April 27, 2016

The Honorable Sylvia Mathews Burwell
Secretary of Health and Human Services
Attention: ONC Health IT Certification Program Proposed Rule
Mary E. Switzer Building - Mail Stop: 7033A
330 C Street, SW
Washington, DC 20201

Dear Secretary Burwell:

On behalf of the American Academy of Family Physicians (AAFP), which represents 120,900 family physicians and medical students across the country, I am responding to the proposed rule titled, "ONC Health IT Certification Program: Enhanced Oversight and Accountability," as published in the March 2, 2016 *Federal Register*.

Overall, the AAFP agrees with the U.S. Department of Health and Human Services (HHS) that the proposed rule's provision for direct authority over ONC-Authorized Testing Laboratories (ATL's) and direct review of certified health IT will promote greater accountability of health IT developers for the performance, reliability, and safety of certified health IT. The AAFP supports the proposed process for HHS to directly assess non-conformities and to prescribe or oversee corrective action plans for developers as appropriate, to include: investigating and reporting on root cause analysis of non-conformities; notifying in a timely way all affected and potentially affected customers; correcting identified issues for all customers; and specifying appropriate remedial actions as necessary.

However, while the proposed rule effectively addresses processes for handling identified non-conformities, it lacks necessary emphasis on testing methodologies and results analysis to be employed by ONC-ATLs. To ensure electronic health records systems (EHRs) and health IT modules receiving certification actually deliver the functionality required by physicians and eligible providers to ensure safe and efficient delivery of care under various clinical scenarios with often unforeseen circumstances, we recommend HHS expand this section. As ATLs are brought under the purview of HHS, the AAFP continues to urge the HHS to consider outlining a testing framework with appropriate testing methodologies to be utilized by ONC-ATLs, such as scenario testing and exception handling, to support certification of safe and efficient information systems and modules. This recommendation supports progress of the U.S. healthcare system toward the goals of improving the quality of care and helping to restrain health care costs.

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The AAFP believes HHS should reconsider the role and composition of its testing processes and certification program to address patient safety risks posed by usability and interoperability issues. Keeping the existing certification process as it is will not improve or ensure the performance of certified EHR technology (CEHRT) or health IT modules deployed in dynamic clinical settings which do not always mirror the laboratory testing environment. While HHS is appropriately expanding oversight over ATLs and outlining the process for correcting non-conformities of health IT, as well as providing recourse for a developer's failure to resolve non-conformities, none of these laudable and necessary efforts addresses the need to direct testing processes employed by ATLs to incorporate scenario testing and exception handling that would ensure certified health IT will perform safely and efficiently in the field.

As the AAFP has done previously, we strongly recommend the testing and certification process incorporate the ability to identify integration errors, or errors that originate from the connection between two EHR functions. We continue to hear from physicians that their systems can be paralyzed by simple errors like alpha-numeric mismatches, text which exceeds character limits, or time-of-day entries that exceed 24 hours (e.g., 78:00). As testing and certification are the last step before health IT is deployed and utilized in the care of patients, it is imperative that as HHS brings ATLs under their authority that appropriate testing procedures be required.

HHS proposes that like the set of rules and conditions for which ONC-Authorized Certification Bodies must adhere, HHS will establish a set of Principles of Proper Conduct (PoPC) within Section 170.524 to which ONC-ATLs must adhere. The proposed PoPC will include requiring ATLs to maintain a training program that contains documented procedures and training requirements to ensure its personnel are competent to test health IT. The AAFP supports having this requirement within the PoPC for ATLs, and also urges HHS to outline appropriate methodologies for the testing of health IT which will ensure reliable performance in the field among various clinical scenarios.

The AAFP fully supports HHS' proposed changes within Section 170.523(i)(2), since standardized and timely quarterly reporting by ONC-ACB's of testing and surveillance results of health IT by product and developer is necessary to provide physicians and relevant stakeholders with a more readily available means of accessing, reviewing and comparing testing results. Also, while HHS has required vendors to publish the results of their user-centered design (UCD) process on the Certified Health IT Product List (CHPL), to date standardized reporting of UCD processes and testing for HIT products is not reported consistently or uniformly. The AAFP continues to request centralized, timely reporting of UCD in the development and testing of health IT.

The AAFP agrees that standardized quarterly reporting of results will both hold developers accountable, and also publicly celebrate successes of developers and health IT that adhere to certification criteria, which *should be* indicative of a testing process that ensures safe and reliable HIT functionality. The AAFP agrees with the proposal to revise Section 170.556(e)(1), for consistency with Section 170.523(i)(2) to add the requirement for ongoing submission of in-the-field surveillance results to the National Coordinator at least quarterly.

The AAFP is concerned that HHS has not yet emphasized the importance for the testing and certification process to incorporate testing methodologies that would ensure safe and reliable performance of health IT in the field. Were HHS to identify mandatory scenario testing and exception handling within the PoPC for ATLs in the testing of health IT, the incidence of non-

conformities would be reduced and costs associated with in-the-field testing during periods of heightened scrutiny for health IT non-conformities would be minimized.

The AAFP believes it is appropriate and supportive of safe information systems for HHS ONC, within Section 170.580(d)(4), to issue a cease-and-desist notice to developers to halt, immediately, sales and marketing of a Complete EHR or health IT module as "certified" if certification has been suspended. We agree with the proposal to modify Section 170.580(d)(3) to require health IT developers to notify all affected and potentially affected customers of a certification suspension in a timely manner. The AAFP also supports the proposal by HHS to publicly report the suspension of certification of any health IT product on the CHPL to appropriately alert users and potential purchasers of health IT. However, we have real concerns that, even with an attempt by the developer of timely notification to customers and centralized reporting of certification suspensions on the CHPL, eligible providers (EPs) may remain unaware of the certification suspensions. The AAFP requests that established EP attesters be granted automatic privilege to continue using health IT products, to comply with federal requirements such as Meaningful Use, throughout a period of certification suspension, and in the event of certification termination EPs should be granted an automatic one-year extension on the ability to use health IT products for which certification has been terminated. Should the developer not provide a cure for the non-conformity and the EP be unable to transition to a new certified health IT product at the end of that one-year period, the EP should then be able to request a hardship exemption similar to provisions currently outlined within CMS EHR Incentive Programs FAQ 12657. The AAFP also supports HHS' efforts toward development of a health IT safety center, to which any such suspension or termination of certification should be immediately reported.

While the proposed rule seeks to promote patient safety by requiring timely notification of any certification suspension, HHS likewise seeks to work with developers to cultivate corrective action plans for any identified non-conformities and to achieve a resolution for all customers impacted rather than termination of certification. While timely notification of suspension is necessary and appreciated, collaborative efforts toward swift correction of non-conformities are also necessary and appreciated, because the consequences of inappropriate certification termination can be substantial. According to HHS' estimates based upon attesters of certified health IT, the monetary costs sustained by health care providers to transition to another certified health IT product when certification termination of a Complete EHR or Health IT Module has occurred can range from $33,000 for a single eligible provider to a median cost for 24 EPs of $792,000 and a mean cost for 190 EPs of $6,270,000. While HHS notes that health IT developers "*may be*" required to pay for transition costs of health care providers due to certification termination, it appears language within the proposed rule fails to ensure that eligible providers are held harmless for non-conformities. The AAFP strongly urges adding a requirement that eligible providers be held harmless for non-conformities. Physicians and providers invest finite resources into EHRs and health IT modules that are reported to have been rigorously tested and certified.

Another concern for the AAFP is the insufficient language to ensure EPs are held harmless in the event that a developer chooses to certify new health IT to cure a non-conformity. While HHS recommends that a developer who chooses to certify new health IT to cure a nonconformity must offer the new health IT to all impacted customers, it also proposes that the developer will not be required to provide the new health IT to any customer who chooses not to implement it. The AAFP fears the new health IT remedy offered as a cure for the non-conformity could potentially pose additional compatibility issues and introduce downstream integration costs

which could render the proposed new health IT solution less than desirable for the physician or EP customer. We recommend that additional language be included, which ensures EPs are held harmless of any incurred costs in this scenario in which a developer may opt to certify new health IT to cure a non-conformity and offer it to affected customers as the solution.

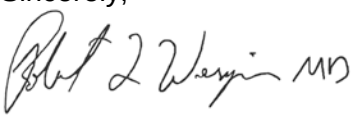
In this same vein, the proposed rule fails to fully address consequences of certification termination for eligible providers. Respectfully, the mention that any consequences of, and remedies for, termination beyond certification requirements are outside of the scope of this proposed rule is less than adequate to ensure all eligible providers are held harmless in the event that certification is terminated for any Complete EHR or Certified Health IT Module. Because certified EHR technology is a requirement for CMS EHR Incentive Programs, it is prudent to incorporate a section within this proposed rule that addresses all aspects of holding eligible providers harmless for non-conformities.

While HHS requests that physicians and providers see CMS EHR Incentive Programs FAQ 12657 for further direction on this issue, we recommend that this language be incorporated into the proposed rule. The above noted recommendations for revision to FAQ 12657 should also be incorporated into language included in this proposed rule. The final rule should be comprehensive and prescriptive as to what pre-established and acceptable remedies are in place to guide developers of health IT in the event of certification termination, as well as the eligible provider users (attesters) of the health IT.

It is reassuring that HHS seeks to work collaboratively with developers through corrective action plans to resolve any non-conformities and support continued certification; however, as HHS noted, while certification termination is rare, it has occurred. While the number of physicians impacted may have been statistically insignificant in comparison with the total number of attesters of certified health IT, the financial impact to those individual physicians was highly significant in terms of operational and capital expense budgets. This is especially true for primary care physicians.

Family physicians and other primary care providers are central to effective and efficient population health management and are key to improving the patient experience of care, improving the health of populations, and reducing the per-capita cost of health care. The AAFP looks forward to continued partnership and collaborative efforts toward achieving our shared goals and urges HHS to adopt these recommendations. Should you have questions, please contact Steven E. Waldren, MD, MS, Director, Alliance for eHealth Innovations at 1-800-274-2237, extension 4100 or swaldren@aafp.org.

Sincerely,



Robert L. Wergin, MD, FAAFP
Board Chair