The Certification Commission for Healthcare Information Technology (CCHIT) Update

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Presented before the National Committee on Vital and Health Statistics

June 30, 2005

Washington, DC



Topics to be Covered

- Origin, Mission and Concept
- Organizational Structure
- Scope, Deliverables, and Timeline
- Development Process
- Overview of Work Products and Public Comment Process
- HHS Health IT Strategy and the Future of CCHIT



Origin, Mission and Concept of CCHIT



Origins of CCHIT

Goals	Stı	rategies ^a
	1.	Incentivize EHR adoption
Goal 1: Inform clinical practice with	2.	Reduce risk of EHR investment
the use of electronic health records	3.	Promote EHR diffusion in rural and underserved
(EHR)	are	eas
Goal 2: Interconnect clinicians so that		
they can exchange health information	1.	Foster regional collaboration
using advanced and secure electronic	2.	Develop a national health information network
communication	3.	Coordinate federal health information systems
Goal 3: Personalize care with	1.	Encourage use of personal health records
consumer-based health records and	2.	Enhance informed consumer choice
better information for consumers	3.	Promote use of telehealth systems
Goal 4: Improve public health through		
advanced biosurveillance methods and	1.	Unify public health surveillance architectures
streamlined collection of data for	2.	Streamline quality and health status monitoring
quality measurement and research	3.	Accelerate research and dissemination of evidence

Source: HHS.

^a Phase I strategies are shown in bold type.

The Certification Commission for Healthcare Information Technology

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

Founding of CCHIT

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



Broadened Funding Support

- Unrestricted grants, \$110k total, from:
 - American Academy of Family Physicians (AAFP)
 - American College of Physicians (ACP)
 - Hospital Corporation of America
 - McKesson
 - Sutter Health

ealthcare Information Technology

- 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 <u>now</u>

Value

- Deliver value for <u>all</u> 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

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

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

Can't offer incentives unless benefits and interoperability of EHRs are assured

Payers/Purchasers



HIT Vendors

Can't bring down costs until provider adoption accelerates

Providers

Hesitant to buy HIT until costs and risks are lower and/or incentives higher

Breaking the Deadlock

Beneficial effects and interoperability assured, unlocking incentives

Payers/Purchasers

HITAdoption

IT Vendors

Growing market attracts investment, lowers costs

Providers

Reduced risk and availability of incentives accelerates adoption

Key Stakeholder Relationships

HIT Users -Providers and
Provider Organizations

Information on market & needs

Increase confidence in investment

HIT Vendors

Information on current and future state of products

Accelerate market; roadmap of future expectations

Payers with Incentives for IT Adoption or IT-Enabled Quality

Commitment to incentives for certified products

Assurance that certified products, properly deployed, can deliver results

HIT Standards Organizations

Standards against which compliance can be tested

Feedback on current standards; drive development of new standards

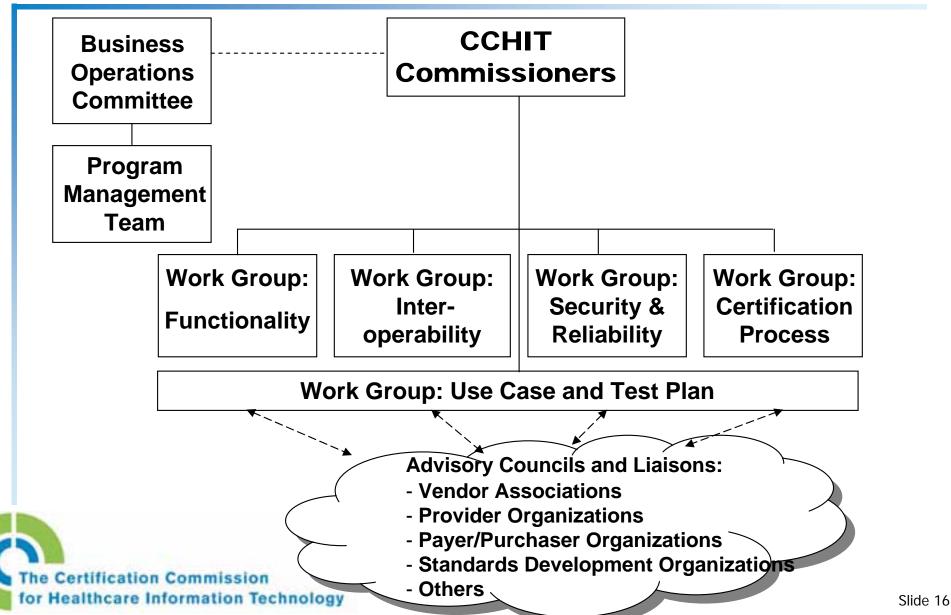
Certification Commission

Additional Stakeholders: consumers, public health, research, quality org's

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

Healthcare Information Technology

Pilot process ready in September 2005

Certification Roadmap Concept

EHR
Product
Attributes

Current Year 1 Year Ahead 2 Years Ahead

Functionality

Interoperability

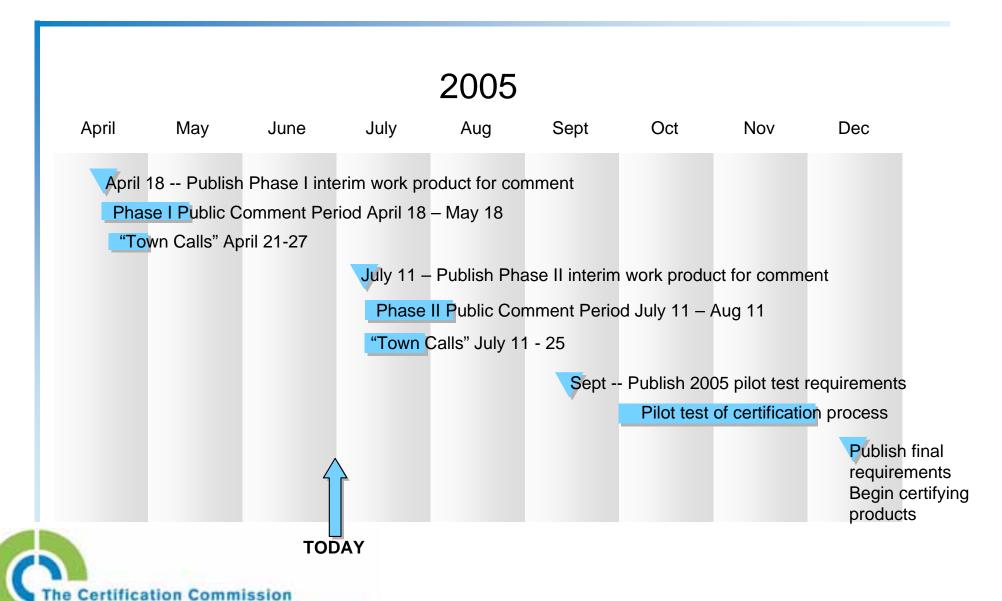
Security & Reliability

,	Final 2005	Forecast 2006	Forecast 2007
	Requirements	Requirements	Requirements
,	Final 2005	Forecast 2006	Forecast 2007
	Requirements	Requirements	Requirements
,	Final 2005	Forecast 2006	Forecast 2007
	Requirements	Requirements	Requirements



Timeline

(Subject to adjustment)



for Healthcare Information Technology

Description of Project Phases

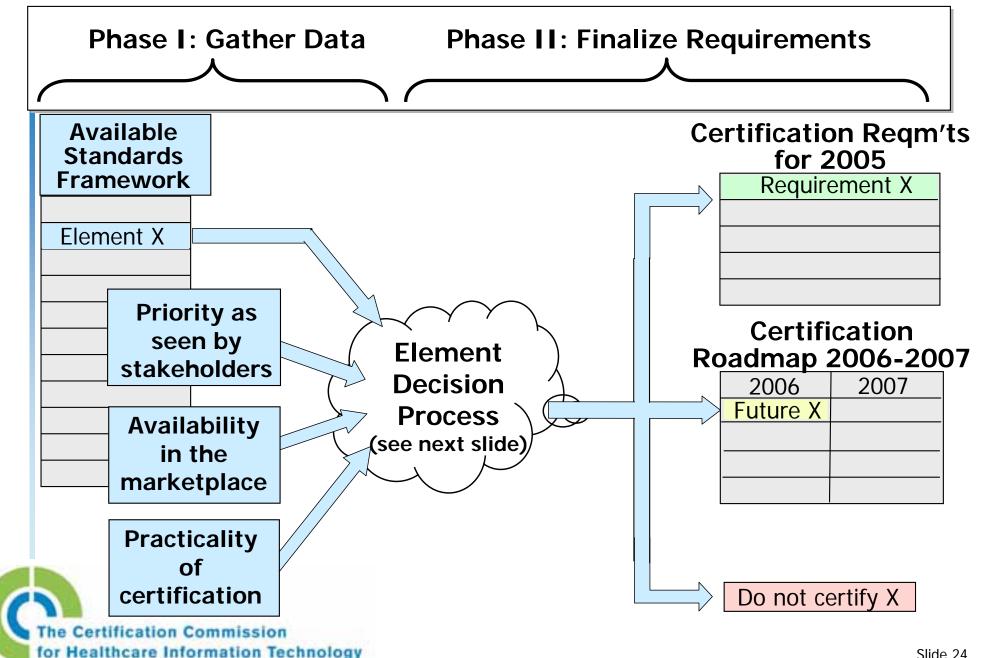
- Phase I Data Gathering
- Phase I Public Comment period
- Phase II Draft requirements
- Phase II Public Comment period
- Finalize requirements and begin pilot test
- Publish final requirements and roadmap
- Launch product certification



Process for Development of Certification Criteria



Work Group Process



Element Decision Process

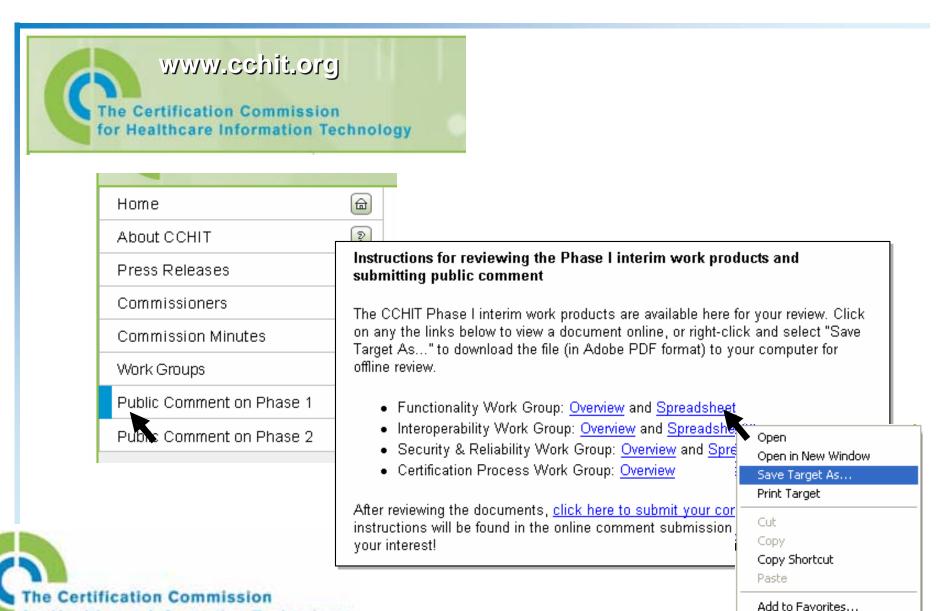
			Availability	
		Widely Available	Available in 2006 or 2007	Availability Uncertain
	Essential	Certify in 2005	Consider for 2006-07 roadmap	Do not certify
Priority	Essential in the Future	Consider for 2006-2007 roadmap	Consider for 2006-2007 roadmap	Do not certify
	Optional	Do not certify	Do not certify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

for Healthcare Information Technology

Overview of Work Products and Public Comment Process



Phase I Work Products on Website (Note: Comment period is now closed)



for Healthcare Information Technology

Rachward Links

Functionality Work Group Spreadsheet – Left Portion

Line #	Criterion Name	WG	Criterion Description	Source (map to Standard source)		Prioriti	98 (L,M,H)		
				,	Providers	Vendors	Payer/ Purchasers	Other	\Box
2	identify & maintain a patient record	Funct	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.						
3									
ļ									
6									MORE
,	Manage patient demographics	Funct	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 fo	DC.1.1.2	These data elements are necessary for determining needed		These individual data elements are needed for tracking disparities in care, trends in		m
0			the provision of care.		care, contacting the patient.		disease patterns with regional variation, and help identify potential		
1							events related to bioterrorism. Age is needed to track appropriate health services such as		
13	Manage summary lists	Funct	Patient summary lists can be created from patient specific data and displayed and maintained in a summary format. The functions below are important,	DC.1.1.3	This is important to providers for quickly assessing the			These are Important to patients who	
	(,				,	/

Functions from HL7 EHR TC DSTU (Subset)

Evidence on Priorities

Functionality Work Group Spreadsheet – Right Portion

Av	ailabil	ity¹				Recomme	ndation
2005	2006	2007	Test Method	Test Specificat ion	Certify in 2005		Roadmap for 2007
Н			The system SHALL create a single patient record for each patient.				
Н			The system SHALL associate (store/link) key identifier information with each patient record.				
Н			The system SHALL store multiple identifiers for each patient record.				
Н			 Using the key identifying information, the systemSHALL identify (look up) the unique patient record. 				
Н			The system SHALL maintain and make available dynamic data element for each patient record.	S			
Н			 The data in the patient record and the integrity or the record itself SHALL be maintained until specifically deleted based on local policies, procedures and/or applicable laws and regulations. 		L		
Н			The system SHALL capture and maintain demographic information as part of the patient record.		O		
Н			The system SHALL provide ability to report demographic information.				
М			The system SHALL keep track of demographic information over time.				
Н			The system SHALL allow a user to modify demographic information about the patient.	, ,			7

Evidence on Availability

Conformance Criteria and Test Specifications

To be developed (Phase II): 2005 Criteria and 2006-07 Roadmap

Interoperability Work Group Spreadsheet

			CCHIT Interoperability	Workgroup Pha			tion of Data and Assessment of the Industry				
Line Num.	Highlig	ID	Use Case Component	Description	Providers	Payers/ Purchasers	Discussion / Barriers to Market Availability	Source Standard or Implementation		Source Available Today?	
1		orato	ry and Imaging	ls " :							
2	ED.	L.1	Receive results	Results using common vocabulary with inbound interface optionality removed	Н	IVI	(1) Interface optionality; (2) lack of standard result and result values vocabularies; (3) non-standard handling of microbiology; (4) Coding standards (once defined) must be kept current. Process must be efficient and fast to keep up with the addition of new tests; (5) Need to provide discrete data and laboratory specific reports. This is especially true for anatomical pathology and esoteric reporting. (6) Myriad of communication architectures increases costs to support send and receipt of results. (7) What is business model to support real-time results feeds? Who will pay? (8) Potential for innovation (technological and clinical) to be throttled by standards bodies.				
3								HL7 v2.4		Х	
4								HL7 v3			
5								LOINC result naming		Х	
6							Result values naming	SNOMED		Х	
7									CCDP Implementation Guide - Batch	Х	

Interoperability
Use Cases –
Priority cases highlighted

Evidence on standards, vocabularies, barriers, and availability

To be developed (Phase II): 2005 criteria and 2006-07 roadmap

Line

Numbers

Security & Reliability Work Group Spreadsheet

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Security Criteria with references and rationale for inclusion/exclusion

Priorities and ranket availability

Preliminary recommendations (to be refined , in Phase II)

Line

Numbers

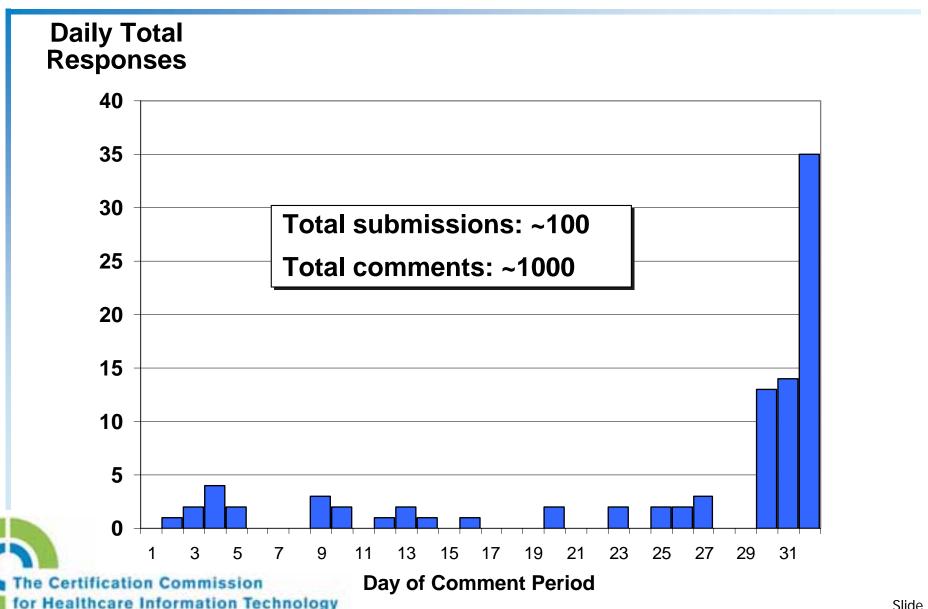
Certification Process Work Group Overview Document

2	Certification Commission for Healthcare Information Technology Certification Process Work Group Phase I Deliverable for Public Comment
4	I. Introduction
5	The Certification Process Work Group (CPWG) is pleased to present its Phase I report on its progress towards identifying the essential
6	elements of a certification process for ambulatory electronic health records. The CPWG is actively seeking feedback on this Phase I
7	deliverable in order to develop a consensus-based model that will serve the needs of the various stakeholders within the process. The
8 9	goal of Phase I was to develop an assessment of current and potential testing methodologies and then provide a summary for public comment.
10	Phase I included the following deliverables:
11	 Research and examine a variety of current certification testing processes that had similar objectives to those of the CCHIT.
12	Develop a summary of possible testing approaches
13	 Research capabilities of current software testing laboratories
14	 Construct a framework for an idealized certification process for electronic health records.
15	Phase II will commence once the initial public comment period has been completed. Phase II deliverables include the following:
16	 Details regarding the specific testing processes for certifying the individual criteria developed by the other Work Groups
17	 Specific cost estimates will be developed once the fundamental decisions regarding the methods, location and sponsoring
18	organization(s) are reached.
19	There are two levels to defining a certification process for electronic health records:
20	The first level is outlining the macro level process. This includes everything from the application process to the
19	organization(s) are reached. There are two levels to defining a certification process for electronic health records:

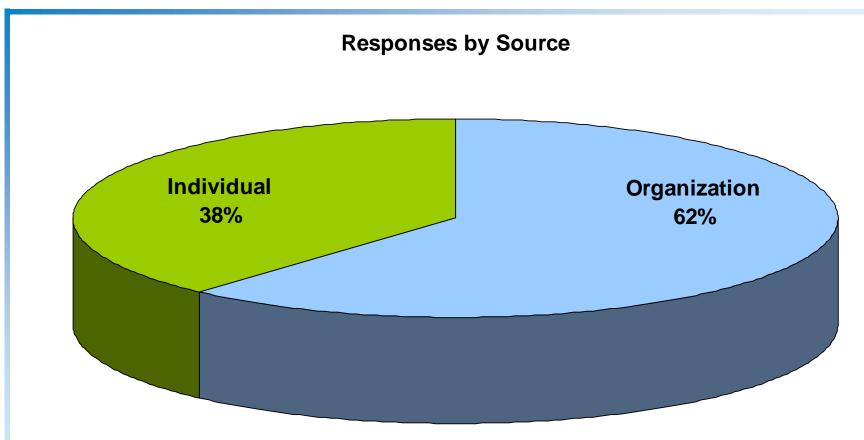
Phase I Public Comment Period: Preliminary Results



Phase I Public Comment: Response Volume and Timing

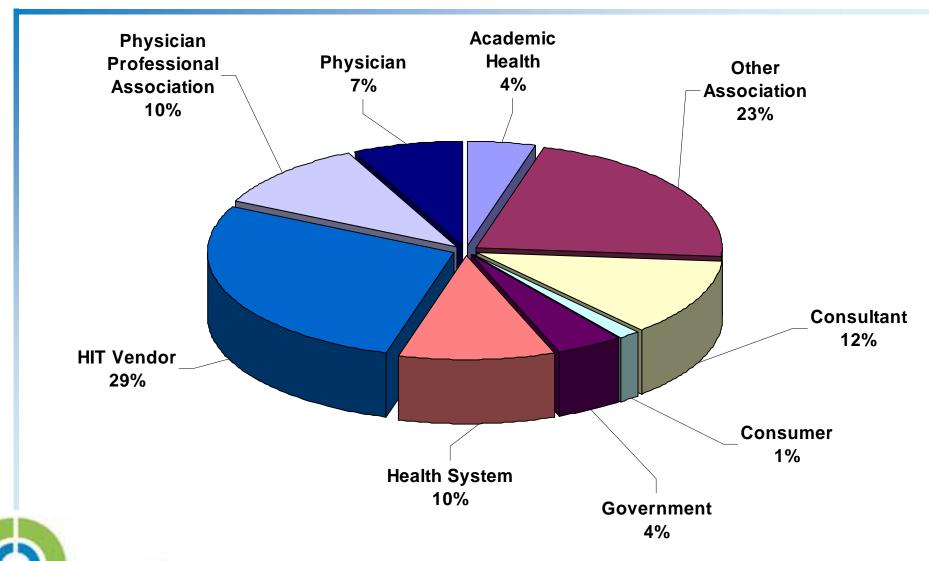


Phase I Public Comment: Responses by Source





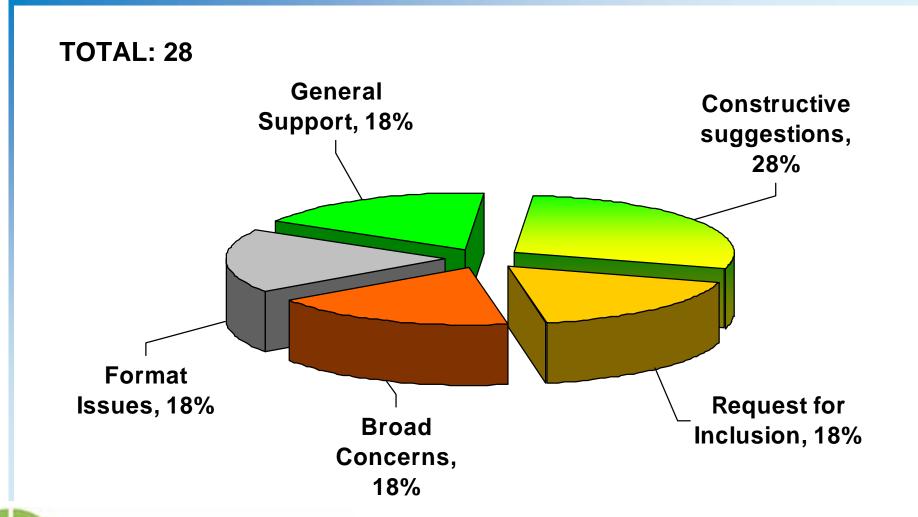
Phase I Public Comment: Responses by Category



Certification Commission

for Healthcare Information Technology

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

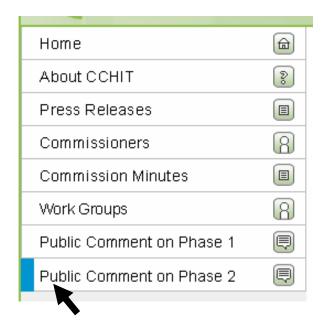


Phase II Work Products: Preview of Changes



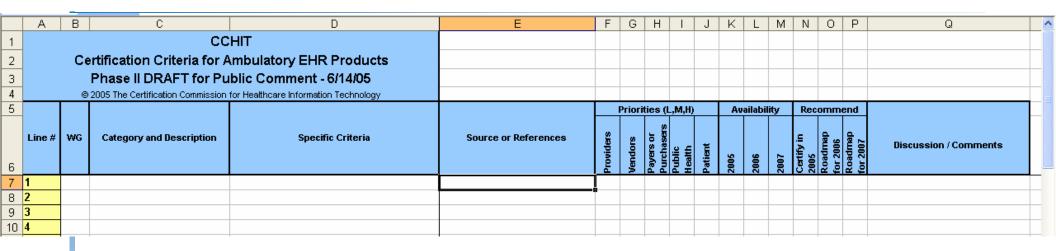
Phase II Work Products Will Be Available on Website July 11







New Common Format



Criteria from Functionality, Interoperability, Security & Reliability Work Groups now "harmonized" in a common format



6	Line#	WG	Category and Description	FOSSW Specific Criteria		ce or References	Providers		Payers or	, =	اڀ			2007	Certify in 2005	Roadmap for 2006	Discussion / Comments
	1	F	Identify & maintain a patient record: Key	The system shall create a single patient record for each patient.	DC.1.1.1							Н					
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	4			Using the key identifying information, the system shall identify (look up) the unique patient.	DC.1.1.1							н					
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Crosswalk: Interoperability

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Crosswalk: Security and Reliability

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	1	SR	Security: /	ccess Control	righ pro	e system shall enfo Its/privileges or acc cesses acting on b formance of specif	cesses nee ehalf of us	eded by use	rs (or	SO 17799: 9.1.1.2.b; HIPAA: 164.312(a)(1)		Н	M	H		Н	X			X			Tied to #20 User starts access. Tie requirement Fundament incorporate (this cover functions) context-ba define refte examples t	with loves to min t under l al princip ed. This d s rights t as well sed are i ria to tes	west levi imum ne Privacy f oles that covers ri to perfor as user- implemer st these.	el of cessary Rule. should b ble-based m certain based or itations - Add
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			- 17			horized administrati ction access level	or to define	e restrictions		FMT_MSA; SP800-53: AC-5 LE PRIVILEGE; HIPAA: 164.312(a)					\											
3	1		V		witi	e system must be al h a user using one ty-based or 3) com	or more of	1)role-Mase	ssions ed, 2)																	
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	15	Contro			TED		81126	94.202(4)(1)	2005	The TCE and 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 fasks.	Tied to privileg towest to minin require Rule. Fit that she This coo covers certain user-be are importerial example users of for adir	e. User level o num ne ment u undame ould be vers ro rights functio seed or lement to test es that and ade	r start of according to the content of the content	ts with eas. T any Privace princip reporate leed (bright as we end-be c - defi e. Add or end- (see #	y Hes His Has used	\ /	M				3			×		
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Considered state of the art

164.012(4)(9)

Access

Control

FDP_ACC

ACCESS

First Draft of "Use Cases"

- Use cases: realistic clinical scenarios for test purposes
- Use cases should demonstrate product fulfillment of functionality, interoperability, and security criteria
- Common use cases will help unify and coordinate efforts in the new HHS health IT strategy



HHS Health IT Strategy and the Future of CCHIT

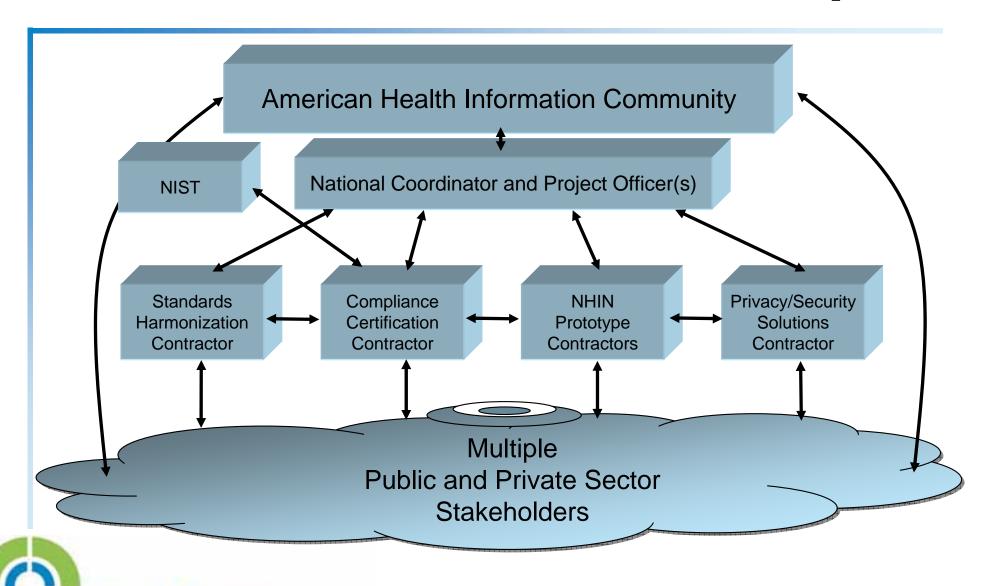


New HHS Health IT Initiatives Announced June 6-7, 2005

- American Health Information Community
 - Chaired by HHS Secretary Mike Leavitt
 - Five specific tasks requiring recommendations
- Four RFP's released June 7
 - Standards harmonization process
 - Compliance certification and inspection process*
 - Prototypes for a National Health Information Network
 - Privacy and security solutions for interoperable health information exchange

*CCHIT is responding to this RFP

Collaborative Relationships



Certification Commission

for Healthcare Information Technology

Thank You! Q and A

For more information, please visit the website:



