears to be an assumption woven through the very basic concepts included in the proposed rule that, if ONC opens a case, the developer is considered guilty until proven innocent, with the burden of proof falling on the EHR developer, with consequences applied to the developer in the meantime. The EHR Association offers several recommendations regarding the proposed appeals process in the response template attached.

We are also very concerned that the NPRM would conflict with the work ONC is currently doing to promote and create a health IT safety collaborative. Specifically, the NPRM assigns both police powers and jury powers to ONC that would preclude any conceivable ONC engagement within the "safe space" of a national learning system health IT safety collaborative as outlined in the recent ONC/RTI roadmap.

Because we do not support most aspects of the proposed rule, the Association strongly recommends extensive review and reconsideration of the direct review portion of this NPRM. As always, we appreciate ONC's consideration of our comments, which are based on our members' extensive experience in developing, delivering, and supporting complex health IT to a broad spectrum of healthcare organizations. The EHR Association looks forward to helping ONC refine this proposed rule to meet its objectives to provide a balanced and transparent oversight program.

Respectfully,

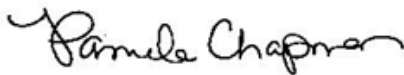


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Chair, EHR Association
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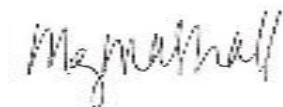
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About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of over 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit www.ehrassociation.org.

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

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:

EHR Association Comments:

The ONC proposal for direct review of certified health IT expands ONC's role in certification far beyond its current approach. ONC's claimed authority for this expansion is inappropriate, counter to Congressional intent in HITECH, and inconsistent with how that intent has been interpreted by ONC for more than six years. We are specifically very concerned with and opposed to the proposal to extend certification authority to non-certified capabilities, as this would require new and complex processes to assess such capabilities where there are no criteria against which to evaluate conformance.

This proposed basis for review is a massive expansion of ONC scope of authority far beyond certified health IT performing as it was certified to perform, and subjecting all health IT offered by a developer to virtually unlimited ONC authority because a portion of its health IT product line is certified. Accordingly, it is clear that any oversight should be limited to certified functionality where there are clearly communicated and properly adopted criteria. Without specific criteria and a definition of conformance for non-certified functionality, it is not possible to define sanctions or remedies in such a way as to be predictable for participating technology companies. In fact, any sanctions not based on evaluation against clear certification criteria would be ad hoc and have the potential to be unfairly applied across developers. In addition, this NPRM does not address in any way the possible perceived "non-conformities" that may result from providers' implementation choices that are beyond vendor control, which is a very significant factor.

In addition, it is important to keep in mind, as ONC has recognized numerous times previously, that organizations purchasing EHRs and EHR users within those organizations do not always follow the implementation recommendations of EHR product developers. The concepts and repercussions within this proposed rule would potentially put developers in the awkward position of attempting to enforce regulations with their customers to avoid sanctions themselves. The NPRM has the potential to interfere with market needs to configure and use certified and non-certified EHR technologies in ways other than designed, intended, and certified by EHR developers who might be forced or choose to constrain workflows and features in order to reduce the risk of sanctions. Such alternative configurations are expressly permitted by ONC and CMS according to CMS FAQ # 3073. This approach could disrupt established clinical workflows and further divert development resources away from innovation and enhancements that customers are requesting.

The Association appreciates the goal of preserving the integrity of the certification program and ensuring that certified products meet certification standards. We suggest, however, that the scope of ONC surveillance should remain limited to certified capabilities, products, and modules; direct review should be limited to exigent (that is, requiring immediate attention) patient safety issues regarding certified capabilities. Unfortunately, the proposed criteria for engaging in such review are overly broad.

We also note that there appears to be an assumption woven through the very basic concepts included in the proposed rule that, if ONC opens a case, the developer is considered guilty until proven innocent, with the burden of proof falling on the EHR developer but consequences applied to the developer in the meantime. The EHR Association offers several recommendations regarding the proposed appeals process below.

Because we do not support most aspects of the proposed rule, the Association strongly recommends extensive review and reconsideration of the direct review portion of this NPRM.

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 patient 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:

EHR Association Comments:

Generally, current processes around ONC ACB oversight are sufficient to maintain the integrity of the certification program. It may be reasonable for ONC to exercise direct oversight in narrow patient-safety focused circumstances where there are gaps or overlaps between or among ATBs and within its existing authority, since ONC is responsible for the establishment of ONC ACBs within the certification program to achieve certified health IT. We agree that the primary goal in all cases should be to correct non-conformities and ensure that certified health IT performs in accordance with certification test script requirements by working with the health IT developer to remedy any non-conformity. As stated in this proposal on page 11067, we agree that “Health IT is tested and certified to meet adopted criteria and requirements. It should continue to meet those criteria and requirements when implemented. If not, it should be corrected.”

However, we are very concerned regarding the expanded authority and scope that is asserted in this proposed rule. It assumes the right of ONC to undertake direct review without a clear and testable definition of “non-conformity”, which could lead to inconsistent application of the regulation and unnecessary disruption in the market for all stakeholders. Rather than the vague approach proposed by ONC, the EHR Association proposes that “non-conformity” be clearly defined as the inability of a health IT module to complete or repeat certification test procedures against which it was previously tested.

In establishing its authority for this proposal, ONC cites Section 3001(b) of the Public Health Service Act (PHSA), which it characterizes as directing “the National Coordinator to establish a certification program or programs and to perform the duties of keeping or recognizing such program(s) in a manner consistent with the development of a nationwide health information technology infrastructure that allows for the electronic use and exchange of information and that, among other requirements: ensures that each patient’s health information is secure and protected in accordance with applicable law; improves healthcare quality; reduces medical errors; reduces healthcare costs resulting from inefficiency, medical errors, inappropriate care, duplicative care, and incomplete information; and promotes a more effective marketplace, greater competition, greater systems analysis, increased consumer choice, and improved outcomes in health care services (see section 3001(b) of the PHSA).”

This section of the PHSA sets out the high-level goals to be pursued by ONC, described as “development of a nationwide health information technology infrastructure that allows for the electronic use and exchange of information.” To accomplish these goals, ONC is to carry out specific duties set out in Section 3001(c). There are eight broad duties enumerated, only one of which is certification. These duties range from standards, to a website, to reports and publications. Clearly, this is a set of duties that, in aggregate, are intended to further these statutory goals and to be designed in a way to do so.

At the same time, it seems inconceivable that it was Congress’s intention that any of the duties individually was to be implemented to cover the full range of the Section 3001(b) goals. With respect to certification, HITECH was precise, focusing on “a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted under this subtitle.” Congress was explicit on the nature of the certification criteria to be used in the certification program, stating that “the term ‘certification criteria’ means, with respect to standards and implementation specifications for health information technology, criteria to establish that the technology meets such standards and implementation specifications.” HITECH also set out roles of the Health IT Standards and Policy Committees in development of certification criteria and the process for adoption of certification criteria by the Secretary through rulemaking. It is clear that Congress intended the process by which such criteria are developed and implemented to support, along with other ONC

duties, the broad goals set out for ONC in HITECH.

The fact remains that, through three regulatory cycles, ONC has developed certification criteria which are the heart of the certification program and stemming from a statutory construct. In the current proposed rule, ONC, seven years after the passage of HITECH and following these three certification cycles, claims new authority and proposes a substantially new certification program, but one without associated certification criteria. This proposed program is not based in certification criteria developed according to statute and regulation, and – based on a logic that is hard to understand – refers to the super-set of goals for the entire mission of ONC to create certification “concepts” that can be applied at ONC’s sole discretion.

In taking this approach, ONC is fundamentally redefining its authority, via § 170.580(a) the “requirements of the ONC Health IT Certification Program”, beyond the published certification criteria when it states that “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.” The proposed criteria by which ONC would determine the need for intervention are very broad and include “[t]he potential risk to patient safety”, “...or other exigent circumstances.”

This vast expansion of ONC authority, which we reiterate seems directly at odds with Congressional intent and the authorizing statutory language, is especially troubling because:

- Commenters must rely on ONC’s current stated desire for limited use of this authority, when there is no guarantee that such limited application would be the approach taken in later years and under different administrations.
- ONC proposes a very high-level framework on which to base what would be ad hoc certification criteria that were never communicated to health IT developers or ONC ACBs, and for which there is no objective basis to assess compliance nor even any clear duty for compliance.
- ONC seeks a broad expansion of its authority to non-certified health IT, and to apply this authority to companies that develop health IT relative to all of their certified products to ensure compliance with issues associated with any single such product.
- ONC has no current structure or experience in place to implement this vast expansion of authority.
- The proposed appeal process is very limited and appears to be based on a presumption of guilt based solely on accusation of non-conformance.

ONC should only exert authority to engage in direct review based upon its scope to address non-conformity with established certification criteria which have been granted to health IT as CEHRT. The scope for ONC direct review should focus on non-conformity against criteria that have been previously tested by an ONC ATL and addressed by an ONC ACB, and based upon the set of criteria for which the product maintains its certification status.

ONC should continue to define, and update as needed, the requirements of the health IT certification program based upon certification criteria issued through the rulemaking process (i.e., NPRM, public comments, final rule), and not through this vague process based upon expanded authority, without specific definitions of functionality through certification criteria and specific guidance for testing and certification to fulfill requirements of the certification program.

We also emphasize that this proposed expanded scope, drawn from this assertion of authority, could apply to many uncertified capabilities both across certified and uncertified capabilities, as in combined clinical and financial applications, or between certified and uncertified components operating with certified health IT. Many of these stated goals could greatly expand the implied scope of certified health IT well beyond functionality currently required for health IT. Since the inception of the program, and through several iterations of certification criteria (2011 edition, 2014 edition, 2015 edition), there has

been no assertion of ONC authority over non-certified capabilities within a certified product, or across combinations of certified and non-certified products. ONC direct review should therefore be limited within that scope to a unique set of circumstances, focused on patient safety beyond which the ONC ACB fails to address through current policies and criteria defined within the scope of certification.

As the program currently exists, testing and certification against specific criteria have required repeated clarification regarding intent within the finalized test procedures. Significant interaction occurs prior to the testing process to refine the certification requirements specified in the final rule with ONC and the ATs. As we have seen, having the expertise to define and test such criteria has been challenging. The proposal to expand oversight through authority and scope without a specific basis of published criteria is extremely subjective and problematic. ONC should not suggest additional novel or complex interpretations or application of certification criteria, or other requirements after the certification process is completed. All potential for inconsistent application of certification requirements should be addressed during the testing and certification process, and should not be a consideration for ONC direct review after certification (as proposed in this rule).

ONC should reconsider this proposed rule with a more narrowly targeted scope. We suggest that in a limited set of circumstances, ONC could assist ACBs in performing surveillance. Such circumstances should meet a well-specified set of criteria (e.g., the interaction of two products certified by separate ACBs and having a proven urgent impact on patient safety). In those circumstances, the role of ONC should be clearly defined, well bounded, and focused on supporting ACBs in performing their role.

ONC and all stakeholders need a better definition of what can rise to the level of an issue that necessitates ONC direct review beyond the criteria proposed, its multiple triggers, and the use of such broad terms as “patient safety” and “public health”. The only exigent circumstances should be those that have patient safety implications, and not be based on other elements of the HITECH goals for ONC that fall outside of the certification responsibilities. Even those related to safety should be identified as posing “exigent” risks in order to trigger ONC direct review. Moreover, determining potential impact upon patient safety must be based upon adherence to known criteria, as opposed to ad hoc ONC judgment, relative to certified capabilities.

Instead of arbitrary enforcement of existing certification criteria or this proposed expanded authority, if ONC has reason to suspect risks to patient safety, a better approach would be for ONC to propose new certification criteria in future editions of certification criteria to encourage best practices that mitigate such risks. Utilization of the public comment process with new proposed criteria would ensure their validity and create new certification criteria as appropriate from lessons learned.

As proposed, the scope of ONC authority to declare non-conformities that are unrelated to existing criteria would have no specifications, standards, test procedures, etc., to ensure conformance to known expectations.

If our health IT system is to be truly a learning health IT system, then it will require a formal, transparent process to identify problems and propose solutions that solve those problems. Direct ONC review and statements of non-conformity seems counter to this expectation. ONC ACBs already have authority to perform both reactive and nonreactive surveillance, and to work with the developer to address corrective action plans.

Further, the included proposals seem very punitive in nature. The inclusion of “other exigent circumstances” is also quite troubling in that it could open the door to discretionary ONC action without any specificity other than a link to the high-level HITECH responsibilities for ONC. The Association is very

concerned that the scope and authority based on HITECH goals as set forth by ONC could unreasonably add many requirements and expectations that are unpredictable and not easily resolved. Proposals for certification criteria needing coordinated government response and deemed outside the scope of the ACBs' authority are very troublesome when considering the potential impact on resources which are being utilized for development of other published certification criteria.

Although the proposed rule states that the expectation to use such authority is low, there is no guarantee of how frequently it might actually be enforced or how many "other exigent" conditions might be applied, effectively mandating a scope of product functionality well beyond the health IT developers' capabilities or markets. As we have seen the approach to certification evolve from complete EHR to modular health IT, many developers will choose to focus on innovative, niche markets and develop new, responsive technologies. It is extremely difficult to understand how such broad authority and scope as proposed could be applied to such health IT modules which satisfy very specific certification criteria, or how ONC would determine non-conformities in health IT modules without having criteria which have survived the vetting process of public comment and pilot testing.

ONC direct review should be a true last resort, focused on exigent threats to patient safety, and specifically tied to conformance to certified capabilities, based on formally adopted certification criteria and partnering with the work of an ONC ACB. Otherwise, we believe that current ONC ACB processes are sufficient. Through the current process of complaint handling and surveillance, non-conformities with ONC certification program criteria should be addressed via the ONC ACBs' relationships with the health IT developers. Only after ONC ACBs have been unable to achieve satisfactory results through their current processes, should ONC be involved in this process. As we gain experience with enhanced surveillance monitoring, we hope that the current process will be given adequate time to mature.

When deciding to conduct a review based on reports received from the general public or users of certified health IT, ONC should take the following factors into account to determine the likelihood of systemic or widespread issues and impacts:

1. Reports are submitted by individuals or organizations that have a license to the certified technology ("the licensed entity"): This distinction is critical in assessing the difference between simple user error and evidence of a systemic problem with the certified health IT. The vast majority of certified EHR technology licenses are sold to organizations. These licensed entities, in turn, provide authorization to individual providers, be it five providers or 500 providers, to utilize the licensed EHR software through user accounts. A report from a single individual user who is not the licensed entity very likely represents user error or insufficient familiarity with the software features and functions, especially if the licensed entity that owns the user's health IT has not likewise submitted a report indicating system-wide issues with certified health IT.
2. Licensed entity's timeliness in implementing all applicable and available releases and "hot fixes" for the certified health IT: Software designers routinely identify software design or other issues and implement fixes through various types of software releases. Implementation of those releases can be either automatic or voluntary. Many EHR platforms are designed to allow licensed entities to implement releases and fixes according to a schedule of their choosing, meaning that it is not uncommon for a licensed entity to wait several months before implementing a new release on the schedule that works best for their organization. As a result, if a licensed entity is not current on implementation of all software releases, it is possible that the error being reported to ONC has already been identified and corrected by a release provided to the licensed entity.
3. An adequate number of reports submitted by multiple licensed entities for the same certified health IT and health IT version to warrant a determination of a systemic issue as opposed to user error.

4. The licensed entity submitting the report contacted the software vendor to seek a remedy to the issue prior to submission of the report to ONC.

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:

EHR Association Comments:

ONC authority over the certification program should only concern products that have been tested and achieved certification in the ONC program. Initiation of the proposed non-conformity and review process should always start with the ONC ACB that has certified the health IT. As an authorized ACB under the ONC program, the ONC ACB currently has the authority to review the health IT, and make a determination of conformance.

With regard to the relationship between ONC and the ONC ACB, the EHR Association does not support ONC initiating the review process. The ONC ACB duties, as currently defined, are based upon surveillance of established certification criteria to ensure that health IT implemented in the field functions properly. As stated previously, non-conformance should be related to criteria used to achieve certification, and not broad duties of the National Coordinator. As such, ONC ACBs should be the initiators of any proposed review for non-conformance.

We agree that the process should be clearly defined so that the ONC ACB or ONC ACBs associated with the health IT in question have essential information to address the non-conformity. We question, however, ONC's proposed intention to override the process with discretionary review when processes are in place to handle such occurrences. ONC should not be the first discretionary line of review, exert exclusive review, or override a review by the ONC ACB that has performed its duties based on due process to protect the integrity of the certified health IT. It is also unclear why ONC ACBs would be deemed inconsistent or incompetent with ONC administration, or why ONC would be required to intervene in satisfactorily addressing the non-conformity, since the product previously achieved certification through the ONC ACB, and not ONC.

ONC ACBs should be empowered to share the necessary information with other ONC ACBs to obviate the need for ONC to intervene if multiple ONC ACBs are involved in the suspected non-conformity. Duplication of review by ONC after an ONC ACB-conducted review is not appropriate. Duplicative processes should be avoided. If a developer chooses to certify with two different ACBs, part of their considered costs and expectations should be the possibility of multiple reviews. Only if two ACBs cannot come to the same conclusion on an area of shared jurisdiction, or a single ONC ACB could not reach a definitive resolution, would we support ONC exercising their authority to assist an ONC ACB following the attempted ONC ACB review and after a request from the ONC ACB to ONC for assistance. If each ACB feels they have resolved the issue in their own way, regardless of how they came to that conclusion, no further ONC review should be allowed nor required.

Review Processes – General Comments

Preamble FR Citation: 81 FR 11062

Specific questions in preamble? *No*

Public Comment Field:

[Click here to enter comments on Review Processes – General Comments](#)

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:

EHR Association Comments:

Any notice of potential non-conformity should refer to the current certification criteria functionality to which the product is certified. A thorough initial and, as needed, follow-up process for evaluating the alleged non-conformity is encouraged to avoid wasting resources on frivolous complaints or investigations. The EHR Association encourages dialog between the health IT developer and the ONC ACB regarding complaints or surveillance-related potential non-conformities as a first step in determining whether a potential non-conformity should be declared.

A notice of potential non-conformity citing the specific certification criteria and alleged non-conformance should always be the first step towards addressing a complaint that the product is not conforming as certified, not a notification of non-conformity as the first step. This notice of potential non-conformity should be handled through a formal receipt verification mail process to assure the health IT developer is aware, and not rely only upon email notification. Once the health IT developer receives the notice of potential non-conformity and assesses it, they should be required to acknowledge the issue if there is non-conformity, or provide documentation to the ONC ACB that there is no non-conformity. The timeframe for this initial response and subsequent consideration must be defined and should not be shortened at will by ONC.

Accordingly, we do not support establishment of any process under which ONC would be in a position to send a notice of (definite) non-conformity without developer engagement, as opposed to sending a notice of potential non-conformity.

We understand there could be some unlikely egregious situations that prompt ONC to make such a proposal, and request specific examples which ONC might deem urgent and exigent patient safety matters, as mentioned as the reason of arbitrarily shortening the timeframes. From our perspective, an identified non-conformity is a non-conformity, and all non-conformities should be addressed with equal urgency if the system when implemented is not performing as tested and certified. We understand that patient safety issues are urgent matters, but are uncertain of specific triggers that would justify a departure from the current process. It is important to health IT developers to maintain the credibility of the entire certification program, with a process in place which will serve the best interests of all stakeholders.

It is crucial that the alleged non-conformity is truly an issue with the performance of the product against its certification criteria and testing results. This determination may require dialog with the ONC ACB in the suggested timeframe. If additional information is needed by the health IT developer to confirm the alleged non-conformity, this should occur as part of the interaction with the ONC ACB. If the documentation provided by the health IT developer does not satisfy the ONC ACB, they should immediately notify the health IT developer and engage in the process to resolve the issue. The health IT developer may need to provide additional documentation or schedule a product demonstration, upon the ONC ACB's request, to assure the ONC ACB of conformance. The timeframe should be based on business days, and not be arbitrarily shortened.

Once a non-conformity is confirmed, ONC should issue the notice of non-conformity and the health IT developer should initiate the process to submit a corrective action plan. With a corrective action plan underway to correct the non-conformity, there should be no further action or sanction on the health IT developer unless extreme implications to patient safety can be determined. Sanctions should not be imposed until such time as the corrective action plan is not fulfilled.

The proposal for records access is exceptionally far-reaching and appears to go far, far beyond what is required for ONC ACB surveillance. It is especially troublesome, given the proposed broad scope of the basis for direct review. The proposed language should be much more narrowly focused on records that directly bear on the specific certified capabilities affected by the non-conformance and only materials relevant to the issue at hand. The “all records” language is much too broad and far reaching, as is the requirement for complaint records that may be unrelated to the issue under review. The most important records at this point would be the proof of conformance provided to the ONC ACB, or a corrective action plan to address the non-conformity.

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:

EHR Association Comments:

As stated previously, we support review of potential non-conformities and non-conformities by the ONC ACB as the typical process to address concerns about non-conformity. More specific circumstances need to be defined than those currently cited in the proposed rule regarding when ONC should exert direct review authority. The authority to require a corrective action plan must be based upon requirements of the certification program as related to existing criteria which have been tested and certified by the health IT developer. The scope for the corrective action plan should be based on the issues with the CEHRT. ONC has clearly stated in presentations on this rule that the rule is not intended to add new certification criteria or for ONC to actually test CEHRT.

ONC has asserted authority to potentially expand a number of duties of the National Coordinator as applicable to the certification program requirements. Any notice of potential non-conformity or non-conformity beyond current certification criteria has the potential to require the equivalent of new certification criteria for any non-conformance unrelated to current certification criteria. The EHR Association is concerned with the language in this proposed rule regarding the authority of ONC to “prescribe” the corrective action and its consequences.

This proposed regulatory language seems to differ significantly from the 2015 edition language used in “§ 170.556 In-the-field surveillance and maintenance of certification for Health IT”. The 2015 Edition language specifies that when an ONC ACB determines through surveillance or otherwise that the health IT does not conform to the requirements of its certification, upon notification, the health IT developer must submit a corrective action plan. The current proposal and the 2015 edition rule are consistent concerning the authority of ONC ACB or ONC to provide direction on the required elements of the corrective action plan. However, the proposal and the rule are inconsistent with regard to the proposed ability of ONC to “prescribe such corrective action as may be appropriate to fully address the identified non-conformity(ies)”.

The EHR Association opposes ONC “prescribing” the specific corrective action and generally supports, instead, language that matches the 2015 Edition rule regarding providing direction on the required elements of the plan, specified as:

1. A description of the identified non-conformity;
2. An assessment of the nature, severity, and extent of the non-conformity, including how widespread they may be across all of the health IT developers customers of the certified health IT;
3. 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;
4. 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;
 - d. How the health IT developer will ensure that all issues are in fact resolved; and
5. The timeframe within which corrective action will be completed.

We suggest the language regarding the ability of ONC to “prescribe” be clear as to ONC’s ability to prescribe the elements required in the plan, but not to prescribe the action. The specific actions

necessary to correct the deficiency must be defined by the health IT developer.

We note that, within the elements of the corrective action plan, the health IT developer is expected to convey a description of the non-conformity. We expect ONC to provide information describing the non-conformity in detail, expressly including a citation of specifically which certification criterion/criteria are not being met as the basis by which the health IT developer complies with this element of the corrective action plan. We also note that, while the proposal assumes that the non-conformity potentially affects a number of customers, there might actually be many non-conformities that affect only individual customers and thus all elements defined may not apply.

We are also concerned with the intent of the requirement in iv (D) regarding the ability to “ensure” correction of the non-conformity. As the health IT developer carries out the corrective action plan, the intent is to make available software that corrects the non-conformity, and to make sure that the correction is available for implementation for all affected customers. This action would fulfill our obligation as we understand the corrective action. However, we cannot guarantee the absolute resolution in a provider’s implementation within the required timeframe, as some providers may not immediately implement the software update, or modify their workflows in all ways necessary to “ensure” success. Further, as noted above, there are issues that could be associated with non-conformity but also deeply interwoven with configuration choices made by the user entities, and this must be reflected in any expectations for resolution.

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

Public Comment Field:

EHR Association Comments:

The EHR Association entirely opposes suspension of health IT products as proposed in this rule. As proposed, health IT could be suspended for any one of multiple reasons that ONC defines, which amounts to de facto additional un-promulgated and untested requirements for the certification program, created through the expanded authority asserted in this rule for duties associated with the National Coordinator in paragraph (i).

Instead, outright suspension should be limited to only two specific circumstances: (1) a proven, not hypothetical, serious risk to patient safety (which must be clearly defined and limited to specific circumstances), or (2) the absolute failure to respond as defined in (i), (iii), (iv) or (v) as required. We recommend that ONC review the [Proposed Amendments to Include ONC-ATLs in the Program - Revocation of ONC-ACB or ONC-ATL Status \(§ 170.565\)](#) to understand our perception that ONC proposes to apply a process to the health IT developers in a way that seems destined to escalate and complicate many potential non-conformities by applying suspension and termination outright rather than addressing them with fact finding and resolution as applied to the ONC ATLs. The process applied to ONC ATLs represents a clear definition of non-conformity upfront, and a process which generally avoids suspension and termination by allowing the proposals of non-conformity to be confirmed before potentially unnecessary actions are taken.

We recommend that this rule focus on exigent and unambiguous risk to patient safety, and complete failure to cooperate as defined as the only outright reasons, without further investigation, which ONC or an ONC ACB should consider appropriate for suspension. Until the extent of the potential risk is actually determined and confirmed, suspension should not be applied. Such punitive action without just cause serves no useful purpose, alarming providers and causing them concern about using products that are, in fact, conformant. In our members' experience, it is not uncommon for health IT modules to be questioned or alleged to be nonconforming, with associated events labeled as risks to patient safety when, in fact, the complaint is not accurate. There must be very clear policies to address real non-conformities; however, there must also not be assumptions of guilt and actions taken without following the proper processes implemented to benefit all concerned parties.

We are unclear about ONC's definition of the term in the proposed rule "encompassed Complete EHR or health IT Module", and ask for clarification of intent from ONC. We assume the intent is to apply the basis for suspension to all modules (certified or noncertified) associated with the product in question. We note that, beginning with the 2015 edition certification, ONC has discontinued the concept of Complete EHR and all certifications will be modular.

ONC asks for comments on the appropriate timeframe for a health IT developer to notify affected or potentially affected customers of the suspension. Based upon the limitations suggested for the basis of suspension being clearly related to patient safety, we believe health IT developers already have policies and procedures in place to define such parameters through their quality management systems, so there is no need for ONC to attempt to define a specific timeframe.

We strongly disagree that ONC should apply suspension for a specific product towards other products that the health IT developer may be testing or certifying within the certification program. Any suspension should apply only to the product in question, and not apply to other unrelated products. Applying suspension broadly to all products offered by the health IT developer under the premise that it would cause the health IT developer to address the non-conformity any differently assumes poor intent on the part of the development community and could actually harm providers who may be in need of

another product or product update requiring certification from the same developer. Suspension across the board has the potential to totally disrupt the health IT product development and innovation cycle, which is frequently mapped many months if not years in advance, and would have profound effects on additional providers unaffected by the suspended product. We are unaware of this approach to product suspension in any other regulatory program. The product in question should be the only product affected.

In response to the ONC request for comment regarding correcting the non-conformity for a certain percentage of customers or certain milestones, we reiterate that suspension should only be applied in circumstances as we have suggested. As such, enabling the correction to the software for the non-conformity and making it available for implementation could take varying amounts of time to accomplish. We believe the important point for lifting the suspension is the availability of the correction to the customer base, and not the completed implementation by all affected providers, as the health IT developer can encourage implementation but cannot control it.

The suspension of the health IT, for reasons stated above, whether based upon an action or inaction, must be carefully defined. Provisions that such a product cannot be marketed, sold, or inherit certification status are significant overreach and not appropriate unless there is a valid reason to take such action to suspend and cause such consequences. The Association encourages ONC to reconsider the impacts of their proposals and the potential to adversely affect providers, as well as health IT developers, with such punitive actions. Consider the impact if the suspension happens to occur when providers are preparing to attest, or the questions that will arise about the validity of the health IT when in use during a reporting period.

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:

EHR Association Comments:

As proposed, the termination process could be implemented without an initial suspension process. We oppose termination as a first step. Any conditions defined here prior to failure of the health IT developer to fulfill its corrective actions should be initiated as a suspension. Failure to respond, failure to provide sufficient or complete information, or failure to submit an accepted corrective action plan should result in an initial suspension. Assuming that there is due process for appeal of a suspension, or a mutually-agreed-to extension of the suspension timeframe, if the health IT developer does not fulfill the corrective action plan, then the result should be termination. The proposed approach seems to be rather drastic and punitive if the goal is indeed to work with the health IT developer to address a potential non-conformity or non-conformity when due process is underway as defined in the majority of these termination considerations.

The EHR Association is also concerned about the implications that ONC could determine that the non-conformity could not be “cured” and, as a result, issue a termination of the product’s certification. Our concern is increased by the fact that the non-conformity could affect a very small portion of the product and, as further stated in the proposed rule, any non-conformity must be corrected without a loss of functionality in order to reacquire certification. We question the ability of ONC to determine the feasibility of curing a non-conformity prior to suspension or without consultation with the developer. We also do not believe that the issues that could lead to suspension or termination can be classified as simple and easily comprehensible by ONC when, in fact, the nature of health IT is often quite complex.

We strongly suggest that this proposal regarding termination of certification be reconsidered as we find it to be counterproductive. We understand that ONC does not want providers to experience untoward and unintended effects if their health IT is found to be non-conformant with certification requirements. Removing the non-conformant health IT module should remain a viable option for the health IT developer in order to keep a certified product on the market until such time as an adequate development process can be undertaken to deliver the solution. The inability to reduce the scope of the non-conformity to a module vs. an entire product seems to be a “Catch 22” that further constrains the corrective process.

In the event that a termination is issued, it should be in writing. It should include the information on which ONC relied to determine the potential non-conformity, as well as any and all of the documentation and analysis which was used by ONC to reach the decision to apply termination. We also recommend that the process to appeal any termination be broken into two distinct steps:

- First, the health IT developer must make a determination as to whether or not to appeal the termination. This process could require consultation with a third party as well as internal consideration to address such a profound business decision. In order to make this preliminary decision, there must be adequate time to research the findings provided by ONC, understand ONC’s analysis, and make a determination if the health IT developer is expected to provide additional documentation to satisfy an appeal of the termination. We request the currently proposed 10 days as the minimum timeframe for the health IT developer to make a decision and file its intent to appeal the termination, and suggest clarification that these are 10 business days. If no intent to appeal is filed, the 10 business days would serve as notice of termination.
- Second, if the health IT developer files its notice of the intent to appeal, we recommend an additional 30 business days as the minimum timeframe adequate for the health IT developer to gather the appropriate documentation for submission of the appeal. We would ask that ONC allow for a mutually agreed upon extension should it be necessary.

Once ONC has made its decision regarding the termination appeal, we request that ONC notify the health IT developer within one business week of its finding. At such time as the appeal process has occurred and ONC has issued its final ruling, it then becomes necessary for the health IT developer to notify the affected customers. The EHR Association considers it inappropriate for ONC to expect any notification to customers during a suspension or termination proceeding until the final decision is reached after the appeal process has been initiated and determined. We question whether such notification prior to the final ruling would serve any purpose except to be punitive and suggest that it would cause significant concern amongst the clients of that company. We reiterate that, if the goal is truly to solve the potential non-conformity or non-conformity, it is the final decision that matters most to the affected providers, not the process as it is conducted.

In addition to termination not being the first step, the ONC should adopt industry standards for managing minor and major non-conformances, as well as the overall process that leads to the termination of certification. ISO accreditation (of any certification) follows a process involving a probation period. In practice, the probation period can be as little as 90 days but is often a full year (or when all major non-conformances are resolved, whichever comes first). An organization under probation submits to additional audits so that the registrar can monitor their progress to resolve any major non-conformances (minor non-conformances are not a cause for probation). The audits are solely focused on addressing the non-conformances, and they are not a full audit of all accreditation components (it is not a recertification). If, after the probation period, the organization has still not resolved their major non-conformances, then the registrar can choose not to renew their certification or to withdraw the existing certification.

While, in some cases an ISO registrar may choose to implement a suspension process instead of a probation process, due to the nature of EHR certification and the significant impact it has on providers who need to attest with CMS, we do not advise ONC to adopt a suspension process. Suspension is the same as probation in relation to the timeframe and additional audit requirements; however, the organization cannot continue to use their vendors' certification for attestation or other purposes while in a suspension.

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:**EHR Association Comments:**

The basis for the appeal seems to be rooted in the assertion by the developer that ONC has incorrectly applied program requirements, standards, or requirements of the certification program. In order for the health IT developer to make such an appeal, the specific standards and requirements must be clear. The EHR Association understands the standards and requirements as they apply to the current certification criteria, which are tested and certified for achieving CEHRT, and supports those criteria as a basis for appeal of a suspension or termination. We do not understand, however, how we could assert a basis for an appeal without recognized certification criteria, as has been proposed in this rule.

Based upon the broad authority that ONC has asserted through the duties of the National Coordinator, it would be impossible for the health IT developer to have such basis for appeal to point to standards and requirements when, in fact, there are no current requirements for testing or certification to these potential non-conformities which ONC could assert. As we have stated throughout our comments on this proposed rule, we support of a limited set of circumstances related to patient safety which can be applied to current certification program criteria, should the implementation of such criteria in the health IT not perform as tested and certified. We reiterate that these should be the basis for any suspension, termination, or appeal.

The second basis for filing an appeal is related to an ONC determination that was not “sufficiently supported” by the information used by ONC to make the determination. We assume this refers to situations where ONC made a determination of non-conformance based on inaccurate or incomplete information. This basis for appeal would not be necessary if the issue were properly investigated before sanctions were applied.

We have previously suggested that filing an appeal should be a two-part process. First, a notice of intent to appeal should be filed. Second, the appeal should be filed as detailed in comments in the previous section. We reiterate that the proposed rule is especially troubling when ONC asserts the authority to file a suspension or termination without going through the due process of addressing the potential non-conformity, confirming the non-conformity, determining a corrective action plan, issuing a notice of suspension, engaging in the appeal process, issuing a notice of termination, engaging in the appeal process, and finally ruling for termination. Unless this process is followed in the specific steps as detailed, it could become very complex and overwhelming where ONC and a health IT developer could be appealing a suspension or termination while in the process of adopting a corrective action plan; or even appealing before a corrective action plan was developed. Punitive actions should be stayed until the process has been followed and failed to resolve the non-conformity. Punitive actions such as suspension or termination should not be applied as proposed in this rule, and should never be levied until after the final findings of an appeal.

The EHR Association does not support the proposal to utilize an ONC-appointed hearing officer. We are uncertain of the selection process or qualifications of such an individual, and recommend that such hearing officer be appointed from outside ONC (e.g., a hearing officer from among the administrative law judges at HHS that deals with similar appeal processes). We disagree strongly that the hearing officer should also make the sole determination on whether to hold a hearing. The health IT developer should always have the right to a hearing to present findings; answer questions, etc., in addition to explaining the documentation which has been provided. We also strongly disagree that, during the appeal process, the hearing officer would not be able or required to receive any new testimony or new information that was not presented with the appeal request. The process of an appeal should be the last resort to present any and all relevant information in support of the appeal of a termination, and not a

closed process to review only materials submitted during the appeal timeline. Relevant documentation could have been missed, thus making the hearing the only opportunity for review.

As proposed in this rule, there is no further process for appealing the decision of the hearing officer as exists in many other types of proceedings. It is critical that this appeal process take into account any new information which might affect the final outcome of the appeal. The proposed rule also stipulates that there should be no adverse finding against ONC if ONC fails to submit the written statement and supporting documentation on its behalf that explains its determination to suspend or terminate the certification. The Association hopes that ONC clearly understands that these materials are required in the appeal process, and failure to provide such detailed information could result in adverse findings towards ONC and could be taken into account by the hearing officer in reaching a determination. We are supportive of 30 business days as the timeframe for an appeal decision. Any extension granted to the hearing officer beyond the 30 business days for a written decision should be approved by both parties, i.e., the health IT developer and ONC.

We recommend reconsideration of the single appeal process as proposed and reiterate that there should be a process for a second level appeal, given the circumstances that a single hearing officer has total jurisdiction not only over the fate of an health IT module or complete EHR, but the health IT developer themselves with regards to participation in the certification program. As this rule is proposed, a single hearing officer should not have the authority to mandate such termination and ban without enlisting another hearing officer to review the decision. We ask that ONC look to other agencies within HHS which perform appeals and consider expanding the process to minimize the impact of such termination upon the marketplace.

Consequences of Certification Termination – General Comments

Preamble FR Citation: 81 FR 11066

Specific questions in preamble? *No*

Public Comment Field:

EHR Association Comments:

The primary remedy for the provider should always be for ONC to work with the health IT developer to settle any non-conformity associated with the health IT modules which were tested and certified under current program certification criteria to deliver specific functionality. The EHR Association is supportive of ensuring proper health IT functionality which was tested and certified. We support identification and correction of any non-conformity that may result after implementation; however, we reiterate that some developer recommendations for proper performance are not always followed by providers. As proposed, the ONC authority and scope to determine non-conformities beyond the current certification requirements have the potential to impose further burdens, not only on the health IT developer, but significant burdens on providers as well.

As proposed, “exigent” situations for which ONC asserts non-conformity may be unrelated to certified capabilities sought by the provider who purchased the CEHRT. The EHR Association questions how providers will react to their EHR being decertified for issues related to functionality for which the EHR was never certified to provide. ONC should be more rigorous in identifying the potential consequences that could be placed upon providers when ONC applies this entire process, or terminates a certification. In order to accurately evaluate the impact of this rule as proposed, ONC must identify other potential negative consequences placed on providers to determine the right level of oversight and authority which ONC must utilize when dealing with health IT issues.

By assessing the significant negative impacts, not only on health IT developers but providers as well, ONC should seek an appropriate balance that takes all factors into account. ONC should also consider the potential for this proposed rule to create incentives to initiate complaints by providers in order to trigger hardship exemptions and thereby eliminate their need to meet meaningful use or other program requirements.

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 non-conformity 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:

EHR Association Comments:

The EHR Association does not support the ONC proposal to allow no reduction in scope as a requirement to attain recertification after termination. As we have stated, there are conditions when a health IT developer encounters problems that may not be solved and which may result in the unlikely decision to remove the product or some of its modular functionality from the marketplace or from certification. There should be no ban on testing and certification of health IT from the health IT developer who chooses this solution of reduced scope. This reduction in scope could involve potential non-conformity related to something as simple as a particular quality measure that cannot be calculated correctly. After due diligence to correct the problem, the health IT developer may simply and appropriately decide that removal of the quality measure from the certified health IT is the best solution.

We also emphasize that ONC is promoting health IT modules since it has eliminated the complete EHR designation for the 2015 edition. This proposal to disallow health IT developers from reducing scope seems counterproductive and inconsistent with ONC policy directions when considering that all CEHRT will be health IT modules going forward. The Association is very concerned about how ONC will assert this proposed authority to address non-conformities which are not clearly associated with recognized certification criteria in the absence of the complete EHR. Identification of specific health IT modules by ONC as non-conformities could be troublesome, as the approach seems to imply simplicity in an environment which is often complex.

If a health IT module is terminated due to a non-conformity based upon the ONC goals, but not an actual certification criterion, how would the non-conformity be evaluated by ONC without test procedures, test data, etc., to evaluate conformance prior to the health IT developer being allowed to participate in the certification program? In the case of a termination issued due to non-conformance unrelated to an existing certification criterion, what would be tested and certified upon applying for recertification from the ONC ATL and ONC ACB? This proposed rule seems to have created a process to impose punitive actions on the health IT developer, where there may be no way to move forward from a termination. By levying such non-conformity designation and the proposed process to address the non-conformity, this proposal seems to basically assert ONC's authority to determine what must be available in the marketplace and which health IT developers will participate.

This section of the proposal also uses the language, "written explanation of the steps taken to address the non-conformities that led to the termination". We suggest instead using language that was previously used and clarified related to Corrective Action Plans for consistency.

After termination, recertification of the health IT module should be limited only to the health IT module that was identified as having a non-conformity, and recertification testing and certification should not include all other modules offered by the health IT developer as this proposed rule seems to state. The EHR Association is supportive of the proposal for heightened security of a health IT module that has undergone termination for a period of six months. This time period will allow adequate time for surveillance and should alleviate any further concerns with the health IT module. The heightened scrutiny should apply only to the health IT module in question, and not to the health IT developer in general. It is very feasible that the health IT developer may have additional modules which are moving through the testing and certification process and upon which clients plan to rely for success in their own endeavors.

Proposing any ban on other health IT modules offered by the same health IT developer could serve to create many unintended consequences to providers who are depending on timely delivery of updates of

CEHRT, and would serve no purpose except to perhaps undermine development timeframes and implementations of unrelated health IT modules from the same health IT developer. Any program scrutiny or ban from the program must be related to the health IT module associated with the non-conformity. There should be no extension to additional health IT modules of the same health IT developer unless additional modules from the same health IT developer also have potential non-conformities and experience termination. The application of program bans to the health IT developer is unfounded in our experience of resolving specific health IT module issues. We recommend the proposal to ban is changed to the following:

- The testing and certification of any health IT module that has the certification terminated under the program or withdrawn from the program when the subject of a potential non-conformity or non-conformity is prohibited, unless:
 - (1) The non-conformity is corrected and made available for implementation by 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.
 - (3) The health IT developer removes the health IT module from the market.

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 non-conformity 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:

*Duplicate --***

EHR Association Comments:

This proposal to disallow health IT developers from reducing scope seems counterproductive and inconsistent with ONC policy directions when considering that all CEHRT will be health IT modules going forward. The Association is very concerned about how ONC will assert this proposed authority to address non-conformities which are not clearly associated with recognized certification criteria in the absence of the complete EHR. Identification of specific health IT modules by ONC as non-conformities could be troublesome, as the approach seems to imply simplicity in an environment which is often complex.

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:

EHR Association Comments:

The EHR Association recognizes that the proposed amendments by ONC to include the ONC ATLS in their jurisdiction, as is currently applied to the ONC ACBs, could strengthen their ability to assure conformance with both the testing and certification components of the certification process. Many of its provisions could enable ONC to interact more directly than has been possible under the current provisions, where guidance and clarification on existing criteria, test procedures, test tool, etc., could help expedite the success of testing and certification. We support ONC contractual oversight of ATLS that mirrors what is in place for ACBs, but not beyond that. We caution, however, that expanded complexity of accreditation processes could introduce additional costs that would be passed along to developers and their clients, and which might discourage qualified ATLS from participating.

We recommend that ONC minimize any additional costs to the ONC ATLS, either through the application process or the ONC direct review process which is proposed. Added to our concerns regarding the implications of the expanded authority to levy non-conformities against health IT developers, we are also concerned that this ONC authority could become part of ONC ATL processes. It is not clear how much duplication of work, or how many additional resources could be consumed, by non-conformities levied based upon ONCs assertion of this authority beyond the current certification requirements. We believe this could add substantial additional costs and many other dependencies to the ONC ATLS, resulting in substantial impact upon the ONC ATLS.

Any cost increases certainly have the potential to flow downstream to both the health IT developers and providers using certified products. We do not know the ultimate impact, but we express concern about the effect this might have upon an organization's ability to operate as an ONC ATL. It seems very likely that the proposed process could add additional review requirements and potentially lengthen the review processes required by ONC of the ATLS, thus generating additional costs. We recommend that ONC carefully consider any additional administrative or financial implications on the certification program resulting from these proposals.

It is important to note that ONC ATLS are accredited by the National Voluntary Laboratory Accreditation Program (NVLAP). NVLAP bases its audits of ATLS for new accreditations or accreditation renewals on both:

- The general ISO 17025 standards for operation of testing laboratories, and
- The specific elements of the ONC certification and testing rules (an IS) 17025 scheme).

Having a third party accreditation of ATLS independent of ONC is a critical quality factor that the proposed increased ONC oversight seems to ignore, or at least bypass or duplicate in some form.

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:

EHR Association Comments:

The Association does not support ONC accreditation in addition to current NVLAP accreditation. The current process conducted by third party organization NVLAP should remain. We are supportive that ONC should propose similar administrative controls over the ATLs as currently exist with the ACBs without imposing additional certification requirements.

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

* * * * *

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.

* * * * *

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.

* * * * *

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:

Click here to enter comments on Proposed Amendments to Include ONC-ATLs in the Program - Definitions (§ 170.502)

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:

Click here to enter comments on Proposed Amendments to Include ONC-ATLs in the Program – Correspondence (§ 170.505)

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:

Click here to enter comments on Authorization Scope for ONC-ACB Status (§ 170.510)

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:

EHR Association Comments:

The EHR Association appreciates the proposed amendment, which would allow applicants to perform testing of a single criterion or portion of a criterion. On several occasions, we have suggested that ONC accept certification results from an organization that has already performed testing and certification of health IT modules which are also designated as ONC certification criteria. We encourage these organizations to pursue such testing and certification as a complement to the existing certification program.

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:

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:

EHR Association Comments:

We are supportive of gap eligibility for certification criteria. We encourage ONC to provide as much flexibility as possible to designate as many criteria as gap eligible as possible to reduce the burden of certification testing.

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:

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:

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

* * * * *

(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.

* * * * *

(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:

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:

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:

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:

EHR Association Comments:

The EHR Association is supportive of remote testing and certification for both development and deployment sites. We also support remote testing capabilities for ONC ACB surveillance activities.

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:

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.

Public Comment Field:**EHR Association Comments:**

As previously stated, we have concerns regarding the establishment of the maximum timeframes allowed to do adequate investigation of complex issues, which could require extensive resources and additional time from both ONC and health IT developers to determine conformance. We respectfully suggest that ONC ATLs and ONC ACBs carefully review the ONC proposed timeframes to ensure adequate time to avoid such processes as suspension or revocation from being implemented. The disruptive consequences to the marketplace from such actions could adversely affect health IT developers and providers for years to come.

The EHR Association has reviewed the proposed process for addressing potential noncompliance for the ONC ATL, and is encouraged that ONC has chosen a process which is based upon determining absolute proof of noncompliance as the first step. We recognize that ONC has proposed a process where the goal seems to be defined to first determine whether or not there is actually noncompliance prior to initiation of other proceedings such as suspension or revocation as was proposed for the health IT developers.

Many of our comments are based upon the perception of the more punitive nature of the proposed rule upon suspected non-conformities of health IT developers. We note that it is essential to clearly include definitions of the violations for health IT developers as ONC has proposed here for the ONC ATLs and ONC ACBs. We appreciate that ONC has chosen what seems to be a less punitive and more diligent process to determine noncompliance for the ONC ATLs to accurately determine noncompliance before proceeding. By issuing noncompliance “notifications,” opportunity to become compliant, “proposed” revocations, and “proposed” suspension with a time for response before proceeding directly to suspension and revocation, we are encouraged that the intent is truly to fix the problem and not create undue negative consequences to the ONC ATLs and ONC ACBs.

We believe this to be a difference in the way that ONC has proposed to respond to an ONC ATL versus a health IT developer under similar circumstances, where suspensions and terminations are issued outright. The EHR Association would appreciate application of the same processes to the health IT developers as has been proposed for the ONC ATLs, where any noncompliance should always be “proposed” and verified before proceeding to potentially damaging and unnecessary steps such as suspension, revocation, or termination. The application of suspension, revocation, or termination should not be taken lightly, and must be reserved for clearly-defined circumstances after a fact-finding process and “proposed” notices have failed to elicit conformance which can be verified against defined performance requirements.

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

Public Comment Field:**NOTES:**

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

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

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

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

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

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

EHR Association Comments:

We understand that ONC has specified in § 170.570 that a Type-1 violation calls into question the legitimacy of the certification issued, and the National Coordinator must review the facts surrounding the revocation of the ONC ACBs status. A Type-1 violation could be related to fraudulent activities that affect the ONC Health IT Certification Program, a program administered by HHS, or any program administered by the federal government. The rule seems clear regarding a Type-1 violation and the National Coordinator's responsibilities. As we understand this proposal, if the National Coordinator believes the health IT module was improperly certified, then the certification is only intact for 120 business days after publishing the notice. Upon such notice, the health IT module must be re-certified by an ONC ACB in good standing. We seek clarification regarding how the National Coordinator would make such assessment for each certified health IT module. Further, we ask that ONC evaluate the likelihood that an ONC ACB would be able to accommodate a request for recertification within that 120-day time period, as they do not always have tremendous flexibility to schedule around other obligations, particularly during busy certification periods.

The National Coordinator could also revoke an ONC ATL's or ONC ACB's status for failing to timely or adequately correct a Type-2 violation which could pertain to the organization's ability to follow all applicable federal and state laws. The Association is concerned that an ONC ATL or ONC ACB could have its status revoked for a Type-2 violation which had nothing to do with fraudulent activity defined as a Type-1 violation. We seek clarification as to how the National Coordinator would apply such recertification requirements for revocation due to a Type-2 violation. Certification is extremely expensive for vendors and should not be required unless there is a question of the validity of the conformance of the certified product.

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)

* * * * *

(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 Comment Field:

EHR Association Comments:

The EHR Association has addressed previous proposals for identifiable surveillance results requirements in the 2015 Edition NPRM. We consider reporting positive surveillance results reasonable as long as the reported information is limited to the summary outcome of the surveillance. The information listed should be specifically limited to the information indicated – which should be a “ceiling” and not a “floor” – and should focus on a summary of the outcome of surveillance. Overall, the availability of a more balanced set of surveillance results could provide a more complete picture of certified EHRs and other health IT. Given the positive outcomes of these additional surveillance results, ONC and the ONC ACBs should provide summary results, using the general approach to information to be released on the ONC CHPL and the definition of “results” used in the 2015 ONC Certification Final Rule.

ONC should use a definition of “results” that does not include interim work product or information obtained in the course of surveillance (i.e., that truly focuses on results) and, that as proposed, does not include proprietary or business sensitive information. “Results” should focus on certified capabilities evaluated and not indicate why surveillance took place (e.g., provider expressed concern), as such information could provide a misleading and incomplete picture to consumers of the information. Finally, ONC and the ACB should clearly indicate that surveillance of specific certified health IT should not imply a problem or potential problem with the health IT when surveillance was initiated by an ONC ACB to satisfy requirements of proper conduct for the certification program.

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:

Click here to enter comments on ISO/IEC 17025:2005 (ISO 17025) as proposed for adoption consistent with the NTTAA

Incorporation by Reference (IBR)

ISO/IEC 17025:2005 (ISO 17025)

Preamble FR Citation: 81 FR 11071

Specific questions in preamble? No

Public Comment Field:

Click here to enter comments on ISO/IEC 17025:2005 (ISO 17025) as proposed for IBR in the Federal Register

Collection of Information Requirements

Collection of Information Requirements	
Preamble FR Citation: 81 FR 11071 -72	Specific questions in preamble? <i>No</i>
Public Comment Field: Click here to enter comments on Collection of Information Requirements	

Regulatory Impact Statement

Regulatory Impact Statement	
Preamble FR Citation: 81 FR 11072 -78	Specific questions in preamble? <i>Yes</i>

Public Comment Field:**EHR Association Comments:**

As stated initially in these comments, the EHR Association understands that ONC direct oversight of ONC ATLS could ensure that, as with ONC ACBs, testing labs are directly and immediately accountable to ONC for their performance across a variety of programs that affect the testing of health IT. There could be situations where it would be desirable to have oversight of the ONC ATLS beyond the current rule of the certification program. However, we question the authority, the need, and the potential consequences of such oversight as proposed in light of the fact that, as stated in this proposal, there has been very little need for such oversight or certification termination and limited effect on a small number of providers thus far.

Many members of the EHR Association have effectively participated in the current program through the 2011 edition and the 2014 edition of ONC certification. To date, we are not aware of situations where we believe the ONC direct review process would have provided substantial value to the program beyond what the ONC ACBs already provide. We agree that ONC should not propose altering the testing structure of the program, make testing and certification determinations, or review all determinations made under the program, as has been stated in this proposal. It is based on this agreement that the Association is very concerned with the approach of ONC to consider responsibilities under section 3001(b) of the PHSA as relevant to the expanded authority as applied to the certification program. We believe this approach is misguided.

This proposal seems contrary to ONCs statement regarding its lack of desire to undertake testing and determination of certification for ONC direct review. There are clearly no current criteria or test procedures associated with the proposed expansion of authority to assert these goals and levy these potential non-conformities on health IT developers. It seems highly subjective that ONC could make such a determination of non-conformity resolution except in the most egregious cases. We do not understand how ONC can assert this oversight, with the potential to suspend or terminate CEHRT which was never tested or certified to these potential non-conformities, without a sound basis of criteria and test procedures as exists in the current certification program. The process for ONC direct oversight and determination of compliance without explicit criteria and test procedures seems misguided. The processes specified in this proposal seem to be contradictory to ONC's intent not to make testing and certification decisions.

The EHR Association also raises concerns regarding costs related to potential non-conformities. Depending on the non-conformity, it could cost considerable development resources if the non-conformity is not based upon current certification criteria. Such proposals could be very disruptive to timelines required for development and updates to support the multiple programs currently using certification criteria. The proposed process also has the potential to stifle innovation by diverting resources that which could otherwise be dedicated to such innovation. It forces health IT developers to address existing problems generated by ONC review before developing other functionality for certification (currently and, in particular, working towards 2015 certification). As proposed, "non-conformities" will require that health IT developers to focus time and energy on responding to this new process as opposed to working on providing certified products to our users.

This has additional implications, such as delaying certification of the product. We are not concerned about the cost of fixing real issues. We are concerned about complications from attempting to address potential non-conformities without criteria or test procedures.