

The Certification Commission for Healthcare Information Technology (CCHIT)

“Town Calls”

Phase II Work Products Public Comment Period

Tuesday, July 12, 2005 -- Healthcare Information Technology Vendors
4:00 pm Eastern/3:00pm Central/1:00pm Pacific -- Call-in number: 888-789-0089

Wednesday, July 13, 2005 -- Physicians and Other Healthcare Providers
4:00 pm Eastern/3:00pm Central/1:00pm Pacific -- Call-in number: 877-888-7019

Thursday, July 14, 2005 -- General Audience
1:00 pm Eastern/12:00 n Central/10:00 am Pacific -- Call-in number: 800-769-8320

Duration of all calls: 60 minutes

Moderator: Mark Leavitt, MD, PhD - Chair, CCHIT



Agenda for Today's Call

- **Origin, Mission and Concept**
- **Organization**
- **Scope, Timeline and Deliverables**
 - With updates regarding the ONCHIT-2 RFP
- **Work Group Process**
- **Brief Overview of Phase I Comments**
- **Introduction to the Phase II Work Products**
- **Q & A**



Origin, Mission and Concept of CCHIT



Origins of CCHIT

July 2004

Goals and Strategies of HHS's Framework for Strategic Action

Goals	Strategies ^a
<i>Goal 1:</i> Inform clinical practice with the use of electronic health records (EHR)	<ol style="list-style-type: none"> 1. Incentivize EHR adoption 2. Reduce risk of EHR investment 3. Promote EHR diffusion in rural and underserved areas
<i>Goal 2:</i> Interconnect clinicians so that they can exchange health information using advanced and secure electronic communication	<ol style="list-style-type: none"> 1. Foster regional collaboration 2. Develop a national health information network 3. Coordinate federal health information systems
<i>Goal 3:</i> Personalize care with consumer-based health records and better information for consumers	<ol style="list-style-type: none"> 1. Encourage use of personal health records 2. Enhance informed consumer choice 3. Promote use of telehealth systems
<i>Goal 4:</i> Improve public health through advanced biosurveillance methods and streamlined collection of data for quality measurement and research	<ol style="list-style-type: none"> 1. Unify public health surveillance architectures 2. Streamline quality and health status monitoring 3. Accelerate research and dissemination of evidence

Source: HHS.

^a Phase I strategies are shown in bold type.

**Private sector certification
of HIT products – a *key
action* in the Framework**

Founding of CCHIT

- **Founded by three HIT organizations:**
 - American Health Information Management Assoc (AHIMA)
 - Healthcare Information and Management Systems Society (HIMSS)
 - National Alliance for Health Information Technology (Alliance)
- **Formed panel to nominate first Commissioners**
- **Provided seed funding and staffing for launch**
- **First official meeting Sept 14, 2004**

Broadened Funding Support

June 2005

- **Unrestricted grants, \$110k total, from:**
 - American Academy of Family Physicians (AAFP)
 - American College of Physicians (ACP)
 - Hospital Corporation of America
 - McKesson
 - Sutter Health
 - United Health Foundation
 - WellPoint Health Networks, Inc.
- **Grants supporting testing development, \$215K total**
 - California HealthCare Foundation



Mission of CCHIT

To accelerate the adoption of robust, interoperable HIT throughout the US healthcare system, by creating an efficient, credible, sustainable mechanism for the certification of HIT products.

Guiding Principles

- **Timeliness**
 - Need decisive private-sector action now
- **Value**
 - Deliver value for all key stakeholders and the larger healthcare community
 - Process must be efficient and not add net costs
- **Integrity**
 - Operate in credible, objective, transparent manner
 - Certification must be objective, laboratory verified to the greatest extent practical

Standards and Certification Create “Tipping Points” for New Technologies



The IBM-standard PC
launched the personal
computing revolution

The Ethernet
networking standard
gave PC's connectivity



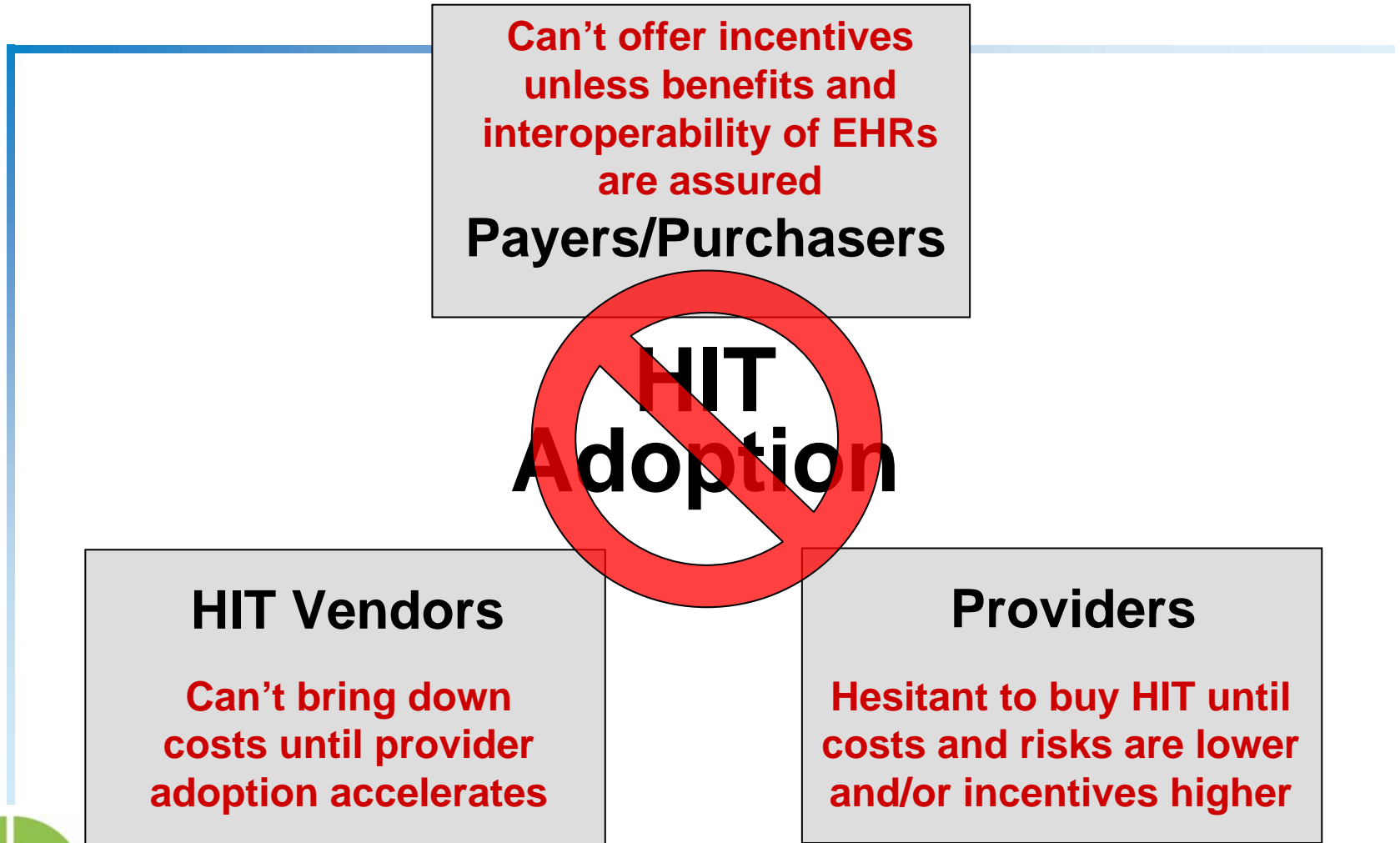
The Wi-fi standard
made it wireless



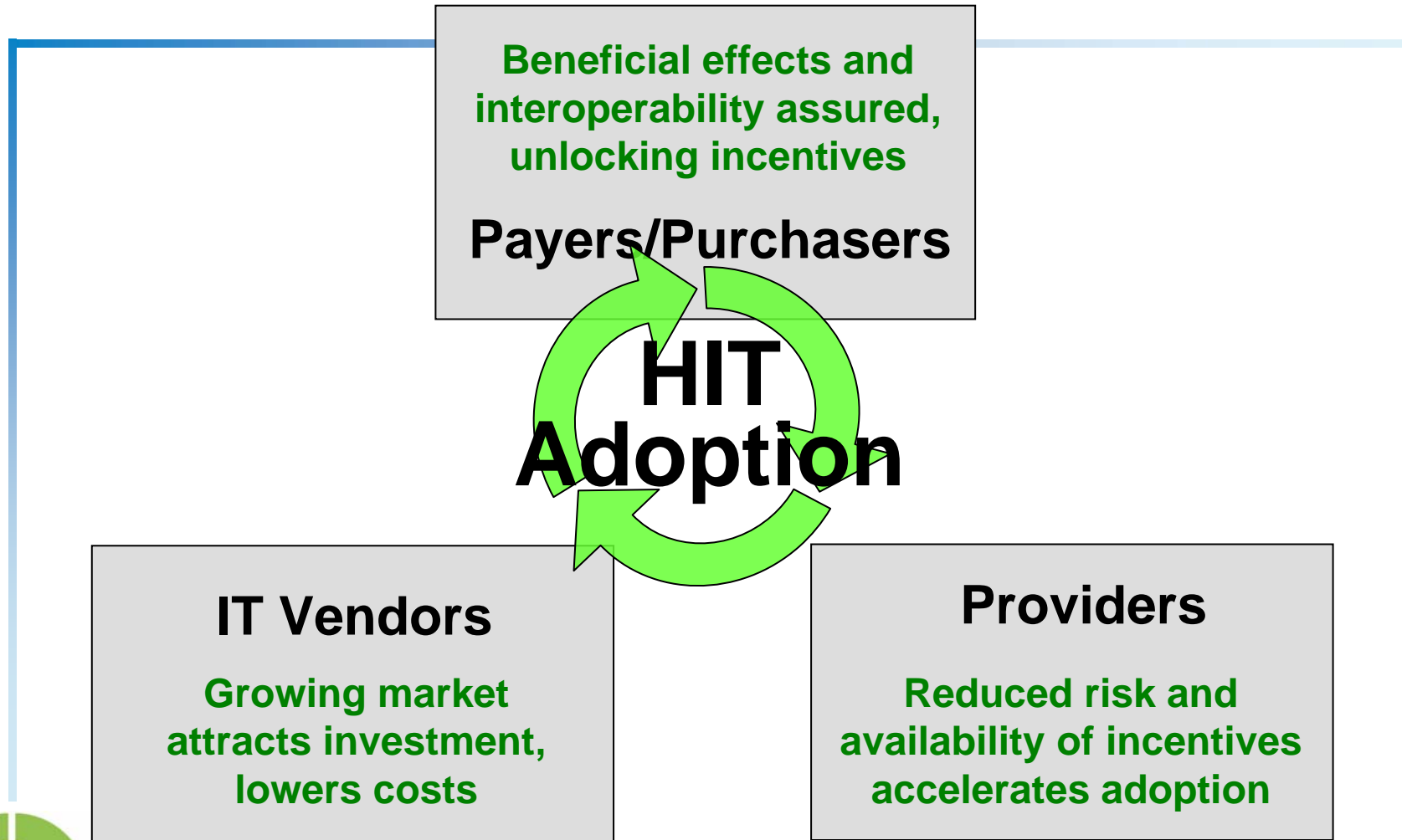
How Product Certification Can Accelerate HIT Adoption

- Increase the confidence of providers to invest in and adopt HIT
- Facilitate interoperability of HIT products within the emerging national health information network
- Enhance the availability of HIT adoption incentives from public and private purchasers/payers

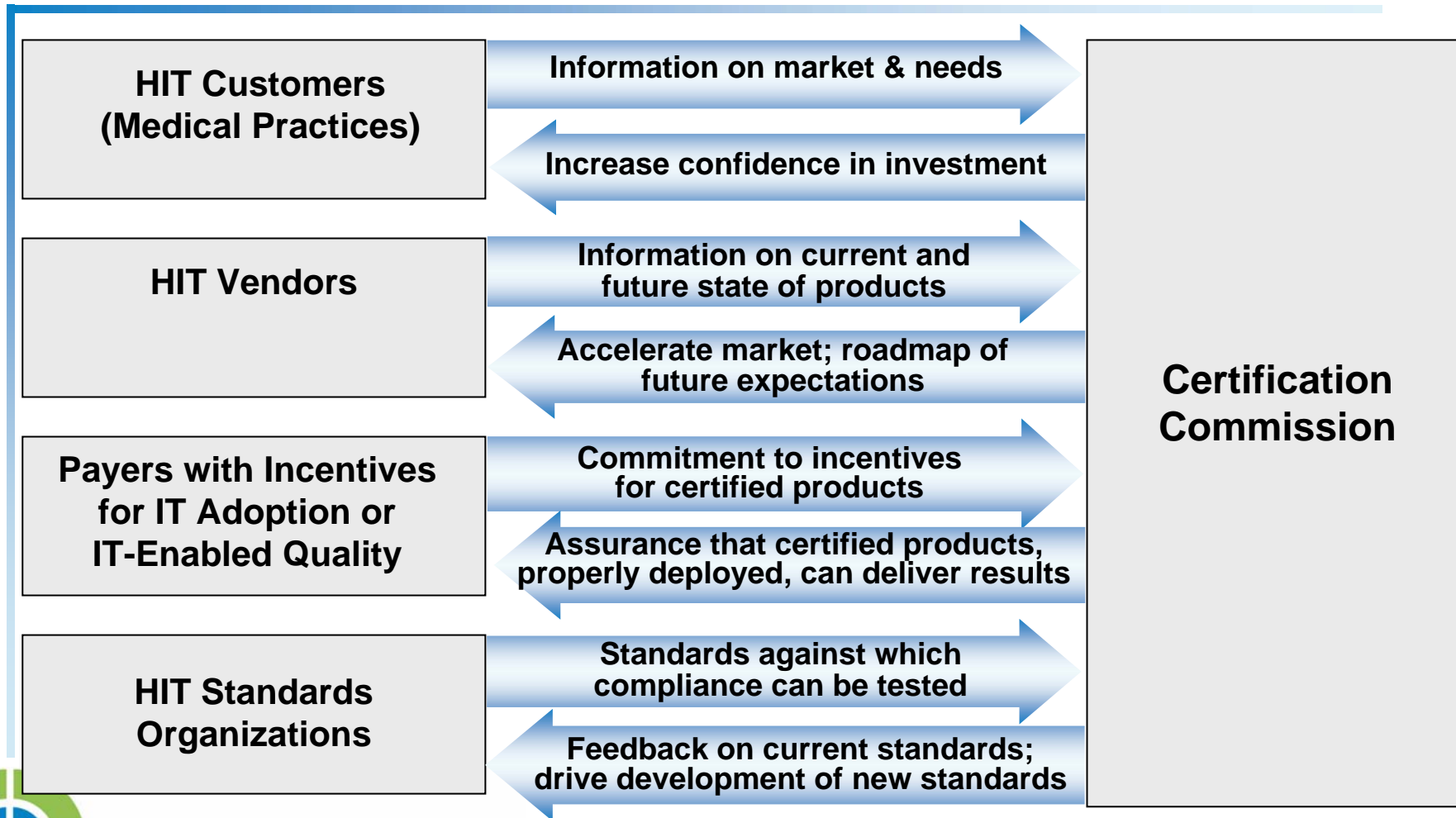
The HIT Adoption Deadlock



Breaking the Deadlock



Key Stakeholder Relationships



Key Points to Clarify

- **Product Certification is different from:**
 - Organizational Accreditation
 - Professional Certification
- **Certification is binary, i.e. “pass/fail”**
 - Not a subjective, comparative rating system
 - Competition and innovation can thrive “above the line”
- **Voluntary process**
 - Initial requirements must be market reality-based
 - A forward-looking requirements roadmap provides the best means to influence market direction

Certification Roadmap Concept

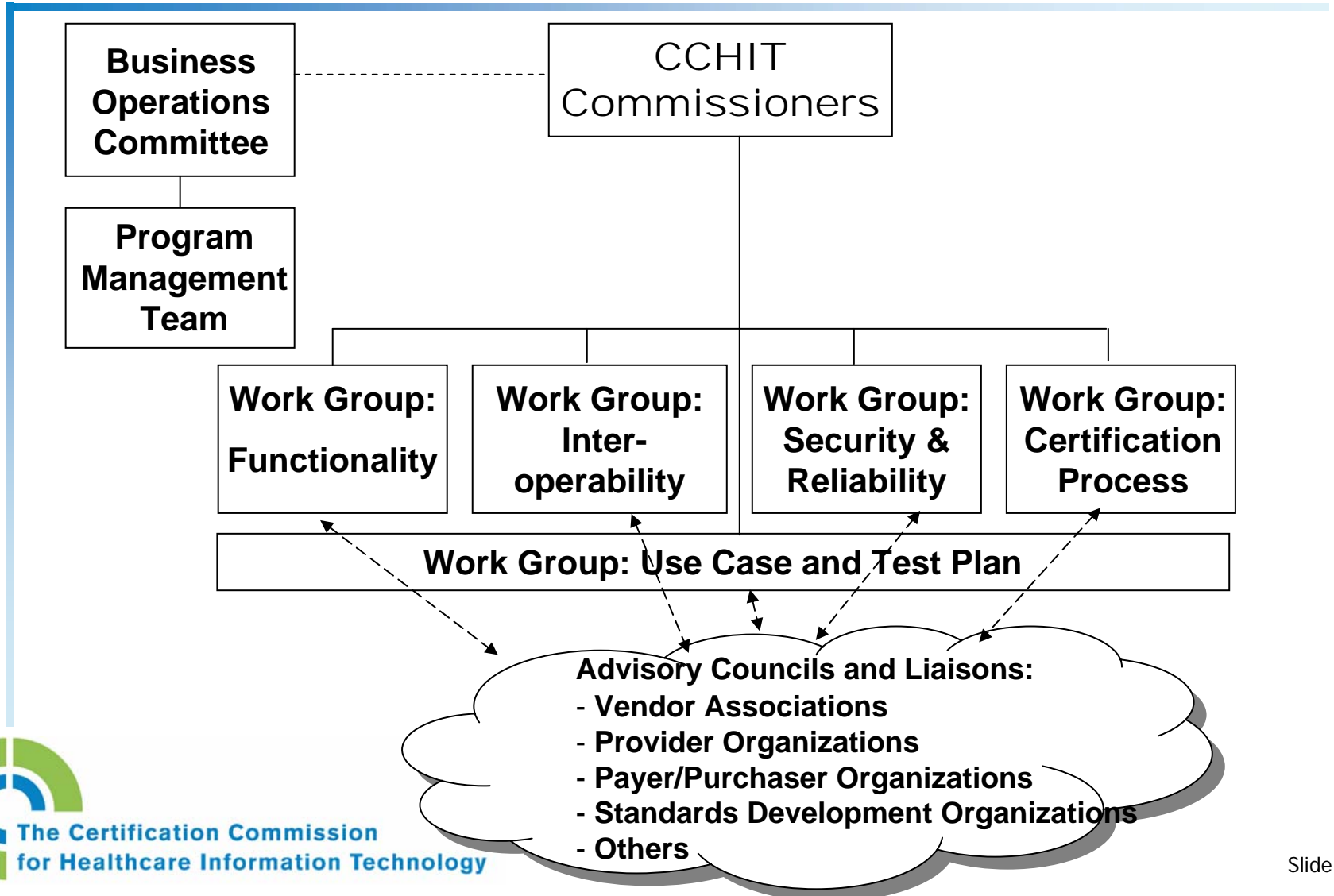
EHR Product Attributes	Current Year	1 Year Ahead	2 Years Ahead
Functionality	Final 2005 Requirements	Forecast 2006 Requirements	Forecast 2007 Requirements
Interoperability	Final 2005 Requirements	Forecast 2006 Requirements	Forecast 2007 Requirements
Security & Reliability	Final 2005 Requirements	Forecast 2006 Requirements	Forecast 2007 Requirements



Organization of CCHIT



CCHIT Organization



Stakeholder Balance and Diversity on the Commission and Work Groups

Commission

- **2 – 4 from each key stakeholder group:**
 - Providers
 - Vendors
 - Purchasers/payers/coalitions
- **2 – 4 total drawn from other stakeholders:**
 - Government (ex-officio, nonvoting)
 - Standards development organizations (e.g. HL7)
 - Others, e.g. healthcare consumer advocates, etc.

Work Groups

- **Open Call for Participation**
 - 275 applicants
 - Commissioners ranked by qualifications then adjusted for stakeholder balance
- **Co-Chairs**
 - Two Co-Chairs
 - Must represent two different stakeholders
- **Members**
 - 8 – 10 members
 - Qualified experts
 - Diversity of backgrounds

Scope, Timeline, and Deliverables



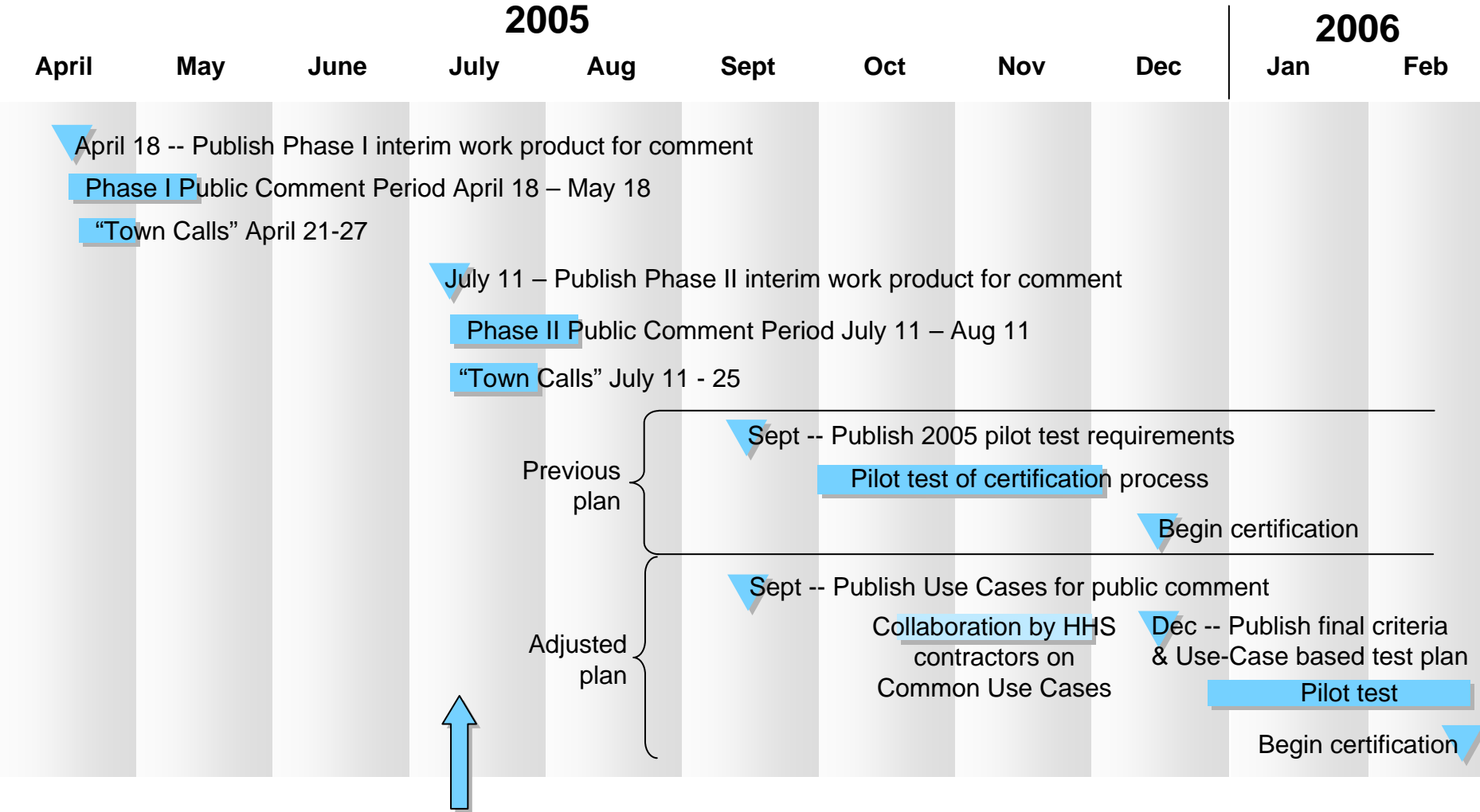
Scope, Deliverables, and Timeline*

- **Initial scope**
 - Certify EHR products for physician offices and other ambulatory care settings
- **Deliverables:**
 - Operational capability for certification
 - Roadmap forecasting future certification plans 1-2 years ahead
- **Timeline**
 - Pilot process ready in September 2005



Timeline

(With adjustments to synchronize with ONCHIT RFP)

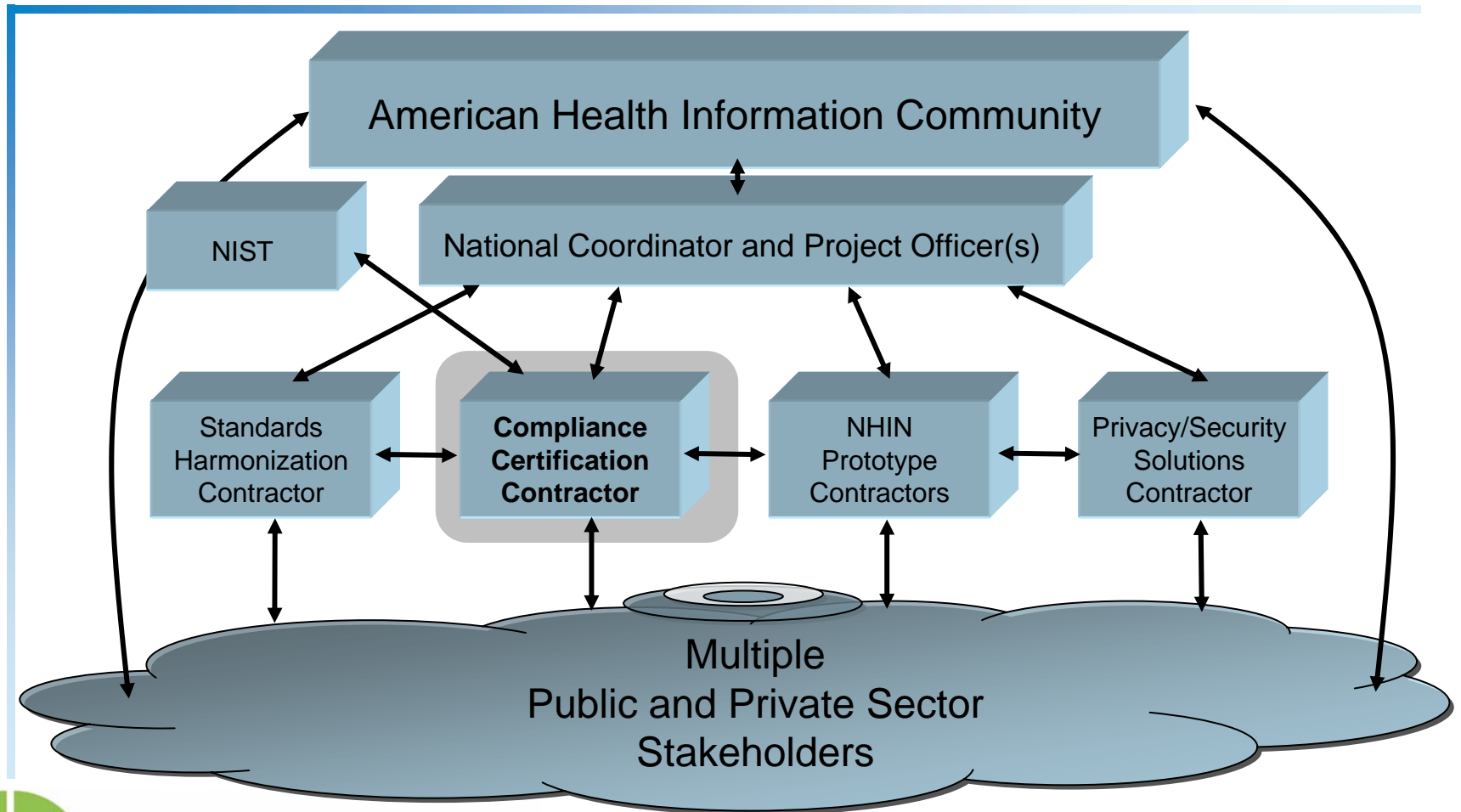


Future Scope Requested in ONCHIT-2 RFP

- **Year 1 (Oct 05 – Sep 06)**
 - Develop and pilot test certification of EHR products for ambulatory care settings
- **Year 2 (Oct 06 – Sep 07)**
 - Develop and pilot test certification of EHR products for inpatient care settings
- **Year 3 (Oct 07 – Sep 08)**
 - Develop and pilot test certification of infrastructure or network components through which EHRs interoperate

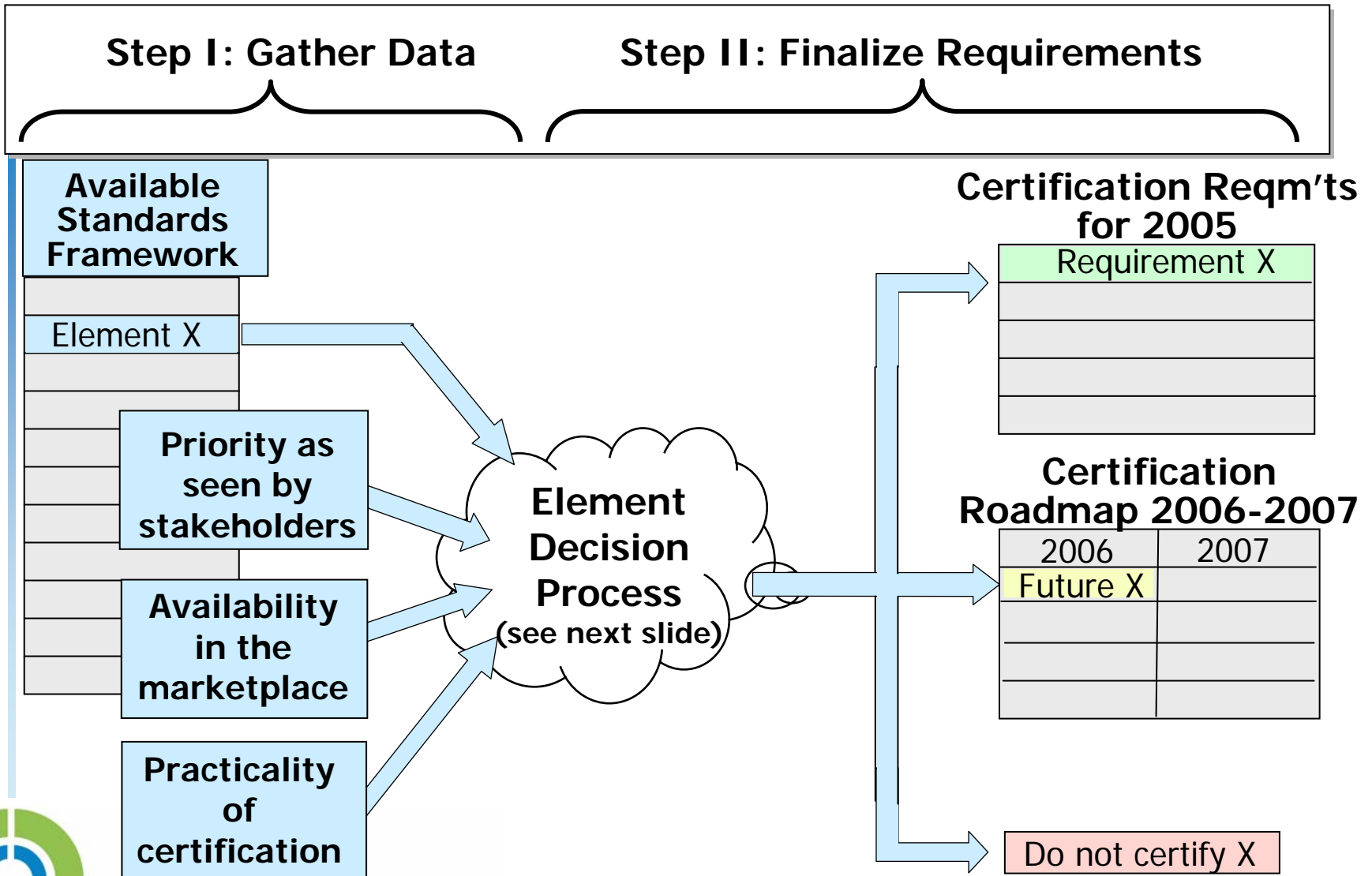


Certification as Part of HHS/ONCHIT Strategy



Process for Development of Certification Criteria

Work Group Process



Element Decision Process

		Availability		
		Widely Available	Available in 2006 or 2007	Availability Uncertain
Priority	Essential	Certify in 2005	Consider for 2006-07 roadmap	Do not certify
	Essential in the Future	Consider for 2006-2007 roadmap	Consider for 2006-2007 roadmap	Do not certify
	Optional	Do not certify	Do not certify	Do not certify



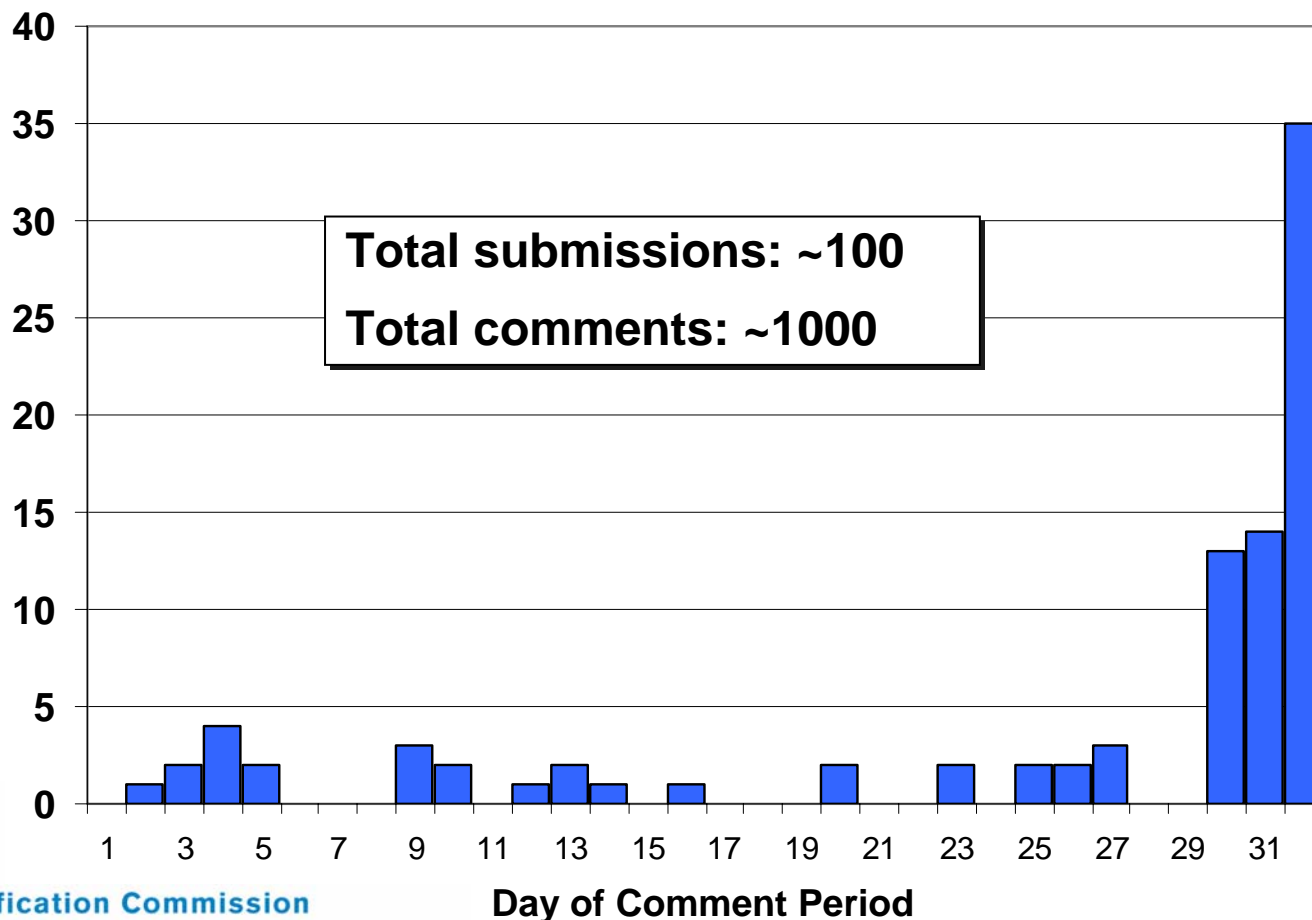
Phase I

Public Comment Period: Preliminary Results



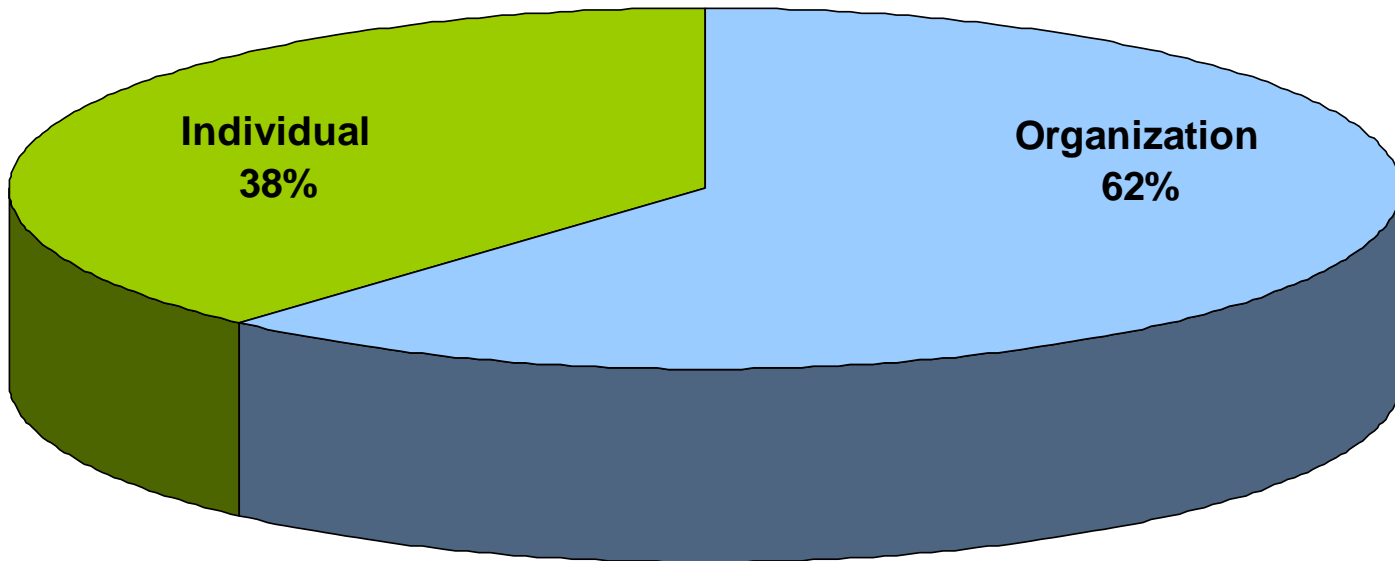
Phase I Public Comment: Response Volume and Timing

Daily Total Responses

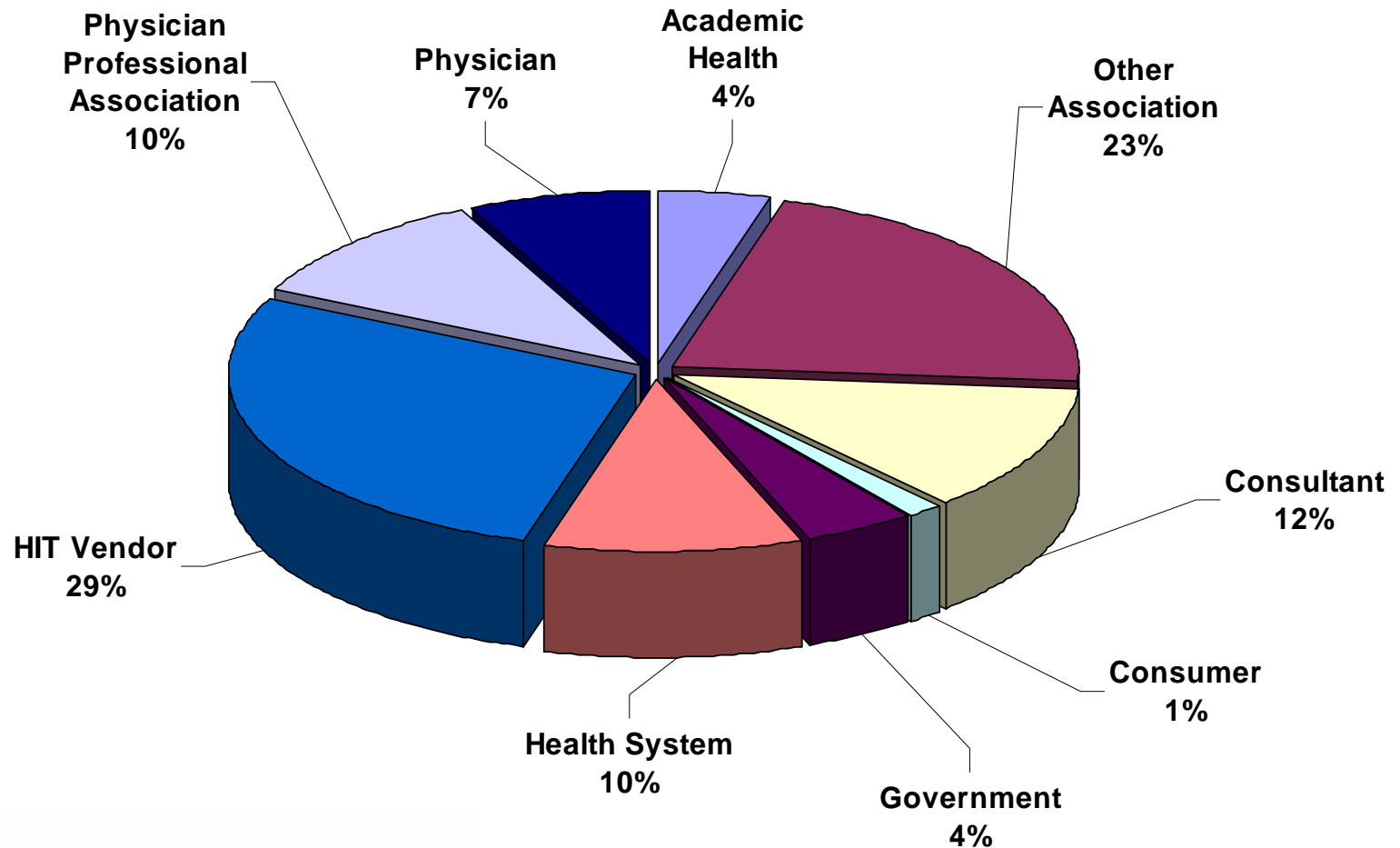


Phase I Public Comment: Responses by Source

Responses by Source

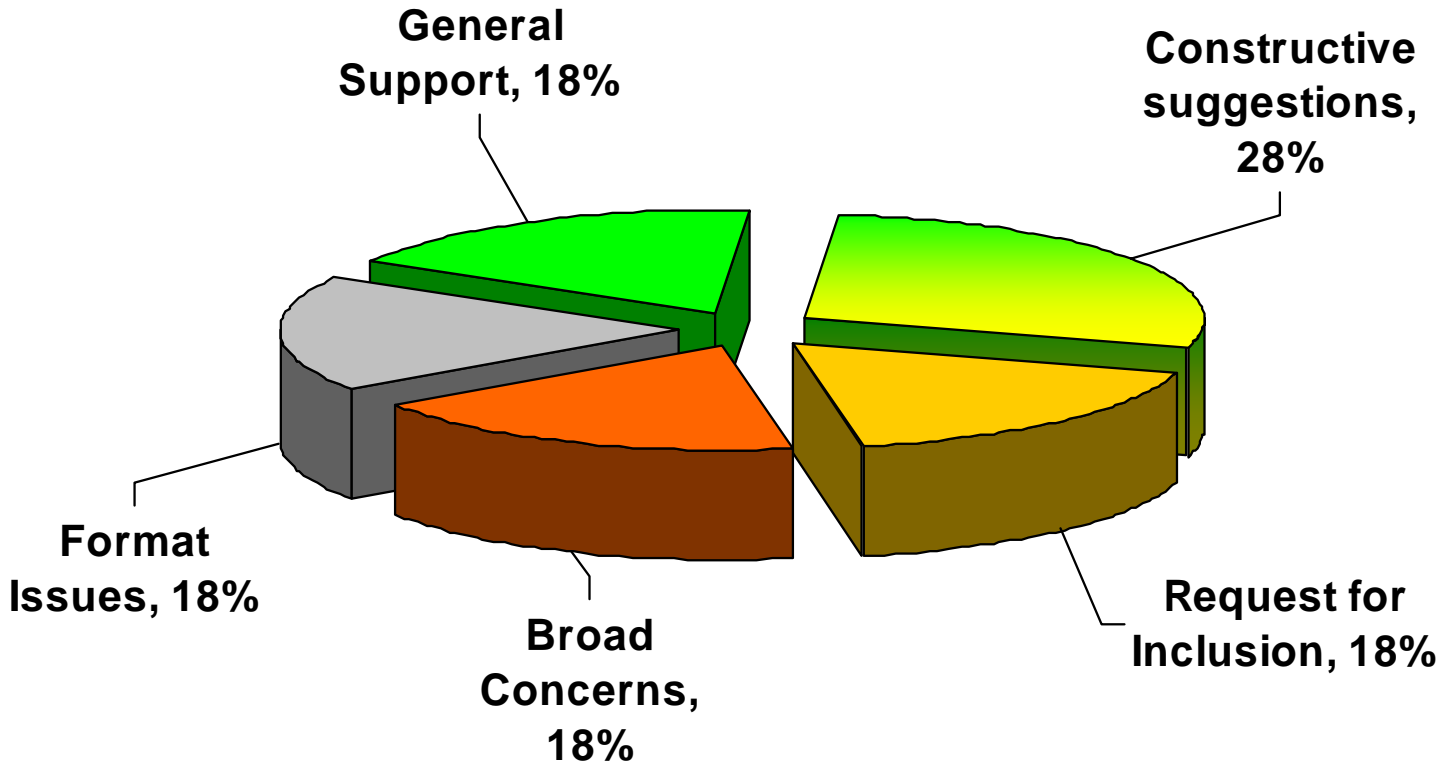


Phase I Public Comment: Responses by Category



Phase I Public Comment: General Responses for Commission (does not include comments for WGs)

TOTAL: 28



Overview of the Phase II Work Products



Phase II Work Products Available on CCHIT website July 11

The screenshot shows the CCHIT website header with the logo and URL www.cchit.org. Below the header is a navigation menu with the following items: About CCHIT, Press Releases, Commissioners, Commission Minutes, Work Groups, Public Comment on Phase 1, and Public Comment on Phase 2. The 'Public Comment on Phase 2' link is highlighted with a blue bar and an arrow pointing to it from the text 'Click here to access the Phase 2 documents'. To the right of the navigation menu is a content area with a text box containing instructions: 'Click on any of the links below to view a document online, or right-click and select "Save Target As..." to download the file (in Adobe PDF format) to your computer for offline review.' Below this text are three bullet points: 'Functionality Work Group: Spreadsheet and Appendix', 'Interoperability Work Group: Spreadsheet and Appendix', and 'Security & Reliability Work Group: Spreadsheet and Appendix'. Below these is another text box: 'If you prefer to download a single ZIP archive containing all three spreadsheets in both Adobe and Microsoft Excel formats, use the link below, right-click and select "Save Target As..."'. Below this text is a bullet point: 'ZIP archive of All Files'. A right-click context menu is open over the 'All Files' link, with 'Save Target As...' selected and highlighted in blue. An arrow points from the text 'Click to view immediately on-line' to the 'All Files' link, and another arrow points from the text 'Best for extensive work off-line' to the 'Save Target As...' option in the context menu. The CCHIT logo is also present in the bottom left corner of the slide.

www.cchit.org
The Certification Commission
for Healthcare Information Technology

- About CCHIT
- Press Releases
- Commissioners
- Commission Minutes
- Work Groups
- Public Comment on Phase 1
- Public Comment on Phase 2**

Click here to access the Phase 2 documents

Click on any of the links below to view a document online, or right-click and select "Save Target As..." to download the file (in Adobe PDF format) to your computer for offline review.

- Functionality Work Group: [Spreadsheet](#) and [Appendix](#)
- Interoperability Work Group: [Spreadsheet](#) and [Appendix](#)
- Security & Reliability Work Group: [Spreadsheet](#) and [Appendix](#)

If you prefer to download a single ZIP archive containing all three spreadsheets in both Adobe and Microsoft Excel formats, use the link below, right-click and select "Save Target As..."

- ZIP archive of [All Files](#)

Open
Open in New Window
Save Target As...
Print Target
Cut
Copy
Copy Shortcut
Paste
Add to Favorites...
Backward Link

Click to view immediately on-line

Best for extensive work off-line

The Certification Commission
for Healthcare Information Technology

New Common Format for Criteria Spreadsheet

CCHIT Certification Criteria for Ambulatory EHR Products Phase II DRAFT for Public Comment - 6/14/05 © 2005 The Certification Commission for Healthcare Information Technology																	
Line #	WG	Category and Description	Specific Criteria	Source or References	Priorities (L,M,H)					Availability			Recommend			Discussion / Comments	
					Providers	Vendors	Payers or Purchasers	Public Health	Patient	2005	2006	2007	Certify in 2005	Roadmap for 2006	Roadmap for 2007		
1																	
2																	
3																	
4																	

**Criteria from Functionality, Interoperability,
and Security & Reliability Work Groups
now “harmonized” in a common format**

Functionality Work Group Certification Criteria

CCHIT Certification Criteria for Ambulatory EHR Products FUNCTIONALITY Work Group Phase II DRAFT for Public Comment - 7/11/05 © 2005 The Certification Commission for Healthcare Information Technology																	
Line #	WG	Category and Description	Specific Criteria	Source or References	Priorities (L,M,H)					Availability			Recommend			Discussion / Comments	
					Providers	Vendors	Payers or Purchasers	Public Health	Patient	2005	2006	2007	Certify in 2005	Roadmap for 2006	Roadmap for 2007		
1	F	Identify & 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 with each patient record. (e.g. the system ID or medical record number)	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 facilitate the ability to store at least one additional 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 identifier.
4			4. Using the key identifying information, the system shall allow a user 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 could be to look up by date of birth, phone number, social security number...
6	F	Manage patient demographics: Contact information including addresses & phone numbers, as well as key demographic information such as date of birth, gender, and other information is stored & maintained for reporting purposes and for the provision of care.	1. The system shall capture and maintain demographic information as part of the patient record.	DC.1.1.2	H	H	H	H	H	H			X				
7			2. The system shall provide the ability to include demographic information in reports.	DC.1.1.2	H	H	H	H	M	H			X				
8			3. The system shall maintain historic information for prior names and addresses.	DC.1.1.2	H	H	H	H	M	M	H				X		Providers need this for look up and contact purposes.
9			4. The system shall allow a user to modify demographic information about the patient.	DC.1.1.2	H	H	H	H	H	H			X				
10			5. Demographic information shall be stored in the patient medical record in separate data fields, such that data extraction tools can be used to retrieve this data.	DC.1.1.2	H	H	H	H	L	H					X		

Functions and Conformance Criteria from HL7 EHR TC DSTU (Subset)

Evidence on Priorities and Availability

Recommendations for 2005 Criteria and 2006-2007 Roadmap*

Line # Include this with your comments

*Note: this is only a first draft of 2006 and 2007 Roadmap columns

Functionality Work Group Appendix

Functionality Workgroup Appendix to Phase II Version of Spreadsheet Released 7/11/05

Purpose:

The Functionality Work Group (FWG) has two major objectives. The first is to develop the functional elements which the FWG believe are necessary to be included in an Ambulatory EHR for the user of that EHR to achieve a threshold level of value. These functional elements should be adequately described so that vendors can build products that include them, CCHIT can test for their presence, and users will understand what to expect from a “certified” product. These functional elements should be categorized as to whether the FWG believes they are required in 2005 or in some future year. The second objective for the FWG is to develop certification criteria for each of the functional elements. These criteria will be used to construct the actual certification process for ambulatory EHR’s. The criteria should specify exactly what a candidate EHR must do in order for that functional element to be judged as present and operable.

Membership:



Interoperability Work Group Certification Criteria

CCHIT Certification Criteria for Ambulatory EHR Products INTEROPERABILITY Work Group Phase II DRAFT for Public Comment - 7/11/05 © 2005 The Certification Commission for Healthcare Information Technology																
Line #	WG	Category and Description	Specific Criteria	Source or References	Priorities (L,M,H)					Availability			Recommend			Discussion / Comments
					Providers	Vendors	Payers or Purchasers	Public Health	Patient	2005	2006	2007	Certify in 2005	Roadmap for 2006	Roadmap for 2007	
1	I	Laboratory and Imaging	Receive general laboratory results using common vocabulary with inbound interface optionality removed	ELINCS 1.0 (pending availability)	H	H	M	M	L	x			x			
2	I		Send orders to lab systems	HL7 V2.3 and V3 avail. now; LOINC test naming avail now; Implementation Guide in dev.	H	H	H	M	M		x			x		Complete order must be defined (minimum dataset). There is no good definition for a minimum data set for an order message.
3	I		Receive PACS images, photos and EKG images: Web access to images, image exchange	DICOM avail. Now IHE Cross-Enterprise Image Information Sharing integration profile (Aug 2005)	H	M	M	L	L		x			x		
4	I		Order and schedule radiology tests			H	M	M	L	L			x			x
5	I	Medications	Send electronic prescriptions	NCPDP SCRIPT 4.2 Surescripts XML	H	H	H	L	H	x			x			1. Not all pharmacies are willing or able to accept electronic scripts. This creates potential workflow issues within the physician office. 2. There are at least 9 states that do not allow this at this time. 3. Standards don't address clinical relevance issues. For example, what information should be displayed for drug to drug interaction?
6	I		Use discrete sigs in ePrescribing	NCPDP/HL7 Sig in dev.*	H	M	H	M	M			x			x	1. Need to standardize on one format, or is mapping sufficient?
7	I		Query and receive medication claims history	NCPDP/RxHub developed*		H	H	H	H	M		X			x	1. Not all PBMs are able or willing to share formulary, medication history and eligibility data. 2. Not all PBMs use RxHub. increases cost and time to on

Interoperability Categories and Criteria with References

Evidence on Priorities and Availability

Recommendations for 2005 Criteria and 2006-2007 Roadmap*

Line # Include this with your comments

Interoperability Work Group

Appendix

Interoperability Workgroup Appendix to Phase II Version of Spreadsheet Released 7/11/05

Note regarding Line 1

Laboratory interoperability- Receive results

- The ELINCS 1.0 specification is not complete but may be completed in time for first year certification.

Note regarding Line 5

Medications- Send electronic prescription

- NCPDP SCRIPT 4.2 and Tele.
 - Most EHRs are sending prescriptions using SureScripts version (XML implementation of CDC script)
- Barrier to availability of RxHub Implementation Guide
 - Not yet approved by NCPDP
- HL7
 - Is being mapped to NCPDP Script
- CeRx
 - Used in Canada
- NCPDP RxFill
 - Notifications



Security & Reliability Work Group Certification Criteria

CCHIT Certification Criteria for Ambulatory EHR Products SECURITY & RELIABILITY Work Group Phase II DRAFT for Public Comment - 7/11/05 © 2005 The Certification Commission for Healthcare Information Technology																
Line #	WG	Category and Description	Specific Criteria	Source or References	Priorities (L,M,H)					Availability			Recommend			Discussion / Comments
					H Providers	Vendors	Payers or Purchasers	Public Health	Patient	2005	2006	2007	Certify in 2005	Roadmap for 2006	Roadmap for 2007	
1	SR	Security: Access Control	The system shall enforce the most restrictive set of rights/privileges or accesses needed by users (or processes acting on behalf of users) for the performance of specified tasks.	ISO 17799: 9.1.1.2.b; HIPAA: 164.312(a)(1)	H	M	H	M	H	X			X			Phase I Original S&R Ref #18; Ties to minimum necessary requirement under Privacy Rule.
2			The system shall provide the ability for an authorized administrator to define restrictions at the function access level	Canadian: Alberta 4.1.3 (EMR); CC SFR: FMT_MSA; SP800-53: AC-5 LEAST PRIVILEGE; HIPAA: 164.312(a)(1)	M	H	H	M	H	X			X			Phase I Original S&R Ref #20;
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).	Canadian: Ontario 5.3.12.e (System Access Management); CC SFR: FDP_ACC, FMT_MSA; ASTM: E1985-98; SP800-53: AC-3 ACCESS AND INFORMATION FLOW CONTROL; HIPAA: 164.312(a)(1)	H	1) H 2) H 3) L	H	L	H	X			X			Phase I Original S&R Ref #22;
4			The system shall support revocation of the access privileges of a user without requiring deletion of the user.		M	L	M	L	H	X				X		NEW REQ: For example, this maintains an audit trail of previous users and their privileges
5			Security: Audit	The system shall be able to generate an audit record when auditable events happen, including but not limited to the following (success, attempt, and failure): system start/stop, User Login/Logout, Chart created/viewed/updated/deleted, Scheduling, Query.	CC SFR: FAU_GEN; SP800-53: AU-2 AUDITABLE EVENTS; HIPAA: 164.312(b)	H	M	H	M	L	X			X		Phase I Original S&R Ref #232;

Security and Reliability Categories and Criteria with References

Evidence on Priorities and Availability

Recommendations for 2005 Criteria and 2006-2007 Roadmap*

**Line #
Include this
with your
comments**

*Note: this is only a first draft of 2006 and 2007 Roadmap columns

Security & Reliability Work Group

Appendix

Security and Reliability Workgroup Appendix to Phase II Version of Spreadsheet

Released 7/11/05

Clarifications

The majority of the comments submitted for the Security and Reliability Workgroup involved requests for clarification. The Work Group wishes to clarify several security and reliability requirements in this report. The Work Group also made other revisions and clarifications in the requirements list. *(Please see the list for details.)*

- **General:** The Workgroup believes the product as a whole should be evaluated, which could include 3rd party products. More specifically, certification of healthcare information technology products is not platform-dependent. If a product to be certified contains or depends on third-party products, the product as a whole will be certified. However, this certification does not cover third-part products(s) in their entirety, but only as there are utilized by the product as a whole. It is the vendor's responsibility to define the scope of the product to be certified.
- **General:** Criteria for reliability, including system performance, will continue to be examined by the Security & Reliability Workgroup. Additional criteria may be added in future years.
- **General:** The Work Group acknowledges that certification of a system can neither guarantee privacy and security protections nor prevent unauthorized access. How a practice secures the system (through policy, training and physical safeguards) also impacts



Certification Process and Use Case/Test Plan Work Groups

- To synchronize with ONCHIT-2 RFP, testing will be Use-Case based
- Use Case/Test Plan WG will draft CCHIT's "Recommended Use Cases" for public comment in ~60 days
- "Common Use Cases" will be developed through collaboration with other HHS contractors and all stakeholders
- Updated certification process will also be circulated for comment in 60-90 days

Thank You!

**Specific comments on the work products
should be submitted online:**

