HIT Policy Committee

Recommendations by the Certification and Adoption Workgroup

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Agenda

- The Workgroup
- The Workgroup's Charge
- Workgroup Process
- Questions Considered
- Initial Learnings
- WG Perspective of the Purpose of Certification
- Initial Recommendations
- Questions Answered
- Next Steps

The Certification/Adoption Workgroup

Chairs:

- Paul Egerman
- Marc Probst, Intermountain

Members:

- Rick Chapman – Kindred Healthcare
- Adam Clark – Lance Armstrong Foundation
- Charles Kennedy – Wellpoint
- Scott White – SEIU Training & Employment Fund
- Latanya Sweeney – Carnegie Mellon University
- Steve Downs – Robert Wood Johnson Foundation
- Joseph Heyman – American Medical Association
- Teri Takai – State Chief Information Officer, CA

ONC Lead:

- John Glaser

The Workgroup Charge

Broad Charge - Make recommendations to the HIT Policy Committee on issues related to the adoption of certified electronic health records that support meaningful use, including issues related to certification, health information extension centers and workforce training.

Current focus of this report – review the existing certification and standards setting processes and make recommendations to the HIT Policy Committee, within four (4) months of the initial meeting of the workgroup, about how these processes should be structured in the future.

Workgroup Process

Through a series of teleconferences and meetings:

- Developed understanding of existing certification processes and issues
- Defined questions to be asked of solution providers and users (current/future)
- Workgroup members solicited input and aggregated information received
- Discussed and commented on information gathered
- Defined initial set of recommendations
- Two–day testimony (July 14th/15th)
- Reviewed initial comments submitted
- Developed recommendations to the HIT Policy Committee

Questions Considered

Criteria

- Should criteria definition be separated from the certification testing of individual systems?

- Who should establish the criteria?

- What should be the scope of the criteria?

- What should be included in the criteria and what should be considered as product ratings?

- Should certification be a "seal of approval" process?

- Should certification include broad features or focused specifically on Meaningful Use objectives?

- How should certification criteria apply to privacy aspects of ARRA?

- Should certification address vendor fitness?

- Should certification address provider readiness?

Questions Considered

Certification Process

- What should be the governance of the certification process?
- Who should conduct certification?
- Should there be more than 1 certifying body?
- How should the accreditation Body be established?
- What role, if any, should ONC play in the certification process?
- Should the certification be only for whole systems or for modules/components?
- What should be the frequency of certification?
- Should the product be certified for all requirements or only gaps?
- How should non-vendor systems be certified?
    - Self developed systems
    - Open source
    - Integrated solutions
- What roles should CCHIT play?

Initial Learnings

CCHIT and the current certification process

1. CCHIT was created prior to the passage of ARRA HITECH and to address different industry challenges. CCHIT has moved very quickly to support the Certification Requirements of ARRA HITECH.

2. There is considerable confusion about the purpose of CCHIT certification, even among individuals who participate in CCHIT workgroups. The overall goal and purpose of current certification is not well understood.

3. There is a feeling that the certification process is excessively detailed. There is too much attention to specific features and functionality.

4. CCHIT has put together a very good system for transparent discussion of new, potential certification requirements.

5. CCHIT has also created a fair system of judges for testing and certifying systems.

6. There has been criticism that CCHIT is too closely aligned with HIMSS or with vendors. While we did not see any evidence that vendors were exerting undue influence on CCHIT, we also understand that the appearance of a conflict is important to address.

7. CCHIT has been criticized because it both sets certification criteria and does the testing (certifying) of vendor systems.

8. A desire for a modular approach was expressed, so that purchasers could obtain components from multiple sources and are not required to use a monolithic system from a single vendor.

Initial Learnings

Non-vendor systems (Self-developed and Open Source)

1. Organizations with self-developed systems, view certification as an aid to purchasers.   Since they already have an operational system that is not intended for use outside of their organization(s), they don't understand why they need to go through the expense of detailed certification processes and potentially developing unneeded functionality for the sole purpose of meeting certification criteria.

2. Some vendors and customers of vendors believe in an egalitarian approach in which everybody is treated the same way.

3. The Open Source community is similarly impacted.

4. Significant concern around curtailing research and development associated with open source and self developed applications if resources must be diverted for certification processes.

5. Timeframe and costs for certification and re-certification are a concern.

Initial Learnings

Is certification a "seal of approval" process?

- The variety of responses to this issue is another indication that the purpose of certification has not been clearly articulated.

Should certification be broad-based or specific?   Should certification expand beyond the functionality needed for implementing the "meaningful use" (MU) measurements?

1. Most vendors advocated for a minimal approach to certification, complaining that CCHIT has "hijacked their development effort" and that they are developing features/functions that nobody will use.

2. Many comments were made about interoperability and the problems associated with exchanging basic data. The comments indicate that there should be more specific criteria for interoperability.

3. There is limited evidence that the current certification process has significantly improved interoperability challenge.

Initial Learnings

Certification and Privacy?

1. It was suggested that the privacy, security, and interoperability criteria should be segregated into foundational infrastructure requirements.

2. It was also suggested that all sub-systems (or applications) that interface with a certified EHR should be required to be certified against the foundational infrastructure.

Should certification include vendor fitness or provider readiness?

1. Most responses were negative to both issues.

2. The responses indicated that the purpose of certification has not been clearly defined.

Purpose of Certification
Clarifying HHS Certification

	Validation	Certification	Assurance
Why	Prove that the EHR systems/components in use by an organization perform per the requirements of Meaningful Use.	Ensure that the EHR systems/components are *capable* (if installed appropriately) to perform per the requirements of Meaningful Use.	A "seal of approval" which suggests that an EHR system/components/vendor includes functionality which meets or exceeds the requirements of Meaningful Use.
Who	All organizations that receive ARRA incentive funds through HITECH	By Law, all organizations that *desire to* receive ARRA incentives funds through HITECH	Whomever feels that this "seal of approval" is important to them.
How	Self Attestation/reporting/audit Government Third Party	Government defined criteria Third Party assessment	Commercial User Group
What	All *software* components required to achieve Meaningful Use.	All EHR components required to achieve Meaningful Use.	To be determined by market.

Work Group area of Focus

Scope of ARRA

Purpose of Certification

Proposed Definition of HHS Certification

HHS Certification means that a system is able to achieve government requirements for security, privacy, and interoperability, and that the system would enable the Meaningful Use results that the government expects.

HHS Certification is not intended to be viewed as a "seal of approval" or an indication of the benefits of one system over another.

Recommendations

1. Focus Certification on Meaningful Use

2. Leverage Certification process to improve progress on Security, Privacy, and Interoperability

3. Improve objectivity and transparency of the certification process

4. Expand Certification to include a range of software sources: Open source, self-developed, etc.

5. Develop a Short-Term Transition plan

Recommendation 1 – Focus on Meaningful Use

- The National Coordinator should determine the criteria for HHS Certification, which should be limited to the minimum set of criteria that are necessary to: (a) meet the functional requirements of the statute, and (b) achieve the Meaningful Use Objectives.

- The focus on Meaningful Use should reduce the barriers currently faced by vendors that focus on specialists.

- Criteria on functions/features should be high level; however, criteria on interoperability should be more explicit.

- These criteria should be updated as the definition of meaningful use evolves.

- The Workgroup encourages the industry to continue to provide advisory services that can rate other aspects of EHRs that are important to purchasers, e.g., non-meaningful use features and functions and vendor viability and support capabilities.

- The Office of the National Coordinator (ONC) is encouraged to explore critical aspects of EHRs for which certification criteria may not exist today, e.g., usability and improved models for system and data architecture.

Recommendation 2 – Progress on Security, Privacy, and Interoperability

- HHS Certification must specifically include requirements addressing all privacy and security policies described in ARRA.

- ONC should develop tighter integration between standards and certification.

- If necessary, ONC should commission (not just harmonize) the development of standards.

- Aggressively establish new, very specific requirements for Interoperability and data exchange.

- Create "test harnesses" that will enable providers and health care organizations to easily self-test the software to validate the product and test it against established interoperability standards.

- Prioritize focusing on criteria for interoperability and data exchange for systems/applications that interchange data with a certified EHR.

Recommendation 3 – Objective and Transparent Process

- The process of defining HHS Certification criteria should be performed by ONC, and separated from organizations that perform certification testing.

- The establishment of criteria and associated standards must be done in a transparent fashion.

- In making decisions about HHS Certification criteria, the National Coordinator should rely on the Policy and Standards Committees for guidance.

- Working with NIST, ONC should develop a comprehensive process for conformity assessment including testing, certification, accreditation and surveillance.

- ONC should develop an accreditation process and select an organization to accredit certifying organizations.

- Multiple organizations should be allowed to perform HHS Certification testing and provide certification. (Vendors will need to get certification only from one certifying organization.)

- This updating should occur no more frequently than every other year and be done in time to allow EHR suppliers and adopters sufficient time for effective implementation.

Recommendation 4 – Flexible Software Sources

- ONC should provide certification support to a wide range of EHR sources to support the "mandatory" nature of incentive payments based on Meaningful Use.

- Certification of components should be available so providers can achieve Meaningful Use with implementation of these components.

- All EHRs should be certified.

- The "lock down" requirements of EHR software should be removed to address concerns of the Open Source community.

- For self-developed software, an alternate certification process could be provided based upon site inspection.

Recommendation 5 – Short Term Transition

- ONC should define missing criteria to address Meaningful Use objectives, e.g., public health.

- ONC should revise the existing criteria to meet Meaningful Use objectives, e.g., e-prescribing.

- Subject to completing a special MU Gap Certification, existing certified products should be deemed certified for 2011.

- New products, not currently certified, should be certified against the revised criteria and gaps.

- Until the new HHS Certification process is established, with ONC approval, CCHIT should continue to perform certifications against ONC defined criteria.

Next Steps

- Present initial recommendations (today)
- Open for Public Comment
- Review Public Comment
- Refine recommendations
- Deliver Certification recommendations to HIT Policy Committee

Addendum

Backup Slides

Questions Answered

Criteria

- Should criteria definition be separated from the certification testing of individual systems? *Yes*

- Who should establish the criteria? *HHS*

- What should be the scope of the criteria? *Meaningful Use Objectives with significantly enhanced focus on foundational requirements for Security, Privacy, and Interoperability*

- What should be included in the criteria and what should be considered as product ratings?

- Should certification be a "seal of approval" process? *No*

- Should certification include broad features or focused specifically on Meaningful Use objectives? *Only on Meaningful Use Objectives plus significantly enhanced focus on foundational requirements for Security, Privacy and Interoperability*

Questions Answered

Criteria *(continued)*

- How should certification criteria apply to privacy aspects of ARRA? *To the extent Meaningful Use requires Privacy and to the extent necessary to meet the requirements of the statute*

- Should certification address vendor fitness? *No*

- Should certification address provider readiness? *No*

Questions Answered

Certification

- What should be the governance of the certification process? *HHS should determine certification criteria. The determination of certification criteria should be decoupled from the testing organization. The accreditation and monitoring of the testing (certifying) body should not be controlled by HHS. Another agency, NIST, should be responsible for overseeing the actual testing. (with oversight by the HIT policy Committee)*
- Who should conduct certification? *Determined by NIST*
- Should there be more than 1 certifying body? *Multiple organizations can apply to become accredited HHS certifiers.*
- How should the accreditation Body be established? *NIST*
- What role, if any, should ONC play in the certification process? *Oversee the definition of requirements*

Questions Answered

Certification (continued)

- Should the certification be only for whole systems or for modules/components? ***All components required to achieve Meaningful Use. Certification of modules should make it possible for organizations to purchase components from multiple vendors.***

- What should be the frequency of certification? ***Every 4 years and should be aligned with Meaningful Use***

- Should the product be certified for all requirements or only gaps? ***All requirements***

Questions Answered

Certification *(continued)*

- How should non-vendor systems be certified? ***All systems require HHS Certification***

    – Self developed systems, Open source, Integrated solutions

- What roles should CCHIT play? ***To be determined by NIST. Like any other organization, CCHIT can apply to perform HHS certification testing. The workgroup noted that CCHIT has shown strong leadership in the development of certification criteria and processes.***