

Certification Commission for Healthcare Information Technology

Certification and Meaningful Use: EHR Product Certification

Testimony before the NCVHS Executive Subcommittee Hearing on "Meaningful Use" Panel 9 – April 29, 2009 Washington, DC

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What role does certification play in promoting meaningful use?



CCHITThe Usual Purpose of CertificationIs to Reduce Risk

| Technology | Risk | Certifying Body | Structure and Funding |
|---------------------------------------|---------------------------|---|---|
| R R R R R R R R R R R R R R R R R R R | Fire, shock | Underwriters Laboratories | Private Nonprofit (funded by certification fees) |
| | Crash injury and death | Insurance Institute for Highway Safety | Private Nonprofit (funded by insurance industry) |
| X | Airworthiness | Federal Aviation Administration | Federal Agency |

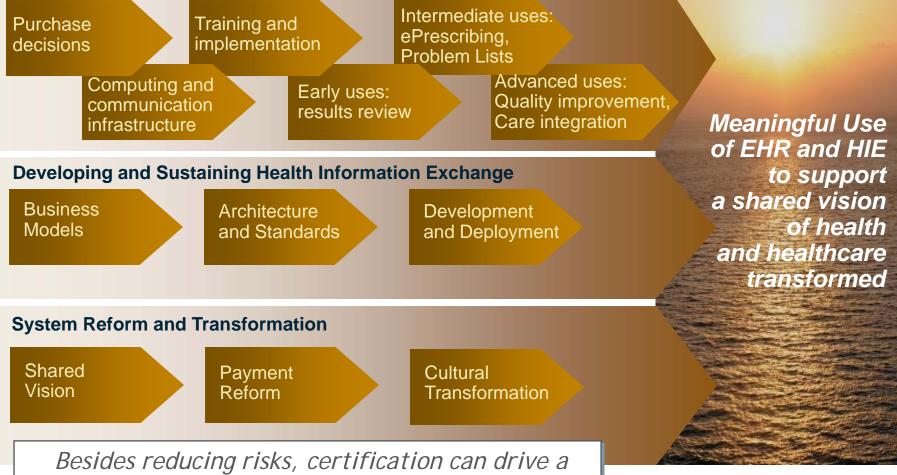
Certification is needed when risks are significant

or when consumers can not readily evaluate product quality and suitability

Health IT Roadmap:

A Complex Journey along Three Concurrent Paths

Promoting Electronic Health Record Adoption and Use



marketplace to comply with evolving policies

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What are the strengths and weaknesses of current CCHIT processes, and how should they change to meet the requirements of ARRA/HITECH?



Certification Process

- Transparent, consensus-based development process
 - Diversity of volunteers, 3 cycles of public comment, and pilot testing
- Robust, repeatable and efficient inspection process
 - 100% compliance with criteria required; zero-tolerance for conflict of interest among staff and jurors (no relationship with vendors permitted)
- Intensive industry engagement and communication
 - >640 volunteers applied to serve this year, double the previous figure
- Broad acceptance by providers
 - The 10 largest professional associations have endorsed CCHIT
- Strong compliance by vendors
 - >50% apply in first year; >75% of market certified in all current areas
 - Substantial numbers upgrade to the latest certification every year
- Confidence of payers / purchasers
 - 21 States, 25% of private payers offer certified EHR incentives

CCHIT Challenges to Address

- Current program only addresses product features, not usability, training, implementation, or 'field' success rates
 - Commission has approved investigation into how these areas can be tested and certified or rated
- Current policies are not sufficiently compatible with open source licensing models
 - Dialog has been started with Open Source community, policy update is under development for launch this Summer
- Certification fees a possible barrier for nonprofit EHR developers serving vulnerable populations
 - Grant funding being sought to partially defray certification costs
- Cost-effective approach to certifying self-developed and self-assembled EHRs that are not for commercial resale
 - Concept of 'experimental' certification is being examined

Rising to Meet the Higher Expectations under ARRA

| Attribute | Before ARRA | After ARRA | | |
|----------------|---|---|--|--|
| Accountability | Accountable mainly to health IT purchasers | Expanded role as guardian of \$34B taxpayer investment | | |
| Transparency | Sufficient to earn trust of health IT stakeholders | Strengthen any processes necessary to earn <u>public</u> trust | | |
| Focus | Focused on <u>features</u> of health IT <u>product</u> | Broaden focus: address usability, implementation and other critical success factors | | |
| Scale | Expand to new domains as resources permit | Expand to all domains with incentives; scale up for increased volume | | |
| Speed | Pace of progress limited by market acceptance | Powerful incentives provide leverage to drive faster progress | | |



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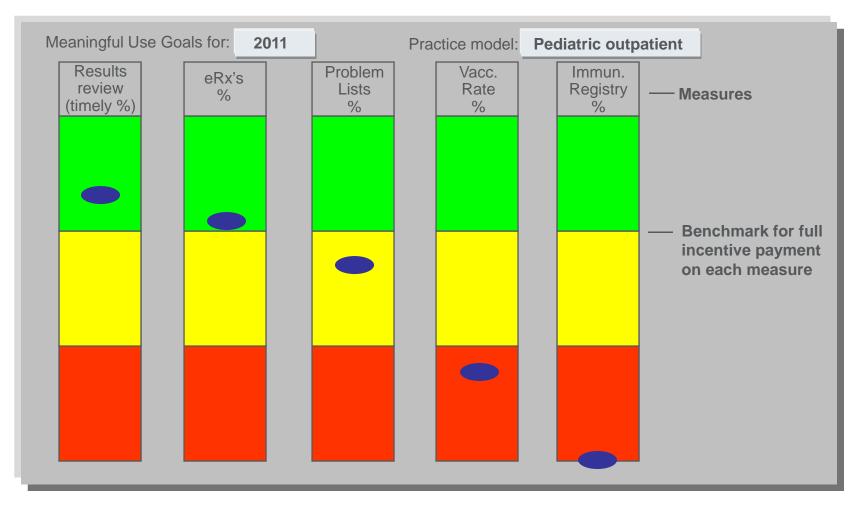
How should the certification process work in 2011, and how should it develop over time in support of increasingly robust requirements for meaningful use in 2016 and later?



CCHIT EHRs, Meaningful Use, and Certification

- Documentation of meaningful use should be collected and submitted electronically -- not manually
 - Risk of fraud would otherwise be excessively high
- EHRs are inherently capable of collecting 'meaningful use' measures in the course of normal operation
 - Certified EHRs already are required to have a detailed 'audit trail' that could support measurement
- Concept: certified EHRs should be able to
 - Register their existence and usage by eligible providers
 - Generate and display a 'meaningful use' dashboard to users
 - Sign and securely submit dashboard statistics to a designated entity when provider applies for incentives
 - Retain audit trails for future verification

Meaningful Use Dashboard (Conceptual Only)



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CCHIT Timeline Concepts for Discussion

- HHS/ONC defines Meaningful Use 'requirements set' on a 2-year cycle
 - 2011-2012 set; 2013-2014 set; 2015-2016 set, etc
 - First set valid from Jan 2011 to Dec 2012, etc.
 - Publish each set 15 months before cycle goes into effect
- Certification follows identical 2-year cycle
 - Begin developing inspection processes as soon as requirements are published by HHS
 - Ready to certify products 6 months before cycle begins; ready to certify usage as soon as cycle begins
 - Certification is valid through the final month of the cycle

Thank You!

Q&A

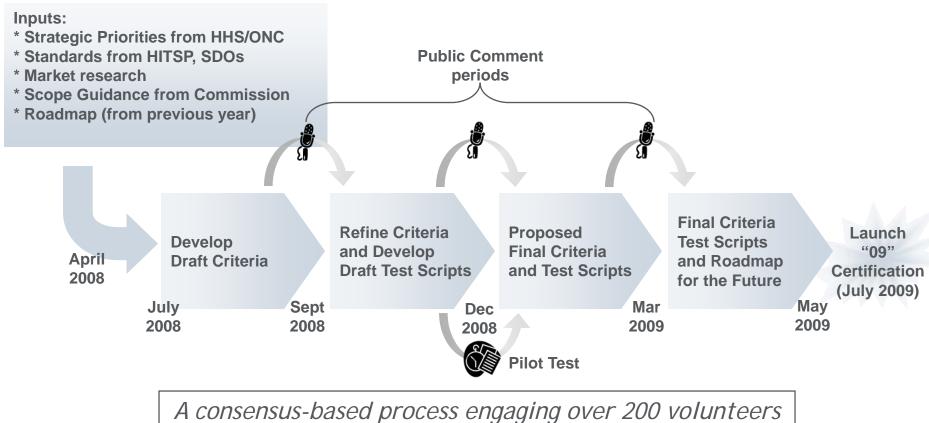
For more information: www.cchit.org



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Appendix A: Additional Details on Strengths of Current Certification Process

CCHIT An Open, Transparent Criteria Development Process



with multiple cycles of public vetting

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CCHIT Wide Range of Certification Programs

| Base Domain | Certification Options (Add-on to Base Domain) | 06 | 07 | 08 | 09 |
|--------------------------|---|----|----|----|----|
| Ambulatory EHR* | | L | | | |
| Ambulatory | Child Health | | | L | |
| Ambulatory | Cardiovascular Medicine | | | L | |
| Inpatient EHR* | | | L | | |
| Emergency Dept | | | | L | |
| Amb+Inpt+ED | Enterprise | | | L | |
| HIE* | | | | L | |
| PHR | | | | | L |
| Stand-alone ePrescribing | | | | | L |

Legend: L = Launch

*Original HHS Contract (all other programs represent voluntary expansion)

Dynamic Expansion to New Domains of Care

| Base Domain | Certification Options (Add-on to Base Domain) | 09 | 10 | 11 | 12 |
|---|--|----|----|----|----|
| Ambulatory EHR | | | | | |
| | Behavioral Health (as add-on) | | L | | |
| | Behavioral Health (as stand-alone) | | L | | |
| | Clinical Research | | L | | |
| | Dermatology | | L | | |
| | Eye Care | | | L | |
| | Oncology | | | L | |
| | Advanced Interoperability | | L | | |
| | Advanced Quality | | L | | |
| | Advanced Security | | L | | |
| | Advanced Clinical Decision Support | | L | | |
| Long Term Care Spectrum | | | L | | |
| Obstetrics/Gynecolog | y | | | | L |
| Note: scheduling of all areas will remain flexible so the Commission can respond to | | | | | |

Note: scheduling of all areas will remain flexible so the Commission can respond to the emerging requirements of the American Recovery and Reinvestment Act.

Legend: **R** = Research (staff level); **D** = Start Development; **L** = Launch (tentative)

CCHIT An Efficient, Reliable Inspection Process

- Objective, rigorous, and reliable testing methods
- 100% compliance required
- Cost-efficient web-conferencing and other virtual presence tools; no travel expense
- Transparency published criteria and test scripts ensure a level playing field for all applicants
- Robust retesting and appeal processes
- Consumer complaint mechanism

CCHIT Endorsement by Major Physician Assocations

Organizations that endorse the Certification Commission

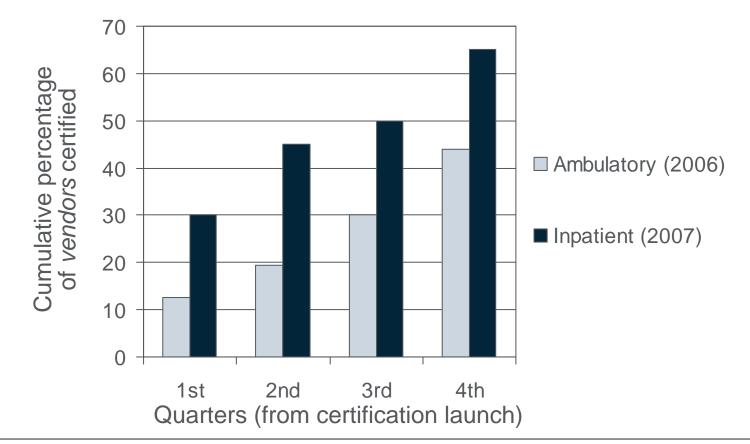
The efforts of the Certification Commission for Healthcare Information Technology (CCHIT) have been endorsed by a number of professional healthcare organizations, adding credence to the Commission's pursuit to advance the adoption of electronic health records (EHR).

Among those organizations who have publicly endorsed CCHIT are:

- American Academy of Family Physicians (AAFP)
- American Academy of Pediatrics (AAP) Certification Support American Academy of Pediatrics (AAP) Special Requirements
- American College of Cardiology (ACC)
- American College of Emergency Physicians (ACEP)
- American College of Obstetricians and Gynecologists (ACOG)
- American College of Physicians (ACP)
- Association of Emergency Physicians (AEP)
- American Medical Association (AMA)
- American Osteopathic Association (AOA)
- Medical Group Management Association (MGMA)
- Physicians' Foundation for Health Systems Excellence and Physicians' Foundation for Health Systems Innovation

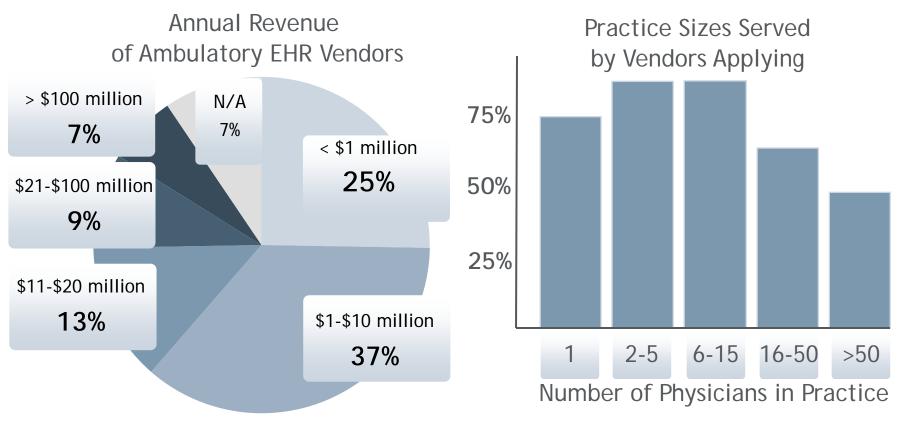
CCHIT Rap Cor

Rapid First-Year Certification Compliance by Vendors



More than 180 EHR products certified over 3 years Certified vendors represent more than 75% of the EHR marketplace

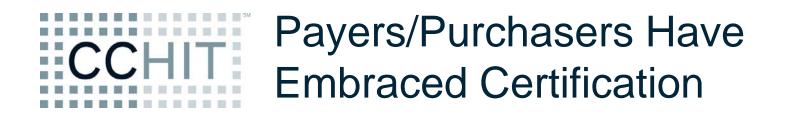
Promotion of a Dynamic and Competitive Marketplace



Certification has created a level playing field upon which a wide diversity of vendors compete

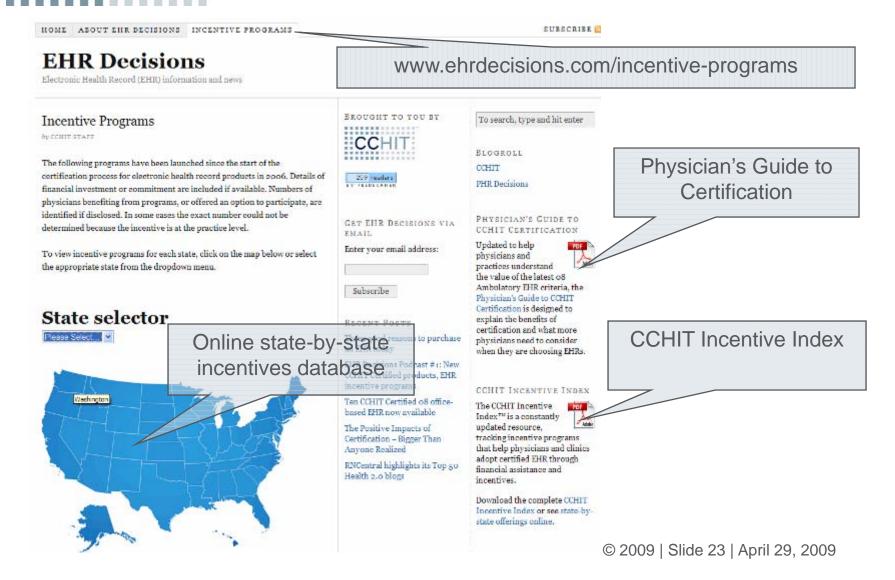
Revenue and Size data from application data of certified Ambulatory EHR 08 vendors as of March 2009; N=77; response rate 100%

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- 44 new Federal, State, and private sector EHR incentive programs keyed to certification – previous to ARRA/HITECH
- 21 States have enacted programs, several naming CCHIT in statute
- >54 EHR rollouts (147 hospitals) under Stark safe harbor rule
- Health plans with P4P incentives for certified EHR doubled (11.3% ► 25.8%) between 2006 and 2007

Communication Channel to Providers



CCHIT Vitality of Industry Engagement

- For the upcoming 2010 development cycle, CCHIT received >1000 volunteer applications from >600 individuals – more than double the number from the previous year
- CCHIT receives and responds to over 2000 public comments during the course of a development year