



Certification Commission
for Healthcare
Information Technology

Update on Activities and Progress of CCHIT

Mark Leavitt, MD, PhD
Chair, CCHIT

Presented before
The National Committee on Vital and Health Statistics
Washington, DC
June 21, 2006



Today's Presentation

- Background and Introduction
- Organization, Scope, Timeline, Process
- The 2006 Criteria for Ambulatory EHRs
- The 2006 Certification Program
- Focus of Development Work for 2007
- Q & A



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Background





Driving Forces

- Broad consensus: must improve quality and cost-effectiveness of US healthcare
 - Highest per capita costs of any country
 - Quality/outcomes rank lower than other developed countries
 - Threat to competitiveness of US industries
- Emerging consensus: lagging adoption of health IT, and lack of interoperable EHRs is part of the problem
 - Per capita HIT investment low compared to other countries
 - Low (14%) penetration of EHR in physician offices¹
 - “Adoption Gap” widest for small practices, representing 50% of all office-based physicians



National Initiatives to Accelerate Health IT Adoption

- January 2004: President Bush calls for computerizing health records in his State of the Union address
- May 2004: President forms ONCHIT, appoints first National Coordinator, David J Brailer, MD, PhD
- July 2004: HHS Strategic Framework for Health IT released, calling certification of health IT a 'key action'
- June 2005: Sec'y Leavitt announces AHIC, issues RFPs for Health IT contracts in four areas
- Sept 2005: Contracts awarded:
 - Standards Harmonization (ANSI-HITSP)
 - Compliance Certification (CCHIT)
 - National Health Information Network Prototypes (NHINs)
 - Privacy and Security Solutions (HISPC)





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Introduction to CCHIT





Founding and Funding

- Sept 2004: AHIMA, HIMSS, and the Alliance form partnership to fund and launch CCHIT
- June 2005: Eight additional organizations add \$325k funding support
- 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

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

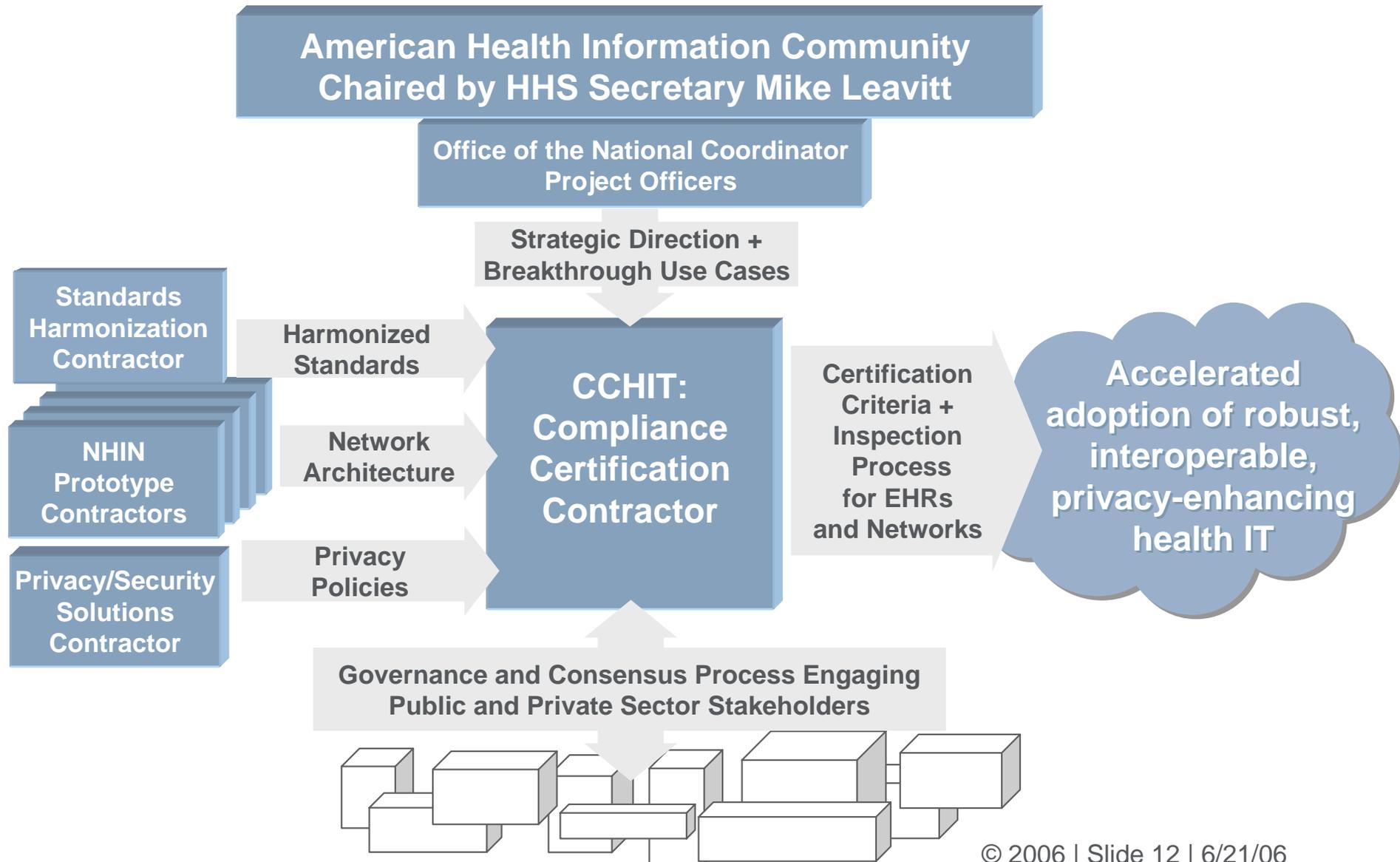


Guiding Principles

- Protect the privacy of personal health information
- Urgent need for private-sector action
- Credible, objective, and collaborative governance
- 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



CCHIT Role within HHS Health IT Strategy





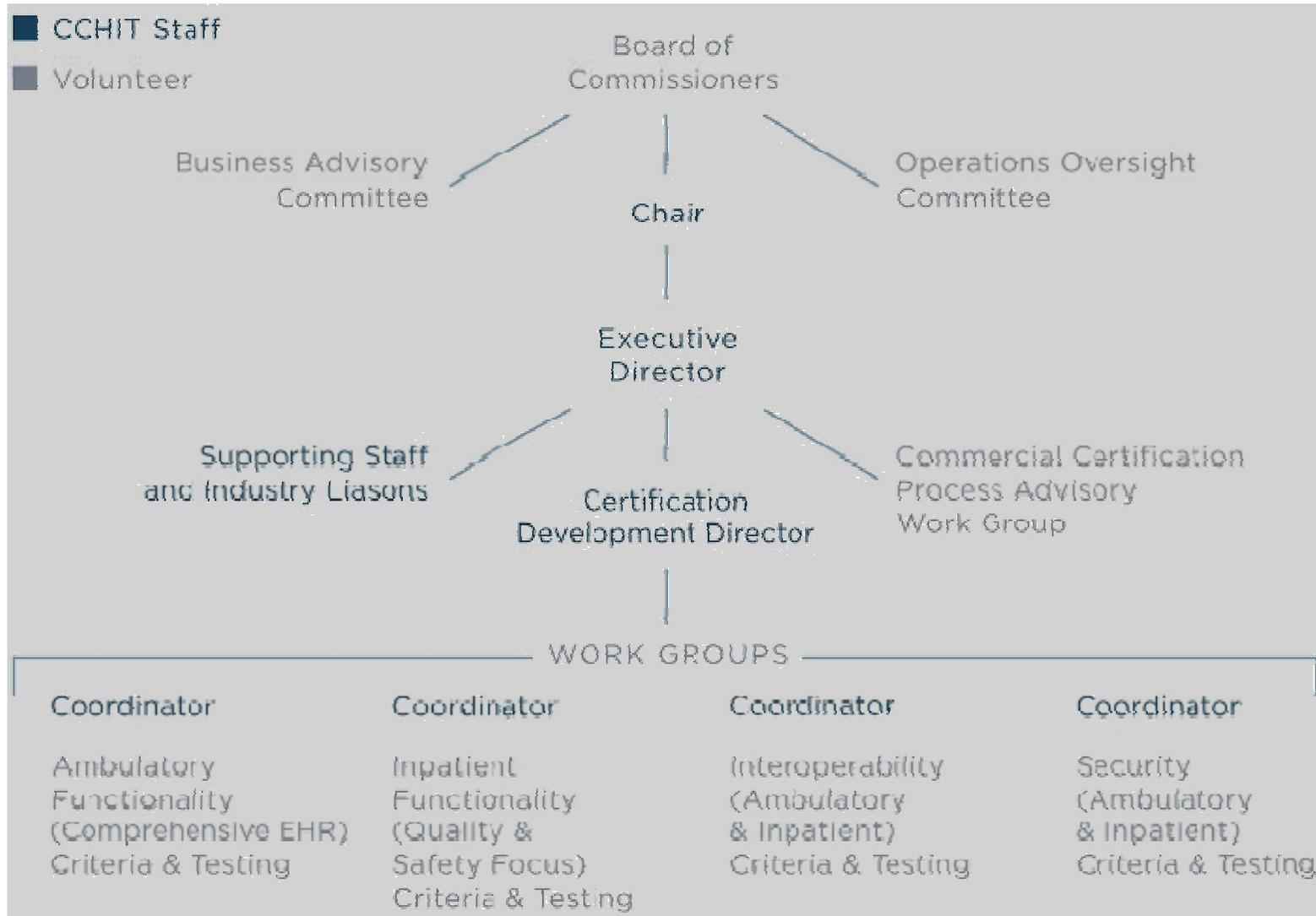
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Organization, Scope, Timeline, and Process





CCHIT Organization





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

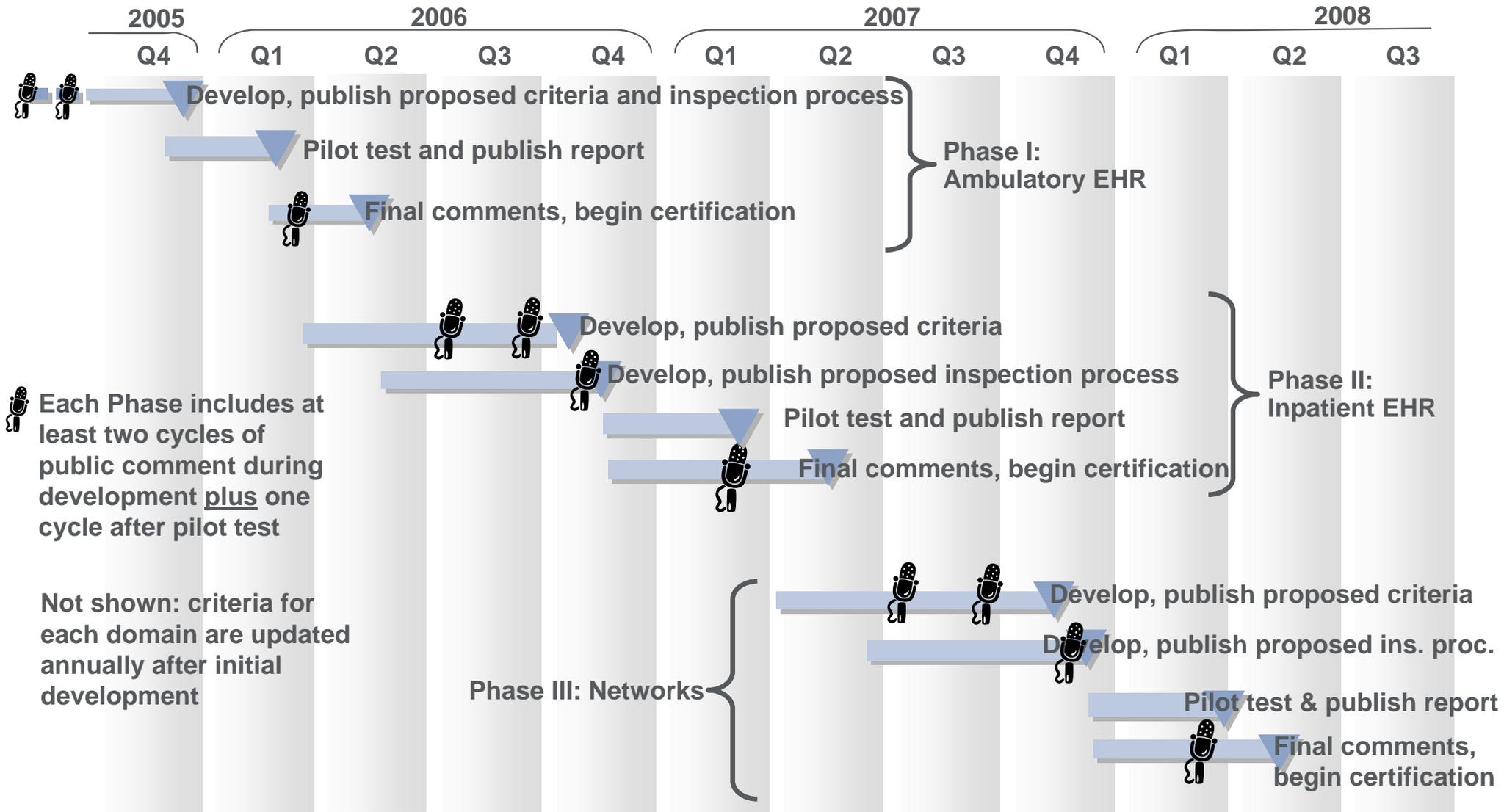


Scope of Work Under HHS Contract

- 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 Developmental Activities





Development Process

**Step A:
Gather Data**

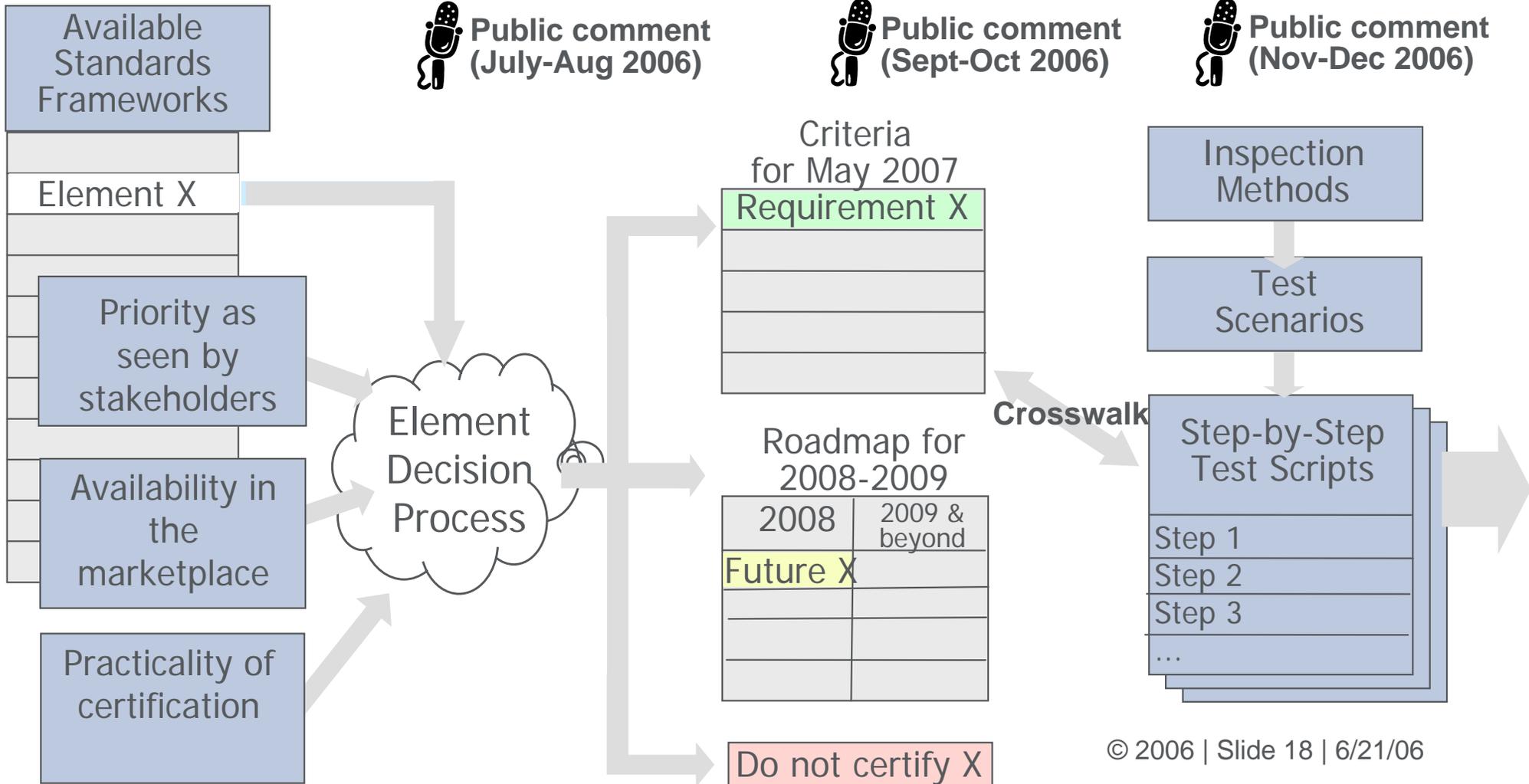
Step B: Develop Criteria

Step C: Develop Inspection Process

**Public comment
(July-Aug 2006)**

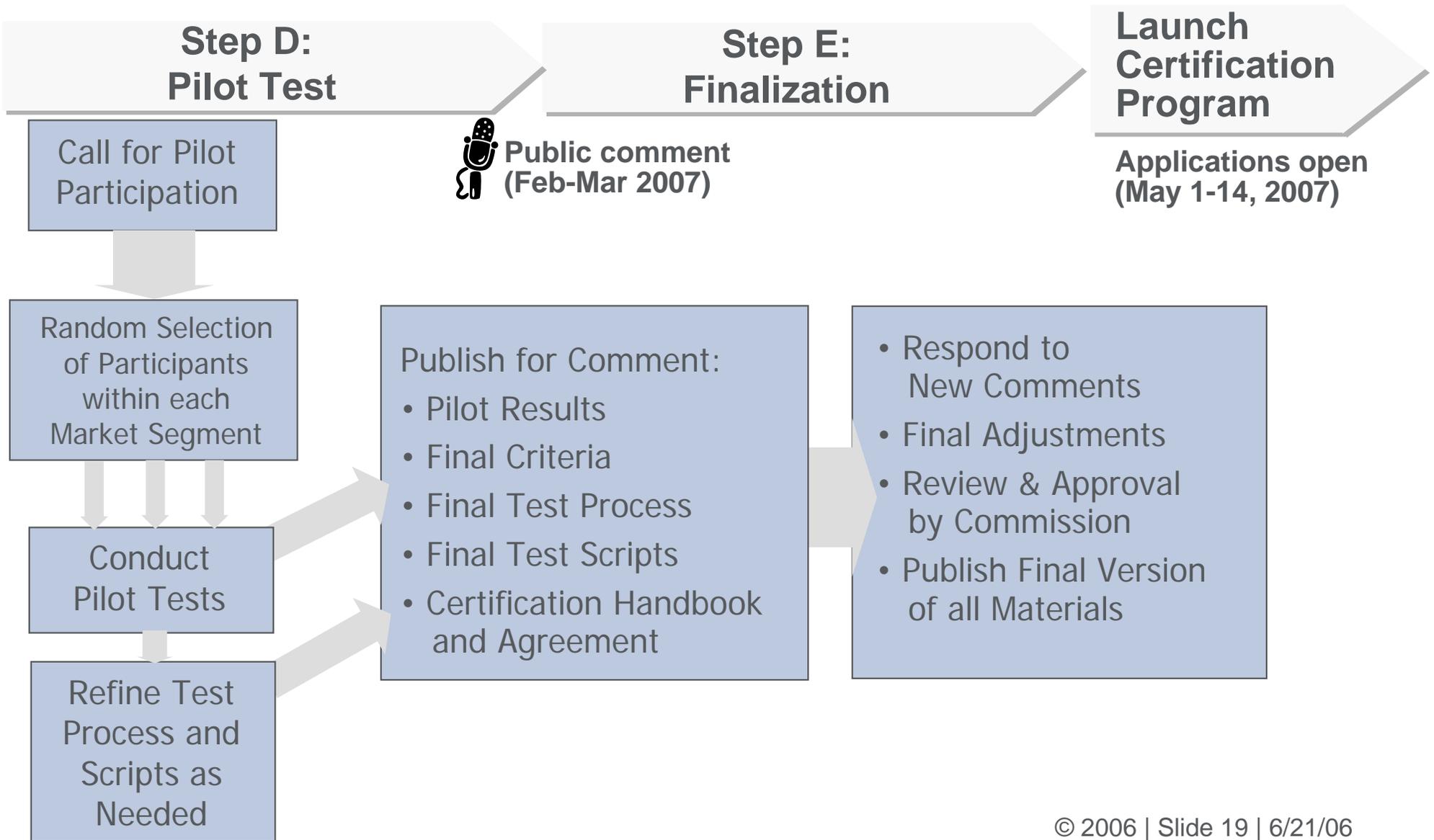
**Public comment
(Sept-Oct 2006)**

**Public comment
(Nov-Dec 2006)**





Development Process





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The 2006 Criteria for Ambulatory EHRs





Accessing the Criteria

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Certification HIT Vendor

- Overview
- Certification Criteria and Inspection Process
- Certification Handbook
- Minutes of Meetings

Information for Payers & Purchasers

Resources for Healthcare Consumers

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Ambulatory Domain
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DOCUMENT TITLE	PUBLISHED	COMMENT PERIOD
2006 Ambulatory EHR Certification: Corrections and Clarifications	05/22/06	
Self-Attestation: Guidelines	05/22/06	
Final Criteria - Functionality	05/01/06	N/A
Final Criteria - Interoperability	05/01/06	N/A
Final Criteria - Security-Reliability	05/01/06	N/A
Final Test Scripts	05/01/06	N/A
Final Certification Agreement	05/01/06	N/A
Final Certification Handbook	05/01/06	N/A
Final Source Documents - All (zip archive)	05/01/06	N/A
Final Cover Letter	05/01/06	

} View or download the criteria



Sample Document: Functionality Criteria

CCHIT		Final Criteria: FUNCTIONALITY For 2006 Certification of Ambulatory EHRs Effective May 1, 2006 © 2006 The Certification Commission for Healthcare Information Technology				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		
					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		Key identifier information must be unique to the patient record but may take any system defined internal or external form.
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.

Roadmap columns forecast future criteria

Provisional Criteria are in yellow



Sample Document: Interoperability Criteria

CCHIT		Final Criteria: INTEROPERABILITY For 2006 Certification of Ambulatory EHRs Effective May 1, 2006 © 2006 The Certification Commission for Healthcare Information Technology						
Line #	WG	Category and Description	Specific Criteria	Source or References	Compliance			Comments
					Certify in May 2006	Roadmap for May 2007	Roadmap for May 2008 and beyond	
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 recommendations.
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 access to digital medical images and reports from EHRs	DICOM avail. Now IHE Cross-Enterprise Image Information Sharing integration profile (Aug 2005)		x		
5	I		Order and schedule radiology tests				x	
6	I	Medications	Transmission of prescriptions	NCPDP SCRIPT 4.2 or later		x		1. Certifying the ability to output a file in a certain format. 2. CCHIT will specify the standard, implementation guide and versions that will be required for interoperability certification requirements. CCHIT will align certification with HITSP standards recommendations.
7	I		Use Standardized Communication of Sig instructions in e-prescribing.	Industry SIG Task Group			x	
8	I		Query and receive medication information	NCPDP/RxHub developed*		x		



Sample Document: Security-Reliability Criteria

	Final Criteria: SECURITY & RELIABILITY For 2006 Certification of Ambulatory EHRs Effective May 1, 2006 <small>© 2006 The Certification Commission for Healthcare Information Technology</small>	Note: Items highlighted in yellow are Provisional for 2006 (see cover letter)
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Line #	WG	Category and Description	Specific Criteria	Source or References	Compliance			
					Items Assignable* (see below)	Certify in May 2006	Roadmap for May 2007	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; SP800-63: AU-2 AUDITABLE EVENTS; HIPAA: 164.310(d)(1)	Y	X		
R3			If the system claims to be available 24x7 then the system shall have ability to run a backup concurrently with the operation of the application.	Canadian: Alberta 7.4.2.5 (Technica+D11); CC SFR: FDP_ROL; HIPAA: 164.310(d)(1)	Y	X		

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



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The 2006 Certification Program





Preparing for Certification

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- Certification Criteria and Process
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IR product
 is an assurance to your
 and other providers – and to
 e – payers, purchasers and
 products meet all basic criteria
 erability and security. CCHIT is
 tion authority for EHRs; it
 paigns designed to help your
 stomers understand the value
 roducts.

CCHIT works with all stakeholders to gain consensus on certification criteria and testing processes related to the industry standards produced by healthcare standards development organizations (SDOs). Certification is a mechanism for enhancing the confidence and orderliness of the HIT marketplace. The inspection and testing process performed when certifying HIT products is based on agreed-upon standards, as well as unbiased inspection and

Ambulatory Domain
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Final Certification Handbook	05/01/06	
Final Source Documents - All (zip archive)	05/01/06	N/A
Final Cover Letter	05/01/06	

Download and review ALL relevant documents



Certification Cycles

Certification Year	Certification Quarter	Application Window	Batch Announcement
2006	1st	May 3-12, 2006 (now closed)	July 18, 2006
	2nd	Aug 1-14, 2006	Nov 2006
	3rd	Nov 1-14, 2006	Feb 2007
	4th	Feb 1-14, 2007	May 2007
2007	1st	May 1-14, 2007	Aug 2007



Certification Process Diagram (from **Certification Handbook**)

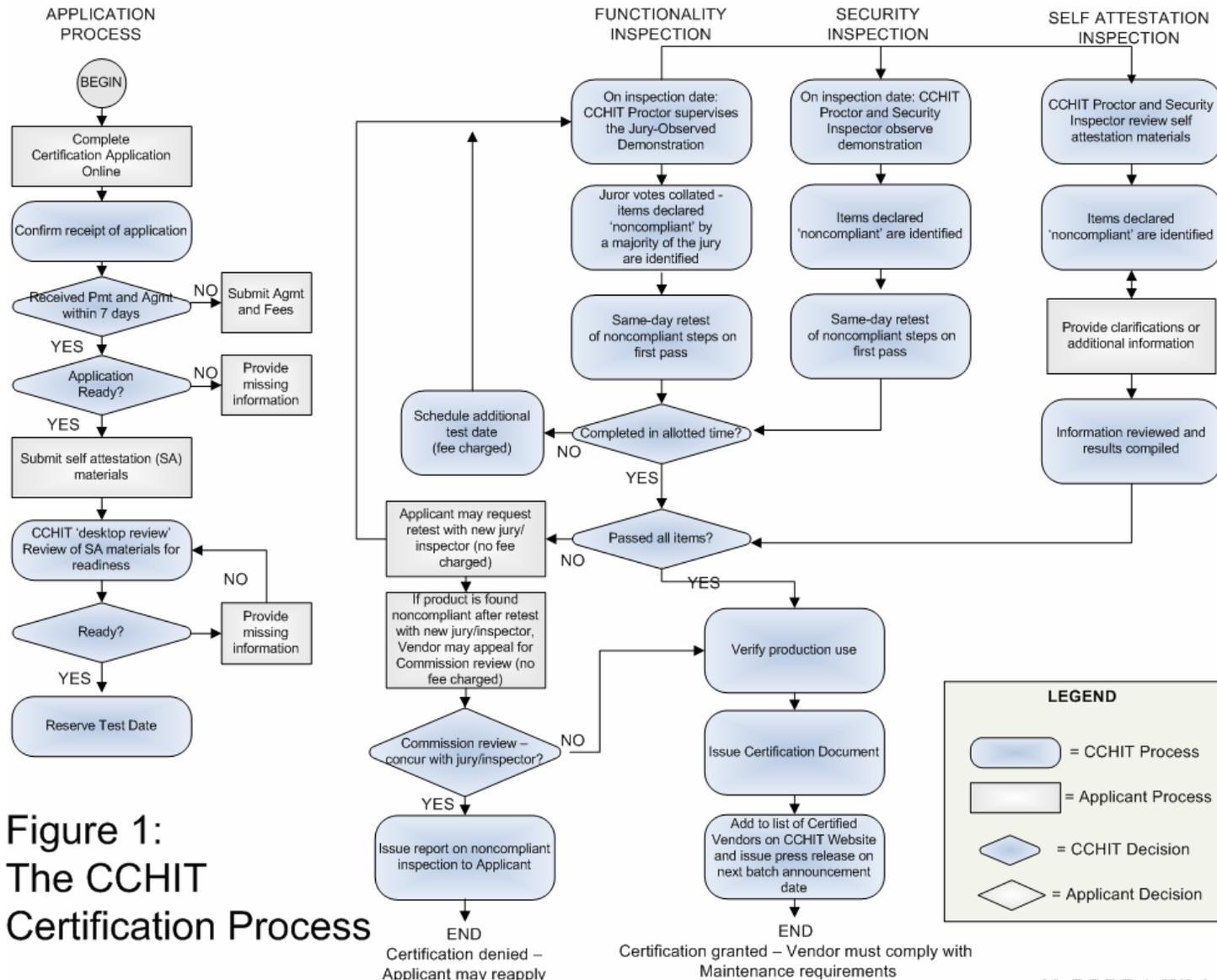


Figure 1:
The CCHIT
Certification Process



Functionality Inspection: Jury-Observed Demonstration



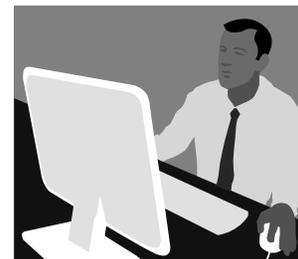
CCHIT Proctor



Juror A
(Practicing
physician)



Juror B



Juror C



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

Web conferencing
(gotomeeting.com)
and concurrent
audio conferencing



Sample Document: Test Scripts (Functionality scenario)



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Operational Test Scripts – Version 1.0

ID	Procedure	Expected Result	Actual Result	Pass/Fail		Criteria and Reference	Comments
				<input type="checkbox"/> Pass	<input type="checkbox"/> Fail		
10	Record reasons for visit: <ul style="list-style-type: none"> • Vision screening • Hearing screening • Immunization boosters 	System accepts reasons for visit		<input type="checkbox"/> Pass	<input type="checkbox"/> 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: <ul style="list-style-type: none"> • DTaP • IPV • MMR 		<input type="checkbox"/> Pass	<input type="checkbox"/> 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.		<input type="checkbox"/> Pass	<input type="checkbox"/> 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.		<input type="checkbox"/> Pass	<input type="checkbox"/> 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.	



Security Inspection: Demonstration and Self-Attestation

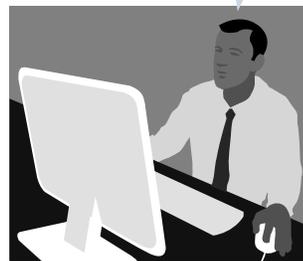


Vendor personnel follow Test Script to demonstrate system at the vendor facility

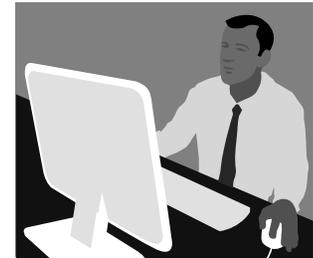


CCHIT Proctor

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



Sample Document: Test Scripts (Security scenario)



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Operational Test Scripts – Version 1.0

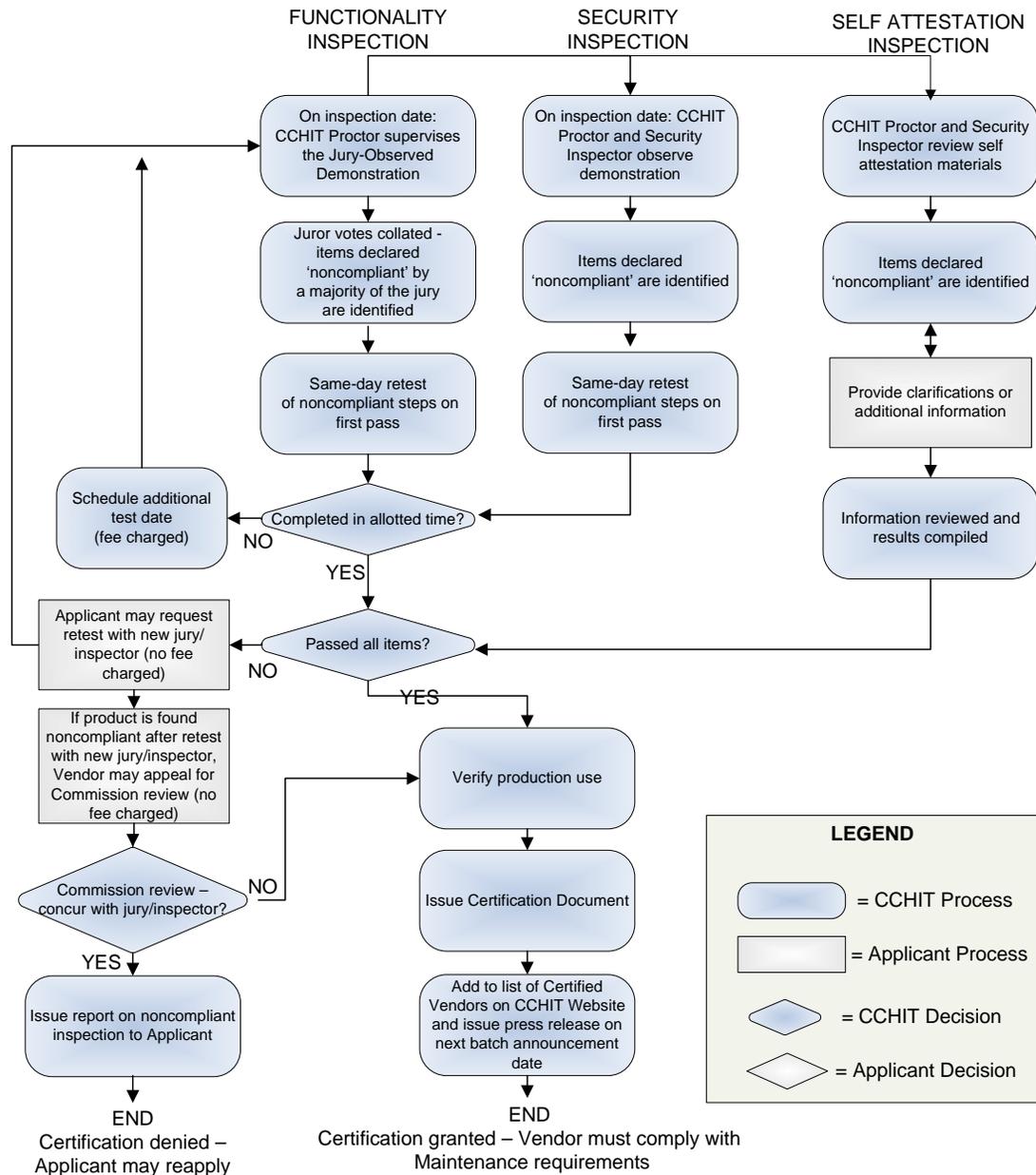
Procedure	Expected Result	Actual Result	Pass/Fail		Criteria and Reference	Assignable	Comments
116	Create one valid clinical user account. This user account will have no administrative rights but will have clinical rights.	User account successfully created as per documentation provided during self-attestation. Appropriate privileges are assigned. If S23 is assigned, see step 181.	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	S 23 The system shall include documentation that covers: Method used to create, modify, and remove user accounts. S 3 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.	<input type="checkbox"/> Pass	<input type="checkbox"/> 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 medicine.	At a minimum, the system shall maintain a directory of identifiers for licensed clinicians including a minimum state medical license, DEA, NPI, and UPIIN number.	<input type="checkbox"/> Pass	<input type="checkbox"/> 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 UPIIN number.	N	Note – if applicant cannot show this information, they may self-attest to it by providing a table of the directory.
119	Set password strength rules to require 8 characters minimum.	Password strength rules are set to 8 characters minimum. If S13 is assigned, see step 182.	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail	S 13 When passwords are used, the system shall support password strength rules that allow for minimum number of characters, and inclusion of alphanumeric complexity.	Y	

Provisional Step

Assignable Step



Failsafe Mechanisms: Retests and Appeals





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Focus of Development Work for 2007 Certification





2007 Scope: Ambulatory Functionality Workgroup

- Update and refine the Ambulatory EHR Criteria for 2007, as well as the Roadmap for 2008, 2009 and beyond
- Introduce functionality criteria as needed to support new interoperability criteria.
- Support the AHIC Breakthrough Use Cases
- Address the issue of specialty-specific products and needs
- Refine the inspection process as needed, working with Certification Process WG



2007 Scope: Inpatient Functionality Workgroup

- Develop Inpatient Functionality Criteria
 - Focus on Quality and Safety components of the EHR first: CPOE, CDSS, Pharmacy, Med Admin
 - Focus also on functionality required to support Interoperability
 - Scope of certification for inpatient EHRs for May 2007 still being determined
- Support the AHIC Breakthrough Use Cases
- Develop the inspection process, working with Certification Process WG



2007 Scope: Interoperability Workgroup

- Update and refine the Ambulatory EHR Interoperability Criteria for 2007, as well as the Roadmap for 2008, 2009 and beyond
- Develop the Inpatient EHR Interoperability Criteria for 2007, as well as the Roadmap for 2008, 2009 and beyond
- Support the AHIC Breakthrough Use Cases
- Develop the Interoperability inspection process for both Ambulatory and Inpatient Domains, working with the Certification Process WG



2007 Scope: Security Workgroup

- Develop the Inpatient EHR Security Criteria for 2007, and the Roadmap for 2008, 2009 and beyond
- Update and refine the Ambulatory EHR Security Criteria for 2007, as well as the Roadmap for 2008, 2009 and beyond
- Support the AHIC Breakthrough Use Cases
- Develop the Security inspection process for the Inpatient Domains, and refine the inspection process for the Ambulatory Domain, working with the Certification Process WG



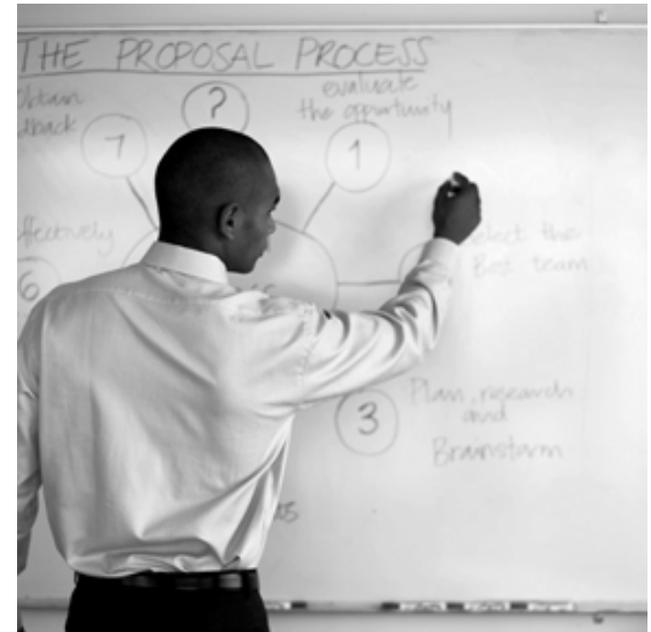
2007 Scope: Certification Process Advisory Group

- Review 2006 Certification outcomes, and recommend improvements to process for 2007
- Review and advise on planned methods for monitoring juror performance
- Review and advise on “appropriate use” of certification results by vendors
- Review and advise on development and launch of a Certification Impact Study
- Work with Interoperability workgroup to develop cost-effective inspection process
- Work with criteria workgroups to develop inspection process for new Inpatient and Network domains



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Summing Up





Summing Up

- CCHIT uses a consensus-based development process that engages a broad array of stakeholders
- CCHIT has successfully developed the first compliance criteria for Ambulatory EHRs, and has launched its 2006 Certification Program
- First announcement will be July 18, 2006, followed by quarterly certification cycles, and annual updates
- CCHIT has begun development of Inpatient EHR criteria for 2007, and will later expand to the Network domain
- CCHIT's success is the result of the tremendous support received from its founders, funders, and volunteers



Thank You!
Q & A

For more information:
www.cchit.org

