



Certification Hearing May 7, 2014

June 10, 2014

Certification Hearing FACA member attendees



- Paul Tang, chair
- Michael Zaroukian, co-chair
- Carl Dvorak
- Paul Egerman
- Jennie Harvell
- Joseph Heyman
- George Hripcsak
- David Kates
- Michael Lincoln
- Nancy Orvis
- Marc Probst
- Donald Rucker
- John Travis
- Charlene Underwood
- Larry Wolf

Hearing Purpose



- Understand what is working and where there are challenges
- Identify opportunities to improve the program, leveraging lessons learned in stages 1 and 2

Hearing Panels



- Panel 1: Providers
- Panel 2: Vendors
- Panel 3: Certification/Accreditation Bodies
- Panel 4: Private sector representatives

Panel 1: Providers



- Ginny Lorenzi, NewYork-Presbyterian Hospital
- Chad Jensen, LaTouche Pediatrics, LLC
- John Berneike, Utah HealthCare Institute
- Colin Banas, Virginia Commonwealth University Health System
- Howard Hays, Indian Health Service
- Cletis Earle, CHIME

- Assuming we could design an ideal program, what is the benefit of having a certification program, from the perspective of your organization? How does a certification program help you? What are you looking for from a certification program?
- Currently certification indicates that certain capabilities exist in an EHR, would certification ever indicate a level of quality?
- What are the challenges you have experienced with the current certification program?
- How would you design a certification program that would achieve the benefits you seek, while minimizing the burden to the participants?

Key points Panel 1: Providers



- EHR products may meet certification criteria, but the way the functions are implemented may disrupt workflow
 - Some functions fulfill the letter of the criteria, but not the intent (e.g., clinical summaries, patient education)
 - Some functions are implemented as "check the box"
 - May be easy for vendor, but creates burden for provider and less useful
- Providers feel constrained to use products as certified, with inefficient work flow
 - Vendors be given enough flexibility to meet the rules without being constrained to a particular workflow
- Some certified products do not work, or do not work in all states

Key pointsPanel 1: Providers (II)



- Certification does not adequately cover interoperability
- Certification program should be less prescriptive; focus on what and less on how
- More flexibility and time for implementation is needed
- An ideal certification program would provide product comparisons in terms of their functionality

Panel 2: Vendors



- Mickey McGlynn, EHRA
- Sasha TerMaat, Epic
- Emily Richmond, PracticeFusion
- Joseph Geretz, SRSsoft
- Sarah Corley, NextGen Healthcare Systems
- Marc Probst, Intermountain
- John Halamka, Beth Israel Deaconess Medical Center

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Key pointsPanel 2: Vendors



- Complete set of requirements are not provided with adequate time for development
 - Requirements change from what was originally defined in the certification rule impacting quality and usability
- Certification criteria for MU objectives, reports that measure these objectives, and the clinical quality measures are not aligned with each other and are not necessarily aligned with clinical practice
- The testing tools and associated data are not properly tested before they are rolled out for use in the vendor community, and change
- Recommend that the complexity of the program be reduced and that a Kaizen process be used to support an effective review of the certification program
- Focus certification on critical few: interop, CQMs

Panel 3: Certification/Accreditation Bodies



- Amit Trivedi, ICSA Labs
- Kyle Meadors, Drummond Group VIRTUAL
- Mark Shin, InfoGard

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Key Points Panel 3: Certification/Accreditation Bodies



- Pilot test new procedures and test tools prior to publication
- Improve consistency between testing labs. Pilot tests should be a venue for all ATLs and ACBs to observe testing to understand the expected results, learn how the test tools operate, and then provide feedback to ONC
- Testing tools need to be more automated to efficiently handle more test cases, reuse test data sets, and employ more robust types of testing methodologies including testing the security of products.
- Focus on certification criteria related to interoperability and security testing.
- How EHRs handle various functionality should be left to developers to innovate

Panel 4: Private sector representatives



- Alisa Ray, CCHIT
- David Kibbe, Direct Trust
- Chris Carr, IHE
- Jitin Asnaani, CommonWell
- Mariann Yeager, Healtheway

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Key Points Panel 4: Private sector representatives



- Need additional up-front testing and quality assurance
- Mid-cycle revisions are disruptive to the overall program
- Need subject matter experts in program development
- Enhanced collaboration between the private sector and the federal government would help
- Focus on critical few

Overall Summary



- No disagreement about intent of MU objective
- Insufficient time for product development and testing
- Concerns about certification include:
 - Specificity of certification criteria locking in vendor-created inefficient workflows for providers
 - Incompletely tested and unstable testing tools delays certification and creates rework
 - Inconsistent interpretations among ATLs, ACBs, and auditors
 - Certification does not guarantee integrated product or interoperability
 - No clearinghouse for timely feedback and response (need faster than NPRM cycles)
- Time required for certification (or documenting certification) crowds out innovation

Final Recommendations (I) Kaizen



- Motivation: current process is inefficient and burdensome
- Objective: Need a coordinated, integrated, well understood certification process with minimum of burden
- Rec: Kaizen covering end-to-end certification process from translation of MU objective to certification criteria to development of testing scripts to development (and QA) of testing tools to conduct of test to auditing
- Involve broad stakeholders from providers to developers to ATLs/ACBs to auditors
- Establish certification roadmap and timelines
- Create a timely PDCA mechanism for feedback and continuous improvement

Final Recommendations II Focus



- Motivation: providers and vendors (and ACBs) feel overwhelmed by the pace of everything going on
- Objective: Focus on critical few
- Limit scope of certification to:
 - Interoperability
 - CQMs
 - Privacy and security
- These require
 - Cross-organizational collaboration (and policy interoperability)
 - Alignment of standards, measures, and programs
 - Overarching governance
 - Public-private collaboration



Discussion