

# Difference Between the EHR Standard and Certification

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*by Donald T. Mon, PhD*

This year promises to be another remarkable year for health IT, particularly for electronic health record (EHR) systems. This month, the Certification Commission for Healthcare Information Technology (CCHIT) will begin certifying ambulatory EHR systems. And by this fall, if everything goes as expected, Health Level Seven (HL7) will determine if the EHR system functional model will be approved as a fully accredited American National Standards Institute (ANSI) standard.

There has been some confusion about the differences between HL7's functional model and CCHIT's ambulatory EHR product certification. Though they work hand in hand and are similar in some respects, they also are quite different in many ways. This article compares and contrasts the two.

## Gold Standard versus Certification

The major difference between the two is their purpose. HL7's functional model serves as a gold standard, identifying functions that must be contained in an EHR system. It describes what each function should do without significant compromises from market or product influences. A gold standard benefits the healthcare industry by answering the question "what is an EHR system?" That answer provides a stable target for product enhancement over time and a benchmark for evaluating EHR system functionality.

The functional model sets the bar high for EHR systems. Keeping the definition detached from the influence of current product development helps maintain its integrity. But the functional model also makes clear that no product on the market today meets all of its requirements. This acknowledgment sets the appropriate expectations of those purchasing EHR systems and eases the pressure on the vendors developing them.

This is where certification comes into play. Certification bridges this gap between gold standard and current marketplace. It provides a road map so that products can gradually reach the functional model.

An example illustrates how the functional model and certification work hand in hand. The HL7 model requires that an EHR system "identify and maintain a patient record." Multiple conformance criteria describe how a system should do this, including:

- When health information has been mistakenly associated with a patient, the system shall leave, but mark as such, the health information in the record of the patient in which it was mistakenly associated.
- When health information has been mistakenly associated with a patient, the system shall provide the ability to associate it with the correct patient.

From a practice perspective, few will argue that an EHR system must provide a mechanism whereby a clinician can correct such errors, taking health information that has been mistakenly linked to one patient and linking it to the correct patient. However, some systems already on the market do not meet the two criteria above and therefore would not conform entirely to the standard. There is a natural tension in developing a gold standard and wanting EHR systems to conform to it all in one process.

How to resolve this issue? One solution would be to compromise--state the criteria in a way that enables current EHR systems to meet the standard. And one way to do that would be to recommend, not require, conformance (for example, replacing "shall" with "should" in the criteria). But if the standard were to only recommend these criteria, a number of questions arise. How robust, then, is the standard? Does it really define what we want an EHR system to do? Getting back to the original question of the gold standard, is this an EHR system if it only meets this level of functionality?

This compromise would occur for dozens of conformance criteria in the functional model. It is not the best solution in this case. The better solution is to break the process into two separate and distinct pieces: maintain the integrity of the EHR

definition and create a road map for gradually reaching it.

Relationship between HL7 Conformance Criteria and CCHIT Certification Criteria							
HL7 Functional Model Standards				CCHIT Product Certification			
Function ID	Function	Conformance Criteria		Certification Criteria	Certification Year		
		No.	Clause		2006	2007	2008
1.0  1.1	ABC						
		1	Shall	Shall	X		
		2	Should	Shall		X	
		3	Shall	Shall	X		
		4	May	Did not adopt			
		5	Should	Shall		X	
		6	Shall	Shall			X

This example illustrates CCHIT's schedule for adopting HL7's conformance criteria through 2008. Note that the HL7 functional model requires some functions, recommends others, and makes still other functions completely optional. For certification, however, there are no options. To be certified, an EHR system must contain all required functions, thus turning "should" and "may" statements in the HL7 functional model to "shall" statements for certification.

Differences between HL7 Functional Model and CCHIT Product Certification		
Dimension	HL7 Functional Model	CCHIT Product Certification
Purpose	A gold standard that tells stakeholders what functions should be contained in an EHR system.	Providers purchasing certified EHR systems will qualify for pay-for-performance incentives. Certification reduces the risk of acquiring EHR systems and increases the confidence of providers to invest in health IT, thereby accelerating the adoption of robust, interoperable IT.
Is it a standard?	Yes. HL7 is an ANSI-accredited organization that can develop standards. Currently, the functional model is a draft standard for trial use, but it may become an ANSI-accredited standard by year end.	No. CCHIT is not a standards development organization and therefore cannot create a standard. Instead, it draws criteria from a number of standards and certifies against them.
Structure	Three major sections: direct care, supportive, and information infrastructure, which contain approximately 130 functions and more than 800 conformance criteria.	Three major sections: functionality, security and reliability, and interoperability, which contain more than 300 certification criteria. Draws from a number of standards, including the HL7 functional model. CCHIT extracted approximately 35 functions from the functional model for its functionality criteria.
Options within criteria	Across the more than 800 conformance criteria, some criteria are: <ul style="list-style-type: none"> <li>Required (the system shall meet this criterion)</li> <li>Recommended (the system should meet this criterion)</li> <li>Completely optional (the system may meet this criterion; it's acceptable if the system does not meet this criterion)</li> </ul>	All certification criteria are required for a product to be certified.
Is the timeframe specified?	Yes, in general. In the early development of the standard, timeframes and optionality were mixed at the function level in one scoring dimension. Functions were recommended as	Yes, timeframes are given in specific years. Moreover, timeframes are recommended at the criterion level. Each of the more than 300 certification criteria is assigned to one of

	being: <ul style="list-style-type: none"> <li>• Essential now (function should be implemented in systems now or within 18 months)</li> <li>• Essential in the future (function should be implemented in systems after 18 months)</li> <li>• Optional</li> </ul> It is recognized that no EHR system will meet the gold standard on day one.	three years: 2006, 2007, and 2008. Thus, to receive 2006 certification, ambulatory EHR products will need to meet a certain set of criteria. For 2007 certification, products will need to meet the 2006 criteria plus those specified for 2007. Each year, more criteria are added, enabling EHR systems to be enhanced over time.
Method of claiming conformance	Profiles (subsets of the functional model) are developed. Vendors produce a conformance statement documenting where they are compliant with a given profile.	Vendors must submit their EHR products to CCHIT for certification testing. When the product passes the test, it is certified for the year in which it passed.

The HL7 standard and the CCHIT criteria work hand in hand, but they are different items with different purposes.

## Certification: The Road Map

Creating standards is not CCHIT's intention. In fact, since CCHIT is not a standards development organization, it can't create standards. CCHIT's primary initial purpose is to certify ambulatory EHR products. Physicians who use certified EHR systems will be eligible for pay-for-performance incentives from a variety of payers. Pay-for-performance reduces physicians' risk in acquiring health IT and encourages them to purchase EHR systems, thereby accelerating health IT adoption. This is a primary goal of the Office of the National Coordinator for Health Information Technology, which it stated in its initial report "The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care." In general, certification reduces risk for physicians by ensuring that products deliver basic EHR benefits.

Whereas a gold standard must be relatively free from market and product influences, product certification must pay close attention to them. With the product market and quality improvement through the use of EHR systems riding on it, both the certification criteria and process must be laid out in a road map that ensures that the standard is rigorous, yet provides a way for vendors to enhance their products over time so that they can then meet the standard.

CCHIT addresses this point by deriving part of its certification criteria from the HL7 functional model's conformance criteria. It schedules the criteria to be adopted over a three-year period. (See "[Relationship between HL7 Conformance Criteria and CCHIT Certification Criteria](#)".)

The table "[Differences between HL7 Functional Model and CCHIT Product Certification](#)" provides greater detail on other differences between the functional model and product certification.

For more information on CCHIT, see the article "The EHR Seal of Approval" (*J AHIMA*, May 2006). The ambulatory certification process, 2006 criteria, and the road map of criteria through 2008 are available on CCHIT's Web site, [www.cchit.org](http://www.cchit.org).

Information on HL7, the functional model, and conformance criteria is available on the HL7 Web site, [www.hl7.org](http://www.hl7.org).

Further information on the functional model and certification is available in the FORE Library: HIM Body of Knowledge, online at [www.ahima.org](http://www.ahima.org).

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