Update on Activities and Progress of CCHIT

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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

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 offices[1]
    - "Adoption Gap" widest for small practices, representing 50% of all office-based physicians

[1]D Gans, J Kralewski, T Hammons, B Dowd, Health Affairs, Sept 2005

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)

CCHIT

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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
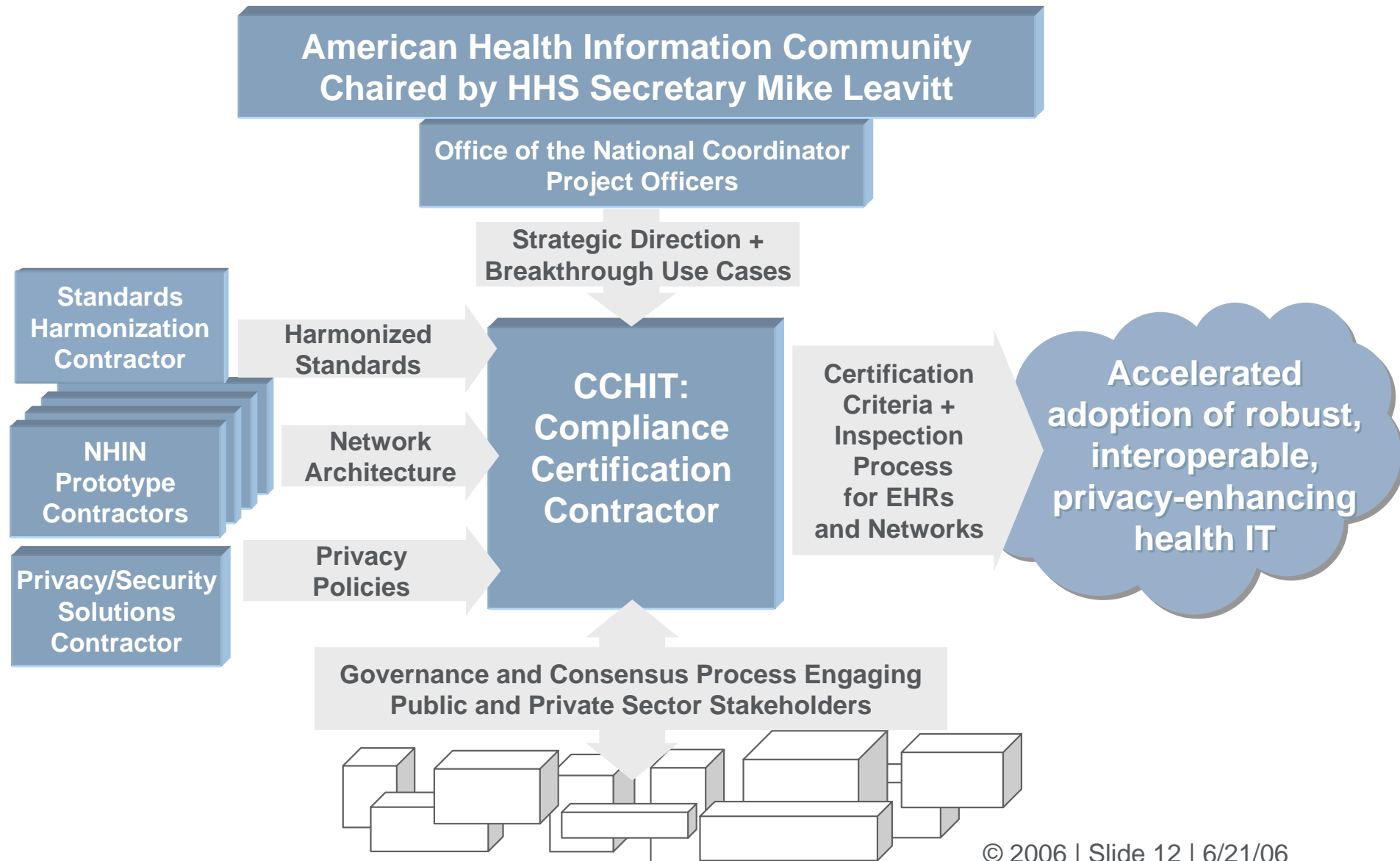 - CMS, VHA, NIST, CDC, DoD, DHS, DoC, NSF, GSA, EPA and others

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
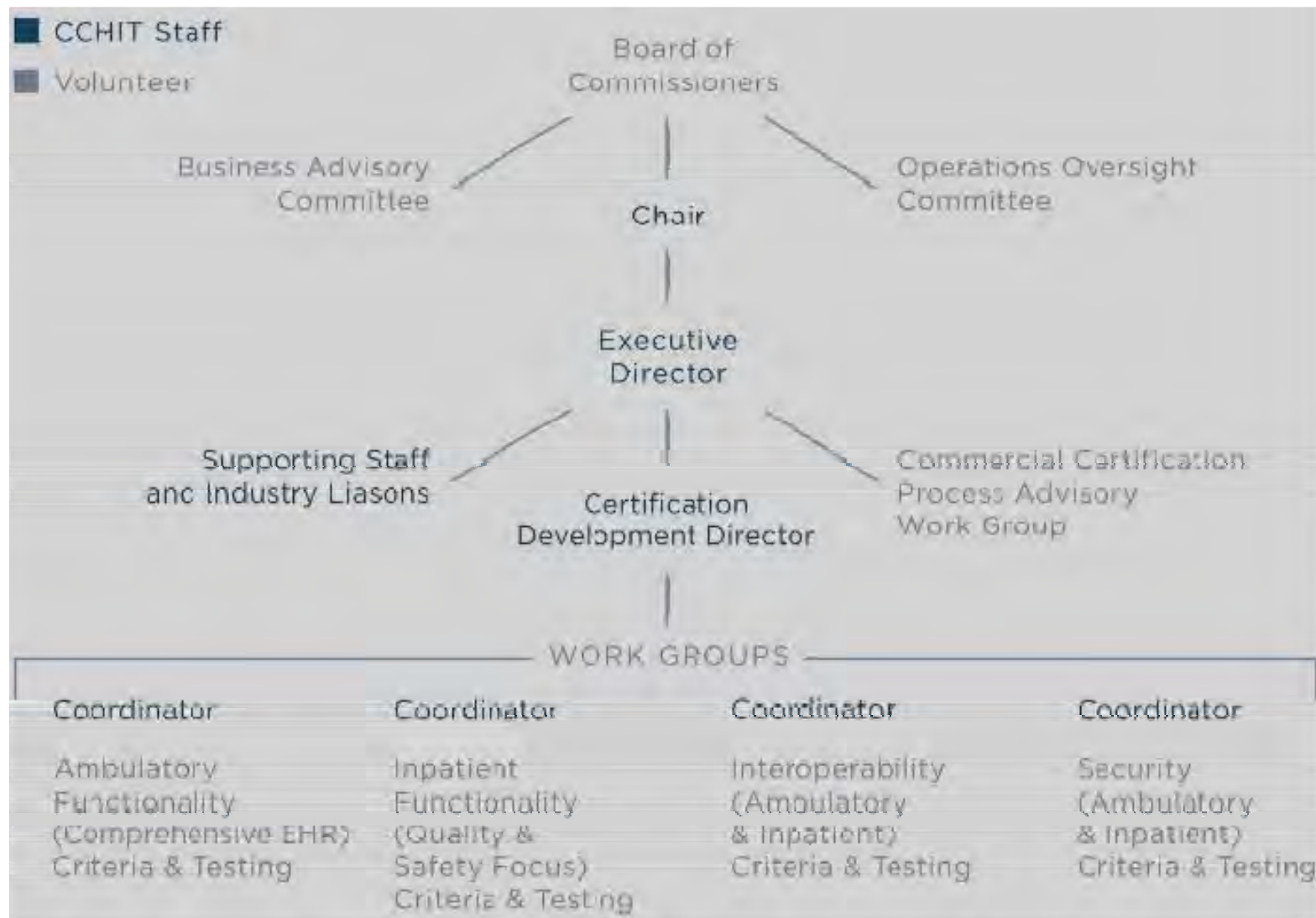
CCHIT Role within HHS Health IT Strategy

American Health Information Community
Chaired by HHS Secretary Mike Leavitt

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

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
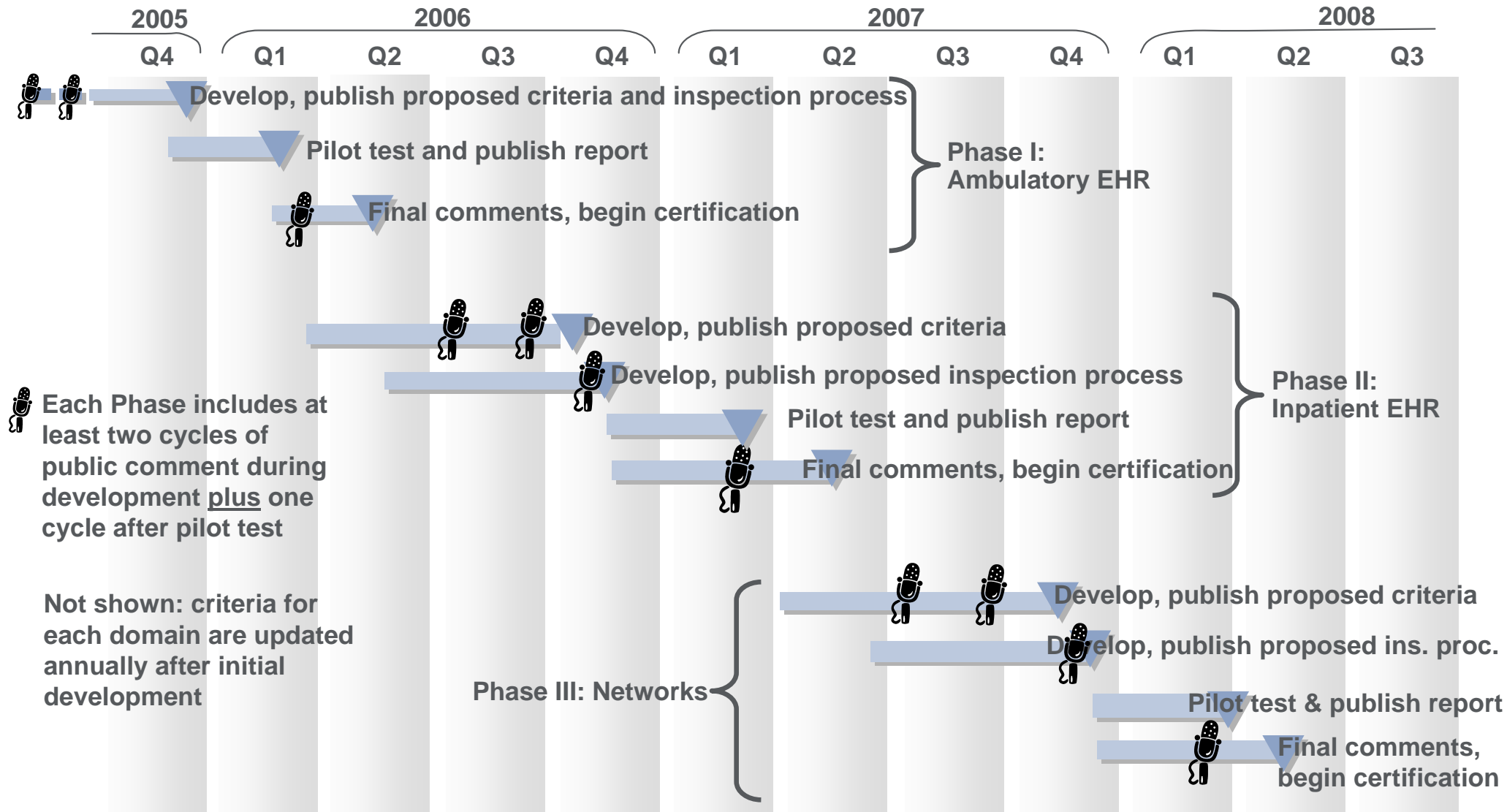 - Specific outreach to stakeholder groups

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

2005	2006				2007				2008		
Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3

Develop, publish proposed criteria and inspection process

Pilot test and publish report

Final comments, begin certification

Phase I: Ambulatory EHR

Develop, publish proposed criteria

Develop, publish proposed inspection process

Pilot test and publish report

Final comments, begin certification

Phase II: Inpatient EHR

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

Phase III: Networks

Develop, publish proposed criteria

Develop, publish proposed ins. proc.

Pilot test & publish report

Final comments, begin certification

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)

Available Standards Frameworks

Element X

Priority as seen by stakeholders

Availability in the marketplace

Practicality of certification

Element Decision Process

Criteria for May 2007

Requirement X

Roadmap for 2008-2009

2008	2009 & beyond
Future X	

Crosswalk

Inspection Methods

Test Scenarios

Step-by-Step Test Scripts

Step 1

Step 2

Step 3

…

Do not certify X

Development Process

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Step D: Pilot Test	Step E: Finalization	Launch Certification Program

Public comment (Feb-Mar 2007)

Applications open (May 1-14, 2007)

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

- Respond to New Comments
- Final Adjustments
- Review & Approval by Commission
- Publish Final Version of all Materials

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The 2006 Criteria for Ambulatory EHRs

Accessing the Criteria

Click here

View or download the criteria

Sample Document: Functionality Criteria

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)

Roadmap columns forecast future criteria

Provisional Criteria are in yellow

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.

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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	Certify in May 2006	Roadmap for May 2007	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 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 recommentations.
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
© 2006 The Certification Commission for Healthcare Information Technology

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)	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; SP800-53: 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+D1l); 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

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

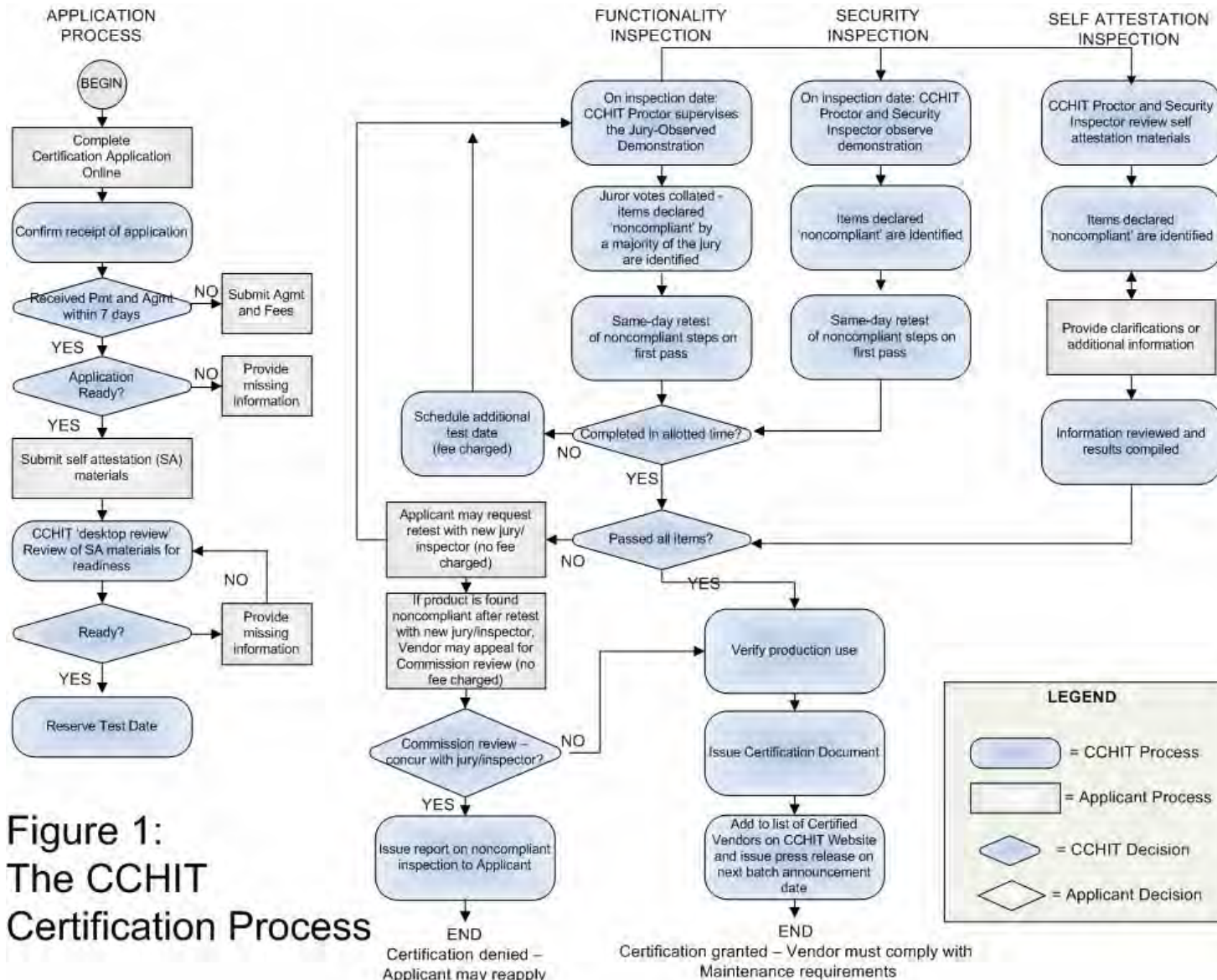# Certification Process Diagram (from **Certification Handbook**)

Figure 1: The CCHIT Certification Process

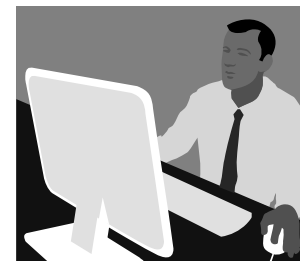# Functionality Inspection: Jury-Observed Demonstration

CCHIT Proctor

Juror A (Practicing physician)

Web conferencing (gotomeeting.com) and concurrent audio conferencing

Juror B

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

Juror C

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	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 182	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.		❑ 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		❑ 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.	

Security Inspection: Demonstration and Self-Attestation

CCHIT Proctor

Web conferencing (gotomeeting.com) and concurrent audio conferencing

Vendor personnel follow Test Script to demonstrate system at the vendor facility
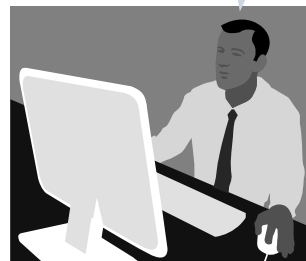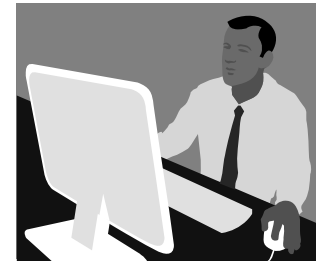
Juror D (IT/Security Expert) also reviews self-attestation material offline, calls or emails vendor as needed for additional documentation

Juror D (IT/Security Expert)

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

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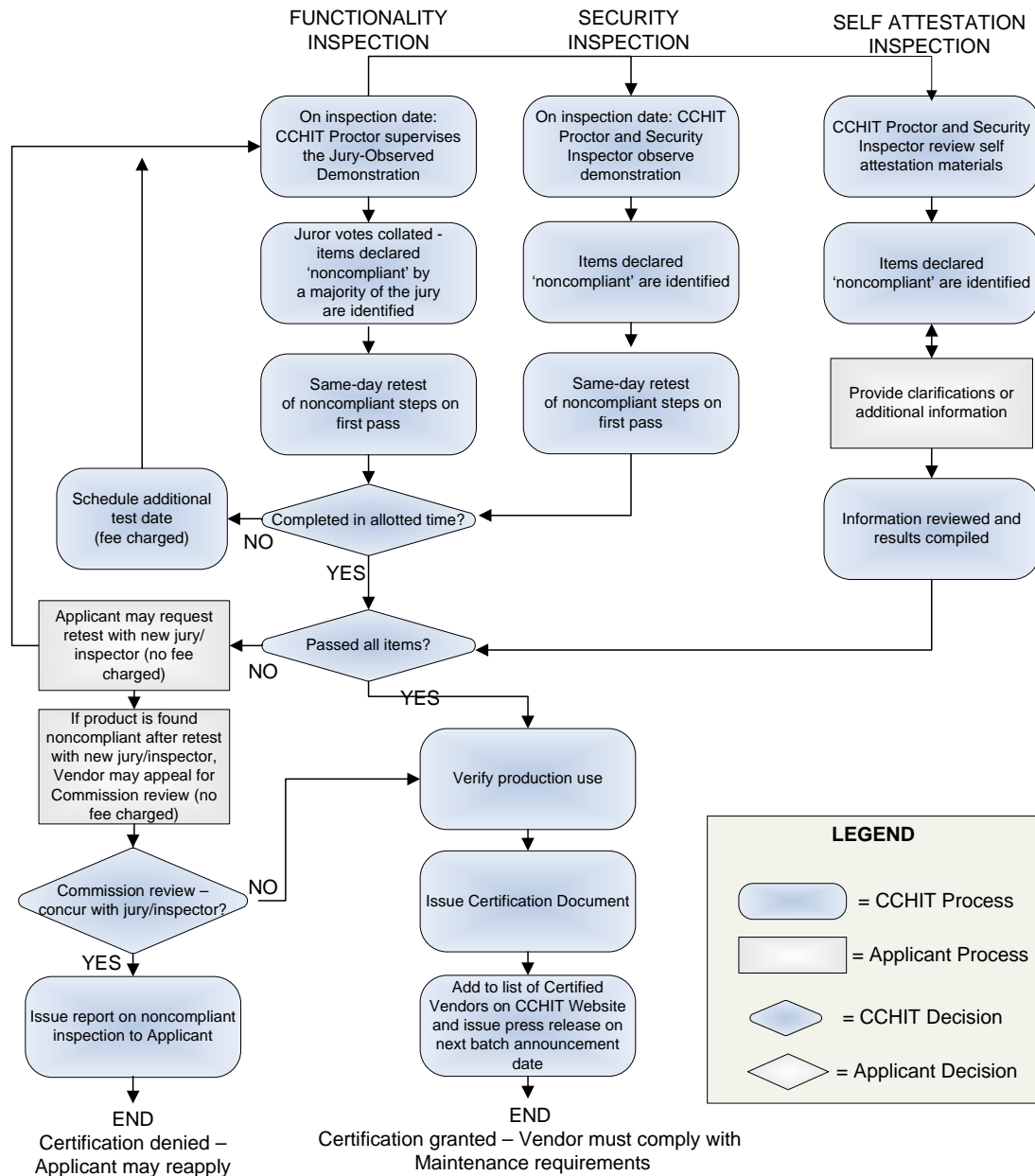
Operational Test Scripts – Version 1.0

	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. Aopropriate 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 medicine.	At a minimum, the system shall mai... of s... DEA, N... 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	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.		☐ 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	

Provisional Step

Assignable Step

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

↓

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

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

Completed in allotted time?
- NO → Schedule additional test date (fee charged)
- YES ↓

Passed all items?
- NO → Applicant may request retest with new jury/inspector (no fee charged)
- YES → Verify production use

If product is found noncompliant after retest with new jury/inspector, Vendor may appeal for Commission review (no fee charged)

↓

Commission review – concur with jury/inspector?
- NO → Verify production use
- YES ↓ Issue report on noncompliant inspection to Applicant

↓

END
Certification denied – Applicant may reapply

Verify production use

↓

Issue Certification Document

↓

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

↓

END
Certification granted – Vendor must comply with Maintenance requirements

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LEGEND

- = CCHIT Process
- = Applicant Process
- = CCHIT Decision
- = Applicant Decision

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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

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

CCHIT

Thank You!
Q & A

For more information:
www.cchit.org