Difference Between an EHR System Standard and Product Certification

Presented by:
Donald T. Mon, PhD
Vice President, Practice Leadership
American Health Information Management Association

HIMSS Annual Conference
February, 2006
Agenda

- Two Initiatives Coming Together
- Current Status
- Distinction Between Standards and Product Certification
- Next Steps
Two Initiatives Coming Together

- At CMS’s request, HL7 begins development of the EHR standard, with guidance from the Institute of Medicine (IOM), April, 2003
- ONCHIT calls for product certification as a way to accelerate EHR adoption, July, 2004
- The Certification Commission for Health Information Technology (CCHIT) established by 3 organizations (AHIMA, HIMSS, NAHIT), Fall, 2004
- MMA Section 649 legislates ePrescribing and certification mechanisms
Current Status

- HL7 EHR Functional Model approved as a draft standard for trial use (DSTU) in July, 2004
- HL7 preparing to promote the EHR Functional Model as an ANSI accredited standard
- Certification criteria developed within last 12 months
- Now pilot testing certification criteria for ambulatory EHR products
Distinction between Standards and Product Certification
Diffs Between Standards & Certification

- HL7 EHR Functional Model is a gold standard
- Certification has a specific purpose
  - To accelerate EHR adoption
  - Linked to pay for performance
- HL7 is a standards development organization (SDO)
- CCHIT is a public/private collaborative
- Both are open processes
Diffs Between Standards & Certification

- Separating standards and certification avoids conflicts of interest (where a single organization both develops the standard and certifies against it)

- Product certification references standards
  - HL7 Functional Model
  - Common Criteria for security
  - Ontario (Canada) EHR standards
The Certification Commission for Health Information Technology (CCHIT)

CCHIT & HL7 exchanged letters in fall, 2004 seeking collaboration

HL7 EHR TC provided CCHIT Functionality Work Group (FWG) with ambulatory minimum function set & conformance criteria

CCHIT FWG & HL7 EHR TC work iteratively on conformance criteria & use cases
<table>
<thead>
<tr>
<th>Function ID</th>
<th>Function</th>
<th>Conformance Criteria</th>
<th>CCHIT Product Certification</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>No. Clause</td>
<td>Certification Year</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2005</td>
</tr>
<tr>
<td>DC 1.0</td>
<td>1.1 abc</td>
<td>1 ...SHALL...........</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 ...SHOULD...........</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 ...SHALL...........</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>4 ...MAY..............</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>5 ...SHALL...........</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6 ...SHALL...........</td>
<td>X</td>
</tr>
</tbody>
</table>

- **Granularity:** Individual conformance criterion may be certified in a year different from other criteria in the same function.
- **Dependent on essential now vs. future, market availability, & priority for improving quality of care.**
### Example: Managing Allergy List

<table>
<thead>
<tr>
<th>Function</th>
<th>Certification Criteria</th>
<th>Certification Year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1. The system <strong>SHALL</strong> capture and store lists of medications and other agents to which the patient has had an allergic or other adverse reaction.</td>
<td>2006: X, 2007:</td>
</tr>
<tr>
<td></td>
<td>2. The system <strong>SHALL</strong> provide the ability to specify the type of allergic or adverse reaction.</td>
<td>2007: X, 2008:</td>
</tr>
<tr>
<td></td>
<td>3. The system <strong>SHALL</strong> provide the ability to remove an item from the allergy and adverse reaction list.</td>
<td>2006: X, 2007:</td>
</tr>
<tr>
<td></td>
<td>4. The system <strong>SHALL</strong> provide the ability to specify the reason for removing an allergy/allergen from the allergy list.</td>
<td>2008: X, 2007:</td>
</tr>
</tbody>
</table>
Next Steps

- Vote to approve the HL7 EHR Functional Model as an ANSI accredited standard scheduled to occur by July, 2006
- Certification of ambulatory EHR products will begin in Spring, 2006
- Inpatient acute and health information exchange networks to be certified in 2007 & 2008 respectively
Want to Know More?

- Join HL7, review the HL7 web site
  - www.hl7.org/ehr
  - http://www.hl7.org/Special/committees/ehr/ehr.htm
- Subscribe to HL7 EHR SIG List server (HL7 members)
  - http://www.hl7.org/special/committees/list_sub.cfm?list=ehr
- Attend open public sessions (no HL7 membership required)
- Get involved in certification process; visit www.cchit.org

© HL7 2006
This Presentation on Electronic Health Records was Sponsored by:

Xpress Technologies
Medical Informatics Since 1984
Difference Between an EHR System Standard and Product Certification

Q & A