Overview of CCHIT: Organization, Process, and Current Status

Presentation to the Healthcare Information Technology Standards Panel (HITSP)

Mark Leavitt, MD, PhD
Chair, CCHIT
HITSP Panel Meeting – May 4, 2006 – Arlington, VA
Topics

• Background
• Organization
• Scope, Timeline, Processes
• Current Status of Work
• Discussion / Q & A
Background
CCHIT History

- July 2004: Certification of HIT products a key action in HHS Strategic Framework
- Sept 2004: AHIMA, HIMSS, and the Alliance fund and launch CCHIT
- June 2005: Eight additional organizations add $325k funding support
- July 2005: HHS issues Health IT RFPs
- Sept 2005: CCHIT awarded 3 year, $7.5M HHS contract to develop compliance criteria and inspection process for EHRs and the networks through which they interoperate
Mission of CCHIT

To accelerate the adoption of robust, interoperable health IT by creating an efficient, credible and sustainable product certification program.
goals of product certification

• Accelerate adoption by reducing the risks of investing in HIT
• Facilitate interoperability of HIT products within the emerging national health information network
• Enhance availability of HIT adoption incentives and relief of regulatory barriers
• Ensure that HIT products and networks always protect the privacy of personal health information
Stakeholders

Private Sector
- Providers
- Vendors
- Payers/purchasers
- Standards Development Organizations
- Quality Improvement Organizations
- Researchers
- Consumers

Public Sector
- HHS/ONC
- HHS Contractors
- Safety Net Providers
- Public Health
- Federal agencies
  - CMS, VHA, NIST, CDC, DoD, DHS, DoC, NSF, GSA, EPA and others
Guiding Principles

• **Always** protect the privacy of the patient/consumer’s health information
• Need for decisive private-sector action **now**
• Governance must be credible, objective, and collaborative
• Seek input and deliver compelling value for all key stakeholders
• Inspection process must be objective, fair, reliable, repeatable
• Certification must be efficient, timely, and cost-effective
Organization
CCHIT Organization

- CCHIT Staff
- Volunteer

Board of Commissioners
- Chair
- Executive Director
- Certification Development Director
- Operations Oversight Committee
- Business Advisory Committee
- Commercial Certification Process Advisory Work Group
- Supporting Staff and Industry Liaisons

WORK GROUPS

Coordinator
- Ambulatory Functionality (Comprehensive EHR) Criteria & Testing

Coordinator
- Inpatient Functionality (Quality & Safety Focus) Criteria & Testing

Coordinator
- Interoperability (Ambulatory & Inpatient) Criteria & Testing

Coordinator
- Security (Ambulatory & Inpatient) Criteria & Testing
Ensuring Fairness, Transparency, and Credibility

• Structure
  – Commission
    • Open call for participation
    • At least two from provider, payer, and vendor stakeholder groups
    • At least one from each of seven other stakeholder groups
  – Workgroups
    • Open call for participation
    • Two co-chairs from different stakeholder groups
    • Members represent balance and diversity of stakeholders

• Policies and Processes
  • Rigorous conflict of interest disclosure policy
  • Minutes of all meetings published on CCHIT website
  • Work products published for Public Comment after each step
  • All comments reviewed and responses published

• Communication
  • Town Halls – open forum at major conferences
  • Town Calls – teleconferences with Q & A; open to all
  • Specific outreach to stakeholder groups
Scope, Timeline, Processes
Scope of Work
Under HHS Contract

• Phase I (Oct 05 – Sep 06)
  – Develop, pilot test, and assess certification of EHR products for ambulatory care settings

• Phase II (Oct 06 – Sep 07)
  – Develop, pilot test, and assess certification of EHR products for inpatient care settings

• Phase III (Oct 07 – Sep 08)
  – Develop, pilot test, and assess certification of infrastructure or network components through which EHRs interoperate
Timeline of Activities and Deliverables

- **Phase I:** Ambulatory EHR
  - Develop, publish proposed criteria
  - Pilot test and publish report
  - Final comments, begin certification

- **Phase II:** Inpatient EHR
  - Develop, publish proposed criteria
  - Pilot test and publish report
  - Final comments, begin certification

- **Phase III:** Networks
  - Develop, publish proposed criteria
  - Develop, publish proposed inspection process
  - Pilot test & publish report
  - Final comments, begin certification

Each Phase includes at least two cycles of public comment during development plus one cycle after pilot test.

Not shown: criteria for each domain are updated annually after initial development.
Development Process

Step A: Gather Data
- Available Standards Frameworks
- Element X
- Priority as seen by stakeholders
- Availability in the marketplace
- Practicality of certification

Step B: Develop Criteria
- Publish for public comment
- Criteria for May 2006
  - Requirement X
  - Roadmap for 2007-2008
    - 2007
    - 2008
    - Future X
  - Do not certify X

Step C: Develop Inspection Process
- Publish for public comment
- Test Scenarios
- Step-by-Step Test Scripts
  - Step 1
  - Step 2
  - Step 3
  - ...

Element Decision Process

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Development Process

**Step D: Pilot Test**
- Call for Pilot Participation
- Random Selection of Participants within each Market Segment
- Conduct Pilot Tests
- Refine Test Process and Scripts as Needed

**Publish for Comment:**
- Pilot Results
- Final Criteria
- Final Test Process
- Final Test Scripts
- Certification Handbook and Agreement

**Step E: Finalization**
- Respond to New Comments
- Final Adjustments
- Review & Approval by Commission
- Publish Final Version of all Materials

**Launch Certification Program**

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Current Status of Work
Functionality Criteria: Recap of the Development Process and Pilot Test Results

• Criteria are all based on HL7 DSTU for Ambulatory EHR
• Criteria vetted and refined through:
  – Pilot Testing with six different ambulatory EHR products
  – Final cycle of Public Comment (3/2006)
• Of the 264 Criteria:
  – 245 fully validated by Pilot Test and stable since publication in 11/2005
  – 12 revised with minor wording changes
  – 6 classified Provisional
  – 1 was deleted

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## Sample Document: Functionality Criteria

**Final Criteria: FUNCTIONALITY**  
For 2006 Certification of Ambulatory EHRs  
Effective May 1, 2006

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### Criteria Details

The table below outlines the specific criteria for Functionality, along with relevant details such as priorities, availability, and compliance. **Provisional Criteria** are indicated in yellow, and *Roadmap columns* forecast future criteria.

<table>
<thead>
<tr>
<th>Original line # Phase I</th>
<th>WG</th>
<th>Category and Description</th>
<th>Specific Criteria</th>
<th>Source or References</th>
<th>Priorities (L,M,H)</th>
<th>Availability</th>
<th>Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>F</td>
<td>Identify and maintain a patient record: Key identifying information is stored and linked to the patient record. Both static and dynamic data elements will be maintained. A lookup function uses this information to uniquely identify the patient.</td>
<td>1. The system shall create a single patient record for each patient.</td>
<td>DC.1.1.1</td>
<td>L H H H H H H</td>
<td>2006</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2. The system shall associate (store and link) key identifying information (e.g., system ID, medical record number) with each patient record.</td>
<td>DC.1.1.1</td>
<td>H H H H H H</td>
<td>2006</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3. The system shall store more than one identifier for each patient record.</td>
<td>DC.1.1.1</td>
<td>H H M M H H</td>
<td>2006</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4. The system shall use key identifying information to identify (look up) the unique patient record.</td>
<td>DC.1.1.1</td>
<td>H H H H H H</td>
<td>2006</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>5. The system shall provide more than one means of identifying (looking up) a patient.</td>
<td>DC.1.1.1</td>
<td>H H H H H H</td>
<td>2006</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>6. The system shall provide a field which will identify patients as being exempt from reporting functions.</td>
<td>DC.1.1.1</td>
<td>H H H H</td>
<td>2006</td>
<td>X</td>
</tr>
</tbody>
</table>

- **Provisional Criteria** are highlighted in yellow.
- **Roadmap columns** forecast future criteria.

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Interoperability Criteria: Recap of the Development Process

• Challenges
  – Workgroup noted existence of conflicting/competing standards, missing implementation guides, and other gaps

• Criteria were developed and vetted:
  – Proposed Criteria and Roadmap published Nov 2005
  – Final cycle of Public Comment (3/2006)

• Intervening events:
  – ANSI-HITSP launched Oct 2005
  – AHIC Breakthrough Use Cases released March 2006

• Status
  – ePrescribing and Lab Result Receiving criteria originally on Roadmap for Sept 2006 moved to May 2007 Roadmap
  – Interoperability Workgroup tasked with supporting the AHIC Breakthrough Use Cases
  – Also urgent to include eRx and Lab criteria in Nov/Dec 2006 Pilot Test
## Sample Document:
### Interoperability Criteria

<table>
<thead>
<tr>
<th>Line #</th>
<th>WG</th>
<th>Category and Description</th>
<th>Specific Criteria</th>
<th>Source or References</th>
<th>Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I</td>
<td>Laboratory and Imaging</td>
<td>Receive lab results in specified format — self attestation</td>
<td>ELNOS 1.3 or later version</td>
<td>x</td>
</tr>
<tr>
<td>2</td>
<td>I</td>
<td>Laboratory and Imaging</td>
<td>Receive general laboratory results using common vocabulary with inbound interface optionally removed</td>
<td>ENOS 1.3 or later version</td>
<td>x</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>Send orders to lab systems</td>
<td>IL7 V2.5 available, LONC test naming available, Implementation Guide in dev.</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>I</td>
<td>Order and schedule radiology tests</td>
<td>DICOM available, HP Cross-Enterprise Image Information Sharing integration profile (Aug 2005)</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>I</td>
<td>Medications</td>
<td>Transmission of prescriptions</td>
<td>NCPDP SCRIPT 4.2 or later</td>
<td>x</td>
</tr>
<tr>
<td>6</td>
<td></td>
<td>Use a standardized communication of SIG instructions in e-prescribing</td>
<td>Industry SIG Task Group</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>I</td>
<td>Query and receive medication information</td>
<td>NCPDP/RxHub developed*</td>
<td>x</td>
<td></td>
</tr>
</tbody>
</table>

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Security Criteria:
Recap of the Development Process and Pilot Test Results

• Criteria drawn from several different sources of standards
• Criteria vetted and refined through:
  – Pilot Testing with six different ambulatory EHR products
  – Final cycle of Public Comment (3/2006)
• Of the 51 Criteria:
  – 6 criteria had minor revision
  – 1 criterion moved to 2007 roadmap
  – 1 criterion removed as redundant with another
  – 25 defined as Assignable
  – 11 classified as Provisional
Sample Document: Security-Reliability Criteria

Final Criteria: SECURITY & RELIABILITY
For 2006 Certification of Ambulatory EHRs
Effective May 1, 2006
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<table>
<thead>
<tr>
<th>Line #</th>
<th>WG</th>
<th>Category and Description</th>
<th>Specific Criteria</th>
<th>Source or References</th>
<th>Assignable</th>
<th>Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
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<td>28</td>
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<td>29</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R1</td>
<td></td>
<td>Reliability; Backup / Recovery</td>
<td></td>
<td></td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Y</td>
<td></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Y</td>
<td></td>
</tr>
</tbody>
</table>

If “Y” appears in Assignable column, the function can be assigned to an external component.
Test Scripts: Recap of the Development Process

- Case Scenarios developed by Use Case Workgroup; Test Scripts developed, crosswalked and refined in conjunction with Functionality, Interoperability, and Security WGs
- Case Scenarios and Test Scripts vetted and refined through:
  - First cycle of Public Comment (10/2005)
  - Pilot Testing with six different ambulatory EHR products
  - Final cycle of Public Comment (3/2006)
- Any Test Steps not fully validated by the Pilot Test (i.e. pass rate <83%) were revised and/or made Provisional
<table>
<thead>
<tr>
<th>Procedure</th>
<th>Expected Result</th>
<th>Actual Result</th>
<th>Pass/Fail</th>
<th>Criteria and Reference</th>
<th>Comments</th>
</tr>
</thead>
</table>
| 10        | Record reasons for visit:  
  - Vision screening  
  - Hearing screening  
  - Immunization boosters  

  System accepts reasons for visit | System accepts reasons for visit | ❑ Pass ❑ Fail | F 231 The system shall provide the ability to document encounters by one or more of the following means: direct keyboard entry of text, structured data entry utilizing templates, forms, pick lists or macro substitution; dictation with subsequent transcription of voice to text, either manually or via voice recognition system. |          |
| 11        | Review required immunization boosters. (If system has already displayed notification of immunizations due, this step may be omitted.)  

  System displays immunizations due at this visit:  
  - DTaP  
  - IPV  
  - MMR | System displays immunizations due at this visit:  
  - DTaP  
  - IPV  
  - MMR | ❑ Pass ❑ Fail | F 180 The system shall provide the ability to establish criteria for disease management, wellness, and preventive services based on patient demographic data (minimally age and gender).  
  F 181 The system shall display alerts based on established guidelines.  
  F 190 The system shall identify preventive services, tests or counseling that are due on an individual patient.  
  F 192 The system shall provide the ability to identify criteria for disease management, preventive, and wellness services based on patient demographic data (age, gender).  
  F 195 The system shall provide the ability to notify the provider that patients are due or are overdue for disease management, preventive, and wellness services. |          |
| 12        | Retrieve the current immunization record from the EHR.  

  Report is displayed that shows summary of immunizations. Report includes immunization, date given, patient name, identifier and demographic information. | Report is displayed that shows summary of immunizations. Report includes immunization, date given, patient name, identifier and demographic information. | ❑ Pass ❑ Fail | F 217 The system shall provide the ability to generate reports consisting of all or part of an individual patient’s medical record (e.g. patient summary).  
  F 228 The system shall create hardcopy and electronic report summary information (procedures, medications, labs, immunizations, allergies and vital signs).  
  F 9 The system shall provide the ability to include demographic information in reports. |          |
| 13        | Review allergies in chart.  

  Allergy to penicillin indicated. | Allergy to penicillin indicated. | ❑ Pass ❑ Fail | F 38 The system shall capture and store lists of medications and other agents to which the patient has had an allergic or other adverse reaction. |          |
<table>
<thead>
<tr>
<th>Procedure</th>
<th>Expected Result</th>
<th>Actual Result</th>
<th>Pass/Fail</th>
<th>Criteria and Reference</th>
<th>Assignable</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>116</td>
<td>Create one valid clinical user account. This user account will have no administrative rights but will have clinical rights.</td>
<td>User account successfully created as per documentation provided during self-attestation. Appropriate privileges are assigned. If S23 is assigned, see step 181.</td>
<td>Pass/Fail</td>
<td>S23, S3</td>
<td>Y – S23, N – S3</td>
<td></td>
</tr>
<tr>
<td>117</td>
<td>Access the directory of users.</td>
<td>Directory of clinical personnel is as in procedure 114 above, and updated with addition of user created in procedure 116.</td>
<td>Pass/Fail</td>
<td>F213</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>118</td>
<td>Show identifiers required for licensed clinicians to support the practice of medicine.</td>
<td>At a minimum, the system shall maintain the following identifier(s): DEA, NPI, UPIN, etc.</td>
<td>Pass/Fail</td>
<td>F211</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>119</td>
<td>Set password strength rules to require 8 characters minimum.</td>
<td>Password strength rules are set to 8 characters minimum. If S13 is assigned, see step 162.</td>
<td>Pass/Fail</td>
<td>S13</td>
<td>Y</td>
<td></td>
</tr>
</tbody>
</table>

**Provisional Step**

**Assignable Step**
Figure 1: The CCHIT Certification Process
The Jury-Observed Functionality Demonstration

Vendor personnel follow Test Script to demonstrate system at the vendor facility.

CCHIT Proctor

Juror A (Practicing physician)

Web conferencing (gotomeeting.com) and concurrent audio conferencing

Juror B

Juror C
The Security Inspection

Vendor personnel follow Test Script to demonstrate system at the vendor facility

Web conferencing (gotomeeting.com) and concurrent audio conferencing

Juror D (IT/Security Expert) also reviews self-attestation material offline, calls or emails vendor as needed for additional documentation
Failsafe Mechanisms: Retests and Appeals

FUNCTIONALITY INSPECTION

On inspection date: CCHIT Proctor supervises the Jury-Observed Demonstration

Juror votes collated - items declared 'noncompliant' by a majority of the jury are identified

Same-day retest of noncompliant steps on first pass

Passed all items?

NO

Schedule additional test date (fee charged)

Commission review – concur with jury/inspector?

YES

Issue report on noncompliant inspection to Applicant

END

NO

Certification denied – Applicant may reapply

SECURITY INSPECTION

On inspection date: CCHIT Proctor and Security Inspector observe demonstration

Items declared 'noncompliant' are identified

Same-day retest of noncompliant steps on first pass

Passed all items?

NO

Certification granted – Vendor must comply with Maintenance requirements

YES

Verify production use

Issue Certification Document

Add to list of Certified Vendors on CCHIT Website and issue press release on next batch announcement date

SELF ATTESTATION INSPECTION

CCHIT Proctor and Security Inspector review self attestation materials

Items declared 'noncompliant' are identified

Provide clarifications or additional information

Information reviewed and results compiled

LEGEND

= CCHIT Process

= Applicant Process

= CCHIT Decision

= Applicant Decision
Current Status: Recent and Upcoming Events

- **March 27, 2006**: Workgroups for Phase II announced
- **May 1, 2006**: Final Certification Criteria and Inspection Process for Ambulatory EHR products released
- **May 3, 2006**: Certification Program officially launched; applications from vendors being accepted online through May 12
- **Early/Mid-July 2006**: Planned announcement of certified products from first quarterly inspection cycle
Thank You!
Discussion / Q & A

For more information: www.cchit.org