
Hearing
Real World Experiences Working with Meaningful Use

Testimony by
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Before the
Implementation Work Group
Health Information Technology Standards Committee

Washington, DC
January 10, 2011

Introduction

Madame Co-Chairs, and Members of the Committee, thank you for inviting me today. My name is Alisa Ray, and I am here in my capacity as Executive Director of the Certification Commission for Health Information Technology (CCHIT). I am happy to have the opportunity to address this hearing on “Real World Experiences Working with Meaningful Use.”

The Commission’s ONC-ATCB Certification Process

Following the Certification Commission’s authorization by the Office of the National Coordinator (ONC) as a testing and certification body on September 3, 2010, the Commission launched its ONC-ATCB certification program on September 20, 2010 and began accepting applications (Figure 1).

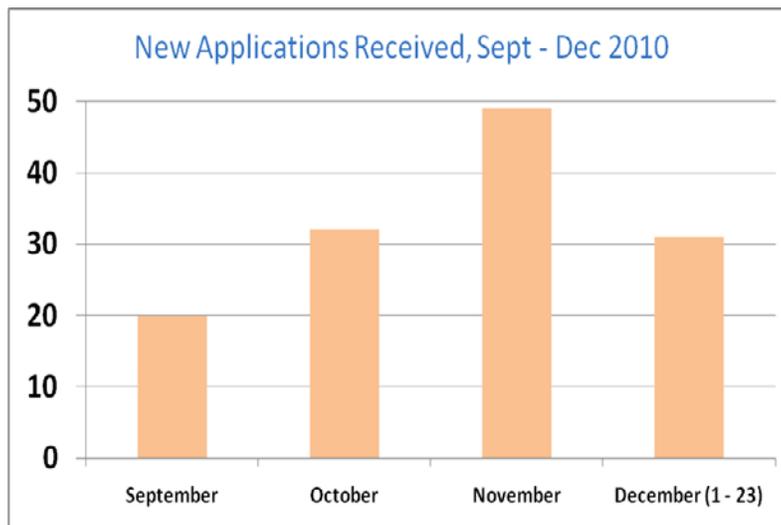


Figure 1 – Applications Received September through December 23, 2010

Using criteria and standards published in a final rule entitled [Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology](#) (45 CFR Part 170, RIN 0991–AB58), published on July 28, 2010 and the [Test Procedures and Tools](#) published by the National Institute of Standards and Technology (NIST) , the Commission developed a supplementary toolkit to help applying EHR technology companies and developers prepare for ONC-ATCB certification. That toolkit includes NIST test procedures arranged in a more convenient format to make preparing for and taking the test more efficient. Where NIST is silent on test data, the Commission’s staff suggests optional test data which may help EHR companies prepare and demonstrate their systems. Also included in the toolkit are an interoperability test guide, security attestation forms and further guidance on how to prepare for an inspection, taking advantage of the Commission’s testing experience.

The Commission ramped up its testing capacity, drawing from an already experienced panel of EHR inspectors, in order that certification applicants could schedule testing without delay. Typically, EHR companies or developers are able to schedule an inspection date within two weeks of application if they are well-prepared. This allows companies to take their certified EHR technology to market quickly, allowing eligible healthcare providers prompt access to technology that will meet the first prerequisite – use of “certified EHR technology” – to qualify for incentive payments made available in the American Recovery and Reinvestment Act of 2009 (ARRA).

Outcomes and Results of the Commission’s ONC-ATCB Program

Since the launch of its ONC-ATCB program in September, the Commission has certified (as of January 3, 2010) 131 EHR technology products (Figure 2). Of the 92 products certified in accordance with the applicable “eligible provider” 2011/2012 certification criteria adopted by the Secretary of Health and Human Services, 73 products represent Complete EHRs and 19 represent EHR modules. Of the 39 products certified in accordance with the applicable “hospital” 2011/2012 certification criteria adopted by the Secretary, 18 represent Complete EHRs and 21 represent EHR modules.

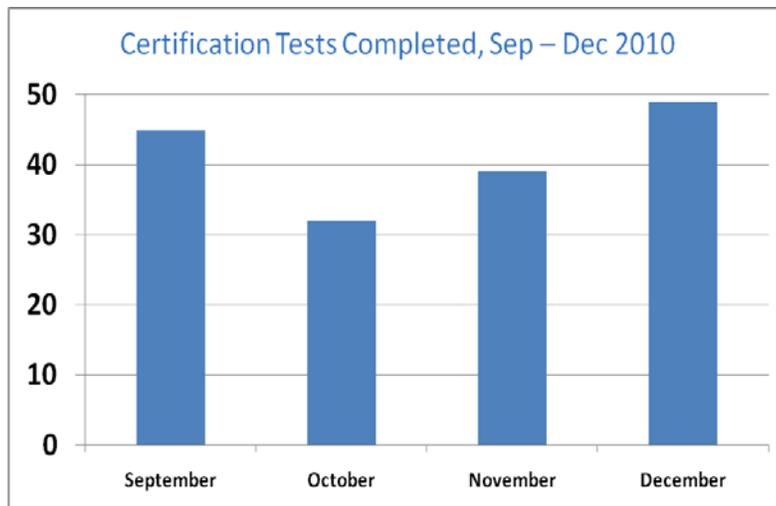


Figure 2 – ONC-ATCB Certification Tests Completed by December 31, 2010

As part of fulfilling its responsibilities as an ONC-ATCB, the Commission regularly surveys its EHR certification customers to determine their satisfaction with the Commission’s processes and services. In voluntary surveys conducted with its customers since the September launch date, the Commission reports a high rate of satisfaction, especially with regard to an EHR company’s overall experience with the Commission’s

program and their ability to schedule testing in a timely manner. Those companies who were very satisfied or satisfied with the certification process represented 92 percent of those surveyed (Figure 3). Those companies who were very satisfied or satisfied with their ability to schedule a testing date that worked for their team represented 97 percent of those surveyed (Figure 4).



Figure 3 – EHR Company Satisfaction with Certification Process

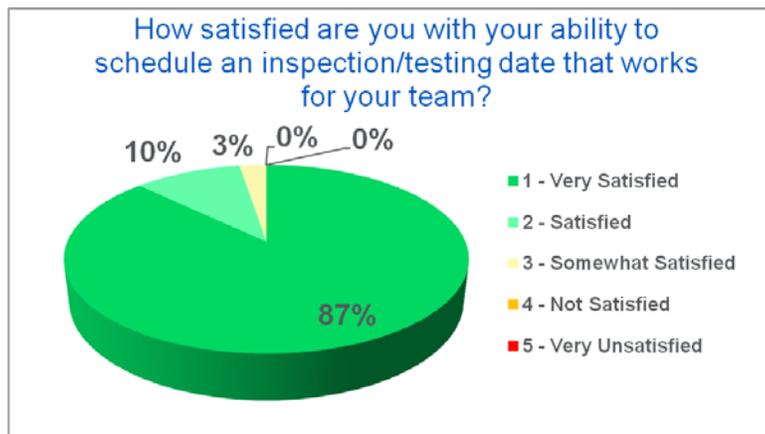


Figure 4 – EHR Company Satisfaction with Scheduling an Inspection

The survey results indicated that the greatest area for improvement lies in the area of satisfaction with the content of the certification materials (Figure 4). Those EHR companies who were very satisfied or satisfied with the content of materials dropped to 74 percent. Despite the supplementary guidance developed by the Commission, there is still confusion with the criteria and standards as published in the Federal Register and with the NIST test procedures and test tools.

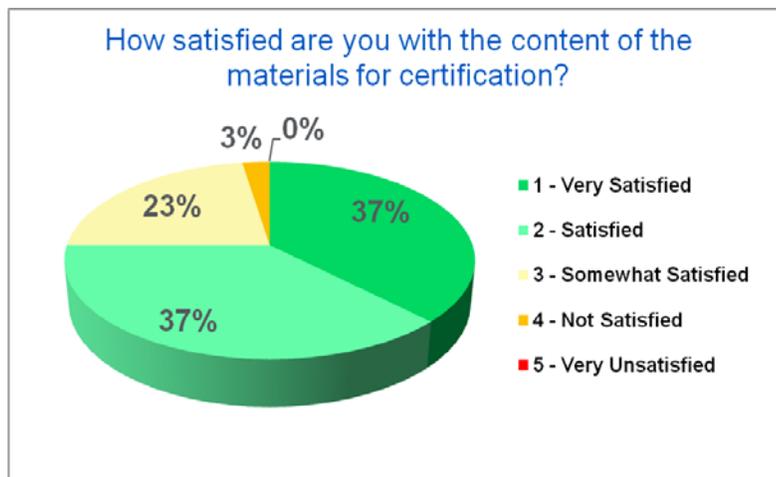


Figure 5 – EHR Company Satisfaction with Certification Materials

Challenges to Certifying a Software Vendor

The Commission experienced several challenges in the early days of the program. EHR companies without experience in certifying their products were unclear about how to interpret the ONC standards and criteria and the NIST test scripts. This confusion was compounded by errors in the final rule with regard to the public health surveillance standard and the evolving nature of the NIST test procedures. In the first case, ONC-

ATCBs were required to use a misstated standard in the final rule to inspect companies seeking early certification of a Complete EHR. This created the potential for leaving some providers ill-prepared to meet that meaningful use measure. This issue has been corrected with the issuance of a correction to the final rule.

A more difficult problem – the evolving nature of the NIST test procedures and test tools – created concern for ATCBs and EHR companies who may have already begun a certification process using an earlier procedure. While ONC and NIST have understood and tried to mitigate the impact of these changes, it still requires ONC-ATCBs to manage two test processes at once for EHR companies who may be in different stages of certification.

The Commission has also identified an issue of special importance to hospitals with already installed technology. As hospitals anticipate the benefits of federal incentive payments for meaningful use of certified EHR technology, some face an unexpected hurdle. Many hospitals will be able to meet the EHR certification requirement through use of certified EHR technology purchased from vendors, but many may need to achieve it on their own. Many hospitals have built their IT capacity over the past decade or so, through multiple commercial products, internal development or a mix of both. Without the ability to certify this self-developed or legacy technology, hospitals will lack the first prerequisite for qualifying for incentives. Hospitals, and some eligible providers, are generally unfamiliar with product certification requirements. Assessing their mix of technology to determine which criteria are covered is a significant undertaking.

To help hospitals, and later eligible providers, meet this need, the Commission has developed a special alternative to commercial EHR certification using the same ONC standards and criteria, and NIST test procedures and tools. The program to be launched within the week includes online, on-demand educational preparation integrated with the use of an online health IT assessment tool, the support of a community of practice, an online application, a virtual EHR technology inspection, and a completed certification for a complete EHR or EHR module.

The Commission's Experience with ONC and NIST

As of the date of testimony submission, ONC had authorized six ATCBs. One challenge to providing standardized policy interpretations, criteria clarification, and application of the NIST test procedures during inspection is having available a clear and consistent way for all ATCBs to communicate uniformly with ONC. Early in the process, to meet this challenge, ONC initiated weekly teleconferences that include representatives from ONC and its consultants, NIST, and all of the current ATCBs. While certainly very helpful, the weekly topics are constrained by time and purely verbal problem resolution has the potential to create differences in interpretation by the ATCBs.

The Commission recommends that ONC consider establishing a private online discussion group for ONC and the ATCBs, allowing each ATCB (and ONC) to setup authorized participants who can establish separate "threads" for each topic of discussion. Other features that would be useful to ATCBs include searching of this online content and enabling RSS subscription to selected discussions.

The Commission also recommends that ONC publish the decisions made on the weekly teleconferences so that all ATCBs, especially those authorized after the beginning of the program, have access to those decisions as a reference. A byproduct of this documentation could be a “policies and procedures” manual for ATCBs that specifies ONC’s expectations on operations and logistics, for example the requirements of the Certified Health IT Product List (CHPL) data submission process.

Earlier in my testimony, I noted the challenges that arise from an evolving set of NIST test procedures. Off-cycle updates to NIST test procedures are disruptive to ATCB operations, EHR companies who are preparing for testing and providers who must make sure they have implemented the correctly certified version. The Commission recommends that updates to test procedures should be planned, allowing adequate notice that they are coming and an opportunity for a review and comment period. The addition of a pilot process for quality assurance would provide further benefit.

The Commission’s staff also notes that good implementation of interoperability testing requires availability of more robust NIST testing tools. Currently few such tools are available, necessitating a manual visual review which can be inefficient, inconsistent and error prone. In addition, guidance documents, as well as orientation and training in the use of the test procedures and tools, would improve the consistency of testing decisions across ATCBs.

Conclusion

The Commission, again, thanks the Implementation Work Group and the Health IT Standards Committee for the opportunity to comment today. We would also like to acknowledge the hard work and dedication of our colleagues at ONC and NIST who have been charged with initiating this certification program. Through our own certification development experience, we understand what a difficult undertaking that has been and will continue to be. We are confident that, as the program evolves, they and we will meet the challenges of accelerating the adoption of health information technology through the development of efficient, credible certification programs.