



Health IT Standards Committee

A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT

January 17, 2012

Farzad Mostashari, MD, ScM
National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. Mostashari,

The HIT Standards Committee's (HITSC) Implementation Workgroup (IWG) conducted a survey to receive stakeholder input on the Certification Process moving into Stage 2 of Meaningful Use (MU). The findings from the survey were presented to the HITSC on August 17, 2011. Utilizing these findings, the IWG developed recommendations for the Certification Process for Stage 2 MU. These recommendations were presented to the HITSC on November 16, 2011 and accepted for transmittal to the ONC.

Recommendations

1. Create a grid that shows the standards, certification criteria, testing methodology, and implementation guidance for each of the Stage 2 MU Measures, including the quality measures.
2. Launch a unified HHS website that serves as the "single source of truth" for CMS's MU and ONC's certification programs.
 - The website should include:
 - A type of repository including value sets associated with elements and the specific data elements in a machine-interpretable form.
 - Vocabulary, value sets, vocabulary subset and the required cross-maps.
The content should support the recommendations presented in the April 28, 2010, June 23, 2011, and September 9, 2011 transmittal memos.
3. Establish a clear process to manage updates to specifications for MU measures and quality measures.
 - Include version numbers and release notes for all updates so users can easily identify the most recent info and clearly understand what has changed since the last update.
 - Indicate whether updates are mandatory or optional.
4. Clarify and simplify requirements for possession and attestation to use of certified EHR technology:
 - Simplify rules for Provider



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- Simplify certification process for vendors and ONC-ATCBs
 - Consider requiring Providers to possess EHR technology certified only against those measures they use for MU
 - List the products included in a certified system by name and indicate the MU measures supported by each named product
 - Give Providers the flexibility to pursue any option:
 - A single complete certified EHR
 - An all-modular EHR comprised of certified modules
 - A complete certified EHR plus certified modules
 - Pieces of a complete certified EHR plus certified modules
5. Build realistic software development and implementation timelines into regulatory requirements.
 - Align certification requirements with stage of MU.
 - Establish effective dates at least 18 months following publication of NPRM for new certification criteria.
 6. Publish the HHS process for conducting MU and Certification compliance audits.
 - Clarify how FAQ's will be used.
 - Identify the type of documentation the Provider will need.
 7. Publish the timeline for publication of the MU Stage 2 Measures, as well as for the associated proposed and final regulations and Certification Test methods.
 8. Revise individual certification criteria and test procedures based on specific comments.
 - Focus more on certified systems for interoperability
 - Incoming and outgoing interfaces should be able to display user-friendly content for the provider and tester-friendly content for certifying personnel.
 9. Create "scripts" with combined test procedures that permit the vendor to satisfy multiple certification criteria at once.
 - More input and analysis required.
 - May be more appropriate for certain scenarios
 10. Publish more guidance for Providers in order to clarify the difference between the Certification Criteria and the Meaningful Use incentive requirements.
 11. Identify pre-defined bundles of certification criteria and standards representing key EHR elements that make up a complete EHR, and reflect the way providers think about health IT.
 12. Make publically available material used for testing
 13. To encourage sound security architecture, engineering, and integration, each security criterion should be treated as addressable, and a vendor must meet the criteria or assign it to an external service.



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The IWG will continue to support the Office of the National Coordinator by providing input on testing. The ONC asked the IWG to gather stakeholder and public input on test procedures for Stage 2 MU. This feedback will be incorporated into the development of the test procedures.

Testing Input: The Scope of Work for the IWG

1. Continue the population of the 'Grid' to include test procedures.
2. Provide the perspective of the provider and vendor/developer on the expected changes in the TPs related to Stage 2 MU
3. Consider the implications of transitioning from test procedures that currently use visual inspection testing and attestations to formalized testing for product certifications.
4. Present formal timeline of activities and description deliverables at December HITSC meeting

We encourage the ONC to consider these recommendations, as we believe they will serve as an effective starting point for development of the Certification Process for Stage 2 MU.

Sincerely yours,

/s/

Jonathan Perlin
Chair, Health IT Standards Committee

/s/

John Halamka
Vice Chair, Health IT Standards Committee