



# HIT Policy Committee

## Review of Initial Recommendations by the Certification and Adoption Workgroup

**Paul Egerman**

**Marc Probst, Intermountain Healthcare**

**August 14, 2009**

# Agenda

- The Workgroup
- Review of Initial Recommendations
- Comments Received
- Focus on the near term
- Policy Committee Comments

# 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

# Purpose of Certification

## Proposed Definition of HHS Certification

HHS Certification means that a system is able to achieve the minimum government requirements for security, privacy, and interoperability, and that the system is able to produce 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 Certification Transition plan

## Recommendation 1 – Focus on Meaningful Use

- Implement a New Certification Process: Focus on Meaningful Use Objectives at a high level, less specificity
- Increase Specificity on Interoperability
- Comprehends that Optional Certifications may exist - Marketplace Advisory Services

## Recommendation 2 – Progress on Security, Privacy, and Interoperability

- Address all privacy and security policies described in ARRA and HIPAA, including audit trails and consent.
- Aggressively establish new, very specific requirements for Interoperability and data exchange.
- Create “test harnesses” that will enable purchasers easily self-test their software.

## Recommendation 3 – Objective and Transparent Process

- Separate Criteria definition from certification testing
- Allow Multiple Certification organizations
- With the National Institute of Standards and Technology (NIST), establish accreditation organization and process

## Recommendation 4 – Flexible Software Sources

- Ensure that all EHR systems are certified against identical criteria, regardless of source
- Provide flexible processes for non-vendor software
- Provide for certification of components so EHRs can be purchased from multiple sources

## Recommendation 5 – Short Term Transition

- Leverage existing Certification work, whenever possible
- Establish Preliminary Certification Process so work can commence prior to completion of regulatory process
- For products that completed 2008 certification, permit an incremental certification process against “Gap Criteria,” which includes privacy review

## Appendix A

# Detailed Recommendations

# 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 Certification 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.
- 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.
- 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.
- 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)
- Any updating of certification criteria 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 3 – Objective and Transparent Process

Accreditation must insure that multiple certification entities use identical criteria and provide a "level playing field" so that all certification organizations offer the same level of scrutiny.

ONC must develop a communications plan to describe the new certification process and to explain the meaning of HHS certification.

The process of obtaining HHS Certification should also qualify for the Stark exception. It should not be necessary to get two certifications.

## 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 against the identical certification criteria, regardless of source.
- 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. Any such certification based upon site inspection should be valid for that site only and cannot be used to commercialize the software.

# Recommendation 5 – Short Term Transition

- There are two goals for the Short Term Transition Plan:
  1. Provide an expedited process so that HHS Certified Products can be in the marketplace as soon as possible. Recognizing that the Meaningful Use criteria and other items relating to certification must complete a regulatory process that is likely to end in early 2010, the short term transition recommendation includes a concept of “Preliminary HHS Certification” so that vendors, who take a risk on the content of the final regulations, can be ready as quickly as possible when final regulatory approval is obtained.
  2. The recommended new HHS Certification process will take time to put into place. The transition plan is intended to provide an operational methodology to be used in the interim.
- \* We recommend that these certifications obtained during the transition period should be valid at least through 2011.

## Recommendation 5 – Short Term Transition

- Leverage Existing Work whenever possible—ONC should ask existing certification organization to submit a proposal for HHS Certification according to the new process. The proposal should include high level criteria for Meaningful Use and greater specificity for security, privacy, and interoperability. Software must have all privacy capabilities as described in statute, including audit trails and consent. Proposed criteria should be submitted prior to September 15, 2009.
- If approved by ONC, the proposed criteria should be used to create a “Preliminary HHS Certification” that could be offered to vendors by October, 2009. This certification is called “preliminary” because the meaningful use criteria and the certification criteria will not yet have completed their paths through the regulatory process.
- When the regulatory process is completed for Meaningful Use, presumably in early 2010, then, if necessary, establish a short “regulatory gap certification” for any necessary changes from preliminary certifications. After completing this “regulatory gap certification”, the National Coordinator should certify those products as qualifying under the statute, with a goal of having HHS Certified products in the marketplace in early 2010.

## Recommendation 5 – Short Term Transition

- For vendors who already completed CCHIT 2008 certification, we recommend providing an optional shorter, expedited process.
- Request that CCHIT submit, as soon as possible, a proposal for “2008 Gap Certification,” which will apply only to vendors who already completed 2008 Certification. The 2008 Gap Certification must cover any missing privacy capabilities (e.g., audit trails, consent) required by statute. It must also cover capabilities for Meaningful Use, and expanded interoperability capabilities. Once approved by ONC, the completion of 2008 Gap Certification should also qualify products for “Preliminary HHS Certification.” Those products will be required to complete the “Regulatory Gap Certification Process” before the National Coordinator similarly certifies those products.
- Working with CCHIT and the Policy Committee, the ONC should investigate whether similar gap certifications are appropriate for products that achieved 2007 certification.

## Appendix B

# Workgroup Charge

# 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.

## Appendix C

# Workgroup Process

# 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
- 2 –day testimony (July 14<sup>th</sup>/15<sup>th</sup>)
- 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.

## Appendix D

# Answers to Questions

# 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.***