May 7 Certification Testimony: Sasha TerMaat, Epic

Members of the Committees:

I appreciate this opportunity to offer feedback on the ONC certification program. At Epic, I'm responsible for oversight of our certification efforts. We are proud to have been one of the first to have both ambulatory and inpatient EHRs certified against the 2011 and 2014 sets of criteria. These certified EHRs have supported more than 80,000 EPs and 650 EHs participating in the Meaningful Use program. I'm happy to share today my experience with the 2011 and 2014 ONC certification programs, as well as my experience with private certification programs that predated the ONC program and certification requirements in other countries.

Question 1: Benefits

Assuming we could design an ideal program, what is the benefit of having a certification program, from the perspective of vendors?

You asked about the benefits of a certification program. Brainstorming with EHR developers and EHR users, an ideal certification program would assure EHR users that they could use the certified features as intended. Here are two examples:

1. In an ideal state, certification would offer a healthcare organization assurance that they can connect to the public health agencies in their region.

2. Similarly, in an ideal state, certification would ensure that hospitals and physicians can submit electronic quality measurement files that CMS will accept.

These examples would be benefits that increase efficiency for both EHR developers and for EHR users. They are not true in the current program:

1. Today, EHR users are still confronted with discrepancies between the requirements of specific public health agencies in their region and the standards used in certification.

2. Today, CMS has determined it is too complex to receive files in all the formats required for certification. For example, CMS is not able to accept hospital QRDA III files in 2014, and has proposed not to accept them in 2015 either, though every hospital application certified on quality measurement must support this file type. The formats CMS does receive have additional requirements that necessitate additional validation tools and testing.

I would also like to address two areas of confusion about the benefits of certification.

- First, I have heard a misconception that certification replaces the testing that EHR developers do as part of their normal quality management processes, or that certification replaces the testing a healthcare organization does of its site-specific configuration. The certification process is not effective at replacing the more comprehensive quality management processes we undergo as software developers and is an additional cost on top of that work. Similarly, certification is not specific to any one site's configuration, and it does not replace or reduce the cost of work that the EHR users at a healthcare organization must do to review their own settings.

- Second, I receive questions as to whether certification simplifies the process of selecting and purchasing an EHR. There is a minor improvement in the process of selection and purchasing, but it is not

proportionate to the effort expended on certification. For every $1000 spent on certification, $1 of savings in the selection process might be achieved.

Question 2: Challenges

What are the challenges you have experienced with the current certification program?

Effort invested

The greatest challenge with the current certification program is that the effort invested in the program is much greater than the value achieved from the program.

For example, ONC must invest in the regulatory process and in contractors who work on the test procedures, test data, and testing tools. Similarly, EHR developers, certifying bodies, and other interested stakeholders often invest in the development and refinement of certification testing. For example, as part of the 2014 certification process, EHR developers volunteered time to report dozens of issues and suggested fixes to test procedures, test data, and testing tools.

Then, certifying bodies must invest in becoming accredited on the certification criteria, and invest in training their staff to perform tests using updated criteria and new tools.

Next, EHR developers interested in certifying their software must invest their staff time to understand the certification process and requirements, to program new features or necessary changes in to their software, to test these changes, and to ready their demonstration systems for certification testing.

Finally, the newly certified features are rolled out to healthcare organizations, where they might require additional implementation effort (for example, to upgrade an interface) or investment in training users (for example, to notify users of a changed workflow).

This investment, of taxpayer dollars invested in the regulatory processes and tools, of the EHR developer's time and money not spent on other user-prioritized features, and of the resources spent by healthcare organizations not dedicated to other initiatives, must be merited by the value certification provides.

Discrepancies in effort required

There is a consistent disconnect about the level of investment certification requires. For example, in response to the ONC 2015 certification NPRM, the Electronic Health Records Association surveyed EHR developers of all types and found that on average, ONC estimates for what it takes to develop and certify an application are only 10-20% of what experienced EHR developers estimate that it takes.

Certification estimates from EHR developers are available for reference here:
http://www.himssehra.org/docs/EHRA%20Cover%20Letter%202015%20Edition%20NPRM.pdf

Understanding the investment that the program requires more accurately will be important to prioritizing our efforts accordingly.

Question 3: Suggestions

How would you propose changing the certification program to enhance its value to you, while minimizing the burden to the participants?

I echo the recommendations of other panelists that a thorough review of the Meaningful Use program broadly and the certification process specifically is merited, and that we would be happy to participate.

I urge that these ongoing discussions consider the following recommendations.

1. First, narrow the focus to only the highest priority criteria: interoperability criteria and quality measurement criteria.

2. Align certification requirements with the needs of users to participate in federal programs. The discrepancies between the quality measurement certification requirements and CMS's additional requirements to accept quality measures reduce the value of the certification program. CMS and ONC should work in concert to ensure that CMS's requirements for submission are defined with the ONC testing tools and criteria. This would significantly enhance the value of quality measurement certification as well as reduce cost by eliminating the need for CMS to develop and pilot with EHR developers separate quality measurement validation utilities.

3. Remove from certification quality measurement submission formats that CMS does not accept. In 2011 certification, every EHR certified on quality measurement had to show generation of a PQRS XML file that was never able to be accepted by CMS. In 2014 certification, every hospital EHR certified on quality measurement has to show generation of a QRDA III file that is not able to be accepted by CMS.

4. Consider asynchronous testing. Today, the certification model is that a certification tester performs the ONC test procedures and evaluations. So for example, I might participate in an online session with a certification tester where we spend an hour entering data, generating HL7 files, and then validating them in a NIST utility. Asynchronous testing where EHR developers could simply submit packages of their files for offline validation by the tester could be significantly more efficient.

5. Use more incremental testing. The current program of gap or inherited certification carrying forward when a criterion is unchanged is helpful. However, there are cases where a criterion changes only very minimally, and in those cases that minimal change requires the recertification of the entire criterion, not simply an inspection of the delta. More streamlined testing could be used in these cases.

6. Permit re-use of test data sets. Each time quality measures are certified, a separate deck of test patients is created and must be entered in the EHR for validation. If the testing process permitted an EHR developer to simply show that they could continue to generate a valid output after a change based on the same previously entered test data set, the effort of quality measurement certification could be reduced to only 5% of the current effort.

7. Finally, reducing the frequency of certification proportionately reduces the cost. We appreciate efforts to clarify when retesting would not be necessary, such as the annual publication of new CQM specifications. Additional efforts to minimize the recurrence of certification will further increase the efficiency of the process.

Thank you for your consideration. I look forward to continued discussion on refining the certification process.