

January 21, 2015

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Technology
Office of the National Coordinator for
Health Information Technology
U.S. Department of Health and Human Services
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Washington, DC 20201

Dear Dr. DeSalvo:

The undersigned organizations are writing to elevate our concern about the current trajectory of the certification of electronic health records (EHRs). Among physicians there are documented challenges and growing frustration with the way EHRs are performing. Many physicians find these systems cumbersome, do not meet their workflow needs, decrease efficiency, and have limited, if any, interoperability. Most importantly, certified EHR technology (CEHRT) can present safety concerns for patients. We believe there is an urgent need to change the current certification program to better align end-to-end testing to focus on EHR usability, interoperability, and safety. We understand from discussions with the Office of the National Coordinator for Health Information Technology (ONC) that there is an interest in improving the current certification program. **For the reasons outlined in detail below, we strongly recommend the following changes to EHR certification:**

- 1. Decouple EHR certification from the Meaningful Use program;**
- 2. Re-consider alternative software testing methods;**
- 3. Establish greater transparency and uniformity on UCD testing and process results;**
- 4. Incorporate exception handling into EHR certification;**
- 5. Develop C-CDA guidance and tests to support exchange;**
- 6. Seek further stakeholder feedback; and**
- 7. Increase education on EHR implementation.**

Patient Safety

Ensuring patient safety is a joint responsibility between the physician and technology vendor and requires appropriate safety measures at each stage of development and implementation. While training is a key factor, the safe use of any tool originates from its inherent design and the iterative testing processes used to identify issues and safety concerns. Ultimately, physicians must have confidence in the devices used in their practices to manage patient care. Developers must also have the resources and necessary time to focus on developing safe, functional, and useable systems.

Unfortunately, we believe the Meaningful Use (MU) certification requirements are contributing to EHR system problems, and we are worried about the downstream effects on patient safety. Physician informaticists and vendors have reported to us that MU certification has become the priority in health information technology (health IT) design at the expense of meeting physician customers' needs, patient safety, and product innovation. We are also concerned with the lack of oversight ONC places on authorized testing and certification bodies (ATCB) for ensuring testing procedures and standards are adequate to secure and protect electronic patient information contained in EHRs.

Security

In addition to patient safety concerns, the certification process lacks necessary security measures to protect patient information. As recently highlighted by the Office of the Inspector General (OIG), EHR certification bodies fell short of addressing common security issues, such as, but not limited to, password complexity and logging emergency access or user privilege changes.¹

To improve the security of patient and health information we support the Health Care Information Technology Standards Committee (HITSC) Transport and Security Standards Workgroup's intent to enhanced security criterion in EHR certification. Their recommendation would require that EHR technology demonstrate the capability to restrict access to the system, or to one or more individual functions within the system, to only those individuals who have presented at least two of the three forms of authentication—knowledge of a secret, possession of a physical object, and biometric. While requiring EHR vendors to demonstrate this capability may help bolster vendor innovation in user authentication, there are rapidly developing authentication methods outside the traditional secret, pin, biometric standards used today that may more closely align with a physician's workflow. Current implementations of multi-factor authentication (e.g., those which are used in electronic prescription of controlled substances (EPCS)) have not provided the utility need to support the needs of most physicians—taking them outside their current workflow and reducing overall usability. We believe the low uptake in EPCS across the physician community is a reflection of the low satisfaction associated with this current process.

We recommend that ONC work with other appropriate agencies and departments to more closely examine the piloted identification solutions associated with The National Strategy for Trusted Identities in Cyberspace (NSTIC). The NSTIC is a White House initiative to work collaboratively with the public sector agencies, advocacy groups, and other organizations to improve the privacy, security, and convenience of online transactions. The Identity Ecosystem Steering Group (IDESG) is leading these organizations to create advancements in the use of federated identity credentials that help ensure a streamlined end-user registration/identity proofing process, widespread portability and acceptance of user credentials, and agreement infrastructures that define the rights and responsibilities of users. These pilots are currently showing that federated identities can support credentialing at a high level of assurance (LoA), and that users could leverage these trusted identities to access and utilize sensitive services—such as EPCS. There are also significant advancements in near field communication (NFC) and biometrics used in cellphones and other portable devices which, coupled with strong identity credentials, are poised to reduce many of the authentication difficulties medical professionals face.

Supporting Long Term Success

As acknowledged by ONC, we strongly support decoupling EHR certification from the MU program. Many MU objectives place excessive burdens on physicians and their practices by tying their successful compliance to measures that require specific patient participation, cumbersome data collection, and complex exchange methods. Particularly, physician specialists have been required to reorient well-established workflows in order to accommodate for these measures. While we believe this separation is critical, we are very concerned that, once separate, the process of EHR certification will remain the same.

¹ Office of Inspector General. (2014). *The office of the national coordinator for health information technology's oversight of the testing and certification of electronic health record* (HHS Publication No. A-06-11-00063). Accessed November 2014. Available at <http://oig.hhs.gov/oas/reports/region6/61100063.pdf>

Only a widespread overhaul with continuous input from all key stakeholders will ensure that CEHRT can support the growing and changing needs of physicians and their patients. In addition, we are concerned that if the Administration were to maintain the program, as currently structured, EHR innovation will languish and improvements in performance, quality, safety, interoperability, and efficiency will continue to be out of reach.

Several converging factors present federal regulators with a unique opportunity to address key EHR certification challenges in the coming months. Both the forthcoming EHR certification proposed rule and the possible development of the Health IT Safety Center can provide avenues to address the concerns we have outlined. In addition, such separation would allow policy decisions to be made apart from the arbitrary deadlines of the EHR Incentive Programs and pivot towards the long-term goal of building and supporting a safe and high-performing national health IT ecosystem.

We believe ONC should reconsider the role and composition of its certification program to address patient safety risks, usability, and interoperability. It is vital that purchasers and users of certified EHRs have confidence in the usability and safety of these tools—allowing them to focus on the care of their patients. In this vein, we also feel the Administration is pushing too quickly for the use of CEHRT beyond the MU program.

Test Methods

In May 2014, stakeholders representing accredited certification bodies and testing laboratories (ACB & ATL), EHR vendors, physicians, and health care organizations provided feedback to ONC on the complexities of the current certification system. Two main takeaways from these comments were for ONC to host a multi-stakeholder Kaizen event and to prioritize security, quality measures, and interoperability in the EHR certification criteria. **We strongly support both of these ideas; however, keeping the existing certification process—even if refocused on the criteria listed above—will not ensure or improve the performance of CEHRT.**

Instead, the certification process should prioritize testing EHR functionality over isolated MU criteria. Seeking feedback from industry stakeholders through ONC's Open Test Method Development Pilot Program was an important first step; however, examining and updating the current test methods is only a short-term solution.

We are also aware of instances where CEHRT deployed in a medical setting performs poorly or lacks the necessary functionality to meet all MU measures. For example, we have learned from several medical professionals that, although an EHR is listed on the Certified Health IT Product List (CHPL) as certified by ONC, there is no guarantee that the software will perform as expected in production. In some instances, certified EHRs have incorrectly calculated measure thresholds, wrongly associated anatomical terms with corresponding problem lists, intermittently lost patient data as charts were being saved, and truncated office notes when sent to a printer. This may be attributed to the fact that CEHRT deployed in dynamic clinical settings do not always mirror the laboratory testing environment of the ONC Certification Program. Ultimately, this can result in medical record errors, inaccurate documentation, lack of interoperability, slow performance, lost patient information, and safety concerns. We believe that certification should not only show that an EHR can meet MU objectives and measures but that tested systems can support interoperability and ensure patient safety.

Exception Handling and Scenario-Based Testing

We believe the best way to ensure high-performing EHRs and to minimize errors is to rigorously test them against a multitude of clinical scenarios that represent the variety of workflows seen in acute and ambulatory care settings. The current certification testing process focusses too heavily on isolated unit-based testing that lacks the necessary sophistication to identify usability issues, exception handling, or end-to-end interoperability. Additionally, the current testing process does little to address the unique workflows and practice needs closely associated with most medical specialties.

Unit test cases are traditionally independent from each other—examining individual procedures in software. While applicable in the development of software, unit testing does little to assure a product’s performance once deployed in a clinical environment. In contrast, exception handling incorporated into the testing of clinical scenarios, would seek to identify how software handles errors such as when a user enters wrong information. Exception handling and scenario-based testing are widely used in the software industry by developers of software applications which directly interact with human users. We believe these methods are better indicators that EHR software can manage anomalies or exceptional events that occur in a clinical environment. “Abnormal” events often change the normal flow of the system’s function and therefore require special processes to mitigate problems that may result in patient harm. Currently, EHR certification testing is done in controlled environments that often do not mimic the flow of medical information in real-world clinical settings and is not capable of identifying safety-related issues.

Furthermore, unit test cases are primarily based on MU criteria rather than testing an EHR’s proficiency in handling the needs of specialists and other medical professionals. Accordingly, certification lacks significant value past identifying which products can be used to meet MU requirements. We have heard from our membership that although EHRs can perform specific tasks, such as electronic medication prescribing, they fall short in aligning with the needs of their users and can cause adverse patient safety events.

Because most EHRs are deployed in fast-paced environments where data accuracy is essential, certification should incorporate the ability to identify integration errors—or errors that originate from the connection between two EHR functions. We have heard 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). Although not representative of most EHR products, the fact that some EHRs have passed the certification process, were posted on the CHPL, and sold to physicians without sufficient and appropriate testing is concerning. Again, if certification is the last step before these applications are deployed in clinics and hospitals, physicians, nurses, and patients should have a high level of assurance that a rigorous process has been followed to verify these tools are sufficient, capable, and safe to use in medicine.

We have made previous comments supporting ONC Contractor, SHARP-C’s recommendations for both summative and formative testing in EHR certification to demonstrate a vendor’s user centered design (UCD) process. While some EHR vendors are implementing UCD to support usability—defined as “the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use”²—few vendors have fully embraced this model.

² International Organization for Standardization (ISO) 9241-11 (1998) Guidance on Usability. Ergonomic requirements for office work with visual display terminals (VDTs) — Part 11: Guidance on usability. Accessed December, 2014 from: <https://www.iso.org/obp/ui/#iso:std:iso:9241:-11:ed-1:v1:en>

It is vital that proper UCD techniques are adhered to so that EHR vendors incorporate both user interface and cognitive workflow design in the development of their products.

Moreover, the use of scenario-based testing is one possible solution to incorporate specialty-specific and clinically relevant scenarios to ensure EHR performance while also identifying workflow bottlenecks.

This form of testing often exposes design errors rather than coding errors and is a critical component in verifying the flow of data through an EHR. While unit testing is utilized to detect problems early in the software development cycle—and therefore not ideal for final certification testing—scenario-based testing is tied to real-world problems, captures the way customers need to use the product, and is more easily validated. Although an ONC Federal Advisory Committee (FACA) explored the use of this framework in the past, scenario-based testing was excluded as a requirement for 2014 EHR certification.

Interoperability & EHR Certification

The exchange, consumption, and use of medical information are at the heart of interoperability. Although there has been an increase in the exchange of patient information, the act of two computers sending and receiving data does not constitute functional interoperability—the ability for information to be exchanged, incorporated, and presented to a physician in a contextual and meaningful manner. We applaud ONC’s renewed effort and attention on improving interoperability; however, charting a multi-year course does not immediately address concerns medical professionals and health care organizations have with the moderate level of exchange currently taking place.

Ensuring electronic health information follows patients during transitions of care is one of the most sought after, yet the least successful exchange paradigms in health care today. MU Stage 2, as a core requirement, establishes a process by which EHR technology must certify it can receive, display, and incorporate transition of care/referral summaries. As stated in the test procedure for 42 C.F.R. §170.314 (b)(1)—Transitions of care, “Both ambulatory EHR technology and inpatient EHR technology presented for certification should be able to receive, display, and incorporate both ambulatory and inpatient summary care records (transition of care/referral summary).”³ Yet, EHR vendors who follow the consolidated clinical document architecture (C-CDA) implementation guidance are left with optionality on the methods they use to create C-CDA documents. This variability in C-CDA construction causes a mismatch between the sending and receiving EHRs and limits the usefulness of information that is actually viewed by the physician and other medical professionals at the point of care.

ONC identified the C-CDA as the backbone exchange technology for meeting all interoperability requirements in Stage 2. This newly developed technology, however, had very little real world testing, nor was it balloted or approved for standardization by HL7 prior to ONC’s decision to require its use in Stage 2. In fact, at the time of this writing, the C-CDA is still considered a draft standard for trial use.

A recent article in the *Journal of the American Medical Informatics Association* (JAMIA) found significant problems with C-CDA, including possible disruptions in critical care activities such as drug-allergy interaction alerting, medication prescribing, and medical terminology representation. Overall, EHR-generated C-CDAs scored on average only 63 percent in accuracy. More than half of the vendor systems scored less than 60 percent accuracy—by all accounts a failing grade. **The article concluded that based on the use of this standard, “C-CDA documents produced from technologies in Stage 2**

³ Office of the National Coordinator. (2013). *Test Procedure for §170.314 (b)(1) Transitions of care – receive, display and incorporate transition of care/referral summaries*. Accessed November 2014. Available at http://www.healthit.gov/sites/default/files/170.314b1receive_display_incorporate_2014_approved_tp_v1.6.pdf

of MU will omit key clinical information and often require manual data reconciliation during exchange.” It also found that unless timely policy changes are made, “robust document exchange will not happen anytime soon.”⁴ This means that although EHR vendors are required to incorporate C-CDAs as the primary method for patient information exchange, the draft standard allows for the C-CDA software, design, or template specifications to change at any time.

This lack of clear and consistent implementation guidance—and the subsequent insufficiency of rigorous certification testing to validate compliance with standards—have led to poor interoperability, placed patients at risk, and created significant costs to our health care system.

Recommendations

Based on the issues identified above, we recommend that ONC:

1. **Re-consider alternative software testing methods:** ONC should look to other industries that meet demanding software and overall system performance requirements. The consumer electronics and the aviation industries utilize advanced testing procedures both in-house and in the field to root-out usability and safety issues. **We believe that ONC should reevaluate its current stance on optional scenario-based testing and work with ATLS to require and incorporate tests that:**

- Make testing clinically plausible;
- Expose failures to deliver desired benefits;
- Increase the value of testing;
- Ensure ability to use data within and across EHRs;
- Improve the efficiency of testing;
- Reduce setup of testing; and
- Make testing consistent and replicable.

Additionally, joint work by the International Organization for Standardization (ISO), International Electrotechnical Commission (IEC), and the Institute of Electrical and Electronics Engineers (IEEE) have recently developed software testing strategies and systems engineering frameworks that provide common terminology and guidelines. This set of standards, and others like it, applied to the testing and certification of medical record technology may improve software quality, reduce EHR aberration, and should be further researched by ONC. If nothing else, this should be evaluated to prevent patient safety issues.

2. **Establish greater transparency and uniformity on UCD testing and process results:** The Version 2014 certification for EHRs required some UCD safety enhanced design. ONC also required vendors to publish the results of their UCD process on the CHPL. As of early January, however, just over 200 vendors’ reports out of 513 were listed. Although all testing reports are required to be publically listed, not all of the accredited certification bodies (ACBs) are reporting the results. The reports are also difficult to locate online and are not easily understandable, even by experts in the field. Lastly, the data reported on each vendor is not uniformly displayed—making it hard to compare vendors and results.

⁴ John D. D’Amore, et al., “Are Meaningful Use Stage 2 certified EHRs ready for interoperability? Findings from the SMART C-CDA Collaborative,” *Journal of the American Medical Informatics Association*, 2014;0:1–9.

Robust UCD testing ensures that EHRs are designed to focus on the needs of the end user—supporting physicians’ care for patients and maintaining a safe decision making process. While some vendors have incorporated UCD processes in their software development, others have not, relying instead on the certification program to validate their methods of UCD. A closer examination shows that the interpretation of successful UCD testing varies widely across products. It is our understanding from UCD experts that ONC’s certification testing requirements do not hold products to a high enough standard when testing for adherence. Additionally, key aspects of both UCD and good software testing are not consistently followed. For instance, UCD is best tested using scenarios, use cases, and administered through simulator technology, which can test multiple permutations in a variety of clinical settings.

It is essential that all EHRs are tested with the same rigor to ensure the best UCD practices are used by each vendor when developing applications used in the care of patients. It is also imperative that EHR vendors utilize medical personnel that represent the end user during their internal testing process. At a recent ONC Health IT Policy (HITPC) meeting the results of a forthcoming study were discussed that cited concerns with the lack of clinical expertise used by EHR vendors to test the functionality of their products. The report shows that fully 25 percent of EHRs were not tested by physicians and ten percent were not tested by clinical staff of any kind. It is very concerning that crucial medical decision making protocols and functions intended to maintain the safety of patients are not being tested by individuals with the appropriate medical knowledge.⁵

We call on ONC to provide clear and consistent guidance to their ATLs regarding what should pass for appropriate UCD testing and to provide EHR vendors specific minimum requirements that meet industry standards when utilizing UCD in the development and testing of their products.

3. **Incorporate exception handling into EHR certification:** EHRs should be rigorously tested against a number of clinical scenarios, including “abnormal ones,” that are indicative of real life workflows in both ambulatory and inpatient settings. Testing performed in controlled environments that do not account for real life anomalies can limit a product’s and the end-user’s ability to correctly navigate workflow.
4. **Develop C-CDA guidance to support exchange:** Given that C-CDA documents are used to transmit patient medical information; significant attention must be paid to their structure and use. Further Implementation guidance and less optionality are crucial to ensure true semantic interoperability. It is imperative that ONC works with HL7 to provide sufficient guidance and testing procedures of the C-CDA draft standard and EHR certification incorporates a method to verify C-CDA documents adhere to strict standards of design. Additionally, we urge ONC to not only think about interoperability in the context of EHR to EHR, but to also consider various levels of connectivity and the exchange of information external to an EHR, such as an EHR connecting to a registry.

⁵ Health Information Technology Policy Committee HIT Implementation, Usability & Safety Workgroup. (November, 7th 2014). Accessed November 2014, from:
http://www.healthit.gov/facas/sites/faca/files/IUS_Transcript_Final_2014-11-07.pdf

5. **Seek further stakeholder feedback:** Other examples of software testing should be explored and incorporated into future EHR certification requirements. The aforementioned certification Kaizen event is one option and we are looking forward to engaging with ONC and other stakeholders on future learning sessions. Alternatively, we believe the same approach used by ONC to investigate and research methods to develop the Health IT Safety Center is well suited and should be reused. We therefore call on ONC to convene a software certification learning session with participants from organizations that have experience producing, testing, and certifying software used in other high-risk or consumer-facing industries such as financial, automotive, aviation, or e-commerce. To advance the certification program and to match the pace of software development, sessions should be routinely convened by ONC and a learning process should be established that feeds best practices back to the ATLS. We are encouraged that an Implementation, Certification and Testing FACA workgroup has been established and believe their participation in any stakeholder feedback is vital. Our organizations are also willing to assist in the development and refinement of certification methods and scenarios.
6. **Increase education on EHR implementation:** We recognize that not all EHR usability issues are vendor related. Some stem, for instance, from less than optimal user implementation practices. We recommend that ONC, as part of its charge to ensure that health IT is implemented safely, coordinate the development of tools and best practices to help physicians and vendors deploy and implement EHRs. ONC should routinely request implementation best practices from the field and disseminate the information back through methods including, but not limited to, ONC's website, blog postings, and in-person or virtual educational sessions. As software is deployed across a variety of settings, new methods of implementation will be developed and refined. It is important that best practices are gathered at a steady pace to facilitate ongoing learning. For instance, consideration should be given to establishing a semi-annual roadshow designed around learning sessions and implementation workshops for health IT vendors, medical and administrative personnel, and other stakeholders involved in system implementation and deployment. At the very least, educational activities should be conducted after each new EHR certification version.

We appreciate the opportunity to offer our ideas to improve the certification process and look forward to discussing these ideas with your staff. Should you have any questions about this letter, please feel free to contact Matt Reid at matt.reid@ama-assn.org.

Sincerely,

American Medical Association
AMDA – The Society for Post-Acute and Long-Term Care Medicine
American Academy of Allergy, Asthma and Immunology
American Academy of Dermatology Association
American Academy of Facial Plastic
American Academy of Family Physicians
American Academy of Home Care Medicine
American Academy of Neurology
American Academy of Ophthalmology
American Academy of Otolaryngology—Head and Neck Surgery
American Academy of Physical Medicine and Rehabilitation
American Association of Clinical Endocrinologists

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American Association of Orthopaedic Surgeons
American College of Allergy, Asthma and Immunology
American College of Emergency Physicians
American College of Osteopathic Internists
American College of Osteopathic Surgeons
American College of Physicians
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American Congress of Obstetricians and Gynecologists
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American Society for Radiology and Oncology
American Society of Anesthesiologists
American Society of Cataract and Refractive Surgery and Reconstructive Surgery
American Society of Clinical Oncology
American Society of Nephrology
College of Healthcare Information Management Executives
Congress of Neurological Surgeons
Heart Rhythm Society
Joint Council on Allergy, Asthma and Immunology
Medical Group Management Association
National Association of Spine Specialists
Renal Physicians Association
Society for Cardiovascular Angiography and Interventions
Society for Vascular Surgery