Taking the Measure of Inpatient EHRs: Hospitals Inch Closer to Certified Products

by Jane Metzger; Emily Welebob, RN; Mark Del Beccaro, MD; and Cindy Spurr, RN, BC

Certification of inpatient EHR products begins this year with an initial focus on orders and medication management.

Increasing the adoption of health IT such as electronic health records (EHRs) has been a major focus of improving healthcare quality and efficiency ever since the Institute of Medicine released its 1999 report on hospital patient deaths due to medication errors. At the federal level, the US Department of Health and Human Services has been working on many levels to increase IT adoption.

One effort is to promote adoption by encouraging private-sector certification of health IT products. Certification has been targeted as a way to:

- Reduce the risks for purchasers facing an evolving marketplace with numerous vendors offering products with varying levels of functionality
- Facilitate the interoperability of IT products as needed to support safe and reliable care
- Make it easier for employers, payers, and others to provide incentives for adopting IT by designating products with the minimum necessary capabilities
- Ensure that products have the capabilities needed to ensure the privacy of personal health information

The private-sector certification body that undertook the work is the Certification Commission for Healthcare Information Technology (CCHIT[SM], see sidebar [below]). The independent, nonprofit organization began work in 2004, announcing the first certified ambulatory EHR products in 2006.

To date, nearly 90 ambulatory products carry CCHIT certification. Application and testing are ongoing. This year the commission is working to finalize the certification process for inpatient EHRs, with announcement of the first certified products expected in the fall of 2007.

CCHIT Background

In July 2004, at the urging of the national coordinator for health IT, three industry associations—the American Health Information Management Association, the Healthcare Information and Management Systems Society, and the National Alliance for Health Information Technology—joined forces to launch CCHIT. They committed resources to support it during start-up beginning in September 2004.

In September 2005 CCHIT received one of four contracts from the US Department of Health and Human Services to support the development of a nationwide health information network. The three-year contract calls for CCHIT to develop certification criteria and an inspection process for health IT products in three areas:

- Ambulatory EHRs for office-based physicians
- Inpatient EHRs for hospitals
- The network components through which EHRs interoperate and share information

CCHIT is governed by a board of commissioners and a board of trustees with wide industry representation. Volunteer work groups and expert panels develop the certification criteria and testing processes.

An Initial Focus on Orders and Medication Management

Certifying the inpatient EHR presented some new challenges. Whereas ambulatory EHRs are largely free-standing and implemented all at once, hospitals typically implement their EHRs in stages, adding individual applications or groupings of applications over a period of years. It is challenging to draw boundaries for certification because clinical applications do not function in isolation, they require ancillary, administrative, and financial applications to send and receive patient data. In addition, vendors organize the multiple applications providing clinical support in many different ways, adding to the certification challenge.

Given this wide scope and complexity, CCHIT decided to focus certification initially on applications that support orders and medication management:

- Electronic medication administration record (eMAR)
- Clinician electronic order writing (often associated with computerized physician order entry—CPOE)
- Clinical decision support for ordering and medication administration
- Medication reconciliation, as performed in hospitals

The commission felt that this focus allows inpatient certification to offer the greatest immediate contribution for three reasons.

First, these modules have the greatest potential to facilitate major improvements in patient safety and quality. They also address areas of low adoption. Many hospitals have purchased and implemented basic applications that incrementally build the inpatient EHR, but few have made final purchase decisions and implemented advanced applications such as CPOE and eMAR. Recent estimates place CPOE adoption, for example, in the range of 4 to 10 percent of US hospitals.

Finally, these functions are in need of standardization and interoperability. Hospitals struggle to achieve closed-loop medication management, which involves processes that cut across departments and often across separate applications in the hospital. Medication reconciliation to reduce gaps in care that occur during hand-offs from one site or level of care to another requires information from outside the hospital at admission and communication at discharge. In both instances, certification could make an important contribution in advancing interoperability.

A survey of major stakeholder groups and industry leaders confirmed the importance of this initial focus. The figure opposite depicts the scope in terms of the processes that it covers.

The Inpatient Criteria and Road Map

As with ambulatory EHR product certification, inpatient EHR certification covers the following areas:

- Functionality—the ability to create and manage electronic records for all patients, as well as automate the workflow in the health system
- Interoperability—the ability to receive and send electronic data to other internal systems such as pharmacy and external systems for purposes of medication reconciliation
- Security and reliability—the ability to keep patient data private and secure

CCHIT work groups have developed both the certification criteria and the road maps that introduce the criteria over a three-year period. The work began in the spring of 2006, with two subsequent versions released for public comment.

As of this writing, the functionality road map includes more than 200 criteria in 18 categories. Fewer than 100 criteria are identified for certification in 2007. In a number of areas, criteria overlap with those for the ambulatory EHR.

Over the three years of the road map, criteria for some functions become more stringent. Interoperability testing in 2007, for example, will require demonstration that orders can be transmitted to a pharmacy system for processing, but testing in future years will require compliance with recognized terminology and messaging standards.

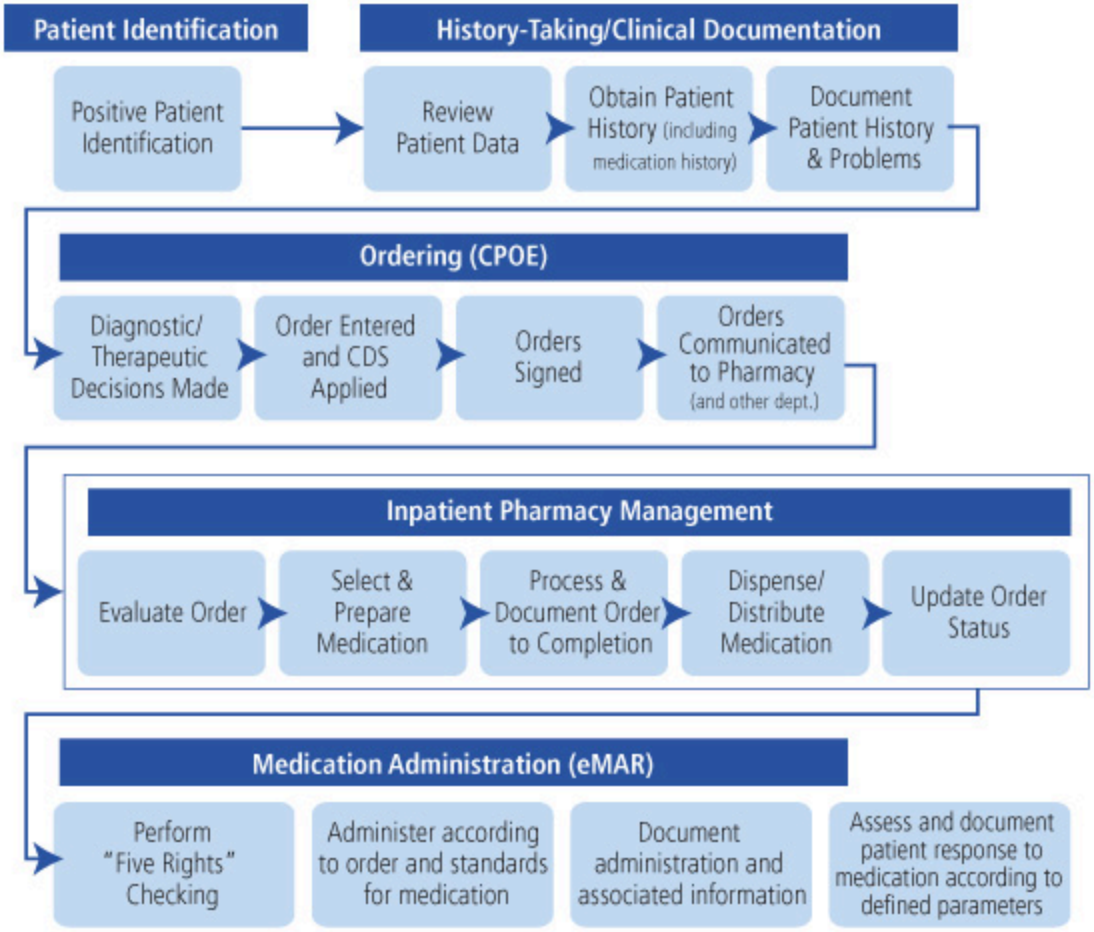
CCHIT is not a standards-setting body and will rely upon the work of the Healthcare Information Technology Standards Panel and others to recommend, test, and develop implementation guidance for standards to be incorporated into certification.

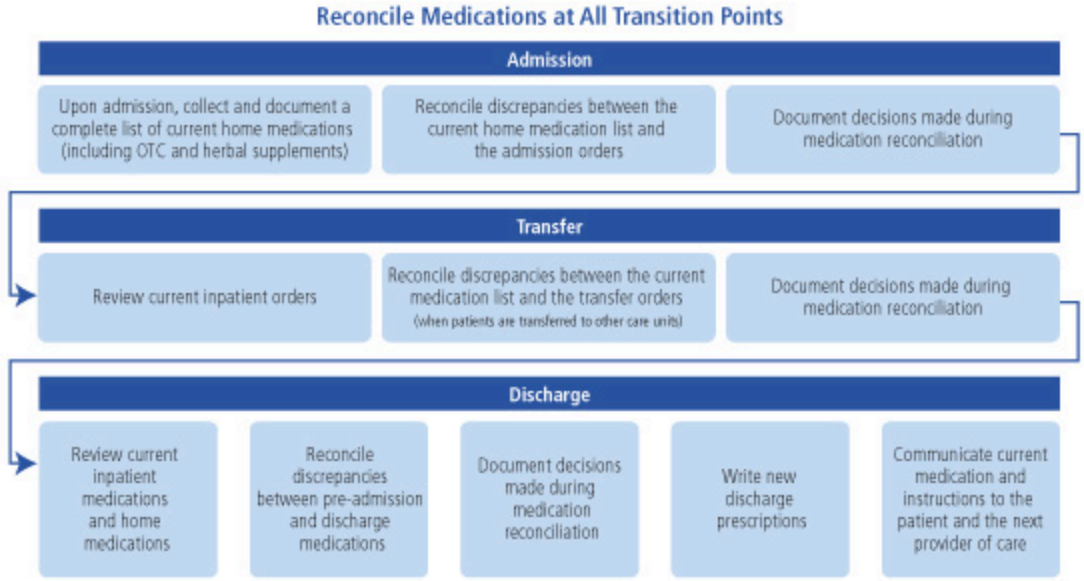
Functionality specifically designed for medication reconciliation, advanced clinical decision support such as drug-diagnosis contraindication checking, and maintenance of the inpatient medical problem list, which are not widely available in vendor products today, are slated for later years in the road map.

Medication Processes in the Initial Focus

Inpatient product certification will initially focus on orders and medication management. The first figure shows the processes covered in clinician electronic order writing and medication administration workflow. The second figure shows the processes in medication reconciliation.

Inpatient pharmacy management functionality is not in the scope for 2007 certification. Criteria include both universal and specific aspects of records management, such as auditing and reporting.





Criteria for Records Management

Of particular interest to HIM professionals are the criteria for health record management. Although the scope of initial certification is limited to the three processes described above, criteria include both universal and specific aspects of records management that apply to these processes.

For example, criteria address the ability to view the audit trail of entries and updates to medical problems and allergies (e.g., user, date, and time), as well as orders and each entry in the eMAR. In addition, certified systems must produce hard copies of medical record elements related to orders and medication administration, as well as permit viewing for past admissions.

Certification addresses security by requiring proper access control, authentication, audit trail and technical services, such as encryption. The Security Work Group develops criteria based on existing standards and best practices, including national standards such as ASTM and NIST SP 800-53 and international standards such as ISO 15408 Common Criteria and ISO 17799 Security Standard.

Some of these requirements include back-ups and recovery, confidentiality of personal health information over the Internet, and integrity of clinical information. For more focus on specific requirements for privacy, CCHIT will add a privacy expert panel during 2007.

CCHIT Volunteering a Natural Fit for HIM Professional

Shirley Eichenwald-Maki, RHIA, FAHIMA, shies away from the HIM ordinary. Although she has been in the field for nearly 40 years, the former HIM department manager turned college professor stays fresh and sharp by getting involved with the latest in technology developments.

One of the best ways to do that is through professional volunteering, she says. “Being involved in those volunteer roles is a way that you stay current, challenged, interested, that you keep your edge,” she says. “That to me is critical for a long-term career.” For Eichenwald-Maki, volunteering with CCHIT was a natural fit for an HIM professional.

Keeping Current through Volunteering

Eichenwald-Maki’s day job is working as an assistant professor at College of St. Scholastica, based in Duluth, MN. Last year, she applied to join the CCHIT Certification Process Advisory Working Group, one of several CCHIT volunteer groups. The group formulates and suggests suitable processes, methods, and procedures that CCHIT should use to accept and evaluate vendor applicants during the product certification process. Four vendors, two HIM professionals, four doctors, five CIOs, one attorney, and one payer serve on the group.

From her working group, which usually met virtually, Eichenwald-Maki also had access to review various other CCHIT working groups’ activities. She paid close attention to the Inpatient EHR Functionality Work Group, which developed the criteria that will be used to certify inpatient EHR systems.

This group was particularly interesting to Eichenwald-Maki because of her interest in EHRs. She was instrumental in an EHR project at the College of St. Scholastica called ATHENS, which implemented a fully functional EHR for academic use. Eichenwald-Maki wrote the federal grant proposal that won $2 million for the EHR installation, and for the last five years she has been operating and teaching with the system.

“I have such great respect for what goes into developing the EHR system,” she says. “I’ve seen what makes one function well, but I can also tell when one doesn’t function well.” She knows the value of strong functional EHR criteria that help healthcare providers select and evaluate EHR systems, she says.

Taking the Criteria from Paper to Practice

Eichenwald-Maki’s interest in the inpatient work group was more than just passive curiosity. With a live inpatient EHR back at her college, Eichenwald-Maki could now compare the CCHIT requirements against her own system and see how it measured up. Other HIM professionals can do this as well, she says, taking the CCHIT specifications off paper and putting them into practice. The criteria also help HIM professionals and their organizations choose new EHR products by eliminating the strain of designing testing criteria themselves.

HIM professionals should be interested in CCHIT’s work because the commission plays a leading role in identifying EHR functionality that will have a major impact on an HIM professional’s work. “HIM professionals and patient records

information systems are like one. No matter what media those patient record systems are in, they are integral to who we are," Eichenwald-Maki says. "Records are our core. So I am always phenomenally distressed and bewildered whenever people say, 'Why would an HIM professional be interested in electronic health records systems.'"

EHR functionality directly affects the quality of the data HIM professionals manage as well as their ability to report that data back internally to other departments and externally to agencies and organizations. CCHIT volunteers help ensure systems meet core functional requirements. "We want to make sure [EHR systems] function well, collect data well, create a legal record," Eichenwald-Maki says. "To do that, we need to be there during its development."

HIM Insights to Contribute

She encourages HIM professionals to volunteer with CCHIT and otherwise get involved. Although the application deadline has passed for the 2007 working groups, CCHIT encourages interested HIM volunteers to check the Web site for updates at www.cchit.org and apply for future sessions. HIM professionals can also watch the site for opportunities to comment on proposed criteria drafted by the work groups. Public comment plays an important role in drafting criteria.

Leaping into a volunteer industry working group can be intimidating. But the butterflies soon disappear for HIM professionals once they realize how their expertise lends to EHR discussions, Eichenwald-Maki says.

Her CCHIT experience has shown her that "you learn your experience and background is valuable, and what you have to contribute is going to be respected. It is just one of those things that I think makes you a better long-term professional."

—Editors

The Test Strategy and Certification Process

The complexity of inpatient products requires two test configurations. Some vendors offer a suite of software products that addresses the full scope of initial certification, others a subset. To provide a level playing field, CCHIT will offer two configurations based on medication administration.

The first test configuration is for a comprehensive product that covers electronic order writing, medication administration, and medication reconciliation. The second is for electronic medication administration. For either configuration, a vendor seeking certification will identify the software applications in its product suite needed to support the certified functions as defined in the test.

Certification testing must ensure that products are able to accomplish the necessary functional integration between their CPOE, eMAR, and related applications and certain external modules or applications. This will require that modules and applications external to those being certified, such as pharmacy, be involved in testing, although the external modules and applications themselves will not be certified.

CCHIT intends to focus testing of data flows on pharmacy and medication reconciliation because these are the most difficult to accomplish today and both are critical to improving medication safety. Consistent with this focus, in 2007 functional integration of all data flows (except to and from pharmacy) will be simulated.

Inpatient EHR certification will employ the same approach to testing as that used in ambulatory EHR certification to date. The inspection process uses a combination of documentation review and attestation and jury-observed demonstration. These occur in a sequence guided by test scripts that incorporate the conformance criteria for functionality, interoperability, and security derived from the road map for the current year.

Test scripts, which depict typical clinical scenarios, are in final testing. They include both pediatric and adult patients to ensure that the needs for both are covered.

As with ambulatory certification, vendors will register with CCHIT to apply for certification, providing the requested data and self-attestation, identifying which test configuration they require, and pay for the testing service. Actual testing is accomplished during one day, with jurors observing a Web-based run-through of the test scripts.

CCHIT will begin accepting applications for inpatient EHR certification in August 2007.

The Certification Development Process

As with ambulatory EHR certification, determining inpatient EHR certification has been a methodical multistep process that allowed for public comment every step of the way.

1. **Environmental scan** (2006). The process began with a scan of the current state and availability of key requirements and functionality for inpatient EHRs. Key stakeholders were surveyed on inpatient functionality issues and priorities. They were also asked to provide additional supporting materials in the form of policy statements, standards, white papers, and position papers.
2. **Criteria development** (2006). Certification criteria were developed based on findings of the environmental scan. The process included determining which criteria would be required in 2007 testing and which would be included on the road map for testing in 2008 and 2009. It also included determining the criteria that would not be certified in the immediate future. This step was again followed by public comment.
3. **Test script development** (2007). Scripts were created by determining the inspection method and test scenarios, followed by public comment.
4. **Pilot test** (2007). Volunteers will be asked to participate in a pilot test to validate the test process and scripts. The latter will be refined based on findings.
5. **Criteria and scripts finalization** (2007). Pilot results will be revealed (vendors will remain anonymous), and final criteria and scripts will be proposed, followed by a public comment period.
6. **Certification** (August 2007). Certification applications will be accepted, and the initial round of certification testing will begin in the fall of 2007.

What's Next?

The third component of CCHIT's original contract calls for the commission to offer certification of the network components through which EHRs interoperate. CCHIT will launch that effort soon.

In late 2006 the US Department of Health and Human Services authorized and funded further work to begin addressing certification for specific populations, specialized care settings, and medical specialties. In March 2007, after significant assessment and comment by the healthcare community, the commission approved a road map for this expansion.

The first population-based requirements will address capabilities needed for safe, quality healthcare for children. The first new care setting addressed will be the emergency department. The first professional specialty area examined will be cardiovascular medicine. Work begins this summer, with launch dates to be determined once exploratory work is complete.

The finalized inpatient certification criteria are publicly available and organizations can put them to work now. Organizations planning system selection prior to the announcement of the first certified inpatient products can use the criteria to help evaluate products. The criteria are also helpful to organizations that are evaluating older inpatient systems or system components they already have in place.

Detailed and up-to-date information on CCHIT certification is available at www.cchit.org.

Certification Criteria for Functionality

Certification criteria for inpatient EHR product cover the following functionality categories:

- Patient demographics and administrative information
- Provider information
- Patient list management
- Problem lists*

- Allergy information
- Medication list
- Results access and view
- General ordering requirements
- Order sets
- Ordering: medication orders
- Medication reconciliation
- Decision support for medication and immunization orders
- General clinical decision support*
- Medication, immunization, and blood products administration
- Decision support for medication, immunization, and blood products administration
- Clinical task management
- Capture patient-originated data*
- Health record management

*No criteria for 2007 testing

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All members of the Inpatient EHR Functionality Work Group contributed mightily to the work that will result in the launch of inpatient EHR certification. For information on CCHIT, please contact Sue Reber at (sreber@cchit.org).

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