Certification Commission
for Healthcare
Information Technology

Overview and Update: CCHIT Certification of Electronic Health Records

Mark Leavitt, MD, PhD
Chair, CCHIT

Vista Community Leadership Meeting
7 Nov 2006
Plano, TX

Today's Presentation

- Introduction to CCHIT
- Organization, Scope of Work, Timeline
- Certification Criteria
- Certification Program
- Summary
- Q & A

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Introduction to CCHIT

Mission and Milestones

Mission: accelerate the adoption of robust, interoperable health IT

- Reduce the risks of investing in HIT
- Facilitate interoperability of HIT products
- Enhance availability of adoption incentives and regulatory relief
- Ensure that the privacy of personal health information is protected

Milestones:

- **Sept 2004:** AHIMA, HIMSS, and the Alliance partner to launch CCHIT
- **June 2005:** AAFP, AAP, ACP and others add $325k funding support
- **Sept 2005:** CCHIT awarded 3-year, $7.5M HHS development contract
- **May 2006:** Ambulatory EHR Criteria released and approved by AHIC/HHS
- **July 2006:** First CCHIT Certified[sm] Ambulatory EHRs announced
- **Oct 2006:** HHS officially deems CCHIT to be a Recognized Certification Body

CCHIT Role within HHS Health IT Strategy

American Health Information Community
Chaired by HHS Secretary Mike Leavitt
AHIC Workgroups

Office of the National Coordinator
Project Officers

Strategic Direction + Breakthrough Use Cases

Standards Harmonization Contractor

NHIN Prototype Contractors

Privacy/Security Solutions Contractor

Harmonized Standards

Network Architecture

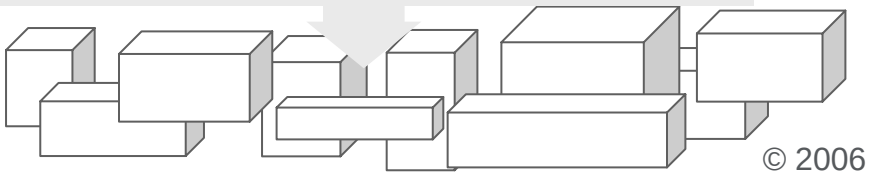
Privacy Policies

CCHIT: Compliance Certification Contractor

Certification Criteria + Inspection Process for EHRs and Networks

Accelerated adoption of robust, interoperable, privacy-enhancing health IT

Governance and Consensus Process Engaging Public and Private Sector Stakeholders



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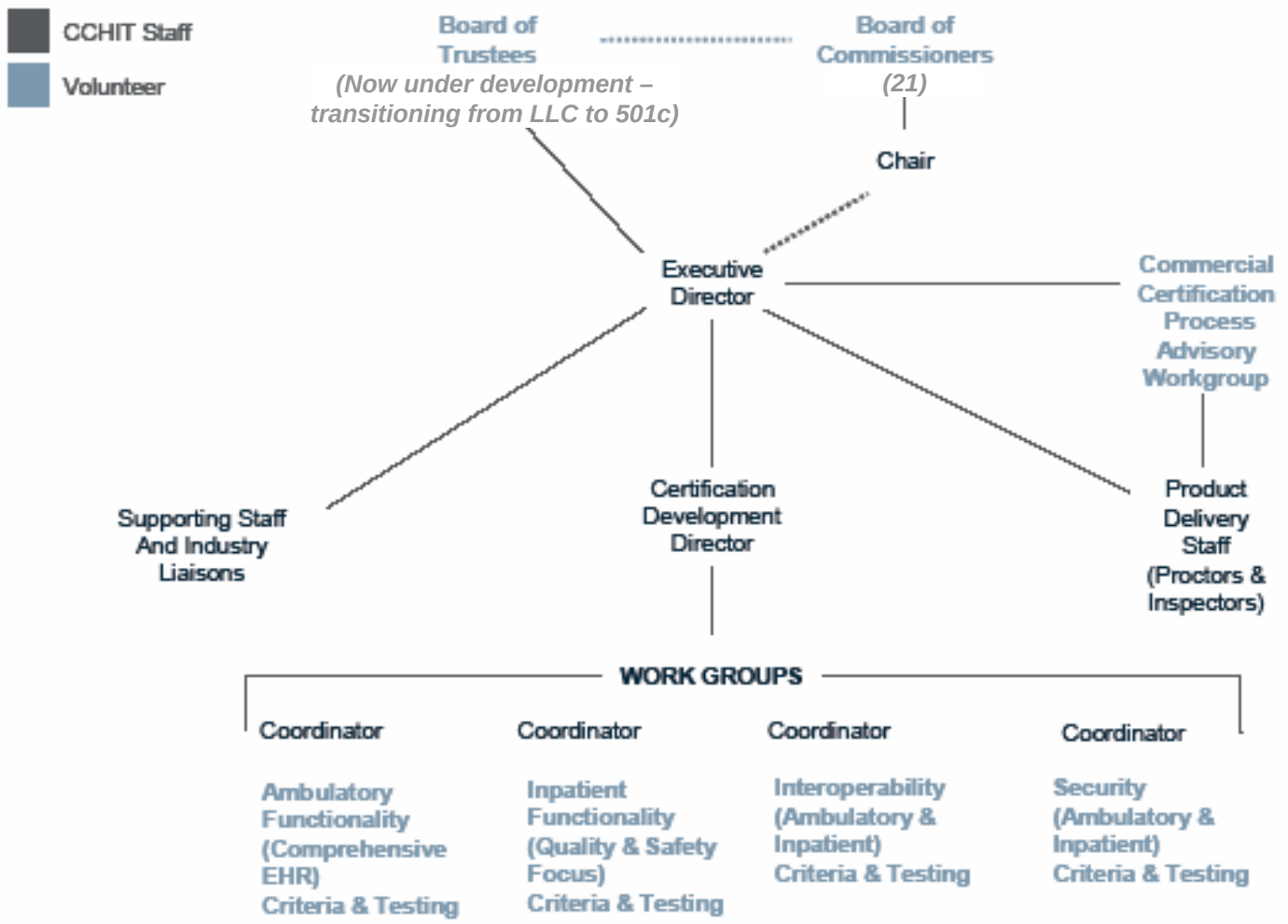
Organization, Scope of Work, Timeline

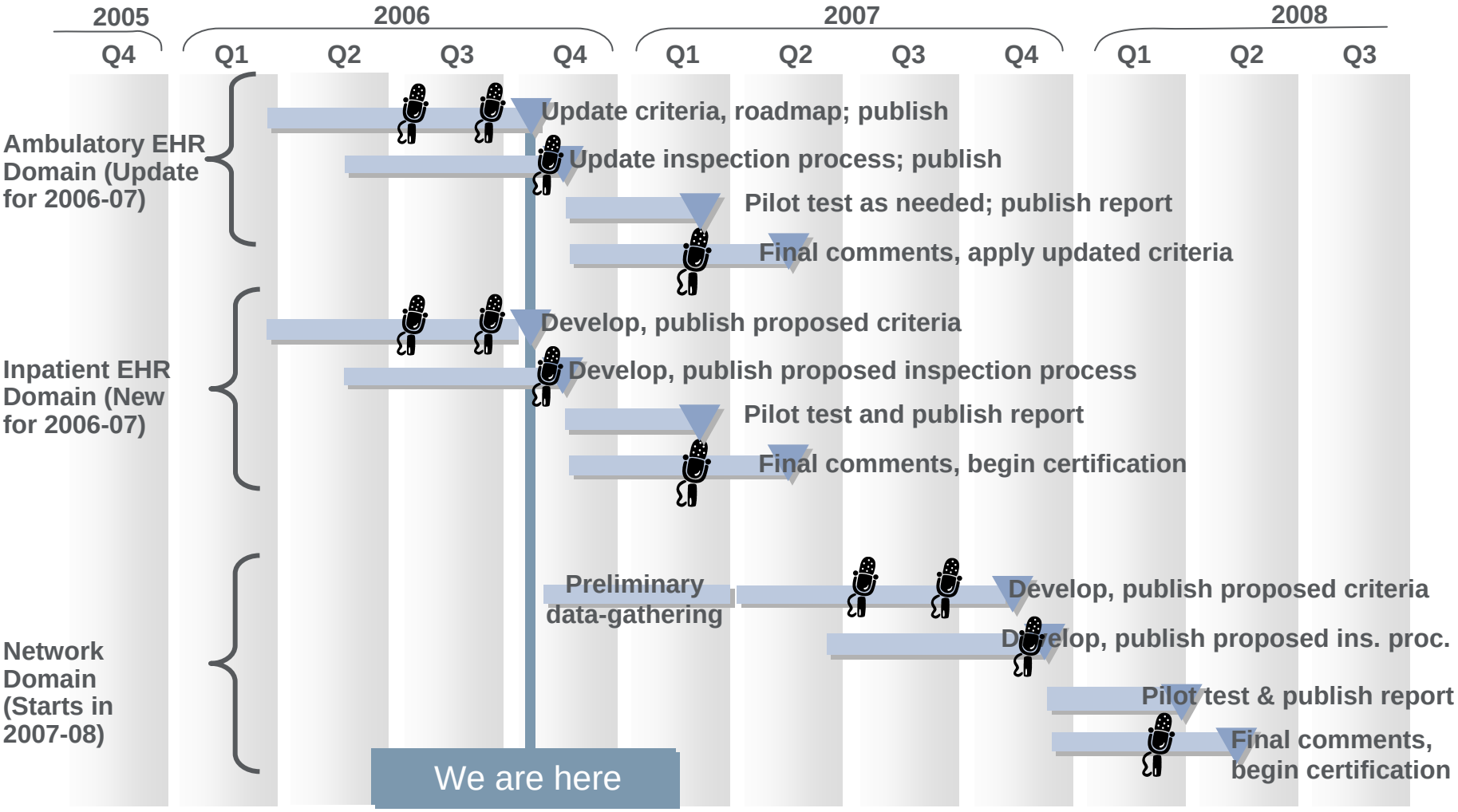
CCHIT Organization



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**
  - **Update ambulatory EHR certification**
- Phase III (Oct 07 – Sep 08)
  - **Develop, pilot test, and assess certification of infrastructure or network components through which EHRs interoperate**
  - **Update ambulatory and inpatient EHR certification**
- Concurrent effort (April 06 – Sep 08)
  - **Transition to become a self-sustaining organization**

Process Timeline for Development of Criteria



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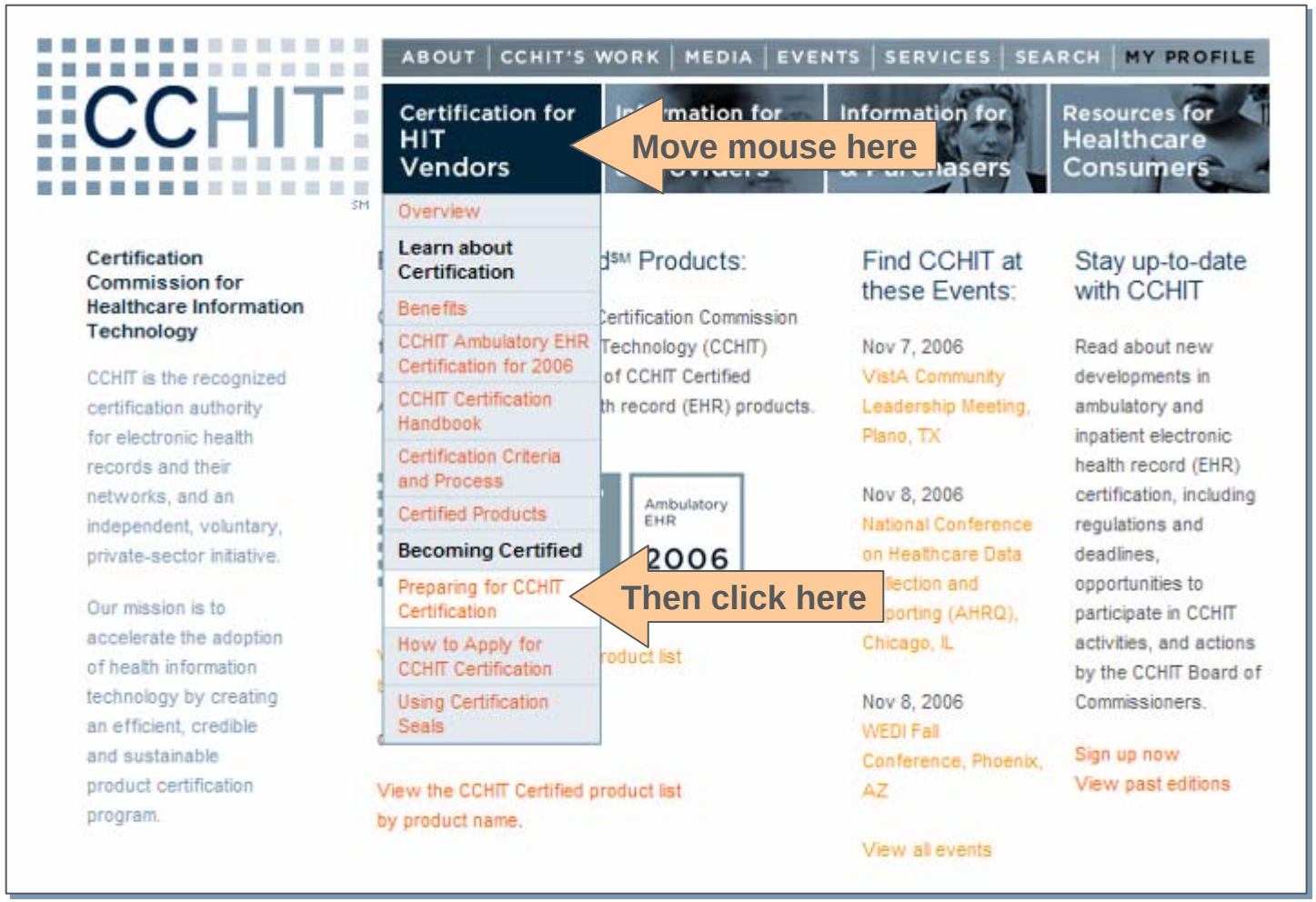
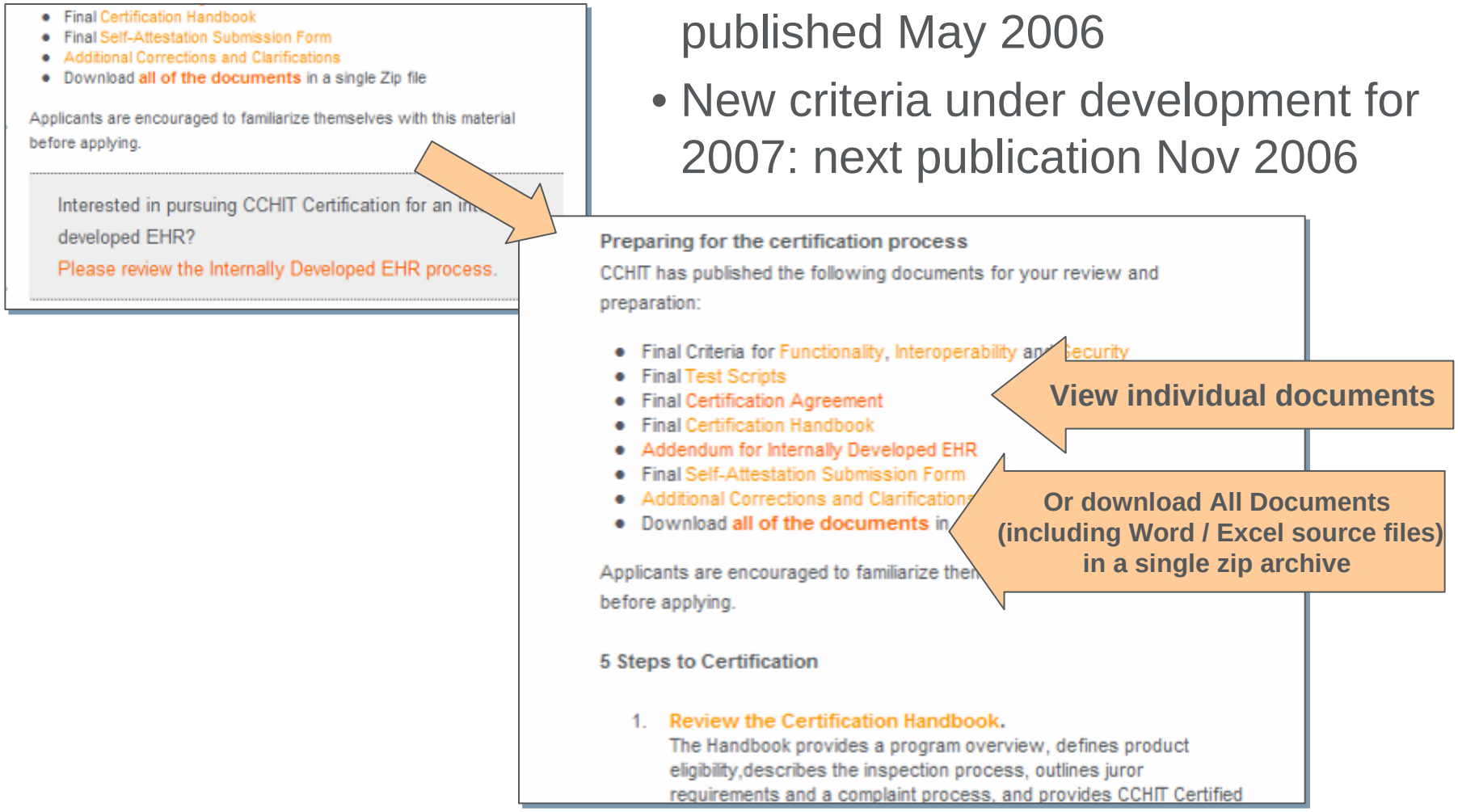
Certification Criteria

Access the Documents at www.cchit.org

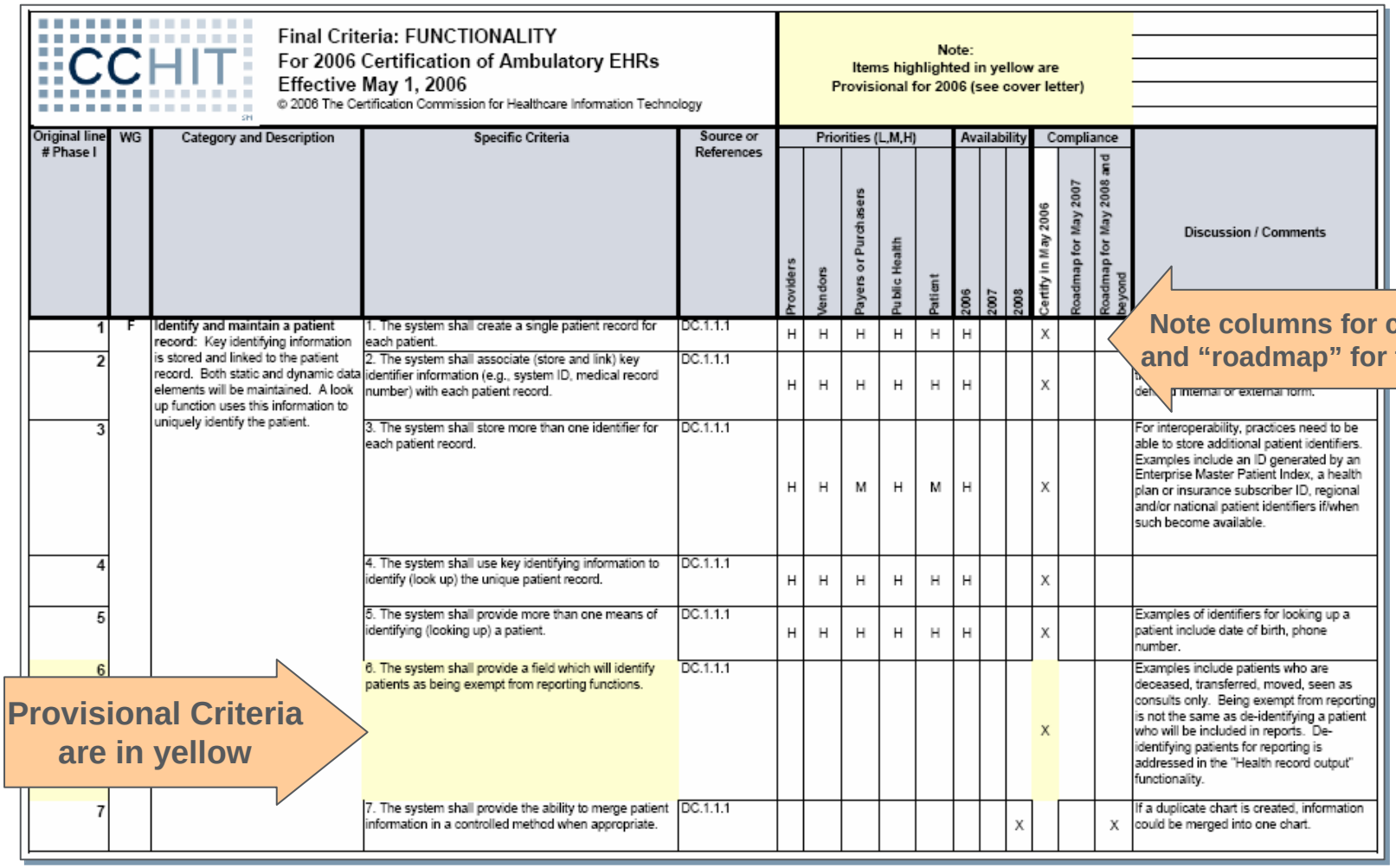


View/Download Documents

- Criteria for 2006 certification: published May 2006
- New criteria under development for 2007: next publication Nov 2006



Sample Document: **Functionality Criteria**



Final Criteria: FUNCTIONALITY
For 2006 Certification of Ambulatory EHRs
Effective May 1, 2006
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Note:
Items highlighted in yellow are
Provisional for 2006 (see cover letter)

Original line # Phase I	WG	Category and Description	Specific Criteria	Source or References	Priorities (L,M,H)					Availability			Compliance			Discussion / Comments
					Providers	Vendors	Payers or Purchasers	Public Health	Patient	2006	2007	2008	Certify in May 2006	Roadmap for May 2007	Roadmap for May 2008 and beyond	
1	F	**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 look up function uses this information to uniquely identify the patient.	1. The system shall create a single patient record for each patient.	DC.1.1.1	H	H	H	H	H	H			X			
2			2. The system shall associate (store and link) key identifier information (e.g., system ID, medical record number) with each patient record.	DC.1.1.1	H	H	H	H	H	H			X			
3			3. The system shall store more than one identifier for each patient record.	DC.1.1.1	H	H	M	H	M	H			X			For interoperability, practices need to be able to store additional patient identifiers. Examples include an ID generated by an Enterprise Master Patient Index, a health plan or insurance subscriber ID, regional and/or national patient identifiers if/when such become available.
4			4. The system shall use key identifying information to identify (look up) the unique patient record.	DC.1.1.1	H	H	H	H	H	H			X			
5			5. The system shall provide more than one means of identifying (looking up) a patient.	DC.1.1.1	H	H	H	H	H	H			X			Examples of identifiers for looking up a patient include date of birth, phone number.
6			6. The system shall provide a field which will identify patients as being exempt from reporting functions.	DC.1.1.1									X			Examples include patients who are deceased, transferred, moved, seen as consults only. Being exempt from reporting is not the same as de-identifying a patient who will be included in reports. De-identifying patients for reporting is addressed in the "Health record output" functionality.
7			7. The system shall provide the ability to merge patient information in a controlled method when appropriate.	DC.1.1.1								X			X	If a duplicate chart is created, information could be merged into one chart.

Note columns for current year and "roadmap" for future years

Provisional Criteria are in yellow

Sample Document: **Security-Reliability Criteria**

Final Criteria: SECURITY & RELIABILITY
For 2006 Certification of Ambulatory EHRs
Effective May 1, 2006
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Note:
Items highlighted in yellow are Provisional for 2006 (see cover letter)

Line #	WG	Category and Description	Specific Criteria	Source or References	Items Assignable* (see below)	Compliance: Certify in May 2006	Compliance: Roadmap for May 2007	Compliance: Roadmap for May 2008 and beyond
S28			The system shall support protection of integrity of all Protected Health Information (PHI) delivered over the Internet or other known open networks via SHA1 hashing and an open protocol such as TLS, SSL, IPSec, XML digital signature, or S/MIME or their successors.	CC SFR: FPT_RCV	Y	X		
S29			The system shall support ensuring the authenticity of remote nodes (mutual node authentication) when communicating Protected Health Information (PHI) over the Internet or other known open networks using open protocol (e.g. TLS, SSL, IPSec, XML sig, S/MIME).	CC SFR: FPT_RCV	Y	X		
R1	SR	Reliability: Backup / Recovery	The system shall generate a backup copy of the application data, security credentials, and log/audit files.	Canadian: Alberta 7.3.16 (Security); CC SFR: FDP_ROL, FPT_RCV; HIPAA: 164.310(d)(1)	Y			
R2			The system restore functionality shall result in a fully operational and secure state. This state shall include the restoration of the application data, security credentials, and log/audit files to their previous state.	Canadian: Alberta 7.3.18.9 (Security); CC SFR: FAU_GEN; SP800-53: AU-2 AUDITABLE EVENTS; HIPAA: 164.310(d)(1)	Y	X		
R3			If the system claims to be available 24x7 then the system	Canadian: Alberta	Y	X		

If "Y" appears in Assignable column, the function can be assigned to an external component

Sample Document: **Interoperability** Criteria

Final Criteria: INTEROPERABILITY
For 2006 Certification of Ambulatory EHRs
Effective May 1, 2006
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Line #	WG	Category and Description	Specific Criteria	Source or References	Compliance: Certify in May 2006	Compliance: Roadmap for May 2007	Compliance: Roadmap for May 2008 and beyond	Comments
1	I	Laboratory and Imaging	Receive lab results (no specified format) – self attestation		x			
2			Receive general laboratory results using common vocabulary with inbound interface optionality removed	ELINCS 1.0 or later version		x		CCHIT will specify the standard, implementation guide and versions that will be required for interoperability certification requirements. CCHIT will align certification with HITSP standards recommentations.
3			Send orders to lab systems	HL7 V2.5 avail. now; LOINC test naming avail now; Implementation Guide in dev.		x		Complete order must be defined (minimum dataset). There is no good definition for a minimum data set for an order message.
4	I		(1) Create and share sets of digital medical images managed by PACS (2) create and share imaging reports like EKGs (3) web	DICOM avail. Now IHE Cross-Enterprise Image Information		x		

Sample Document: **Test Scripts** (Functionality scenario)

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Operational Test Scripts – Version 1.0

	Procedure	Expected Result	Actual Result	Pass/Fail		Criteria and Reference		Comments
10	Record reasons for visit: • Vision screening • Hearing screening • Immunization boosters	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		❑ Pass	❑ Fail	F 180 F 181 F 190 F 192 F 196	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). The system shall display alerts based on established guidelines. The system shall identify preventive services, tests or counseling that are due on an individual patient. The system shall provide the ability to identify criteria for disease management, preventive, and wellness services based on patient demographic data (age, gender). 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.		❑ Pass	❑ Fail	F 217 F 228 F 9	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). The system shall create hardcopy and electronic report summary information (procedures, medications, labs, immunizations, allergies and vital signs). The system shall provide the ability to include demographic information in reports.	
13	Review allergies in chart.	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.	

Sample Document: **Test Scripts** (Security scenario)

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Operational Test Scripts – Version 1.0

	Procedure	Expected Result	Actual Result	Pass/Fail		Criteria and Reference		Assignable	C
116	Create one valid clinical user account. This user account will have no administrative rights but will have clinical rights.	User account successfully created as per documentation provided during self-attestation. Appropriate privileges are assigned. If S23 is assigned, see step 181.		❑ Pass	❑ Fail	S 23 S 3	The system shall include documentation that covers: Method used to create, modify, and remove user accounts. The system must be able to associate permissions with a user using one or more of the following access controls: 1) user-based (access rights assigned to each user); 2) role-based (users are grouped and access rights assigned to these groups); or 3) context-based (role-based with additional access rights assigned or restricted based on the context of the transaction such as time-of-day, workstation-location, emergency-mode, etc.)	Y – S 23 N – S 3	
117	Access the directory of users.	Directory of clinical personnel is as in procedure 114 above, and updated with addition of user created in procedure 116.		❑ Pass	❑ Fail	F 213	The system shall allow authorized users to update the directory.	N	
118	Show identifiers required for licensed clinicians to support the practice of	At a minimum, the system shall maintain a directory of state medical license, DEA, NPI and UPIN number.		❑ Pass	❑ Fail	F 211	The system shall maintain a directory which contains identifiers required for licensed clinicians to support the practice of medicine including at a minimum state medical license, DEA, NPI, and UPIN number.	N	Note – if applicant cannot show this information, they may self-attest to it by providing a table of the directory.
119		Password strength rules are set to 8 characters minimum. If S13 is assigned, see step 182.		❑ Pass	❑ Fail	S 13	When passwords are used, the system shall support password strength rules that allow for minimum number of characters, and inclusion of alpha-numeric complexity.	Y	

Assignable Step for Criteria S23

Provisional Steps are in yellow

Concept of **Provisional** Criteria

- Provisional Criteria are criteria that will be tested for informational or data gathering purposes only in 2006, but that will not be considered in the Applicant's certification results.
  - Applicants will be asked to demonstrate or self attest to these items in 2006.
  - CCHIT will evaluate these steps in 2006, but will not consider the outcome in the Applicant's certification results.
  - CCHIT will gather data from the inspection process to verify that the criteria are appropriately tested and vetted before including them in the 2007 certification program.

Concept of **Assignable** Criteria

- Applicants may “assign” certain required functionality to a third party component
  - Example: security functions handled by the operating system, such as screen inactivity time-out
- For Assignable functions, applicants may indicate they are “assigning” that function
- Applicant must then provide documentation for self-attestation of Assignable functions.

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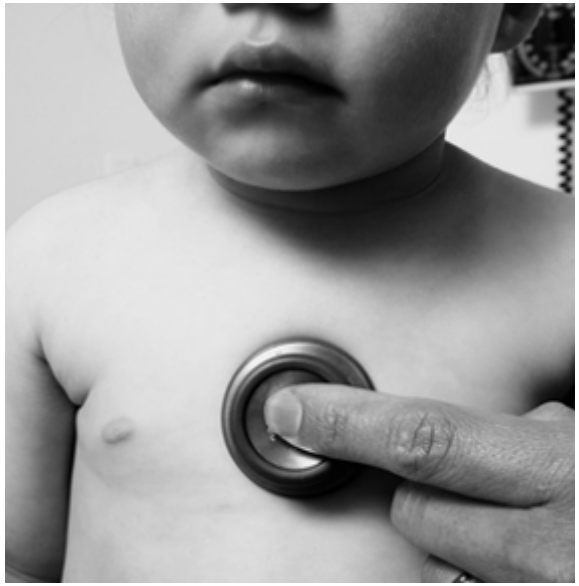
Certification Program



Certification Program

- Vendors review criteria and test process, all published on www.cchit.org :
  - Criteria for Functionality, Interoperability, Security
  - Test Scripts
  - Certification Handbook
  - Certification Agreement
  - Additional Guidance and Clarifications
- Vendors apply, complete documentation requirements, and receive an inspection date
- Multiple fail-safe mechanisms during inspection
- Appeals process is available

Functionality Inspection: Jury-Observed Demonstration

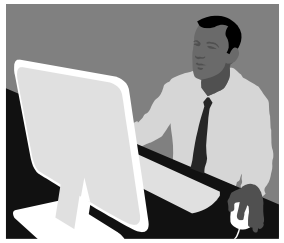
CCHIT Proctor

Juror A (Practicing physician)

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

Web conferencing (gotomeeting.com) and concurrent audio conferencing

Juror B



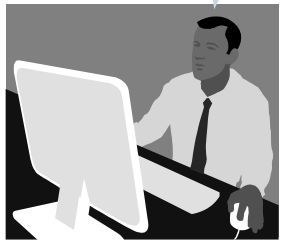
Juror C

Security Inspection: Demonstration + Self-Attestation

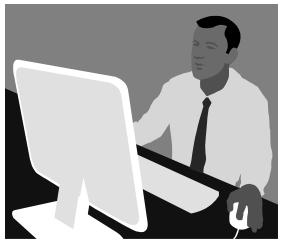
CCHIT Proctor

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)



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

Certification Schedule

Certification Year	Certification Quarter	Application Window	Announcement
2006 Ambulatory EHRs	1st	May 3-12, 2006	22 Certifications Announced
	2nd	Aug 1-14, 2006	11 Certifications Announced
	3rd	Nov 1-14, 2006 (Now Open)	Feb 2007
	4th	Feb 1-14, 2007	May 2007
2007 Ambulatory and Inpatient EHRs	1st	May 1-14, 2007	Aug 2007

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Summary

Summing Up

- A public/private initiative to accelerate the adoption of robust, interoperable health IT in the USA
- Broad array of stakeholders engage in a consensus-based process to develop criteria
- Certification is fully operational for Ambulatory EHRs; additional domains to be added in 2007 and 2008
- CCHIT has been deemed a Recognized Certification Body by HHS
- CCHIT appreciates the dedication and commitment of its more than 100 volunteers and all other participants

More information: www.cchit.org

Thank You!
Q & A

For more information:
www.cchit.org