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June 30, 2015

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

Dear Dr. DeSalvo,

Representing the nearly 40 members of the Electronic Health Record Association (EHRA), we submit the attached comments on the draft test procedures that were released concurrently with the *Notice of Proposed Rule Making (NPRM) for 45 CFR Part 170: 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Program Modifications*.

We appreciate the efforts of the Office of the National Coordinator for Health Information Technology (ONC) to develop simpler, less prescriptive certification test procedures. We make specific note of a number of EHRA recommendations.

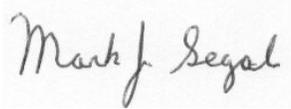
- We support the proposal to adopt a new format for the test procedures. We offer several suggestions for improving the format of test criteria, as well as suggestions for information that developers require to successfully achieve the expected results. We believe these suggested changes will improve consistency and efficiency in the testing process by having all of this information in one place.
- Overall, we recommend that attestation be allowed for criteria that have not significantly changed and for features that have long been available in EHRs (e.g., medication lists), along with criteria that require testing tools to validate EHR output. We encourage development of testing tools that produce results documents capable of satisfying attestation requirements without the need for visual inspection.
- We request clarification on several criteria regarding when attestation might be allowed, when visual inspection is required, and when testing tools are to be used. EHRA recommends that Authorized Test Labs (ATLs) publish their test scripts, testing process, and any guidance from ONC to both increase transparency and improve consistency across test labs.
- As noted in earlier comments, we have concerns regarding the availability of testing tools. If they are not available before certification testing is required, developers should be allowed access to prototypes in order to do their own

preliminary testing. If they are not available in a fully-tested and well-documented state at least 18 months before certification testing begins, alternative methods should be available (i.e., attestation).

- We caution that field surveillance may reveal that end users have implemented workflows that, while reflecting similar functionality, differ from test scripts. End-users will not be familiar with test scripts and certification requirements; and ATL and Authorized Certification Body (ACB) staff may not be familiar with EHRs to the extent that they can easily determine that expected results are being met by varying workflows. We discourage the use of field surveillance.

Finally, we appreciate the opportunity to provide this feedback, along with a number of other specific questions and comments on the individual criteria. As always, EHRA looks forward to working with ONC to ensure that certification testing achieves our shared objectives of assuring providers that their EHRs can support their efforts to meet meaningful use requirements.

Sincerely,



Mark Segal, PhD
Chair, EHR Association
GE Healthcare IT

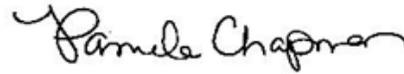


Sarah Corley, MD
Vice Chair, EHR Association
NextGen Healthcare

HIMSS EHR Association Executive Committee



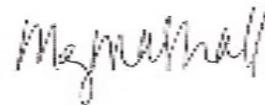
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About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of nearly 40 companies that supply the vast majority of operational EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

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

CC:

Steven Posnack, Director, ONC Office of Standards and Technology

Alicia Morton, Director, ONC Health IT Certification Program