

EHR Seal of Approval: CCHIT Introduces Product Certification to Spur EHR Adoption

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Next month the first certified EHR products will appear on the market. A critical piece of the EHR adoption puzzle is falling into place.

This summer, physician practices, clinics, and other providers of outpatient services will get much-needed help in shopping for electronic health record (EHR) products. Beginning in June they can look for a seal of approval on EHR box tops as the first certified products for ambulatory care appear on the market. This initial certification represents the first step in an initiative to develop baseline standards for commercial EHR products, for both ambulatory and inpatient settings.

Certification is a much-anticipated piece of the EHR adoption puzzle. A successful certification process has the potential to open the flow of health IT incentives and reduce the risk for purchasers, because certified products will meet basic functionality, interoperability, and security criteria. For providers currently inundated with products difficult to compare and assess, certification promises assurance that a product is robust enough to deliver the anticipated benefits of an EHR.

Behind the seal is the Certification Commission for Healthcare Information Technology (CCHIT), a voluntary, collaborative, private-sector initiative that has become the recognized authority for EHR certification in the US.

Providers: Waiting for Someone Else to Go First

Health IT is still in its relative infancy, and the task of developing, implementing, and certifying widely accepted and verified product standards sometimes seems insurmountable. However, other technologies began in similar circumstances and have gone on to success. Videocassette recorders, personal computers, and wireless computer networking all went through a period of competing formats and multiple standards. Like the health IT market now, these technologies in their early stages were characterized by wide variations in product quality and functionality, large numbers of vendors with small fragments of market share, proprietary data formats that were incompatible with each other, and low levels of technology adoption engendered by general confusion on the part of buyers.

That is an apt description of today's EHR marketplace, with more than 200 vendor offerings, proprietary data structures, and considerable confusion and hesitancy among potential buyers. With the notable exception of DICOM standards-based imaging systems in radiology, there is practically no plug-and-play interoperability between health IT systems. Most data exchange requires costly development or fine-tuning for each installation. The lack of certified products and the diversity of available products require a commitment on the part of early adopters to be immersed in and highly knowledgeable of the technology they are using. This accounts for the low market penetration of technology in an early-stage technology marketplace. The large share of providers are waiting for someone else to go first.

Physicians are one group understandably frustrated and confused. They are often considered the critical adopters in the ultimate success of EHRs and health information exchange, yet in the current market they are finding it difficult to judge product suitability, quality, interoperability, and data portability.

For this reason, the industry has come to recognize the need for baseline standards on EHR products. Certification was one of the key needs cited in the 2004 landmark report "The Decade of Health Information Technology," released by David Brailer, MD, PhD, national coordinator for health IT. In the report Brailer called for private sector certification of health IT product to "develop minimal products standards for EHR functionality, interoperability and security."

Properly implemented, certification delivers benefits to healthcare providers, patients, and technology vendors. In every one of the nonhealthcare examples cited above, adoption grew rapidly once standards and certification (or some alternate means of ensuring standards compliance) emerged. There is every reason to believe health IT will follow this pattern and that, once certification is enacted, physicians and providers will have confidence they are purchasing qualified products, resulting in the acceleration of health IT adoption. Increased adoption will in turn lead to increased patient safety and the improved delivery of care.

Spurring Adoption through Certification

CCHIT's mission is to accelerate the adoption of health IT throughout the US healthcare system by creating an efficient, credible, sustainable mechanism for certification for EHRs. Certification seeks to:

- Reduce the risk of health IT investment by providers
- Ensure interoperability of health IT products with emerging health information infrastructures
- Enhance the availability of health IT adoption incentives from public and private purchasers and payers
- Protect the privacy of patients' personal health information

Certified EHR products benefit many groups and individuals, including:

- Physicians, hospitals, health systems, safety-net providers, public health agencies, and other purchasers of health IT products, who seek quality, interoperability, data portability, and security
- Purchasers and payers, both in the government and the private sector, who are prepared to offer financial incentives for health IT adoption but need assurance that products are capable of delivering expected benefits
- Quality improvement organizations that seek an efficient means of measuring that criteria have been assessed and met
- Standards development and informatics experts that gain consensus on standards
- Vendors, who benefit from having to meet a single set of criteria and from having a voice in the process
- Ultimately, and most important, consumers, who will benefit from a reliable, accurate, and secure record of their health
- CCHIT works in an open forum, communicating the progress of its work and seeking input from these groups. CCHIT also works cooperatively with standards development organizations (SDOs), which develop voluntary local or national consensus on standards for particular domains, such as healthcare, or subdomains, such as pharmacy, medical devices, or imaging. While SDOs set standards, independent third parties such as CCHIT are responsible for measuring and determining fulfillment of those standards, providing a certification of compliance.

CCHIT is working to gain consensus on certification criteria and testing processes related to the industry standards produced by healthcare SDOs. Certification is a mechanism for enhancing the confidence and orderliness of the health IT marketplace. The inspection and testing process performed when certifying health IT products must be based on agreed-upon standards, as well as unbiased inspection and testing. (For more on CCHIT's organization, see "A Short History: CCHIT's Origin and Organization," below.)

A Short History: CCHIT's Origin and Organization

Three health IT industry associations launched CCHIT. The American Health Information Management Association, the Health Information and Management Systems Society, and the National Alliance for Health Information Technology joined forces in July 2004 to establish a voluntary, private-sector initiative to certify health IT products. The three associations committed resources to support the commission during its organizational phase.

In 2005 additional funding support was provided by the American Academy of Family Physicians, the American Academy of Pediatrics, the American College of Physicians, the California HealthCare Foundation, Hospital Corporation of America, McKesson, Sutter Health, United Health Foundation, and WellPoint, Inc.

In September 2005 CCHIT was awarded a three-year, \$7.5 million contract from the Department of Health and Human Services (HHS) to develop and evaluate certification criteria and an inspection process for EHRs in three areas--ambulatory care, inpatient care, and the network components through which they interoperate. An optional

\$1.2 million extension to continue refinement and assessment of the processes during a fourth year will be up for consideration as the base period is completed. Under the contract HHS charged CCHIT to become an independent, self-sustaining certification agency.

CCHIT is governed by a 19-member board of commissioners from academic, private sector, and governmental agencies. The board oversees the work of CCHIT's professional staff and volunteer work groups. The commissioners represent stakeholders, provide strategic direction, ensure objectivity and credibility, provide guidance to and review the reports of the work groups, and approve the final certification criteria and processes.

The commission is made up of at least two representatives each from the provider, payer, and vendor stakeholder groups, and at least one from seven other stakeholder groups, including safety-net providers, healthcare consumers, public health agencies, quality improvement organizations, clinical researchers, standards development and informatics experts, and government agencies. Commissioners serve staggered two-year terms. Nominations are open in the summer.

Commission products are created by volunteer work groups, each with two cochairs from different stakeholder groups and approximately 14 to 16 members representing the diversity of stakeholders. Public calls for work group volunteers occur annually. The work groups focus on developing criteria--including health IT product functionality, interoperability, and security--and an inspection process by which products can be judged to be certified.

The commission and its work groups strive for transparency, communicating work status frequently. Minutes of all meetings are published on CCHIT's Web site at www.cchit.org. Work products are published for public comment after each step. All comments are reviewed, and the responses are published.

Ambulatory Criteria and a Map for the Road Ahead

CCHIT has focused its first efforts on ambulatory EHR products for physician offices and clinics because this is where most Americans get their care. (The timeline for CCHIT's forthcoming work through 2008 is shown [below](#).) Volunteer technical work groups, facilitated by staff, established product criteria in the following areas:

- Functionality--setting features and functions to meet an initial set of requirements
- Interoperability--enabling standards-based data exchange with other sources of healthcare information
- Security and reliability--ensuring data privacy and robustness to prevent data loss

There are more than 300 criteria in the initial, 2006 ambulatory certification. The majority occur in functionality. The criteria represent what the commission believes to be the bar for a basic, comprehensive EHR. For example, functionality criteria include managing a problem list, a medication list, an allergy list, and a patient history. Creating prescriptions, checking for drug interactions, and documenting medication and immunization administration are required, as are alerts for disease management, prevention, and wellness. Interoperability criteria are expected to increase over time, keeping pace with the work of the Healthcare Information Technology Standards Panel, the HHS standards harmonization contractor whose work is also under way. For 2006, that will include basic laboratory data interchange and e-prescribing criteria.

A certification process work group developed the process by which vendors will apply for certification. It also determined how testing for compliance will be handled and how the database of certified products will be maintained and publicized. In February a test pilot program verified the process certification. Six vendors volunteered for the test, representing enterprise, mid-range, and small vendor market segments.

CCHIT works in a dynamic health IT environment, collaborating within HHS and with the American Health Information Community. Many standards are just gaining consensus, while standards for interoperability are at an earlier stage of development. Moving forward, CCHIT will develop initial certification criteria that evolve considerably, along with the standards, from year to year. Certification criteria are expected to grow in depth and range as the industry matures. CCHIT plans to provide guidance to the industry by developing a road map for certification in coming years, offering SDOs a timeline to work against as well as providing vendors a guide for their own development plans.

CCHIT's work--including the ambulatory certification criteria, the road map, and applications for certification--is available online at www.cchit.org. A database of certified products will be available once the first certifications are announced beginning in June.

A Look at the Calendar through 2008

The scope of CCHIT's work under the HHS contract will progress through three phases spanning three years. An optional fourth year for continued refinement and assessment of the processes will be up for consideration as the base period is completed. Certification of ambulatory products (phase I) is currently under way. The certification program was launched in April, with product certifications expected in June.

- Phase I: October 2005 to September 2006
Develop, pilot test, and assess certification of EHR products for ambulatory care settings
- Phase II: October 2006 to September 2007
Develop, pilot test, and assess certification of EHR products for inpatient care settings
- Phase III: October 2007 to September 2008
Develop, pilot test, and assess certification of infrastructure or network components through which EHRs interoperate v

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