



**American Hospital
Association**

Liberty Place, Suite 700
325 Seventh Street, NW
Washington, DC 20004-2802
(202) 638-1100 Phone
www.aha.org

May 18, 2005

Mark Leavitt, MD, Ph.D.
Chair, Certification Commission on Health Information Technology
Medical Director, HIMSS
230 East Ohio Street, Suite 500
Chicago, IL 60611-3269

Dear Dr. Leavitt:

On behalf of the American Hospital Association's (AHA) 4,700 member hospitals and health care systems and our 31,000 individual members, the AHA appreciates this opportunity to comment on the Certification Commission for Health Information Technology (CCHIT) Phase I Deliverables.

Certification of health information technology (IT) products promises to increase the confidence of buyers in the market while providing guidance to vendors on the functions and standards to build into their products. Policymakers may also require certification of products funded with public monies. If successful, certification will undoubtedly help accelerate the pace of IT adoption. For years, America's hospitals have called for improved standardization of IT products; CCHIT's work is an important step toward that goal.

The work of the CCHIT has begun with certification of electronic health records (EHRs) for ambulatory settings, with an emphasis on physician offices. However, two of the areas covered by the report – interoperability and security and reliability – are relevant to IT products used in all health care settings. In addition, the discussion of the certification process will set the stage for certification of other IT products in the future. The AHA will focus its comments on those areas. We would also suggest two other topics for consideration. First, assessing a products' ease of use. Second, differentiating between EHRs used in physician offices and those used in hospitals or other institutional settings. For example, how would CCHIT classify IT systems that are developed in a hospital, but then shared with community physicians?

Interoperability

The interoperability work group provided a helpful compilation of current standards. It is clear from the review that in some cases multiple standards are available, while in others there are



very few. In no case, however, is there a consensus on the standards to use. In addition, the standards that exist are not supported by analysis of the clinical and business transactions that occur and the level of detail needed to operationalize standards.

For example, we agree that laboratory results should use a common vocabulary, but we do not know the costs of acquiring and maintaining the vocabulary standards, the ease of using them, and the extent to which they can stay current with changing medical developments and findings. Similarly, for imaging, while Digital Imaging and Communications in Medicine (DICOM) appears to be the standard of choice, there are no business rules governing the exchange of digital images. In other areas, such as medications, immunizations, and clinical documentation, there is less agreement on vocabulary and messaging standards, or even the definition of the concept. We need greater understanding of the business routines that define how clinical documents are used by a given provider, from provider to provider, provider to patient, and provider to health plan. What information is transferred? Who provides it? Who captures it? For what subsequent use?

Interoperability is key to realizing the promise of EHRs. The AHA shares the vision of interconnected health care and will be a partner in the effort to harmonize standards and make them operational. However, CCHIT will not be able to certify products as inter-operable before the health care community has gone through a collaborative, public-private effort to reach agreement on which standards to adopt and how to implement them.

The phase I report lays out many of the important data exchange scenarios, or use cases, that require interoperable systems. Priority areas that were mentioned include receiving and sending orders for laboratory and imaging tests, referring or transferring clinical care, and quality improvement reporting.

On quality improvement, EHRs should be able to calculate quality measures based on clinical data to facilitate the quality improvement and reporting efforts that providers choose to undertake. In addition to physician measures, CCHIT should certify that EHR products can, at a minimum, generate the quality measures based on clinical data that are part of widely-used national initiatives on accreditation and quality reporting, such as the Hospital Quality Alliance and the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO). These measure sets evolve over time, so the certification criteria will need to be revised regularly to reflect changes in the measures.

CCHIT could require that EHRs calculate all measures approved by the National Quality Forum (NQF) for certification. While AHA strongly believes that the NQF consensus process is valuable, there are a couple of reasons why NQF endorsement may not be the right criterion. First, not all measures that have been endorsed by the NQF may actually be used in broad-based data collections. For example, some of the measures in the hospital measures set are insufficiently specified for hospitals or electronic health record vendors to know exactly what data elements need to be collected. Unless these specifications are developed, it would be impossible for vendors of EHRs to know if their systems could correctly collect the desired data.

Second, some influential organizations are asking for quality measures that have not yet been endorsed by NQF. For example, the JCAHO will invite hospitals to submit data on quality in intensive care units this summer, but those measures are not yet endorsed by NQF. The Ambulatory Care Quality Alliance has recommended a set of 26 measures for assessing quality in the ambulatory setting, but those measures have not yet been through the NQF consensus process. Yet, clearly, physicians' ability to submit these data will be greatly enhanced if EHRs can retrieve it easily. We urge the CCHIT to engage in a process that will lead to the identification of a parsimonious list of key national quality measurement efforts for which EHRs must be able to collect data to have certification.

We recommend adding transfer of information on patient responsibilities for copayments and deductibles as a use case under administrative and financial data. Both providers and patients would benefit from having this information available from payers in real time, so that patients know their liabilities and providers can bill appropriately.

Security and reliability

The draft report outlines basic security and reliability standards that are important for all applications. While the first certification effort is for ambulatory EHRs, CCHIT is laying the groundwork for other applications as well. We believe the Health Insurance Portability and Accountability Act (HIPAA) of 1996 security standards are sufficient. Providers have invested considerable resources in planning for and complying with those standards. We agree strongly with the statement that EHRs "must support HIPAA compliance for the provider in a transparent manner with the least intrusive impact on clinical operations" (line 369).

Certification process

The certification process workgroup outlined a sensible structure for reviewing and testing IT products for certification. To be useful to buyers, certification must be transparent and objective. For this reason, we appreciate the discussion of the kind of testing needed (line 87). The workgroup identified a spectrum of options, ranging from independent testing in a controlled lab to self-reporting by vendors with independent verification. For certification to increase buyers' confidence in EHRs, the testing process must be credible and independent. We suggest rejecting any approach that includes self-testing.

We agree with the workgroup's discussion of the need to disseminate certification results (line 59). All of the cited methods of dissemination are valuable (Web site, trade press, professional associations, etc.). CCHIT should ensure that when it publicizes results, it also adequately describes the certification process and the meaning of certification. The work group proposes to publish only positive results to ensure vendor involvement (line 71). However, buyers would also benefit from knowing which applications are in the process of being certified, particularly as certification begins.

The work group sought feedback on how to update certification criteria (line 74). This process will be important, particularly in the short term, as the health care community progresses toward

Mark Leavitt, MD, Ph.D.

May 18, 2005

Page 4

standards development and harmonization, quality and safety measures evolve, and products develop. For the buyer, updating of certification standards must be balanced against the costs of upgrading. IT investments are large and complex and require considerable training; upgrading can be difficult. For these reasons, compatibility with a vendor's older systems should also be considered in the certification process.

We thank CCHIT for its hard work. If you need further information, please contact Chantal Worzala, senior associate director for policy, at 202-626-2319.

Sincerely,

Carmela Coyle
Senior Vice President

cc: CCHIT Commissioners