



**Certification Commission
for Healthcare
Information Technology**

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An Introduction to Health IT Certification

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Wanted: a mechanism to speed up health IT adoption

For any national plan to succeed in using information technology to make healthcare better, cheaper and faster, its first challenge is to get the technology adopted where most healthcare happens: in the offices of the nation's physicians. This is one big challenge, and the barriers to adoption are many. Doctors are apt to ask penetrating questions about electronic health records (EHRs), the key unit of a health IT infrastructure, and they need to be confident and comfortable about the answers before they'll commit to the serious financial investment an EHR requires. Among them:

- I'm a physician, not a software expert. What should I be looking for? Are there certain functions and features that I just have to be certain are included?
- Out of a couple hundred EHRs on the market, which ones have these critical functions and features? How can I be sure?
- Will the EHR product I invest in remain at the leading edge of innovation and expectations over the next five, 10 or even 20 years?
- How can I be sure that the sensitive information I enter in the EHR is secure from unauthorized prying and can be disclosed selectively to me, my staff and medical colleagues who assist me?
- As EHRs become more common, will mine be able to communicate and exchange information with others according to whatever the state of technology innovation is at a given time?
- As governments and insurance companies increase their demands for my practice to adhere to quality guidelines in order to get paid, will my EHR be up to the task of helping me do it right?

Since 2004, the Certification Commission for Healthcare Information Technology (CCHIT®) has led efforts to address these questions and build consensus and acceptance for an assertive yet reasonable pace of requiring features, functions and future innovation in EHR products. Those that meet 100% of these requirements receive a seal that certifies they have demonstrated all of them in a rigorous live test.

The Commission is a nonprofit, 501(c)3 organization with the sole public mission of accelerating the adoption of robust, interoperable health IT. Since 2005 it has been successfully executing a contract from the Department of Health and Human Services (HHS) to develop certification programs for electronic health records and health information exchanges. CCHIT was recognized by HHS as a certifying body in 2006, and remains the only organization of its type to have received federal approval.

Since its first cycle of certification in 2006 for EHRs designed for use in physician offices and clinics, the Commission and its volunteer work groups of medical and technical experts in healthcare have established a minimum set of criteria for certification, raised the bar each year, and set both near-term and longer-range targets for EHR developers to start working on if they want to be recertified in years to come.

The scope of certification now also encompasses EHRs for use in hospitals, in emergency rooms, and by organizations managing health information exchange beyond the bounds of a single healthcare enterprise. They are all part of the emerging healthcare IT infrastructure, but this discussion centers on

office-based, or ambulatory, EHRs because of their longer certification track record and their central role in the IT plan.

What CCHIT demands of EHRs

Let's be explicit about the benefits to medical care and what's at stake in encouraging IT adoption. EHRs, properly designed and used, can transform the process in many ways: records are instantly accessible, incoming information is immediately figured in, and diagnoses and other treatment decisions are made with a fuller knowledge of what's ailing the patient and what to do about it. EHRs reduce wasted movement, duplication, dictation-transcribing and other inefficiencies. Data collected from many EHRs constitute the raw material of insightful observations and otherwise unattainable intelligence about the sickness and health of large groups of people and what's succeeding or failing in efforts to deliver care more effectively.

To deliver on those prospects, as well as address the concerns of physician buyers as expressed above, any EHR on the market must be organized to accomplish a set of objectives and be held to them by an objective and trusted advocate for the physician community. These objectives are categorized around:

- **Functionality**—the ability to create and manage electronic records for all of a physician practice's patients, as well as automate the flow of work in the office.
- **Interoperability**—the ability to receive and send electronic data between an EHR and outside sources of information such as labs, pharmacies, and other EHRs in physician offices and hospitals.
- **Security**—the ability to keep patient information safe and private.

The certification criteria furnish a consensus baseline for these main aspects of an EHR. Certified products must demonstrate to trained, objective jurors all of the capabilities called for by the criteria. That said, the criteria development and testing process builds in a number of checks and balances to position certification requirements so they advance the progress of EHR capabilities while being careful not to require IT vendors to do the impossible. This give and take has improved with experience and relies on three interdependent considerations:

- The advance of software innovations and nationally recognized standards for healthcare data creation, storage and exchange.
- The capacity of EHR vendors to incorporate innovations and standards into their development cycles and adequately test the resulting products before release to new or currently supported customers.
- Timing.

The process for building a continually solid basis for EHRs, especially in the area of interoperability, takes a healthy appreciation for how to schedule progressively higher levels of sophistication at the optimum pace and in the most logical sequence. The phased approach and tactical timeline for

incorporating new standards that enable interoperability are addressed in more detail later in this discussion.

The certification process for ambulatory EHRs is maturing in the area of required functionality. Now in its fourth cycle of developing, refining and testing criteria, certification efforts are focused on judicious refinement to keep the basic requirements of EHRs up to date for the benefit of healthcare professionals while avoiding unnecessary additions that could drive up the cost of systems.

Summarizing the scope of functionality

Much of the criteria for ambulatory EHR functionality have to do with managing information and activities at the heart of a physician practice's interaction with its patients. These criteria can be summarized into:

Organizing patient data – demographics, clinical documentation and notes, medical history

Compiling lists – problems, medication, allergies, adverse reactions

Receiving information – test results, consents, authorizations, clinical documents from outside the practice

Creating orders – ordering medication or diagnostic tests; managing order sets, orders, referrals; generating and recording patient-specific instructions

Supporting decisions – presenting alerts and reminders for disease management, preventive services, wellness; checking for drug interactions and guiding appropriate responses; supporting standard care plans, guidelines and protocols; updating decision support guidelines

Authorized sharing – managing practitioner/patient relations, enforcing confidentiality, enabling concurrent use among multiple practitioners and healthcare personnel

Managing workflow – assigning and routing clinical tasks, managing the taking of medication and immunizations, communicating with a pharmacy

Administrative and billing support – using rules to assist with financial and administrative coding; verifying eligibility and determining insurance coverage

Starting in the current 08 certification cycle, which began in July 2008 and continues through June 2009, the Commission began offering optional additional certifications to designate special capabilities in ambulatory EHRs to improve care for children, and for heart patients. This promotes development of EHR innovation in areas of more specialized patient care without requiring all EHR vendors to incur the costs and time of including functions not typically necessary for general primary care. But EHRs that go to those extra lengths can be recognized for it, and doctors serving children or heart patients will know exactly what those extra features are.

Building national priorities into EHRs

A significant portion of the functionality criteria are devoted to establishing in EHRs the ability to support clinical decisions using patient-specific information, supply guidelines for providing recommended care, and make medication prescribing and ordering safer and more efficient. These capabilities serve several national initiatives: to reorient medicine around illness prevention and chronic-disease management; to switch doctors from scribbling on prescription pads to electronically prescribing directly to pharmacies; to pay doctors based on adherence to clinical standards of care and outcomes; and to reduce the incidence of medication errors and consequent harm to patients.

Following are descriptions of specific decision support capabilities that an EHR must demonstrate. For the current 08 certification cycle, the EHR must be able to:

- Provide access to a standard care plan, protocols and guideline documents when requested during a clinical encounter between doctor and patient; create a site-specific care plan as well as modify such documents from outside sources.
- Identify criteria for disease management, wellness and preventive services based on factors such as age and gender and clinical data such as listed problems, current medications and results of lab tests; display alerts based on established guidelines; issue reminders for these services in the patient record; modify the criteria that trigger the reminders; and update the guidelines and associated references.
- Modify parameters of guideline-based alerts, including individualizing alerts based on a patient's specific clinical situation; override the guidelines and provide a reason for it.
- Identify preventive services, tests or counseling due on a patient, and document that preventive or disease management services have been performed; produce a list of patients overdue for such services, and then notify the provider as well as generate letters to remind patients.
- Export predefined sets of data out of the system, such as performance measures and tools for chronic-disease management.
- Export structured data with identifying information removed, while leaving the actual personal health information intact in the original record (follows HIPAA privacy requirements).
- Check for potential interactions between a medication about to be prescribed and the medication allergies and intolerances listed in the record; alert the computer user to the interactions; and be able to set the level of severity at which warnings are displayed.
- Provide alerts at time of ordering about potential interactions among drugs on a patient's current medication list, between a prescribed medication and current medications, or in relation to a drug's possible effects on a disease (within the limitations of current databases).
- Provide the ability to view the rationale for an interaction alert, maintain at least one reason for overriding it, and provide the ability to prescribe the medication despite the alert.

In the coming 09 certification cycle, draft criteria include the ability of a clinician to enter a structured response when overriding a warning about interactions between a drug and allergy or one drug with another drug. This provides enhanced opportunities to sift through collected data for trends and other types of analysis.

The path of progress for interoperability

All electronically represented information enables improved access by clinicians. But the value multiplies as data becomes more structured, standardized and readily exchangeable among different information systems, bringing a new level of integration to our currently fragmented healthcare process. These are the building blocks of interoperability, and the Commission is methodically building interoperability into certified EHRs.

One benefit of this phased introduction of interoperability tools is the spreading of standard data-generation and exchange coding into the commercial marketplace through the application of nationally recognized standards identified by the Healthcare Information Technology Standards Panel (HITSP). Current and planned requirements for lab, pharmacy and EHR-to-EHR transactions are built on HITSP foundations.

Certified EHRs in the current 08 cycle are required to receive and store lab results, differentiate between a preliminary and final result, process a corrected result, and include information on test accuracy, enabled by the use of standard coding called LOINC as stipulated by HITSP in its EHR Lab Reporting Interoperability Specification (v2.1, 2007). In the 09 cycle, the number of codes from the voluminous LOINC set are doubled, raising the bar for EHRs and putting more codes into practice to improve lab data.

EHR exchanges with labs are useful to physician practices but relatively uncomplicated when compared with swapping patient information among various EHR systems. The reliable exchange of clinical documents requires the use of standardized modes of transport and retrieval in order to both move whole documents and for systems to be able to take in and use the information in those documents.

Before any data element can be shared between EHRs, for example, there has to be a technical standard for creating it, a common way of “saying” it, and a uniform and secure method of transporting it from one place to another. The Commission and its work group on interoperability have planned out a logical sequence of requirements, recognizing that construction of standard data elements comes first and that requiring interoperability makes sense only after EHRs can generate standard elements to share and process.

The set of HITSP specifications for representing summaries of information on patients is contained in the Continuity of Care Document (CCD), also known as HITSP C32. The vehicle for transporting subsets of the CCD among care settings is called Cross Enterprise Document Sharing (XDS), part of the HITSP Transaction Package.

With that in mind, the incorporation of interoperability building blocks into certification criteria is under way:

- In 08, an EHR must be able to receive and display standard CCD documents using subsets of the standard for registration summaries, medication and immunization history, and be able to file them intact in the record.
- Also in 08, an EHR must be able to generate and format standard CCD documents using subsets of the standard for registration summaries, medication and immunization history.
- In 09, requirements for use of structured vocabularies/terminologies are added to both of the above.
- Also in 09, an EHR must perform several activities that demonstrate it can send documents using XDS transactions, plus be able to support either of two standard approaches for coordinating patient identification between an EHR and another system. This marks the first true interoperability testing, validating the actual transfer of standard information between EHRs rather than the demonstrated capability to do so.

For various technical reasons, it's easier to develop a capability to send information out than to take information in. The next degree of difficulty is to enable an EHR to do something with the information it receives. Plans for the 10 cycle are to further require EHRs to use the XDS transactions to receive discrete elements of coded data. This is the point at which information from other points of origin can be used as needed in the receiving EHR—for example, selectively importing medications and adding them to the patient's list of medications, or updating demographic information.

Assuring a secure information environment

To be trusted by physicians and patients alike, EHRs must incorporate state-of-the-art technical standards and techniques for assuring that the personal health information created and shared by healthcare professionals is securely maintained and kept confidential. The provision of such security is a core aspect of certification dating to the first certified EHRs in the 06 cycle, and currently there are more than 40 security criteria related to:

- Access controls based on user role or the context of a care situation.
- Authenticating users before allowing access to protected health information.
- Auditing the access and use of records according to certain rules or events.
- Supporting protection of confidentiality.

Access control is important to regulate the balance between using patient information for its intended purpose—enabling clinicians to make fully-informed decisions about diagnosis and treatment—and restricting people without a specific need to know from seeing information. Audit trails allow monitoring for instances of unauthorized viewing, copying or diverting as a backup to access controls.

These highly technical and sophisticated functions were criticized in some healthcare quarters as too burdensome several years ago, but all certified EHRs are now able to perform these functions. In 08, the criteria for certification include:

- Ability for authorized administrators to assign restrictions or privileges to users/groups.
- Ability to enforce the most restrictive set of rights/privileges or access needed by users/groups (system administration, clerical, nurse, doctor, etc.).
- Ability to associate permissions with a user according to controls that are based on type of user (individual access rights), role (access rights for groups of users) or context (roles combined with circumstances or settings, such as time of day, location, emergency situation etc.).
- Ability to remove a user's privileges without deleting the user from the system (to preserve a history).
- Ability to detect security-relevant events that it mediates and generate audit records.
- Prohibiting access to the audit records to all except those explicitly granted authority to read them.

In 09, an EHR will have to support logging in to a common audit engine using a standard for audit log specifications, which is intended to support interoperability.

In support of confidentiality, an EHR in 08 must use strong encryption methods and protocols when delivering all protected health information over the Internet or other known open networks. An EHR also must be able to identify certain information as confidential and make only that information accessible to authorized users. In 09, an EHR must be able to block specified individuals from accessing a chart (for example, someone with a personal relationship with the patient), but allow an exception for access in emergency situations (dubbed “breaking the glass”) and then provide the ability to audit such overrides.

An acknowledged impact on adoption

By building interoperability and security into EHRs, and reducing the risk that physicians and other providers face when investing in health IT for their facilities, the certification process is having its intended impact on healthcare. The Commission’s highly open, transparent process during every phase of certification development, and its unbiased and consistent approach to inspection, has earned the trust of stakeholders across the industry. Every major physician professional organization endorses and supports the Commission’s work. Certified products represent more than 75% of the marketplace. Market research has shown that certification has created a competitive playing field that encourages new entrants.

The open, transparent process of determining requirements for certification is driven by balanced, multi-stakeholder participation in criteria and inspection process development, and decision-making, beginning at the top. The 21-member board of commissioners includes at least two representatives each from the provider, payer and vendor stakeholder groups, as well as representatives from such other areas as quality improvement, medical informatics, health information exchanges and public health agencies. Work groups for ambulatory functionality, interoperability, security and privacy are similarly balanced. All development work is subject to several periods of public comment, response and refinement. The result is an authoritative and consensus-based approach to moving health IT forward.

Recently, as the importance of health IT is more widely recognized, many new initiatives have emerged to stimulate the uptake of this technology. The majority have relied on Commission certification to qualify eligible health IT. These range from Federal Programs, such as the Medicare EHR Demonstration, to more than 20 State programs and another 25 private initiatives. In addition, nearly 60 medical centers have announced projects to supply EHRs to doctors under the exception and safe harbor of the Stark and Medicare anti-kickback laws, keyed to certification. Even several physician liability insurers are offering premium discounts for successful implementation of certified electronic records. In total, over \$700 million in health IT incentives have been launched – but that remains a small amount relative to the task that the nation faces in accelerating the adoption of robust health IT.

With trusted health IT certification already in place, healthcare policymakers need not be concerned with the details of how to qualify health IT products and can focus instead on designing policies and incentives to further encourage adoption, bringing the benefits of a 21st century healthcare system to all Americans.

For additional information, visit www.cchit.org, <http://ehrdecisions.com>, or contact Sue Reber, sreber@cchit.org, or 503.703.0813.