



May 2, 2016

The Honorable Karen DeSalvo, MD, MPH, M. Sc.
Acting Assistant Secretary for Health,
National Coordinator for Health Information Technology,
U.S. Department of Health and Human Services
Hubert H. Humphrey Building,
Suite 729-D
200 Independence Avenue, SW
Washington, DC 20201

Re: ONC Health IT Certification Program: Enhanced Oversight and Accountability NPRM [RIN 0955-AA00]

Dear Dr. DeSalvo,

On behalf of the American College of Physicians (ACP), I am writing to share our comments on the notice of proposed rulemaking (NPRM) for the Office of the National Coordinator (ONC) Health Information Technology (Health IT) Certification Program: Enhanced Oversight and Accountability. We appreciate the hard work by ONC staff that goes into this rulemaking process, and acknowledge their commitment to working with stakeholders from across the health IT spectrum that will be affected by what is finalized from this proposed rule.

The College is the largest medical specialty society and the second-largest physician membership organization in the United States. ACP members include 143,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

Overall, ACP supports the intent of ONC's proposals to initiate a direct review process of software certified under the ONC Health IT Certification Program as there is an evident need for oversight of health IT for purposes of patient safety and effectiveness of quality care. **However, the College is concerned that the scope under which ONC would initiate the direct review (activities listed in Section 3001 [b] of the Public Health Services Act) is too broad and encompasses scenarios that fall outside the published requirements for electronic health record (EHR) certification.** Currently, the certification process consists of a series of fully

specified tests that check for the presence or absence of functional criteria that are also specified in current regulation. This proposed rule would hold EHR vendors liable for functionality that is not specified anywhere in regulation, and would provide no useful guidance to vendors in advance of receiving a complaint.

ACP urges ONC to establish clear boundaries around the scope of ONC's involvement in the direct review process and subsequent decertification and suggests focusing on issues that affect EHR usability, interoperability, clinical documentation requirements, Electronic Clinical Quality Measure (eMeasure) Reporting requirements, all of which ultimately affect the safety of and quality of care provided to patients.

Moreover, ACP is concerned that the factors contributing to the possible suspension or decertification of any encompassed complete EHR or health IT module are too vague and the immediate suspension of these EHRs would be harmful to physicians as it would jeopardize their eligibility and participation in numerous programs that require certified EHRs. **ACP urges ONC to establish strict and field-tested guidelines for factors warranting decertification and for ONC to continue to utilize the established regulatory processes for improving the ONC Health IT Certification Program, which provide the opportunity for public comment and a broad range of stakeholder input.**

ACP welcomes this opportunity and hopes that you will consider our comments, which are listed below in the ONC provided public comment template, as you work to develop your final rule. Should you have any questions, please contact Thomson Kuhn, Sr. Systems Architect, at tkuhn@acponline.org.

Sincerely,

A handwritten signature in black ink, appearing to read "P Basch", with a long horizontal flourish extending to the right.

Peter Basch, MD, MACP
Chair, Medical Informatics Committee
American College of Physicians

Enclosure: ACP recommendations to specific questions posed by ONC

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:

This proposal has the potential to be useful to physicians or a vehicle to add a lot of pain to vendors. It appears as if ONC would need a department or division of people to collect complaints and review and determine non-conformities; as well as prescribing corrective actions. Again, this might be useful but the College is concerned about the current climate of many doctors hating their EHRs and whether it would be a system that would get quickly overloaded with complaints. Also, while there is a process for vendor appeal, what is the process that ONC is proposing to essentially limit the power of an “angry mob” from filing complaint after complaint against an EHR company? Is there any mechanism for prohibiting or penalizing frivolous complaints?

The EHR issues that most concern physicians and other clinicians – usability, documentation requirements, reporting requirements, loss of efficiency, etc. – are not addressed by anything in this proposed rule. All of the provisions of this rule could be implemented, and the users of EHR systems could find themselves no better off for all of the additional processes and procedures.

This proposed rule expands the scope of the EHR certification program beyond the published requirements for certification:

Excerpted from II.A.1.a – Authority and Scope: We believe there could also be other exigencies, distinct from public health and safety concerns, which for similar reasons would warrant ONC’s direct review and action. For example, ONC might directly review a potentially widespread non-conformity that could compromise the security or protection of patients’ health information in violation of applicable law (see section 3001(b)(1) of the PHSA) or that could lead to inaccurate or incomplete documentation and resulting inappropriate or duplicative care under federal health care programs (see section 3001(b)(3) of the PHSA).

Excerpted from II.A.1.c.(3) Suspension - Such results would conflict with section 3001(b) of the PHSA, which instructs the National Coordinator to perform the duties in keeping or recognizing a certification program that, among other requirements, ensures patient health information is secure and protected in accordance with applicable law, reduces medical errors, increases efficiency, and leads to improved care and health care outcomes.

We are concerned that a different administration could use the expanded scope in ways that are not intended by the current administration. Clear boundaries to the scope of ONC involvement are needed. Currently, the certification process consists of a series of fully specified test procedures that test for the presence or absence of functional criteria that are also specified in regulation. The above quoted paragraphs, and other wording in the proposed rule, would hold system vendors liable for functionality that is not specified anywhere in regulation, and would provide no useful guidance to vendors in advance of receiving a complaint. Furthermore, while there is some evidence that poorly usable systems can decrease clinician efficiency, there is also evidence that clinician efficiency is affected by other health IT related factors - including implementation and training, as well as non-health IT related factors, such as office workflow and payer healthcare operations demands and rules. It thus seems on its face unfair and unreasonable to invoke the ultimate penalty of decertification for clinician inefficiency, where the root cause may be unrelated to software. Conversely, there is no evidence that highly usable systems consistently improve outcomes; and in fact, just as with clinician efficiency, outcomes improvement is multi-factorial. We would have the same concern with ONC decertifying an EHR that was not associated with consistently improved outcomes.

ONC Review of Certified Health IT – Authority and Scope (§ 170.580)

(a) Direct review. ONC may directly review certified health IT whenever there is reason to believe that the certified health IT may not comply with requirements of the ONC Health IT Certification Program.

(1) In determining whether to exercise such review, ONC shall consider:

(i) The potential nature, severity, and extent of the suspected non-conformity(ies), including the likelihood of systemic or widespread issues and impact.

(ii) The potential risk to public health or safety or other exigent circumstances.

(iii) The need for an immediate and coordinated governmental response.

(iv) Whether investigating, evaluating, or addressing the suspected non-conformity would:

(A) Require access to confidential or other information that is unavailable to an ONC-ACB;

(B) Present issues outside the scope of an ONC-ACB's accreditation;

(C) Exceed the resources or capacity of an ONC-ACB;

(D) Involve novel or complex interpretations or application of certification criteria or other requirements.

(v) The potential for inconsistent application of certification requirements in the absence of direct review.

Preamble FR Citation: 81 FR 11060 - 61

Specific questions in preamble? Yes

Public Comment Field:

1.) It is interesting that ONC is not responsible for reducing errors contributed to by the MU program; or more practically, errors caused by components of mandated EHR functionality that do not address safety issues.

2.) Statements of new authority paired with the lines “we anticipate that this ‘direct review’ of certified health IT would be infrequent” are somewhat concerning given all of the negativity we are seeing now in the MU program that was not anticipated. ACP suggests looking at what is both expected, and then working through the same scenarios with reasonable “what ifs.” Thus, this program should have mechanisms to avoid disgruntled physicians from burying an EHR company with frivolous complaints. These mechanisms could include regulations about which complaints warrant a formal investigation; how the same issue cannot be re-investigated with the same complaint by the same physician – unless there are valid reasons (software update, etc.)

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

Review Processes – General Comments

Preamble FR Citation: 81 FR 11062

Specific questions in preamble? *No*

Public Comment Field:

Under the review process, ACP would like to see more detail about what ONC deems to be reliable and actionable information in order to further inquire into the certified health IT. The existing literature around root cause analysis demonstrates the complexities and difficulties that are routinely encountered in attempting to assign responsibility for a system failure. Each report of a problem supposedly caused by an EHR system could take months of time and significant expert human resources to even attempt to identify root causes.

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:

ACP is concerned that except for a clear patient safety issue – the 30-day time period is too short. Vendors would have to first understand what the notice meant, and conduct their own review. It is entirely possible that ONC's notice might be based on a misunderstanding or an understanding of a customer's misunderstanding of functionality.

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:

ACP’s concern of timeframe for ONC response is also an issue here. Decertifying an EHR can have dramatic consequences on customers – ACP suggests that the decertification process is also thought through from the perspective of EHR customers. Thus, if vendor A receives notice of decertification today – when would that be effective for the customer base? Hopefully not immediately, as that would give customers no time to change EHRs. It is difficult to establish appropriate timeframe for this, as it would take most practices over a year to switch. Perhaps the better approach would be to allow existing customers to be able to continue attestations and whatever other requirements they have with the software for a 2 year period – but not to grant that leeway to new customers.

Review Processes – Suspension (§ 170.580)

(d) Suspension. (1) ONC may suspend the certification of a Complete EHR or Health IT Module at any time for any one of the following reasons:

(i) Based on information it has obtained, ONC believes that the certified health IT poses a potential risk to public health or safety or other exigent circumstances exist. More specifically, ONC would suspend a certification issued to any encompassed Complete EHR or Health IT Module of the certified health IT if the certified health IT was, but not limited to: contributing to a patient's health information being unsecured and unprotected in violation of applicable law; increasing medical errors; decreasing the detection, prevention, and management of chronic diseases; worsening the identification and response to public health threats and emergencies; leading to inappropriate care; worsening health care outcomes; or undermining a more effective marketplace, greater competition, greater systems analysis, and increased consumer choice;

(ii) The health IT developer fails to timely respond to any communication from ONC, including, but not limited to:

(A) Fact-finding;

(B) A notice of potential non-conformity within the timeframe established in accordance with paragraph (b)(1)(i) of this section; or

(C) A notice of non-conformity within the timeframe established in accordance with paragraph (b)(1)(ii) of this section;

(iii) The information provided by the health IT developer in response to any ONC communication, including, but not limited to: fact-finding, a notice of potential non-conformity, or a notice of non-conformity is insufficient or incomplete;

(iv) The health IT developer fails to timely submit a proposed corrective action plan that adequately addresses the elements required by ONC as described in paragraph (c) of this section;

(v) The health IT developer does not fulfill its obligations under the corrective action plan developed in accordance with paragraph (c) of this section.

(2) When ONC decides to suspend a certification, ONC will notify the health IT developer of its determination through a notice of suspension.

(i) The notice of suspension will include, but may not be limited to:

(A) An explanation for the suspension;

(B) The information ONC relied upon to reach its determination;

(C) The consequences of suspension for the health IT developer and the Complete EHR or Health IT Module under the ONC Health IT Certification Program; and

(D) Instructions for appealing the suspension.

(ii) A suspension of a certification will become effective upon the health IT developer's receipt of a notice of suspension.

(3) The health IT developer must notify all affected and potentially affected customers of the identified non-conformity(ies) and suspension of certification in a timely manner.

(4) If a certification is suspended, the health IT developer must cease and desist from any marketing and sale of the suspended Complete EHR or Health IT Module as "certified" under the ONC Health IT Certification Program from that point forward until such time ONC may rescind the suspension.

(5) Inherited certified status certification for a suspended Complete EHR or Health IT Module is not permitted until such time ONC rescinds the suspension.

(6) ONC will rescind a suspension of certification if the health IT developer completes all elements of an approved corrective action plan and/or ONC confirms that all non-conformities have been corrected.

Preamble FR Citation: 81 FR 11064 - 65

Specific questions in preamble? Yes

Review Processes – Suspension (§ 170.580)

Public Comment Field:

The factors contributing to the possible suspension or decertification of any encompassed complete EHR or health IT module are too vague.

- Simply being an EHR would be a contributing factor to an online hacker and not necessarily contributing to unsecure or unprotected information. That is not a reason to suspend certification.
- “increasing medical errors” needs to be fully defined as a poorly trained user might not know to look at the banner or that a RED stop sign means a serious drug allergy – which would not be the fault of the EHR.
- Decreasing the detection, prevention, and management of chronic diseases compared to what – the practices historical rate?
- So where EHRs lead to inappropriate choices of lower cost medications because the information from PBMs to EHRs is inaccurate or not actionable – is the action to decertify the EHR?

Additionally, immediate suspension is too harsh and would affect all customers.

ACP agrees with the following statement: “whether a health IT developer should only be permitted to certify new Complete EHRs and Health IT Modules while the certification in question is suspended if such new certification of other Complete EHRs or Health IT Modules would correct the non-conformity for all affected customers.” Correcting the problem for a percentage of customers sounds like a versioning or installation issue. If the issue is truly software dependent – then the correction should be the required fix for customers on the latest release. It would be unreasonable to demand that the vendor fix problems on prior releases that were fixed on new releases.

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

Review Processes – Termination (§ 170.580)

Public Comment Field:

The reasons for termination all sound good – but these determining factors need to be field tested in some way to check for flaws as this could potentially put companies out of business and thus a potential negative impact on the EHR vendor’s customers.

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:

Is the EHR vendor who appeals a suspension able to continue to operate until the appeal is denied? If that is NOT the case, the time for the hearing officer to make a determination should be ASAP. If EHR companies may continue to do business while an appeal is in play – then a hearing officer should not be rushed into a written determination – so extending the time to 60 or even 90 days seems reasonable.

Consequences of Certification Termination – General Comments

Preamble FR Citation: 81 FR 11066

Specific questions in preamble? No

Public Comment Field:

ACP believes that “the consequences of, and remedies for, termination beyond recertification requirements “should be inside the scope of this proposed rule. If part of ONC’s mission is HIT-related safety, then rushing a practice into a new implementation to comply with a CMS program requirement is inviting serious problems. ONC has a duty to physicians and the public to consider the consequences of rulemaking as done in the EHR Flexibility rule in 2014.

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

(a) Testing and recertification. A Complete EHR or Health IT Module (or replacement version) that has had its certification terminated can be tested and recertified (certified) once all non-conformities have been adequately addressed.

(1) The recertified Complete EHR or Health IT Module (or replacement version) must maintain a scope of certification that, at a minimum, includes all the previous certified capabilities.

(2) The health IT developer must request, and have approved, permission to participate in the Program before testing and recertification (certification) may commence for the Complete EHR or Health IT Module (or replacement version).

(i) The request must include a written explanation of the steps taken to address the non-conformities that led to the termination.

(ii) ONC must approve the request to participate in the Program.

(b) Heightened scrutiny. Certified health IT that was previously the subject of a certification termination (or replacement version) shall be subject to heightened scrutiny for, at a minimum, one year.

(c) Program ban. The testing and certification of any health IT of a health IT developer that has the certification of one of its Complete EHRs or Health IT Modules terminated under the Program or withdrawn from the Program when the subject of a potential nonconformity or non-conformity is prohibited, unless:

(1) The non-conformity is corrected and implemented for all affected customers; or

(2) The certification and implementation of other health IT by the health IT developer would remedy the non-conformity for all affected customers.

Preamble FR Citation: 81 FR 11066 -67

Specific questions in preamble? Yes

Public Comment Field:

ACP Comment: We do not believe that purchasers of IT now believe that the ONC certification program is responsible for more reliable and better functioning EHRs. The prescriptive nature of EHR functional measures, which was the basis of EHR certification requirements, is a double-edge sword that is not through with its work (and/or carnage). If there were to be relaxations in regulations for end-users, damage may still be done to EHR companies. It may be ONC’s intention in publishing this proposed rule to do something useful for physicians and other clinicians. However, this overly burdensome new set of requirements could result in voluntary withdrawal of EHRs from the program or cause additional expenses to companies and physicians.

ACP agrees with the following statement: “In correcting the non-conformity for all affected customers, we note that this would not include those customers that decline the correction or fail to cooperate”

ONC Question: We further request comment as to whether correcting the non-conformity for a certain percentage of all affected customers or certain milestones demonstrating progress in correcting the non-conformity (e.g., a percentage of customers within a period of time) should be sufficient to lift the prohibition.”

ACP Response: If the issue is one of a software defect, and the requirements for conformity are to use the latest version – how does a defect occur with some customers when all are on the same software? If the version of the software is the issue, the company cannot be decertified for customers that decline to upgrade their product.

Consequences of Certification Termination - ONC-ACB Response to a Non-Conformity (§ 170.523) and (§ 170.581)

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

(o) Be prohibited from reducing the scope of a certification when the health IT is under surveillance or under a corrective action plan.

Consequences Due to the Termination of a Certification (§ 170.581)

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

Preamble FR Citation: 81 FR 11067

Specific questions in preamble? *No*

Public Comment Field:

ACP believes these specific regulations could potentially be too prescriptive and unreasonable and could stifle innovation among health IT developers.