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The Honorable Karen DeSalvo, MD, MPH, M. Sc.
Acting Assistant Secretary for Health,
National Coordinator for Health Information Technology,
Department of Health and Human Services
Attention: RIN 0955-AA00
Submitted electronically to: <http://www.regulations.gov>

Re: ONC Health IT Certification Program: Enhanced Oversight and Accountability NPRM

Dear Dr. DeSalvo:

The American Medical Informatics Association (AMIA) appreciates the opportunity to submit comments regarding the notice of proposed rulemaking (NPRM) meant to enhance oversight and accountability for the Health IT Certification Program (Program) maintained by the Office of the National Coordinator for Health Information Technology (ONC). This NPRM was published by ONC in the March 2, 2016 issue of the *Federal Register* at 81 FR 11056.

AMIA is the professional home for more than 5,000 informatics professionals, representing researchers, front-line clinicians and public health experts who bring meaning to data, manage information and generate new knowledge across the health and healthcare enterprise. As the voice of the nation's biomedical and health informatics professionals, AMIA members play a leading role in moving basic research findings from bench to bedside; evaluating interventions across communities; assessing the impact of health innovations on health policy; and advancing the field of informatics.

Generally, AMIA is supportive of ONC's proposal to initiate a direct review process of software certified under the Program, as we see a need for systemic oversight of health IT for purposes of safety and effectiveness. However, we strongly recommend ONC narrow the scope to non-conformities involving potential medical errors or those that potentially contribute to patient safety harms. We are greatly concerned by the absence of a national system to oversee the safe use and safety of health IT. Our healthcare system needs both more data around known interaction of health IT and patient safety, as well as information on emerging and new areas of interaction. Insofar as this rule would create processes to identify and address potential or demonstrated harm to patient safety due to health IT, we support this effort.

Evidence gathered through experience in the last six years of certified EHR deployment confirms that software design, implementation decisions, user training and maintenance processes can all have a material impact on the safety of health IT. From 2010 to 2013, 120 health IT-related Sentinel

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Events (SEs) – an event that has resulted in an unanticipated death or major permanent loss of function – were reported to the Joint Commission.¹ Further, the *Journal of Patient Safety* reviewed a medical malpractice claims database from 2012 to 2013 and found that while less than one percent of claims involved health IT, a total of 248 cases demonstrated that “Adverse events associated with health IT vulnerabilities can cause extensive harm and are encountered across the continuum of health care settings and sociotechnical factors.”² In both instances, experts believe malpractice claims and SEs represent a small fraction of the total number of adverse events that go unreported and unanalyzed.

Additional research indicates even arcane, seemingly innocuous, decisions made by developers and implementers of health IT can have serious patient safety implications. For example, a 2015 study found that when comparing eight certified EHRs’ graphing capabilities for diagnostic test results against a set of eleven criteria considered best practice, the average vendor only met six of eleven criteria.³ These findings are important as they underscore the possibility for lab results to be incorrectly interpreted by clinicians at the point of care, which may have consequences for patient safety.

Finally, the current landscape involving e-prescribing (eRx) highlights the need for enhanced oversight, not necessarily limited to certification issues, due to safety concerns that can arise among health IT and its users.

As required by the 2015 Edition, all certified EHRs must have the ability to *send* a “change prescription” and “cancel prescription” message as part of their eRx module.⁴ However, there is no federal or uniform state regulation that requires pharmacies be able to *receive* or *process* those messages. Indeed, 2014 data from a national prescribing network indicates less than two percent of U.S. pharmacies have the ability to process this message. A 2012 study puts into perspective what this gap means on a national scale.⁵ The study found that nearly 1.5 percent of all discontinued prescription medications in their sample were dispensed by pharmacies. At least 50 patients, or 12 percent of those receiving discontinued medications, experienced some adverse outcome that ranged from mild side effects to life-threatening allergic reactions.

¹ Castro G. Investigations of Health IT-related Deaths, Serious Injuries, or Unsafe Conditions. ONC Health IT Safety Webinar Series. Beginning slide 23.

http://www.healthitsafety.org/uploads/4/3/6/4/43647387/webinar_1_full_deck_2014-12-18_v5.pptx. 2014.

² Gruber, et al “Electronic Health Record – Related Events in Medical Malpractice Claims,” *Journal of Patient Safety* Nov. 2015 <http://www.ncbi.nlm.nih.gov/pubmed/26558652>

³ Sittig, D., Murphy, D. Graphical Display of Diagnostic Test Results in Electronic Health Records: A Comparison of 8 Systems. *J Am Med Inform Assoc.* <http://bit.ly/1OPIHeH> 2015

⁴ 45 CFR §170.315(b)(3) Electronic Prescribing

⁵ Allen A., Sequist T., “Pharmacy Dispensing of Electronically Discontinued Medications,” *Ann Intern Med.* 2012;157(10):700-705. <http://annals.org/article.aspx?articleid=1391698>

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In our view, these cases illustrate the need for more breadth and rigor in how the federal government addresses known gaps in health IT safety, and they highlight the important obligation we have to improve the safety and safe use of health IT.

Our support for concrete action to improve health IT safety notwithstanding, AMIA recommends ONC narrow the circumstances under which it would initiate direct review of certified health IT. **Specifically, AMIA recommends ONC prioritize its direct review efforts on non-conformities that increase medical errors or contribute to patient safety harms, and focus as much as possible on certification criteria developed through the existing statutory and regulatory processes for such criteria.**

We are concerned with the general and far-reaching nature of activities listed in section 3001(b) of the Public Health Services Act (PHSA) insofar as they are used by ONC to justify direct review. We believe the goals enumerated by this section of the PHSA give ONC its broad authority to establish any number of programs to achieve said goals, but find it difficult to understand how ONC could justify a suspension or termination of a certified Health IT Module because it failed to “reduce health disparities,” for example. Additionally, we are concerned that actions taken for non-conformities against unpublished or generalized certification criteria could be a source of confusion for developers, or capricious application by regulators. Developers will have a difficult time determining how they should be conformant to Congressional goals as opposed to clear certification criteria. We suspect ONC will find it difficult to describe consistently categories of non-conformity not considered part of certification.

Further, AMIA recommends that ONC continue to utilize its established regulatory processes to implement and improve its Certification Program. These include those processes that provide for robust public comment opportunities and a period of refinement and adjustment following finalization of certification criteria. By using established processes for incorporating new and updating existing certification criteria, ONC has the opportunity to make evidence-based improvements that both developers and providers can understand.


Below, we address individual proposals and provide additional context to our general comments. Should you have any questions about these comments or require additional information, please contact Jeffery Smith, Vice President of Public Policy at jsmith@amia.org or (301) 657-1291. We look forward to continuing this dialogue, and we offer our assistance to improve the current landscape of issues.

Sincerely,

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Douglas B. Fridsma, MD, PhD, FACP,
FACMI
President and CEO
AMIA



Thomas H. Payne, MD, FACP
AMIA Board Chair
Medical Director, IT Services, UW Medicine
University of Washington

Enclosure: AMIA recommendations to specific questions posed by ONC

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II.A. ONC’s Role under the ONC Health IT Certification Program

The NPRM proposes to establish processes for ONC to directly review health IT certified under the Program and take action when necessary, including requiring the correction of “non-conformities” found in health IT certified under the Program and suspending and terminating certifications issued to Complete EHRs and Health IT Modules. The proposed rule includes processes for ONC to authorize and oversee accredited testing laboratories under the Program. It also includes a provision for the increased transparency and availability of surveillance results collected by ONC-Authorized Certification Bodies (ONC-ACBs). Specifically, ONC wishes to initiate a direct review whenever it becomes aware of information that indicates that certified health IT may not conform to the requirements of its certification or is, for example, leading to medical errors, breaches in the security of a patient’s health information, or other outcomes that are counter to ONC’s responsibilities under section 3001 of the PHSA.

ONC Review of Certified Health IT – General Comments	
Preamble FR Citation: 81 FR 11060	Specific questions in preamble?
<i>No</i>	
Public Comment Field:	
<p>AMIA supports ONC’s right under statute to have direct review, rather than rely solely on ACBs, in limited circumstances. We urge ONC to explicitly narrow its focus on non-conformities that will negatively impact patient safety, and focus as much as possible on certification criteria adopted through existing statutory and regulatory processes. We note that Congress enabled ONC to create a suite of processes to support a certification program and certification criteria, which includes: a request for information or advanced notice of proposed rulemaking, notice of proposed rulemaking, final rule, development of test scripts and test procedures. We prefer that ONC utilize these and other established processes to improve the safety and effectiveness of health IT by proposing criteria it believes would accomplish targeted aspects of its charge under the PHSA, such as reducing medical errors or improving the security of patient data. Given the far-reaching number of circumstances ONC could claim its right to direct review, we note the difficult position health IT developers face in determining how they should be conformant to Congressional goals as opposed to clear certification criteria.</p>	

II.A.1.a Authority and Scope

ONC recognizes there are certain instances when review of health IT is necessary to ensure continued compliance with Program requirements, but such review is beyond the scope of an ONC-ACB’s responsibilities, expertise (i.e., accreditation), or resources. ONC describes a set of situations where direct review authority would ensure that certified health IT performs in accordance with Program requirements in ways that complements the existing role of ONC-ACBs.

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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:

ONC seeks comment on these and other factors that it should consider in deciding whether and under what circumstances to directly review certification.

AMIA believes this list is overly broad, and subject to ad hoc / arbitrary application, for example, its reference to “other exigent circumstances.” We reiterate our call for ONC to explicitly state its intention to focus on potential risks to public health or safety or medical errors caused by health IT. We also believe ONC should include consideration of how the consequence of direct review may impact providers and users.

II.A.1.b ONC-ACB’s Role

ONC says its ability to directly review certified health IT would be independent of, and may be in addition, to any review conducted by an ONC-ACB and that these reviews would be complementary to ONC-ACBs’ purview. To ensure consistency and clear accountability, ONC proposes that if it deems necessary it could assert exclusive review of certified health IT as to any matters under review by ONC and any other matters that are so intrinsically linked that divergent determinations between ONC and an ONC-ACB would be inconsistent with the effective administration or oversight of the Program. ONC proposes that in such instances, ONC’s determinations on these matters would take precedent and a health IT developer would be subject

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to the proposed ONC direct review provisions in this proposed rule, including having the opportunity to appeal an ONC determination, as applicable.

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:

ONC encourages comment on our proposed approach and the role of an ONC-ACB.

Rather than giving itself ultimate authority to adjudicate discrepancies between ACB and its own determinations, AMIA recommends third-party arbitration. We agree that it would be problematic for ACB and ONC determinations to be in conflict, but we do not agree that the solution in such conflicts is total deference to ONC. Additionally, we caution against creating duplicative reviews where ONC's review is additive to an ACB review. We also reiterate our preference that such reviews focus on non-conformities associated with published certification criteria whenever possible.

II.A.1.c. Review Processes

ONC could become aware of information that indicates certified health IT may not conform to the requirements of its certification or is, for example, leading to medical errors, breaches in the security of a patient's health information or other outcomes that do not align with responsibilities under 3001 of the PHSA. If ONC deems the information to be reliable and actionable, it would conduct further inquiry into the certified health IT. Alternatively, ONC could initiate an independent inquiry into the certified health IT that could be conducted by ONC or a third party(ies) on behalf of ONC (e.g. contractor or inspection bodies under the certification scheme).

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Review Processes – General Comments	
Preamble FR Citation: 81 FR 11062 <i>No</i>	Specific questions in preamble?
<p>Public Comment Field: AMIA appreciates the development of a clear review process, and we support many of the proposed steps in the process outlined by ONC. We below identify certain instances where ONC should consider additional steps, absent immediate and certain threats to patient safety.</p>	

II.A.1.c.(1) Notice of Potential Non-Conformity or Non-Conformity

If information suggests to ONC that certified health IT is not performing consistent with Program requirements and a non-conformity exists with the certified health IT, ONC would send a notice of potential non-conformity or non-conformity to the health IT developer. To ensure a complete and comprehensive review of the certified health IT product, ONC proposes the ability to access and share within HHS, with other federal agencies, and with appropriate entities, a health IT developer’s relevant records related to the development, testing, certification, implementation, maintenance, and use of its product, as well as any complaint records related to the product. Unless otherwise specified in the notice of potential non-conformity or non-conformity, health IT developers would be required to respond within 30 days of receipt of the notice and, if necessary, submit a proposed corrective action plan. ONC proposes to have discretion in deciding the appropriate timeframe for a response and proposed corrective action plan from the health IT developers to advance the overarching policy goal of ensuring that ONC addresses and works with health IT developers to correct non-conformity.

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(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

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

Public Comment Field:

ONC requests comment on its proposed processes, including whether the timeframe for responding to a notice of potential non-conformity or non-conformity is reasonable and whether there are additional factors that it should consider.

AMIA recommends that ONC establish separate processes for notices of potential non-conformity and notices of non-conformity and believe that, in general, a notice of potential non-conformance should be the first step. The former appears to be a precursor to the latter type of notice, and we believe ONC should treat them as such. **We recommend a minimum response time of 30 business days for a notice of potential non-conformity and notices of non-conformity.** Again, we point out the difficulty of identifying non-conformity(ies) not considered part of certification – both in ONC describing the non-conformity and the developer addressing the non-conformity.

With a corrective action plan underway, we recommend that there be no further action or sanction on the developer working to correct the problem unless extreme consequences to health and safety are determined, thus allowing the corrective action plan to be fulfilled without imposing any sanctions on the health IT developer unless the corrective action plan is not fulfilled.

Finally, we are concerned that the proposal for Records Access is too far-reaching and appears to go well beyond what is required for ONC-ACB surveillance. Given the proposed scope for direct review, this could be especially difficult. We recommend the proposed language should be 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.

II.A.1.c.(2) Corrective Action

ONC emphasizes that remedying a non-conformity may require addressing both certified and uncertified capabilities within the certified health IT. The corrective action plan would provide a means to correct the identified non-conformities across all the health IT developer's customer base and would require the health IT developer to make such corrections before the certified health IT could continue to be identified as "certified" under the ONC Health IT Certification Program, or sold or licensed with that designation to new customers.

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(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
No

Specific questions in preamble?

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Review Processes – Corrective Action (§ 170.580)

Public Comment Field:

ONC requests comment on its proposed processes for corrective action.

AMIA supports the requirements for a corrective action plan. However, we encourage ONC to refrain from being prescriptive over the specific methods and actions through which the developer intends to address the non-conformity. Rather, ONC should prescribe the dimensions of the plan, similar to what is the current process for ACBs, with the scope of the corrective action plan based on issued with certified capabilities.

ONC proposes to report the corrective action plan and related data to the publicly accessible CHPL.

AMIA supports posting of the corrective action plan and related data to the publicly accessible CHPL.

II.A.1.c.(3) Suspension

ONC proposes that it may suspend the certification of a Complete EHR or Health IT Module at any time because ONC believes that the certified health IT poses a potential risk to public health or safety, other exigent circumstances exist concerning the product, or due to certain actions or inactions by the product's health IT developer as detailed below.

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(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.

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- (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
Yes

Specific questions in preamble?

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Review Processes – Suspension (§ 170.580)

Public Comment Field:

ONC requests comments on these processes, including how timely a health IT developer should notify affected and potentially affected customers of a suspension and what other means ONC should consider using for publicizing certification suspensions.

Generally, AMIA supports aspects of the processes described by ONC for the suspension of certified health IT, with several specific recommendations.

We recommend requiring health IT developers notify affected and potentially affected customers within 10 business days after receipt of a suspension notice. ONC should also post information regarding the suspension on a public website, public listserves and through media not earlier than 30 business days following notice of suspension. This timeframe ensures that customers of suspended health IT will be made aware of the suspension, while also giving the developer additional time to inform customers – and potentially correct the non-conformity before a wider public announcement.

ONC also requested comment on 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 would correct the non-conformity for all affected customers.

AMIA recommends the suspensions not be inclusive of all products certified by the developer, but rather should be as targeted as possible, with explicit processes in place to expand the suspension should the developer be unresponsive. We are concerned that a complete freeze on new certification could be needlessly disruptive for users depending on the nature of the suspended product. For instance, if there is something wrong with the CPOE function of a certified Complete EHR, and the developer is prohibited from certifying clinical quality measures, or some other aspect of the product, it could cause problems for broad segments of users unaffected by the identified non-conformity.

ONC also requests 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.

AMIA reiterates its recommendation that suspensions be targeted with an ability to expand the suspension/prohibition if needed. This approach outlined above has the added benefit of avoiding the more complicated approach of “lifting the prohibition” contingent on an arbitrary percentage of all affected customers or obtainment of arbitrary milestones demonstrating progress. We reiterate, any suspension should only apply to the product in question and not to other unrelated products certified by the health IT developer.

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II.A.1.c.(4) Termination

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<p>(e) <u>Termination</u>. (1) ONC may terminate a certification issued to a Complete EHR and/or Health IT Module if:</p> <ul style="list-style-type: none"> (i) The health IT developer fails to timely respond to any communication from ONC, including, but not limited to: <ul style="list-style-type: none"> (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. <p>(2) When ONC decides to terminate a certification, ONC will notify the health IT developer of its determination through a notice of termination.</p> <ul style="list-style-type: none"> (i) The notice of termination will include, but may not be limited to: <ul style="list-style-type: none"> (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: <ul style="list-style-type: none"> (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. <p>(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.</p> <p>(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.</p>	<p>Preamble FR Citation: 81 FR 11065</p> <p>Specific questions in preamble?</p> <p><i>Yes</i></p>

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Public Comment Field:

ONC requests comment on these proposed reasons for termination and on any additional circumstances for which commenters believe termination of a certification would be warranted. Additionally, ONC proposes to publicize the termination on the CHPL to alert interested parties, such as purchasers of certified health IT or entities administering programs that require the use of health IT certified under the Program.

AMIA supports, in general, the proposed reasons for termination and the publicizing of such terminations on the CHPL to alert interested parties. We have similar concerns and suggestions for termination as we outline for suspension. We recommend ONC should first issue a notice of suspension before issuing a notice of termination, as a matter of process, and we recommend ONC not preclude the developer from moving forward with additional certifications, unless the developer has demonstrated an incapacity to address the non-conformity for which it received a notice of termination.

ONC requests comments on these processes, including how timely a health IT developer should notify affected and potentially affected customers of a termination of a Complete EHR's or Health IT Module's certification and what other means ONC should consider for publicizing certification terminations.

AMIA recommends requiring health IT developers notify affected and potentially affected customers within 10 business days after a notice of termination has been issued. ONC should also post information regarding the suspension on a public website, public listserves and through media not earlier than 30 business days following notice of suspension.

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II.A.1.c.(5) Appeal

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.

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Review Processes – Appeal (§ 170.580)

Preamble FR Citation: 81 FR 11065 - 66

Specific questions in preamble? *Yes*

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Review Processes – Appeal (§ 170.580)

Public Comment Field:

ONC proposes that, similar to the effects of a suspension, an appeal would stay a termination, but that a Complete EHR or Health IT Module would be prohibited from being marketed or sold as “certified” during the stay.

We recommend an appeal should stay the suspension or termination until a final ruling is issued, including the prohibition on marketing or selling.

ONC describes the role, responsibilities and authority of a hearing officer, including the discretion to conduct a hearing. The hearing officer would 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 to suspend or terminate the certification by ONC.

AMIA requests ONC include specific requirements for the qualifications of and oversight for the hearing officer and indicate whether the hearing officer is an ONC employee or agent. If so, such a role raises conflicts of interest concerns absent specific processes to ensure independence; we believe that the hearing officer should have an assured level of independence from ONC management.

We also recommend ONC strike the proposal at § 170.580(f)(6)(iii) stating 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. We believe information that is developed during the course of a hearing should be able to be considered by the hearing officer.

ONC proposes to require a developer submit a request for an appeal within 10 calendar days of receipt of the notice of suspension or termination. ONC also requests comment on whether the allotted time for the hearing officer to issue a written determination should be lessened or lengthened, such as 15, 45, or 60 days, from the proposed 30 days. ONC also request comment on whether an extension should be permitted and whether it should only be permitted under the circumstances proposed or for other reasons and circumstances.

We agree with the 30 days as proposed for the hearing officer to render a decision and that extensions should require the consent of both parties. We also believe that 10 calendar days to file an appeal, as opposed to provide notice of intent to appeal, is insufficient, especially if no new information is allowed to be included as part of the hearing. The materials needed for the appeal could be time consuming and complex. At a minimum, this time should be expressed as business days.

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II.A.1.d. Consequences of Certification Termination

ONC states this NPRM does not address the remedies for providers participating in the EHR Incentive Programs that may be using a Complete EHR or Health IT Module that has its certification terminated.

AMIA understands this NPRM does not impact policies and procedures outlined by other agencies, but ONC must be cognizant of the many ways its determinations could impact users of certified technology, and work to coordinate policies across various programs that reference, or require, the use of certified health IT. For example, the Centers for Medicare and Medicaid Services (CMS) EHR Incentive Program includes guidelines around how providers may avoid payment adjustments for certified technology that has had its certification revoked. However, the availability of hardship exemptions for loss of certification, which we assume could include suspension, does not address less clear-cut implications of this proposed process, such as new products or product enhancements that cannot be certified due to company-wide bans on further certification activities. Overall, we believe that ONC must take full account of the provider implications of the various aspects of its proposal.

II.A.1.d.(1) Program Ban and Heightened Scrutiny

If the Complete EHR or Health IT Module (or replacement version) is recertified (certified), ONC proposes that the certified health IT product should be subjected to some form of heightened scrutiny by ONC or an ONC-ACB for a minimum of one year.

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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
Yes

Specific questions in preamble?

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Public Comment Field:

ONC requests comment on the forms of heightened scrutiny (e.g., quarterly in-the-field surveillance) and length of time for the heightened scrutiny (more or less than one year, such as six months or two years) of a recertified Complete EHR or recertified Health IT Module (or replacement version) that previously had its certification terminated.

AMIA recommends that the forms of heightened scrutiny should be commensurate with the nature and the scope of the non-conformity. Scrutiny for a Complete EHR that has resulted in widespread and significant patient harm should be different than scrutiny for an individual module with limited risk of patient harm. Similarly, ONC should be judicious in determining length of time for heightened scrutiny and it should be reflective of the kind of non-conformity.

ONC seeks comments on this proposal, including how the health IT developer should demonstrate to ONC that all necessary corrections were completed. They 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.

AMIA recommends the prohibition should be lifted once ONC is satisfied with a corrective action detailing how the developer will make available the solution to correct the non-conformity, and not depend on provider adoption of these solutions. For example, we note that decisions to implement patches may very well dictate when the customer's non-conformant technology will be corrected, and that the availability of such a patch should be a determining factor to consider the issue resolved.

ONC requests comment on whether heightened scrutiny (surveillance or other requirements) should apply for a period of time (e.g., six months, one year, or two years) to all currently certified Complete EHRs or certified Health IT Modules, future versions of either type, and all new certified health IT of a health IT developer that has a product's certification terminated under the Program.

Again, AMIA reiterates its earlier recommendation that such determinations should be made based on the nature and scope of the non-conformity, and the focus of such heightened scrutiny should be targeted towards those specific instances of certified health IT that are non-conformant. We interpret ONC's proposal to mean that a developer cannot cure an identified non-conformance by reducing the scope of what it had certified to. Stated differently, that curing the problem by withdrawing specific functionality from the market or from certification is not an option. We recommend ONC revisit this proposal because we do not agree with the requirement that certified health IT maintain a scope of certification as broad as previously in place. Withdrawal of the module or part of the module might be the best action to enable the majority of the HIT to remain viable in the marketplace, serving providers' needs, and ONC should permit this outcome. We are concerned the proposed program ban could have unintended negative consequences, and we recommend that ONC not apply termination for one

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

product to all products the developer may be testing or certifying. We are unaware of this approach to product suspension in other analogous regulatory programs.

II.A.2.b. Program Ban and Heightened Scrutiny

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:

AMIA supports the proposals to include ONC-ATLs in the Program, generally. We have no specific comments other than ONC should strive to ensure that its relationship with ATLs align with its relationship to ACBs, minimize any additional costs associated with this more direct ONC-ATL linkage, and continue to rely on applicable ISO standards and NVLAP certification.

II.B. Public Availability of Identifiable Surveillance Results

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

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

Public Comment Field:

ONC requests comment on the types of information to include in the surveillance results and the format (e.g., summarized or unrefined surveillance results) that would be most useful to stakeholders. In addition to the proposal for ONC-ACBs to publish these results quarterly on their websites, we request comment on the value of publishing hyperlinks on the ONC website to the results on the ONC-ACBs' websites.

AMIA supports making identifiable surveillance results publicly available for the reasons articulated by ONC, and we support the publication of hyperlinks to ONC-ACB results.

We recommend ONC focus first on summary results, based on what is required as part of the 2015 Edition Certification Rule. AMIA also supports ONC's explicit mention that proprietary and sensitive information will not be included as part of these public results. Finally, ONC and the ACB should clearly indicate that surveillance of specific certified HIT should not imply a problem or potential problem with the health IT.