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July 13, 2009

Judy Sparrow
Office of the National Coordinator for
Health Information Technology
Health and Human Services
330 C Street, SW.
Washington, DC 20201

HIMSS EHR ASSOCIATION COMMENTS TO THE HIT POLICY COMMITTEE'S CERTIFICATION / ADOPTION WORKGROUP

Dear Ms. Sparrow:

As the Executive Committee of the HIMSS Electronic Health Record Association (EHR Association), we are providing response to questions from the HIT Policy Committee Certification/Adoption Workgroup. We hope that the Committee and the Workgroup will find these comments and recommendations useful in their deliberations.

A. Who should perform certification? Should there be more than one certifying body? Going forward, what role should CCHIT or other groups play?

- The EHR Association (the Association) has supported the concept of EHR certification since it was introduced in 2005. Given time constraints and CCHIT's experience in certifying EHRs, the Association supports CCHIT as the single certifying entity to avoid duplication of effort, unnecessary expense and confusion in the market.
- To avoid market confusion and enhance consistency, we prefer that there be one single certifying body. In any event, certification should be based on a common set of certification criteria.
- CCHIT, or any certifying group, should focus on essential criteria to support objectives and intended outcomes of "meaningful use" as described in ARRA, as well as the dimensions of a qualified EHR (i.e., comprehensive) as specified in ARRA. Per the legislation, a qualified comprehensive EHR is defined as record of health-related information on an individual that:
 - includes patient demographic and clinical health information, such as medical history and problem lists;
 - has the capacity to provide clinical decision support;
 - supports physician order entry;
 - captures and queries information relevant to health care quality; and
 - is able to exchange electronic health information with and integrate such information from other sources.

B. How should non-vendor systems be certified? Should there be special procedures for self-developed ("in-house") systems? What about open source systems?

- Modular EHRs are appropriately deployed in inpatient settings and some medical specialty practices. Likewise, site-level certification can meet the needs of certain providers with self-developed systems.
- Comprehensive, modular and site certification, whether non-vendor, single vendor or multi-vendor, should use the same process (conceptually) and the same criteria. A lower bar should not be set for some EHRs or their components relative to others. All must be evaluated using a similar process and consistent criteria to support "meaningful use" objectives. In developing this consistent criteria and bar, we recommend consideration be given to the fact that the new process, now required for traditional EHR vendors, niche vendors, open source providers and provider entities (hospitals and practices) should not be overly burdensome and should add value to the process.
- Careful consideration should also be given to moving away from the current pass/fail process in light of the new role of certification with the stimulus.

C. Should certification be viewed as a "seal of approval" process?

- No, to the extent that a "seal of approval" implies endorsement of the product. Certification should indicate that the product meets certification criteria indicating that it is a qualified, comprehensive EHR and is capable of enabling providers to achieve "meaningful use" requirements.

D. Should certification be broad-based or specific?

- Certification should broadly address the variety of healthcare delivery environments - e.g., ambulatory, inpatient and specialty environments.
- Criteria should be focused on the ability to perform functions (i.e., CPOE), not on the methodology used or the specific detailed workflows/process used to deliver those functions to end-users; nor should test scenarios and scripts required for certification dictate system design. Any area of specificity should be based on the specifics called out and required to evaluate the ability to achieve the "meaningful use" objectives.
- The certification process and criteria must recognize that functionality and interoperability have somewhat different requirements in terms of testing and specificity. A higher degree of specificity is needed than for many functional criteria.
- Given the critical need to deploy interoperable EHRs nationwide, we recommend that a focused discussion on interoperability issues be organized to include representatives from the provider community who have self-developed EHRs, as well as EHR vendors, developers of open source EHRs and systems integrators. The EHR Association specifically recommends that ONC and the HIT Policy Committee leverage the experience of IHE in this effort.

E. How should certification criteria apply to the privacy aspects of ARRA?

- Privacy and security policies that require EHR support or implementation should be considered for certification, as has been the case with CCHIT criteria.
- As new disclosure and privacy protections are more clearly defined and we understand how these should be supported by EHRs, consideration should be given to including these in future certification requirements.

F. Should the certification process also certify vendor fitness? Should it certify provider readiness?

- The EHR Association does not believe that certifying “vendor fitness” is an appropriate role for certification nor prudent use of limited certification funds and resources. The marketplace already contains vast amounts of information related to vendor capabilities.
- Certification of “provider readiness” should not be a part of the certification process. The Health IT Regional Extension Centers (HITRECs) have been created to address this need and should be able to determine readiness at a high level (e.g., evaluate training needs for provider staff, review network infrastructure).

G. What general comments are there about the certification and standardization process?

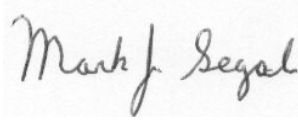
- Certification should take practical consideration of how long it takes vendors to develop and deliver new capabilities, as well as the time required for practices and hospitals to install or upgrade software, and to achieve “meaningful use” and the attendant benefits for patients and the healthcare system overall. The ability to accomplish these objectives requires more time than simply acquiring and installing an EHR.
- To meet 2011 objectives for “meaningful use” for inpatient EHRs, the EHR Association suggests using CCHIT 2007 certification criteria which include CPOE, clinical decision support and closed-loop medication administration - all of which support patient safety and evidence-based care - plus additional capabilities for interoperability and quality reporting needed for ARRA.
- To meet 2011 objectives for “meaningful use” for ambulatory EHRs, the Association suggests using CCHIT 2008 certification criteria plus additional capabilities for interoperability and quality reporting needed for ARRA.
- As CCHIT does now, certification should seriously consider market readiness in selecting standards and criteria. That is, the criteria reflect functionality and standards that the market is ready to implement and use.
- Certification criteria for a given period must anticipate future “meaningful use” requirements as well as software development cycles. Certification needs to focus on a two-year cycle (i.e., new criteria issued every two years), and be valid for two years. The certification criteria for a given two-year period should focus on the full “meaningful use” roadmap and not just the requirements for that same two-year period.
- Objectives and a roadmap are needed as soon as possible to enable resource planning for both vendors and providers, and to achieve maximum efficiency across the market. The time required for a provider organization, whether a small physician practice or a larger hospital-centered organization, to achieve “meaningful use” must also be factored into the timeline when updating the certification requirements and “meaningful use” objectives.

EHR Association member companies provide a valuable resource for ONC, based on our unmatched experience in developing, deploying and supporting EHRs in physician practices of all sizes and specialties, as well as hospital organizations large and small. We encourage you to call on us to as these important deliberations progress.

Sincerely,



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Vice President, Marketing & Government Affairs
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Mark Segal
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HIMSS EHR Association Executive Committee



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EHR Association Executive Committee

About HIMSS EHR Association

HIMSS EHR Association is a trade association of Electronic Health Record (EHR) companies that join together to lead the health information technology industry in the accelerated adoption of EHRs in hospital and ambulatory care settings in the US. Representing a substantial portion of the installed EHR systems in the US, the association provides a forum for the EHR community to speak with a unified voice relative to standards development, the EHR certification process, interoperability, performance and quality measures, and other EHR issues as they become subject to increasing government, insurance and provider driven initiatives and requests. Membership is open to HIMSS corporate members with legally formed companies designing, developing and marketing their own commercially available EHRs with installations in the US. The association, comprised of more than 40 member companies, is a partner of the Healthcare Information and Management Systems Society (HIMSS) and operates as an organizational unit within HIMSS. For more information, visit <http://www.himsssehra.org>.