

The Certification Commission for Healthcare Information Technology Town Hall

Mark Leavitt, MD, PhD
Chair, CCHIT

Karen Bell, MD, MMS
Director, Office of HIT Adoption, ONC

Alisa A. Ray
Executive Director, CCHIT

9:45-11:45 AM, Tuesday, Feb 14, 2006
HIMSS '06 Annual Conference
San Diego, CA

Topics

- **Introduction**
- **Strategic Role of CCHIT**
- **Scope, Organization, Timeline, Process**
- **Status Report on Phase I:
Ambulatory EHR Certification**
- **Preparation for Phase II:
Inpatient EHR Certification**
- **Opportunities for Participation**
- **Q & A**

Introduction

Background

- **July 2004: Certification of HIT products a key action in HHS Strategic Framework**
- **Sept 2004: AHIMA, HIMSS, and the Alliance fund and launch CCHIT**
- **June 2005: Eight additional organizations add \$325k funding support**
- **July 2005: HHS issues Health IT RFPs**
- **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 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.**

Stakeholders and Partners

Private Sector

- **Providers**
- **Vendors**
- **Payers/purchasers**
- **Consumers**
- **Quality Improvement**
- **Researchers**
- **Standards Developers**

Public Sector

- **HHS/ONC**
- **HHS Contractors**
- **Safety Net Providers**
- **Public Health**
- **Federal agencies**
 - NIST, DoD, VHA, DHS, DoC, NSF, GSA, EPA and others

Guiding Principles

- **Always protect the privacy of the patient/consumer's health information**
- **Need for decisive private-sector action now**
- **Governance must be credible, objective, and collaborative**
- **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**

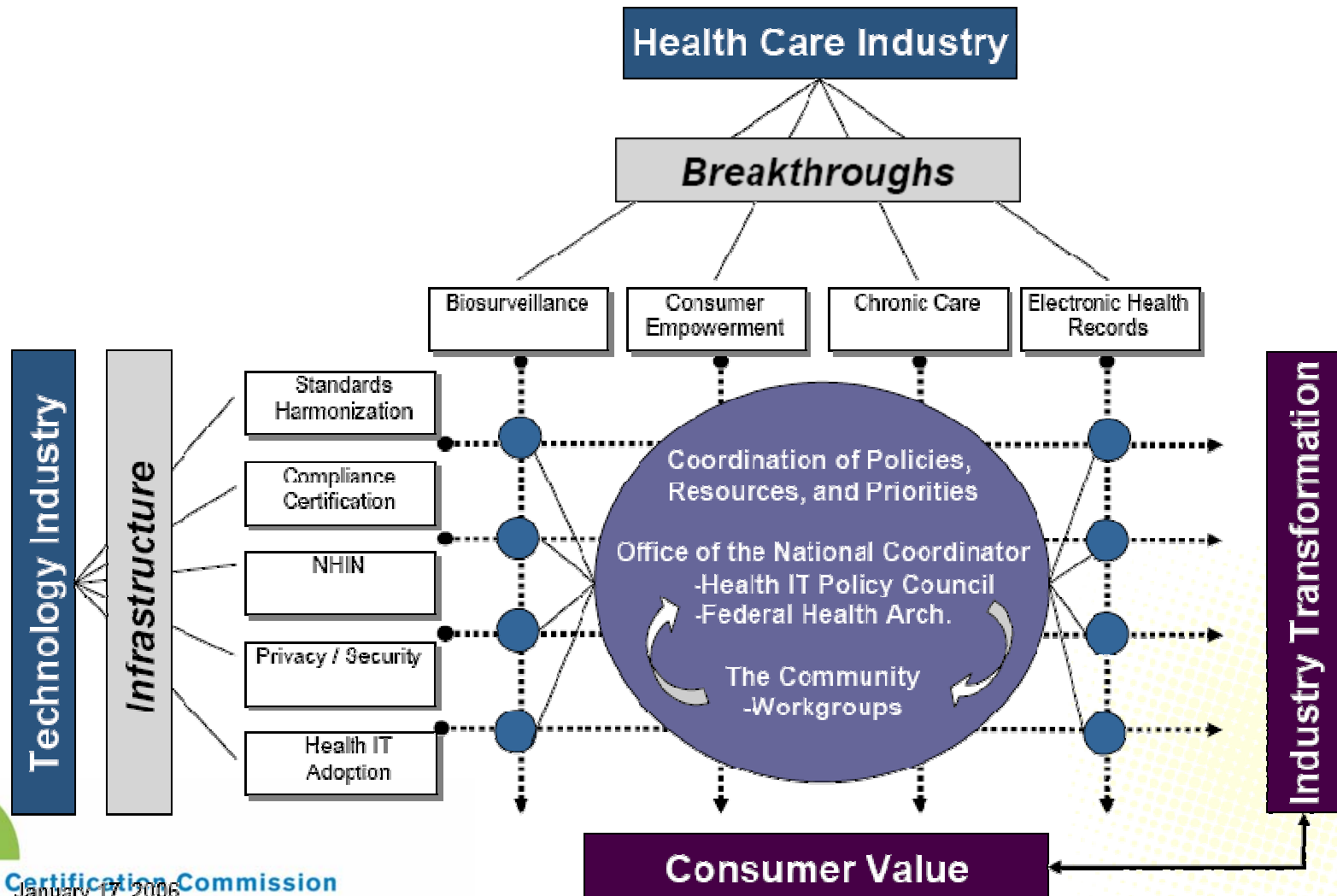
Goals of Product Certification

- **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**

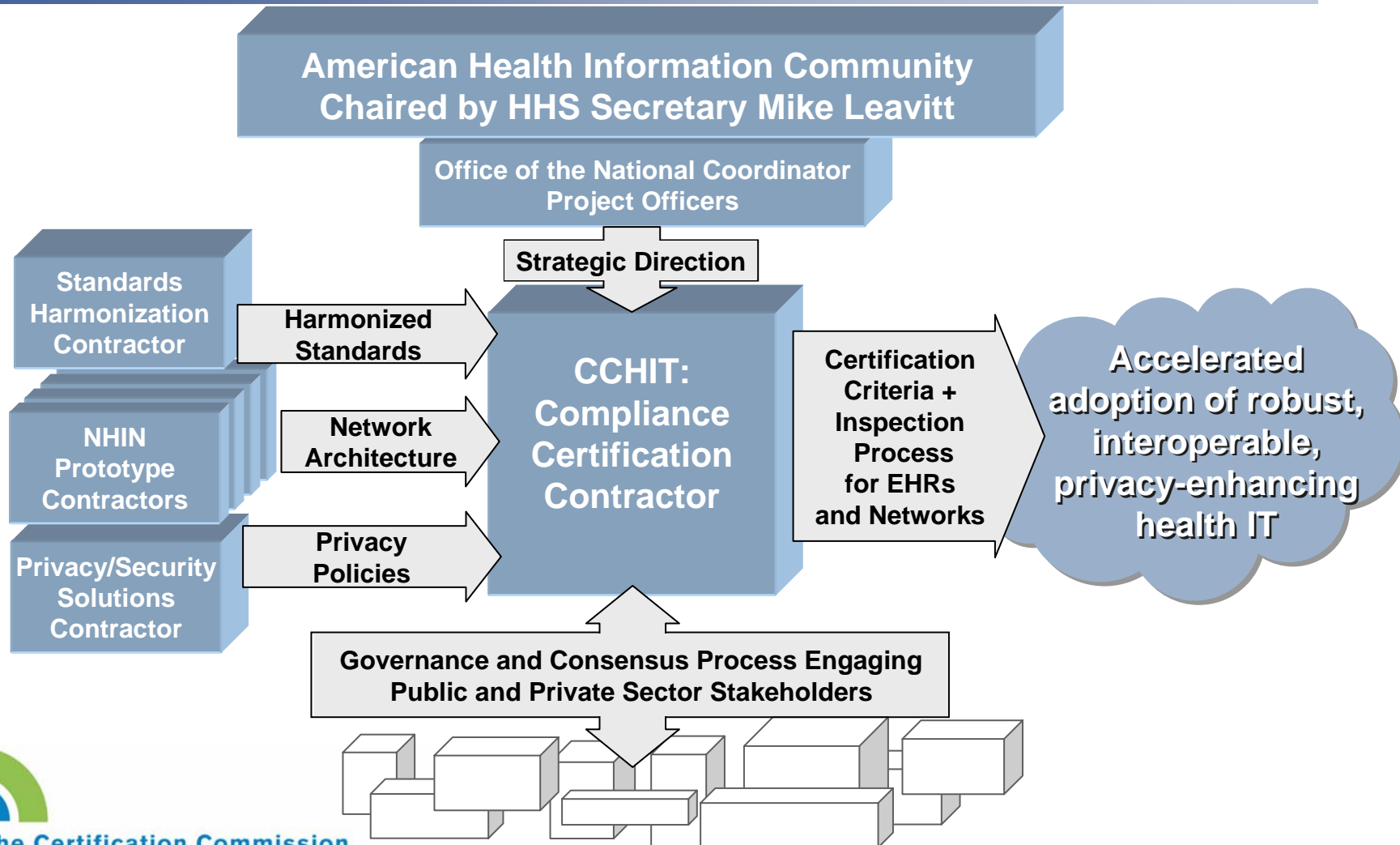
Strategic Role of CCHIT

Health IT Deployment Coordination

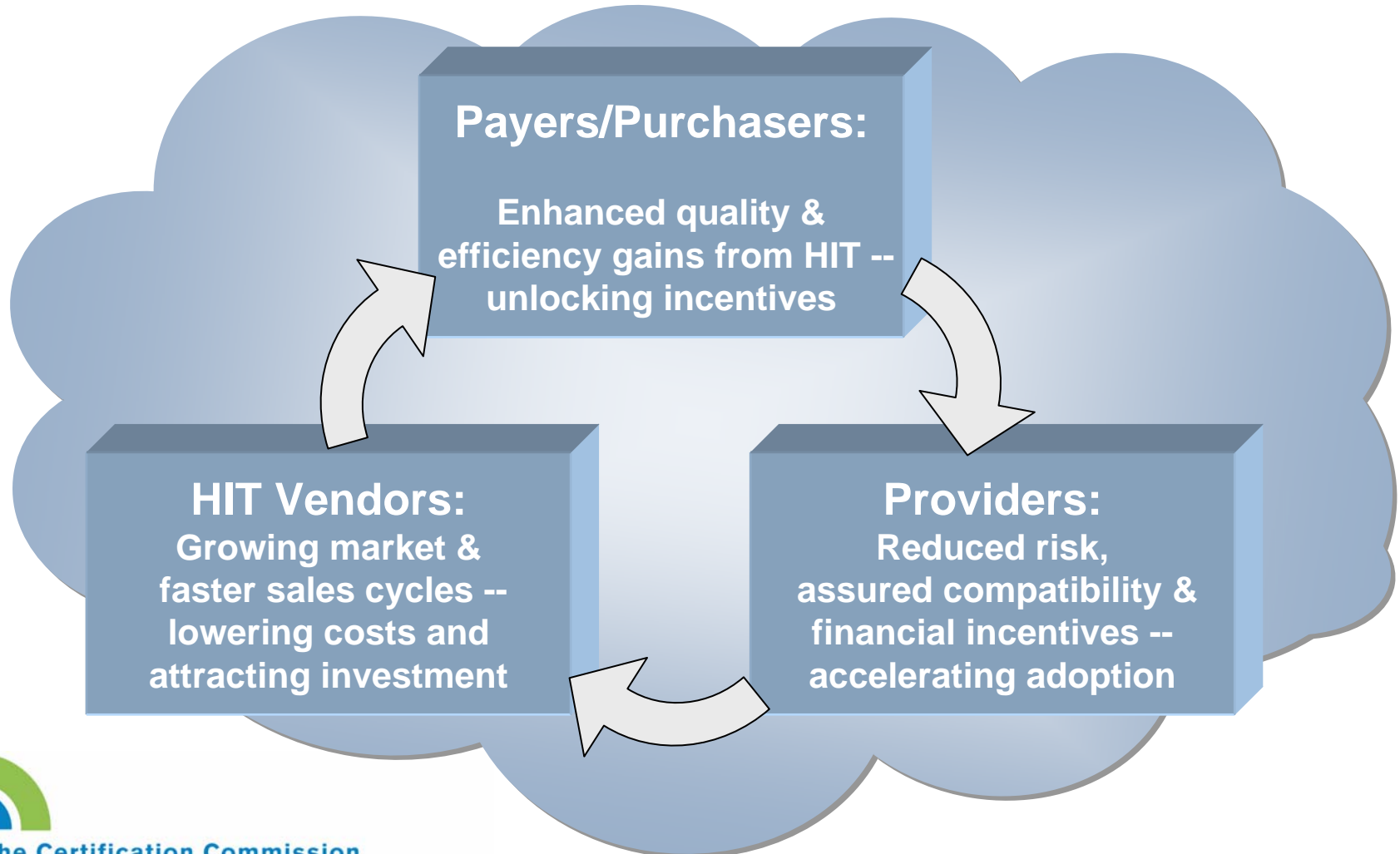
(From AHIC meeting of 1/17/06)



Role of CCHIT within the HHS Health IT Strategy



How Product Certification Can Catalyze HIT Adoption

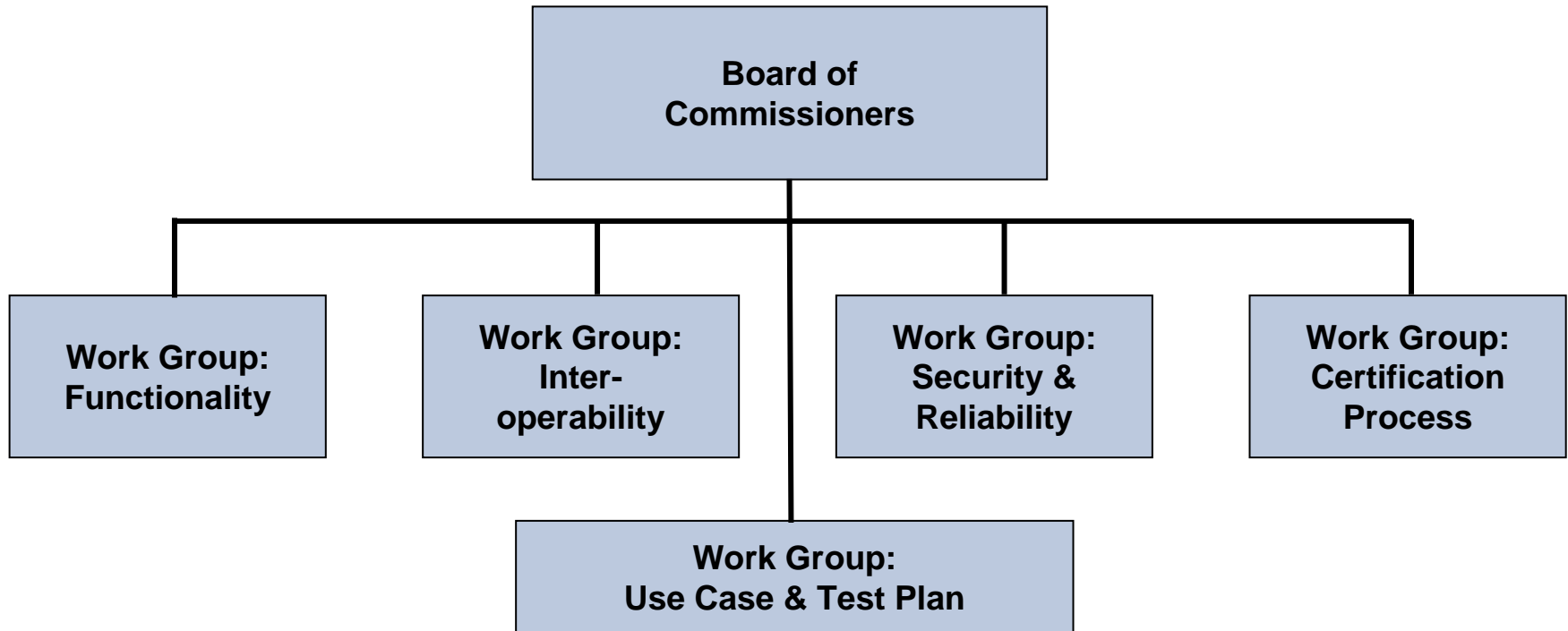


Scope, Organization, Timeline, and Process

CCHIT 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

Volunteer Organization (Current)



Board of Commissioners

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Director, Medical Informatics
Kings County Hospital
- **Stephen Badger**
Chief Executive Officer
GWU Medical Faculty Associates
- **David W. Bates, MD, MSc**
Chief, General Medicine
Brigham and Women's Hospital
- **Karen M. Bell, MD**
Director, Office of HIT Adoption
ONCHIT
- **Bruce Nedrow (Ned) Calonge, MD**
Chief Medical Officer
Colo. Dept of Public Health & Environment
- **Kelly Cronin**
Senior Advisor to the Administrator
CMS
- **Suzanne Delbanco**
Executive Director
The Leapfrog Group
- **Jane L. Delgado, PhD, MS**
President and CEO
National Alliance for Hispanic Health
- **John Hummel**
Corporate CIO & Senior VP of IS
Sutter Health
- **Sam Karp**
Chief Program Officer
California HealthCare Foundation

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Research Director
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- **John Tooker, MD, MBA, FACP**
Executive Vice President / CEO
American College of Physicians
- **Reed V. Tuckson, MD**
Senior VP, Consumer Health
United Health Group
- **Andrew G. Ury, MD**
Chief Executive Officer
Physician Micro Systems, Inc.

Workgroups

Functionality

Co-Chair: Sarah T. Corley, MD, Governor, Virginia Chapter, American College of Physicians

Co-Chair: David Kates, MSEE, MBA, COO, Hx Technologies, Inc

Vincent E. Kerr, MD, President, Care Solutions, Uniprise

Lynne A. King, RN, BS, MBA, Division Information Officer, Clinical Informatics, University Hospital Health System

Steven R. Lane, MD, MPH, FAAFP, Clinical Lead, Ambulatory EHR, Sutter Health, Medical Director, HIM, Sutter, Palo Alto Med. Found.

Eugenia Marcus, MD, American Academy of Pediatrics

Eric Rose, MD, Product Manager, Physician Micro Systems, Inc.

Todd R. Rowland, MD, Director of Medical Informatics, Bloomington Hospital and Healthcare System

Khiang C. Seow, Director of Software Development - Clinical Enterprise Products and Care Everywhere, Epic Systems Corporation

Steven J. Steindel, PhD, Sr Advisor Data Stds Vocab, CDC

David L. Winn, MD, CEO, President and Founder, e-MDs Inc.

Interoperability

Co-Chair: Peter J. DeVault, Director of Enterprise Integration and Interoperability, Epic Systems Corporation

Co-Chair: Carol C. Diamond, MD, MPH, Managing Director, Health Program, Markle Foundation

Richard Elmore, Vice President, IDX Systems Corporation

Mary Hall Gregg, PhD, VP Clinical Information Solutions, Quest Diagnostics

Patricia L. Hale, MD, PhD, FACP, CMIO, Glen Falls Hospital

David C. Kibbe, MD, Director – Center for Health Information Technology, American Academy of Family Physicians

Ronald A. Paulus, MD, MBA, Chief HIT Officer & Special Assistant to the President/CEO, Geisinger Health System

Kent A. Spackman MD, PhD, Professor, Oregon Health & Science University

David K. Tao, DSc, IT Architect, Siemens Medical Solutions Health Services

Alan E. Zuckerman, MD, Primary Care Informatics Program Director, Georgetown University

Workgroups

(continued)

Security & Reliability

Co-Chair: Solomon I. Appavu, Director Systems Planning, John H. Stroger, Jr. Hospital & Cook County Bureau of Health Services

Co-Chair: John F. Moehrke, BS CS&E, Enterprise Security Architect, GE Healthcare

Daniel S. Bormann, BA, MS, Chief Security Officer, Epic Systems Corporation

Rita K. Bowen, MA, RHIA, CHPS, Chief Privacy Officer/HIM/UR Dir, Erlanger Health System

Edward J. Coyne, PhD, MA, BS, Security Architect, Veterans Health Administration

John A. Gildersleeve, BA, System Privacy Officer, Geisinger Health System

Joseph C. Gilfus, BSBA, MBA, Project Manager, Blue Cross Blue Shield of Florida, Inc.

Glen F. Marshall, BBA, IT Architect, Siemens Medical Solutions

Marian E. Reed, Corporate Director, Product Security, McKesson Corporation

Certification Process

Co-Chair: Steve Arnold, MD, MS, CPE, President & CEO, Healthcare Consultants International

Co-Chair: Michael L. Kappel, Sr. VP - Government Strategy and Relations, McKesson Corporation

Bonnie S. Cassidy, MPA, RHIA, FAHIMA, FHIMSS, Independent Consultant

John C. Durham, MD, Vice President and Chief Medical Officer, Greenway Medical Technologies

Gerry Hinckley, Partner, Davis Wright Tremaine LLP

Linda L. Hogan, PhD, Director, Medical Informatics & Clinical Transformation, Catholic Health East

Dan S. Michelson, MBA, Chief Marketing Officer, Allscripts Healthcare Solutions

Joseph H. Schneider, MD, MBA, CMIO, Children's Medical Center

Robert M. Tennant, MA, Senior Policy Advisor, Health Informatics, Medical Group Management Association

Use Case / Test Plan

(comprised of members from the other Workgroups)

Co-Chair: Marian E. Reed

Co-Chair: Steve Arnold, MD, MS, CPE

Edward J. Coyne, PhD, MA, BS

Peter J. DeVault

Eugenia Marcus, MD

Solomon I. Appavu

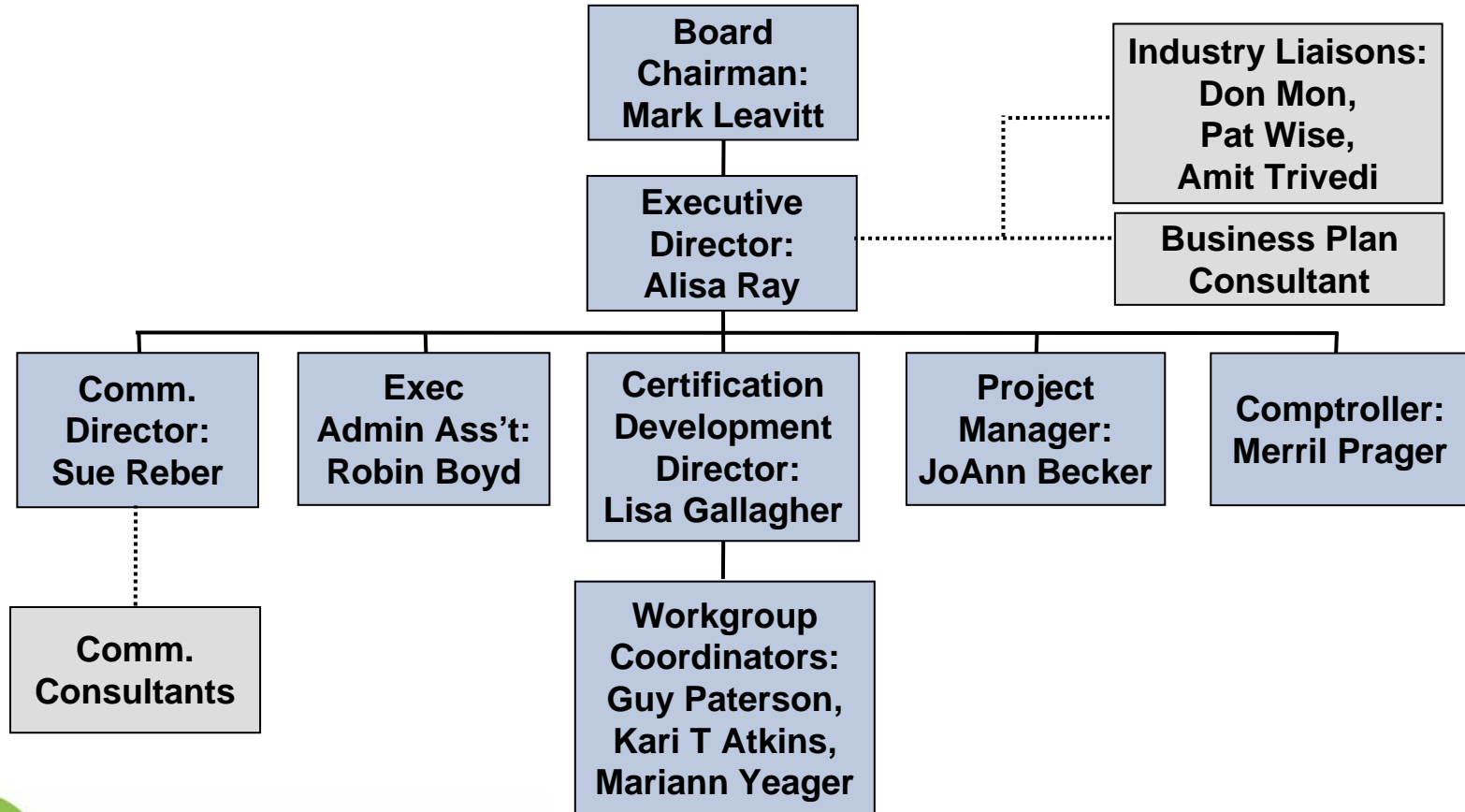
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Alan Zuckerman, MD

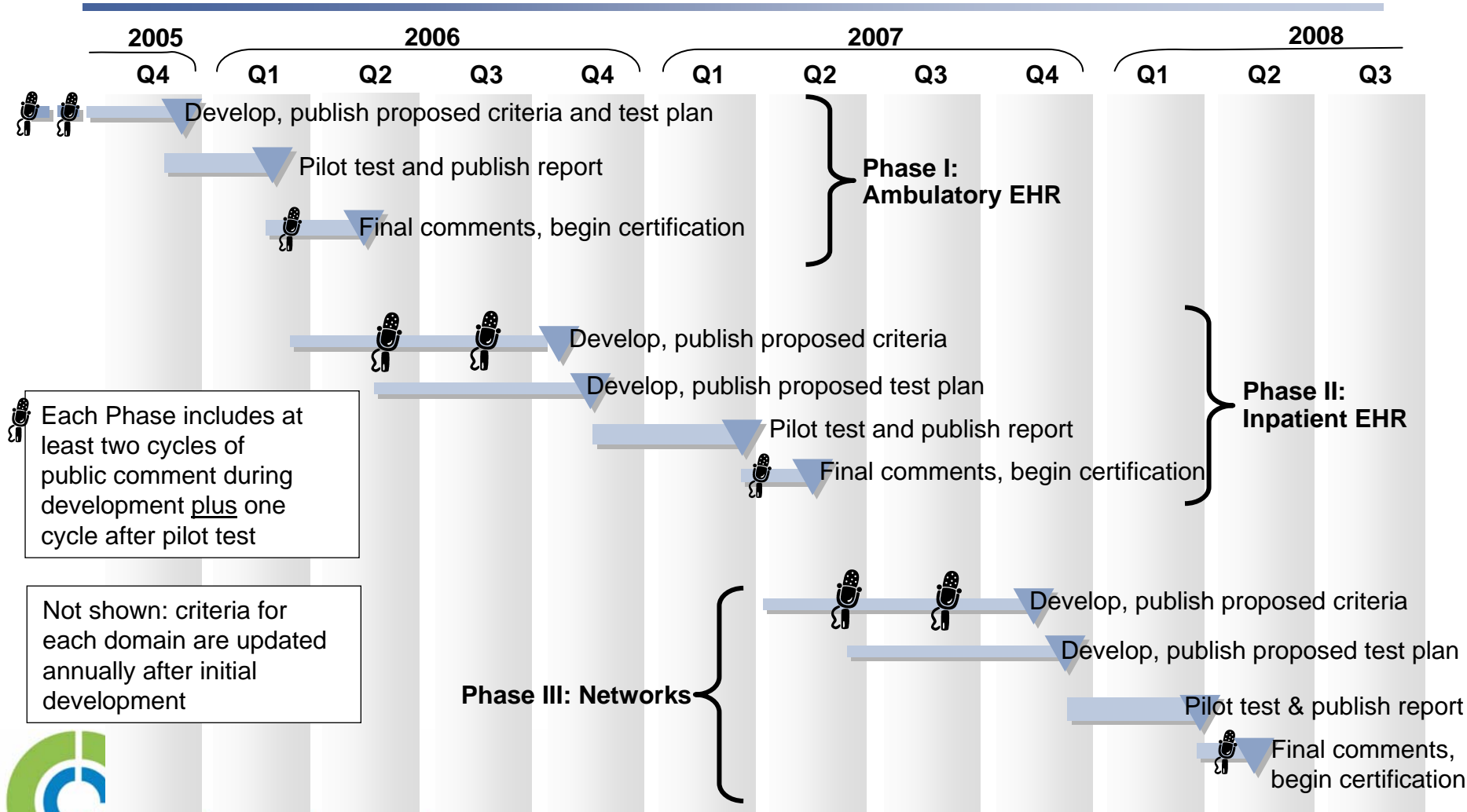
CCHIT Staff



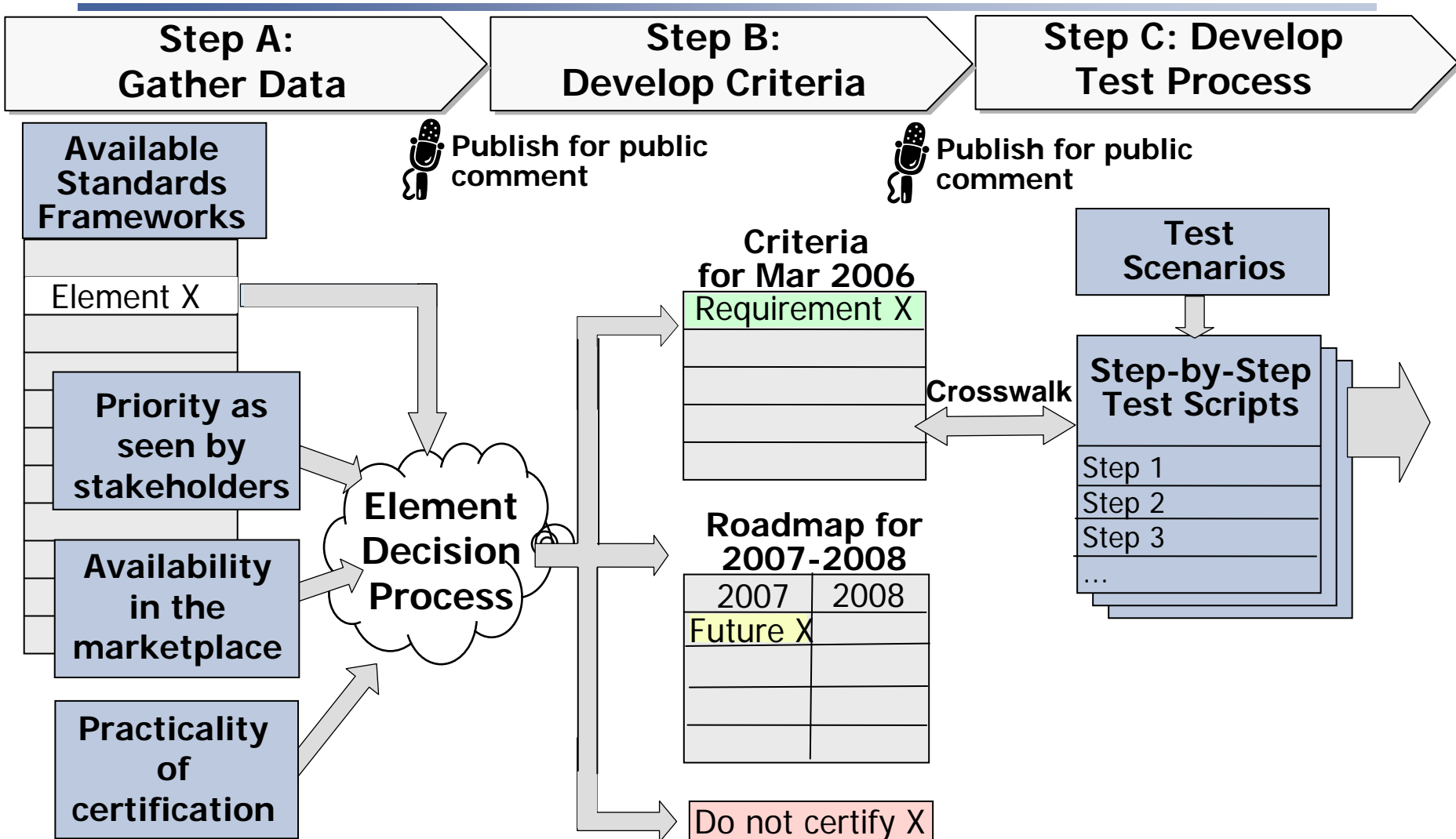
Mechanisms to Enhance Openness, Transparency and Credibility

- **Commission structure**
 - At least two from provider, payer, and vendor stakeholder groups
 - At least one from each of seven other stakeholder groups
- **Workgroup structure**
 - Two co-chairs from different stakeholder groups
 - Members represent balance and diversity of stakeholders
- **Transparency**
 - Commissioners and WG members disclose potential conflicts of interest
 - Minutes of all meetings published on CCHIT website
 - Work products published for Public Comment after each step
 - All comments reviewed and responses published
- **Communication and outreach to stakeholders:**
 - Town Halls – open forum at major conferences
 - Town Calls – teleconferences with Q & A; open to all
 - Specific outreach to stakeholder groups
 - Speaking engagements and press coverage of work

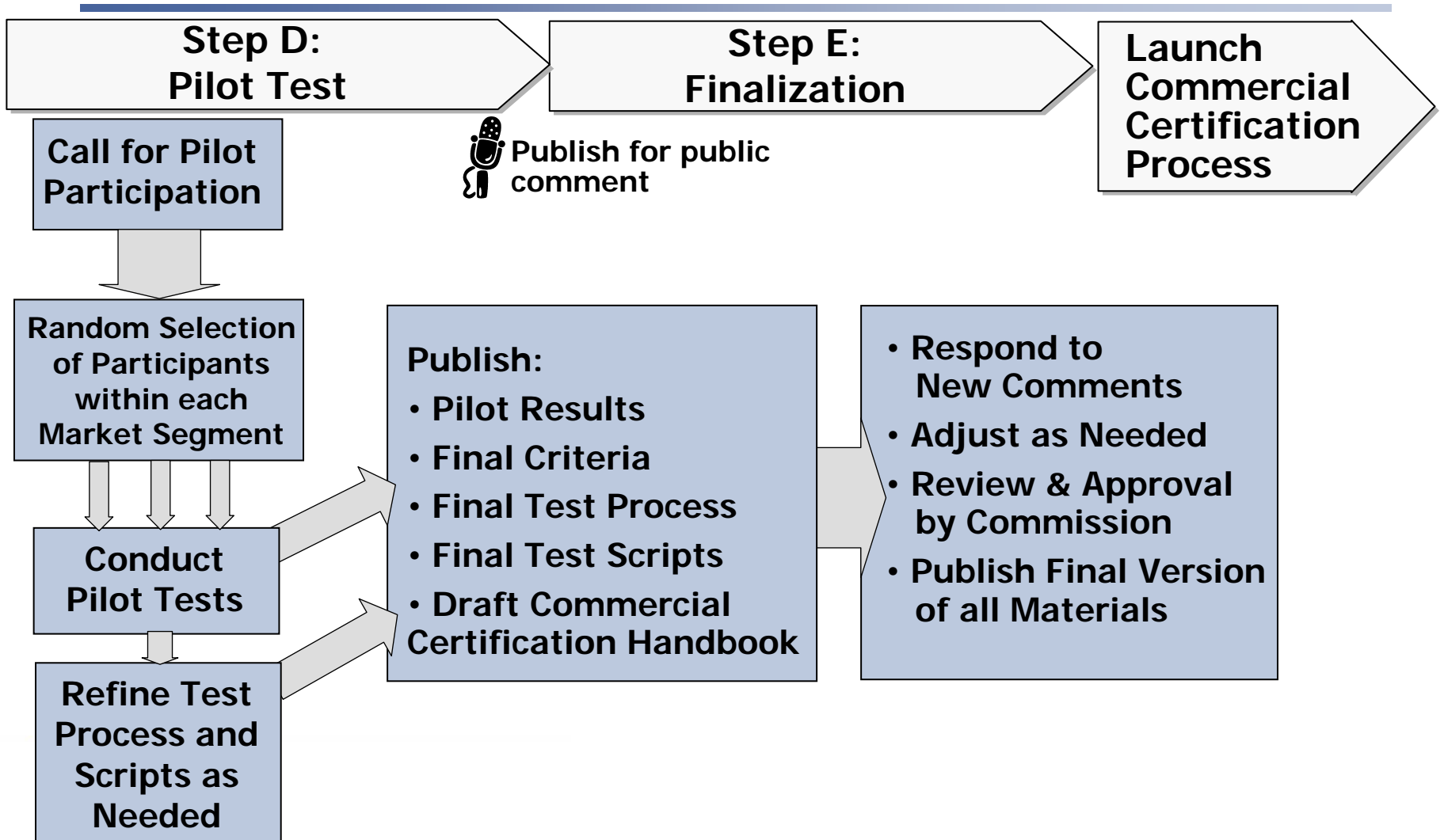
Timeline of Activities and Deliverables



Development Process



Development Process



Status Report on Phase I: Ambulatory EHR Certification

- **Accomplishments**
- **Current activity: Pilot Test**
 - **Remaining steps**

Ambulatory EHR Certification: Accomplishments

- **Developed and published
Proposed Final Criteria for 2006**
- **Developed and published
Roadmap for 2007 – 2008 Criteria**
- **Two rounds of Public Comment
Received/responded to >1000 comments**
- **Developed and published
Test Process and Test Scripts**

Format of the Final Criteria Documents

Example from Functionality Criteria - "Managing Allergy and Adverse Reaction List"

CCHIT Certification Criteria for Ambulatory EHR Products Final Version - 10/30/05 © 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 2006	Roadmap for 2007	Roadmap for 2008			
38	F	Manage allergy and adverse reaction list: Create and maintain patient specific allergy and adverse reaction lists.	1.The system shall capture and store lists of medications and other agents to which the patient has had an allergic or other adverse reaction.	DC.1.1.3.3	H	H	H	M	H	H			X			The user determines what defines an allergy or adverse reaction.		
39			2. The system shall provide the ability to specify the type of allergic or adverse reaction.												X		Allergy type may be specified as a discrete data element and/or as a free text description. This should be a modifiable field.	
40			3. The system shall provide the ability to remove an item from the allergy and adverse reaction list.	DC.1.1.3.3	H	H	H	L	H	H				X			This could include removal, marking as erroneous, or marking as inactive.	
41			4. The system shall provide the ability to specify the reason for removing an allergy/allergen from the allergy list.													X		Reason for removing an allergy type may be specified as a discrete data element and/or as a free text description.
42			5. The system shall record the removal of items from the allergy list, including the ID of the user who removed the item and attributes of the items removed.	DC.1.1.3.3	H	H	L	L	L	M	H				X			Necessary for medico-legal purposes
43			6. The system shall provide the ability to review the allergies for a patient and record the date the review was performed and the ID of the user who performed it.	DC.1.1.3.3	H	H	L	L	H	H					X			Medico-legal and regulatory compliance
44			7. The system shall provide the ability to explicitly indicate that a patient has no known drug allergies.	DC.1.1.3.3	H	H	H	H	H	H					X			Medico-legal and regulatory compliance. This is meant to be specific to drug allergies.
45			8. The system shall provide the ability to display information which has been removed from the list or prior information that has been modified.	DC.1.1.3.3	H	H	L	L	L	L	L	H				X		
46			9. The system shall capture non-drug agents to which the patient has had an allergic or other adverse reaction.	DC.1.1.3.3	H	H	H	L	H	H					X			These could include items such as foods or environmental agents. This need not be accomplished within the same portion of the chart where medication allergies are noted.
47	F	Manage patient history: Capture, review, and manage	1. The system shall capture, store, display, and manage patient history.	DC.1.1.4	H	M	H	H	H	H				X		Examples include past medical/surgical problems, diagnoses, procedures,		

Functionality Criteria for 2006: Highlights

- Maintain patient demographic data and identifiers
- Manage problem list
- Manage medication list
- Manage allergy/adverse reaction list
- Manage patient history (basic)
- Display/print summary health record
- Capture clinical documents/notes
- Capture external documents
- Generate patient-specific instructions
- Create prescriptions
- Order diagnostic tests
- Manage results (basic)
- Manage consents and authorizations (basic)
- Manage advance directives (basic)
- Care plans (basic)
- Drug interaction checking
- Medication and immunization administration (basic)
- Alerts for disease management, prevention, wellness
- Reminders and notifications
- Task assignment and routing
- Inter-provider communication
- Provider database of access levels
- Scheduling (basic - display from external system)
- Report generation (basic)
- Health record output (basic)
- Encounter management (basic)
- Coding assistance (basic)
- Concurrent access to the record

Interoperability Criteria for 2006: Highlights

- **Receive lab results (basic capability in 06; must use defined standard in 07)**
- **Send electronic prescriptions**
 - This certification requirement becomes effective **Sept 2006**
 - Vendor may comply with ePrescribing standard by using a partner (i.e. clearinghouse)
 - ePrescribing standard must be available in public domain
- **Send immunization reports to registry**

Interoperability continued on next page...

Interoperability Criteria on 2007 Roadmap

- Receive lab results using defined standard
- Send orders to lab systems
- Access to digital images and EKGs
- Transmit medication refills
- Receive medication fulfillment history
- Register documents with network/query network for documents
- Refer or transfer care of patient
- Public health reporting
- Quality improvement reporting
- Practice management interface using defined standard

Note: all are dependent on Standards Harmonization and/or Implementation Guide development

Security/Reliability Criteria for 2006: Highlights

- **Control access to system**
- **Record audit trail of all events**
- **Require authentication**
- **Provide encryption for transmission of PHI**
- **Provide for backup and recovery**
- **Documented procedures for installation, updating, and protecting from viruses/malware**

Inspection Process

Combines Three Methods

- **Self-Attestation**
 - Vendor supplies documentation of the system, signs attestation as to accuracy
- **Jury-observed demonstration**
 - EHR product running at vendor facility, jurors and proctors observe via simultaneous web conference / audio conference (no travel required)
 - Test is 100% guided by published test scripts
- **Technical tests**
 - Requires access beyond normal user interface -- administrative access to files, logs, etc. Performed remotely in separate session from demo.

Jury Panels

- **For Commercial Certification, panel would be:**
 - Two clinically-experienced jurors (at least one physician)
 - One 1 IT/security juror
 - One CCHIT staff member serving as Proctor
- **Jurors must sign Conflict of Interest Disclosure as well as Confidentiality Agreement**
- **Persons with a financial interest in any vendor or product in that market may not serve**

Interim Observations from Pilot Test (50% complete)

- **General Observations**
 - Virtual web-based testing works well – no travel costs for vendor or CCHIT
 - Validity of Proposed Final Criteria appears high -- fewer than 3% of the 300+ criteria need review/rework
 - Concerns being addressed:
 - Test duration running 5 – 9 hrs. Plan to reduce to 4 hours by eliminating duplication in scenarios and emphasizing importance of vendor preparation

Interim Observations from Pilot Test (50% complete)

- **Jury Process**
 - Including a practicing clinician is essential
 - Juror training/orientation is essential – must judge system against CCHIT criteria and not personal expectations
 - Concerns being addressed:
 - Jury “deliberation until consensus reached” model does not appear optimal. Working on alternative voting/resolution models.

Interim Observations from Pilot Test (50% complete)

- **Test Scripts**
 - Use of clinically relevant scenarios is proving to be appropriate
 - Concerns being addressed:
 - Second and third scenarios cover some criteria already tested. Simplify scripts to reduce duplication.
 - Security testing to be removed from scenario portion and made part of technical test.

Interim Observations from Pilot Test (50% complete)

- **Documentation / self-attestation portion**
 - Vendors need clearer guidance of what is required – CCHIT needs to provide examples.
- **Usability**
 - Jurors need clear guidance that “usability” (speed, efficiency of workflow) is not being tested in 2006
- **Other**
 - Vendors should use production configuration, not ‘demo version’ with capabilities omitted
 - Policy regarding technical aberrations during observed demo

Key Activities and Dates to Complete Phase I

- Complete the Pilot Test – Feb 28
- Publish results – March 3
- Prepare and publish draft of Commercial Certification Handbook – March 3
- Public Comment period on all of above – March 3 – March 31
- Workgroups make final adjustments to Criteria and Test Scripts based on Pilot Test results and Public Comments
- Review and Approval of final package by Commission -- April 24
- Begin accepting applications late April 2006
- First round of certification results June 2006

Commercial Certification Handbook – Topics to Address

- Pricing of Certification
- Duration of certification (3 years)
- Software versions and updates (self-attestation for updates, but need clear definition)
- Application process and test scheduling
- Preparation and education resources for vendors
- Pre-test “desktop review” of applications
- Retest and appeal process

Commercial Certification Handbook – Topics to Address

- **Validation of operational use at 'live site'**
- **Options for pre-market conditional certification**
- **Questions regarding certifying self-developed, non-marketed EHRs**
- **Certification announcement batching and scheduling**
- **Communication guidelines for vendors**
- **Process for handling end-user complaints**

Preparation for Phase II: Inpatient EHR Certification

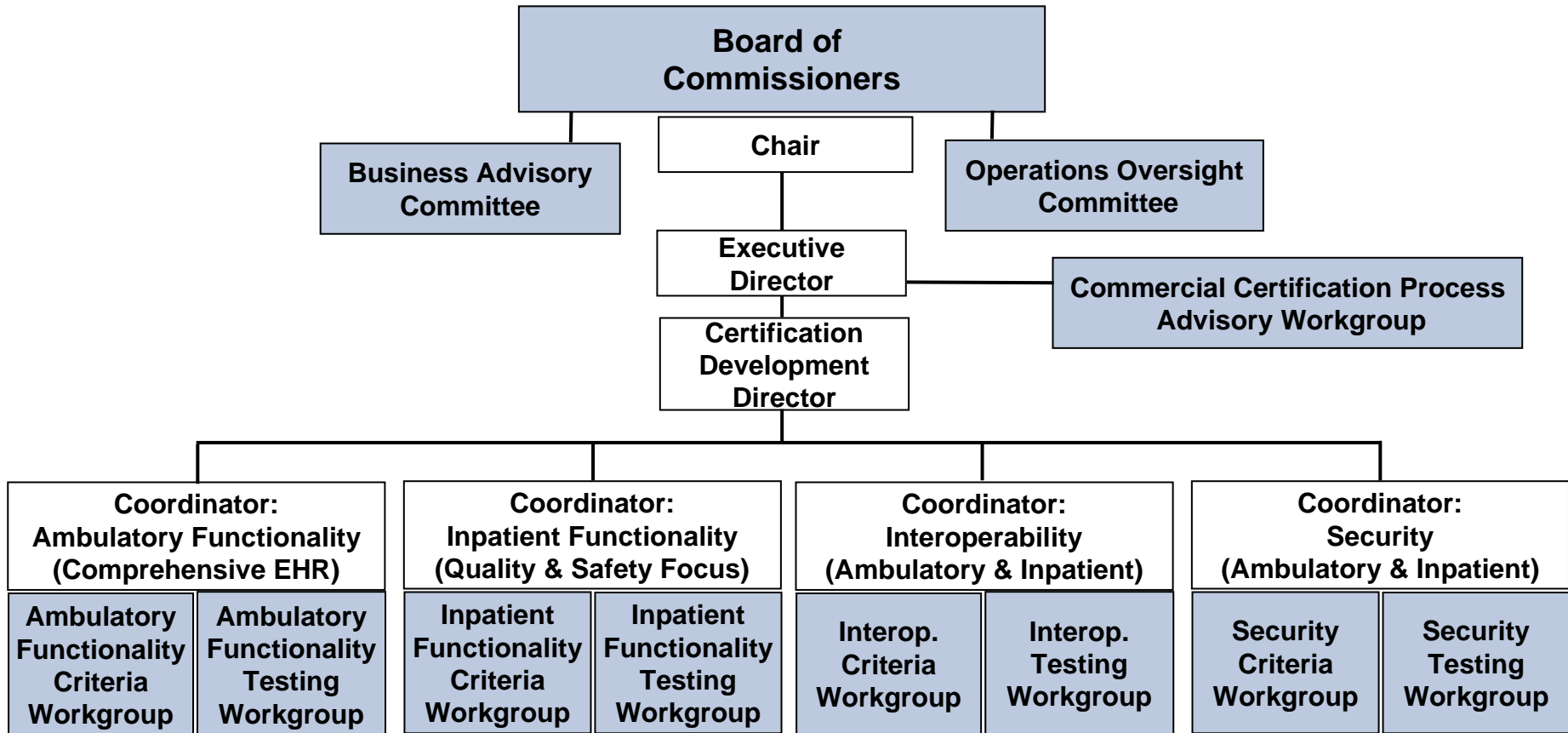
Ambulatory vs Inpatient EHRs: Contrasting the Environments

	Ambulatory	Inpatient
Organization size	Most < 10 people	Many > 1000 people
Purchase price	\$10k - 500k	\$1M - \$50M
Total market	~\$2B	~\$20B
Installation time	2 – 6 months	1 – 5 years
Number of vendors supplying EHR components at a single site	1 or 2	1 (“single vendor” strategy)
		2-5 (“best of suite” strategy)
		>5 (“best of breed” strategy)

Initial Thoughts on Inpatient EHR Certification – Discussion Invited

- **Functionality**
 - Impractical to cover the broad spectrum of all inpatient workflows with any reasonable set of criteria
 - CCHIT should focus on functional areas of high potential benefit and low current penetration. Candidate: Quality and Safety Systems (e.g., CPOE - CDSS – Pharmacy - Med Admin loop)
- **Interoperability**
 - Others are addressing intra-enterprise data exchange standards
 - CCHIT should focus on external portability of the record: hospital-to-hospital, hospital-to-physician, hospital-to-patient
- **Security**
 - Important area for potential CCHIT contribution

CCHIT Organization (Proposed Phase II Structure)



Opportunities for Participation

Opportunities for Participation

- **Today – EHR Vendor Orientations**
 - 12:30 – 1:30pm, repeated 1:30 – 2:30 pm
 - Mezzanine room 13
- **Provide your input**
 - Online public comments - posting March 3, deadline March 31
 - Participate in Town Calls and other outreach events
- **Volunteer as Workgroup Co-Chair or Member**
 - Applications open Feb 17, deadline March 3
- **Nominate a Juror, or Volunteer as a Juror**
 - Applications open soon
- **Serve on the Commission**
 - Nominations open this summer

Thank You!

Q & A

For more information:

