Department of Health & Human Services
Office of the National Coordinator for
Health Information Technology

Device Interoperability and the National Health IT Agenda

FDA-Continua-CIMIT Meeting

January, 2010

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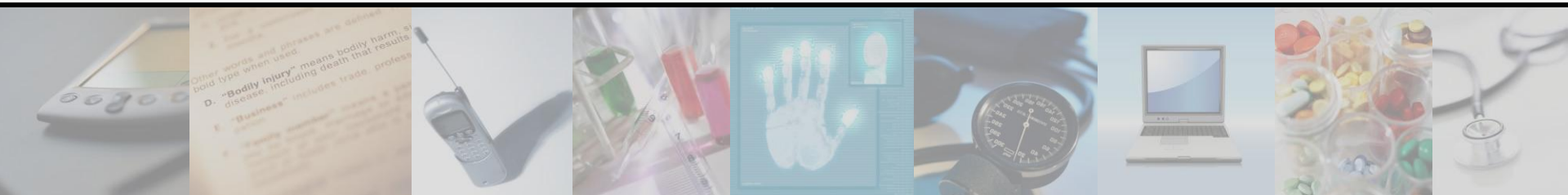
Chief Scientific Officer
Office of the National Coordinator
for Health Information Technology (ONC)



Still in the Cutting Room…

This Talk

- Health IT and the Winds of Change
- Where We are Right Now
- Toward Meaningful Use: A Nationwide Health IT Agenda
  - Plan
  - Progress
- Meaningful Use and Device Interoperability

Office of the National Coordinator (ONC)

Executive Order, April 2004:

Then President Bush created the National Coordinator position

- To achieve the goal of widespread adoption of interoperable electronic health records (EHR) by **2014: "majority of Americans"**

Key Role for the Office of the National Coordinator (ONC):

Provide **leadership** for the development and nationwide implementation of an **interoperable health information technology infrastructure**

This established a National Health IT Agenda

President Obama's First Weekly Address
Saturday, January 24th, 2009

"To lower health care cost, cut medical errors, and improve care, ***we'll computerize the nation's health records in five years,*** *saving billions of dollars in health care costs and countless lives."*

American Recovery and Reinvestment Act (ARRA)

TITLE XIII—HEALTH INFORMATION TECHNOLOGY

SEC. 13001. SHORT TITLE; TABLE OF CONTENTS OF TITLE.

(a) SHORT TITLE.—This title (and title IV of division B) may be cited as the "Health Information Technology for Economic and Clinical Health Act" or the "HITECH Act".

TITLE IV—MEDICARE AND MEDICAID HEALTH INFORMATION TECHNOLOGY; MISCELLANEOUS MEDICARE PROVISIONS

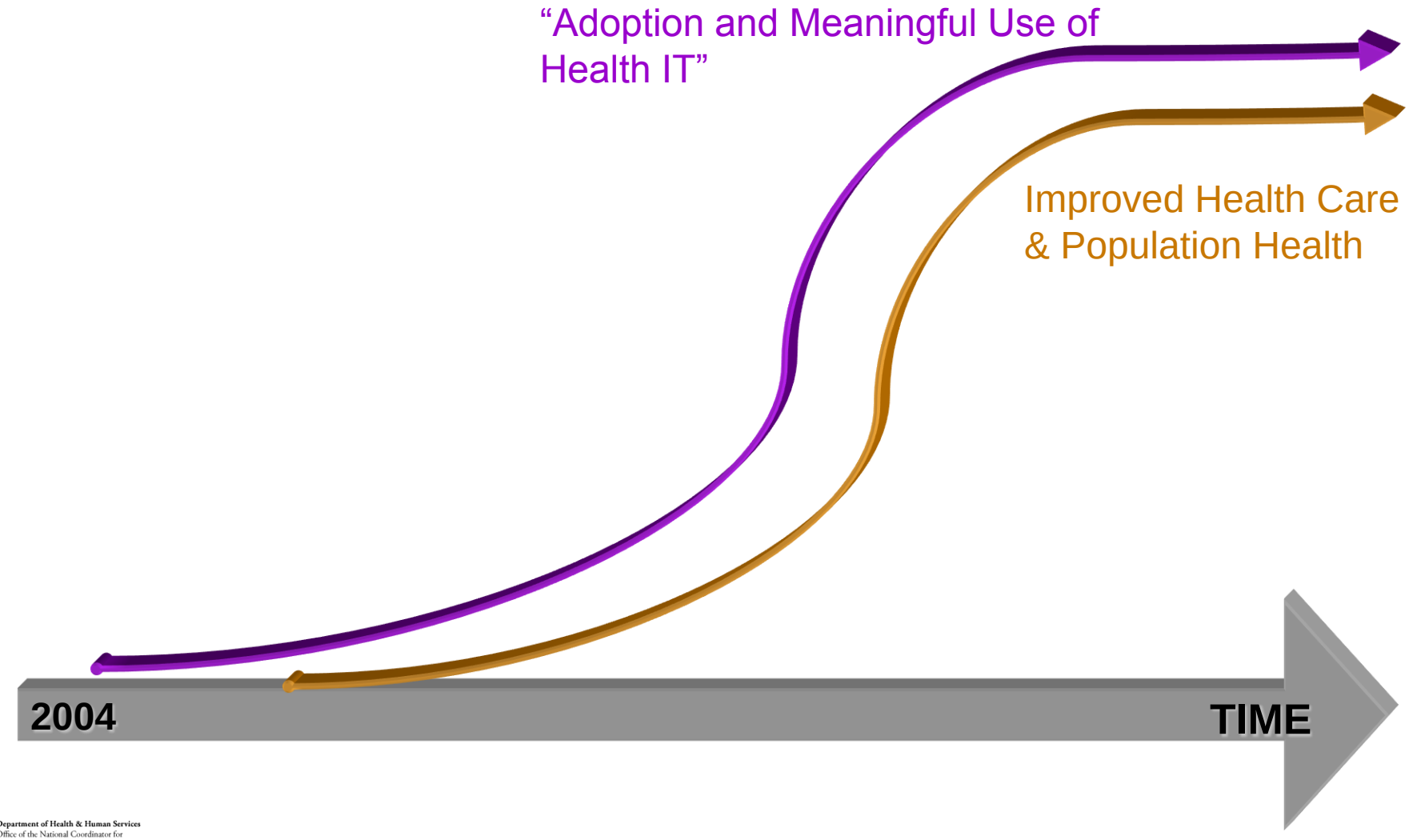
OFFICE OF THE SECRETARY

OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY

(INCLUDING TRANSFER OF FUNDS)

For an additional amount for "Office of the National Coordinator for Health Information Technology", $2,000,000,000, to carry out title XIII of this Act, to remain available until expended: *Pro-*

Envisioning a "Tipping Point"



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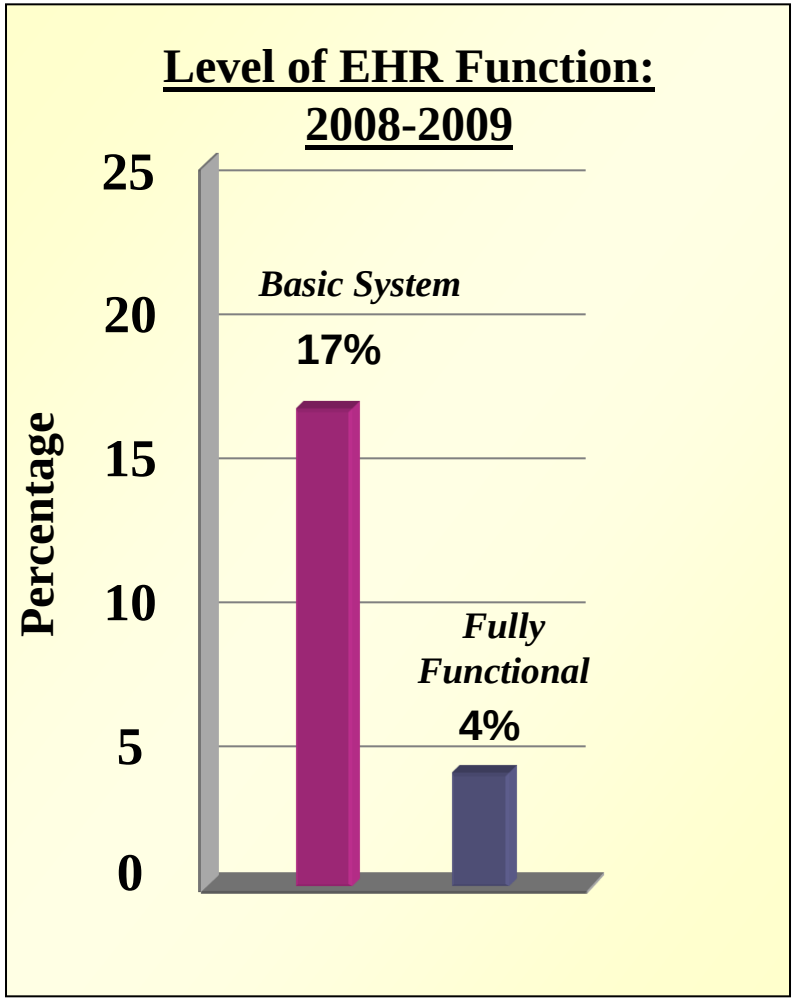
EHR Adoption: Where are we in office practices?



Adoption in Hospitals: Jha et al. NEJM 2009

- By panel definition:
  - 1.5% have comprehensive system
  - 9.4% have basic system
  - Installed across major clinical units

Table 2. Selected Electronic Functionalities and Their Level of Implementation in U.S. Hospitals.

Electronic Functionality	Fully Implemented in All Units	Fully Implemented in at Least One Unit	Implementation Begun or Resources Identified*	No Implementation, with No Specific Plans
	percent of hospitals			
Clinical documentation				
Medication lists	45	17	18	20
Nursing assessments	36	21	18	24
Physicians' notes	12	15	29	44
Problem lists	27	17	23	34
Test and imaging results				
Diagnostic-test images (e.g., electrocardiographic tracing)	37	11	19	32
Diagnostic-test results (e.g., echocardiographic report)	52	10	15	23
Laboratory reports	77	7	7	9
Radiologic images	69	10	10	10
Radiologic reports	78	7	7	8
Computerized provider-order entry				
Laboratory tests	20	12	25	42
Medications	17	11	27	45
Decision support				
Clinical guidelines (e.g., beta-blockers after myocardial infarction)	17	10	25	47
Clinical reminders (e.g., pneumococcal vaccine)	23	11	24	42
Drug-allergy alerts	46	15	16	22
Drug–drug interaction alerts	45	16	17	22
Drug–laboratory interaction alerts (e.g., digoxin and low level of serum potassium)	34	14	21	31
Drug-dose support (e.g., renal dose guidance)	31	15	21	33

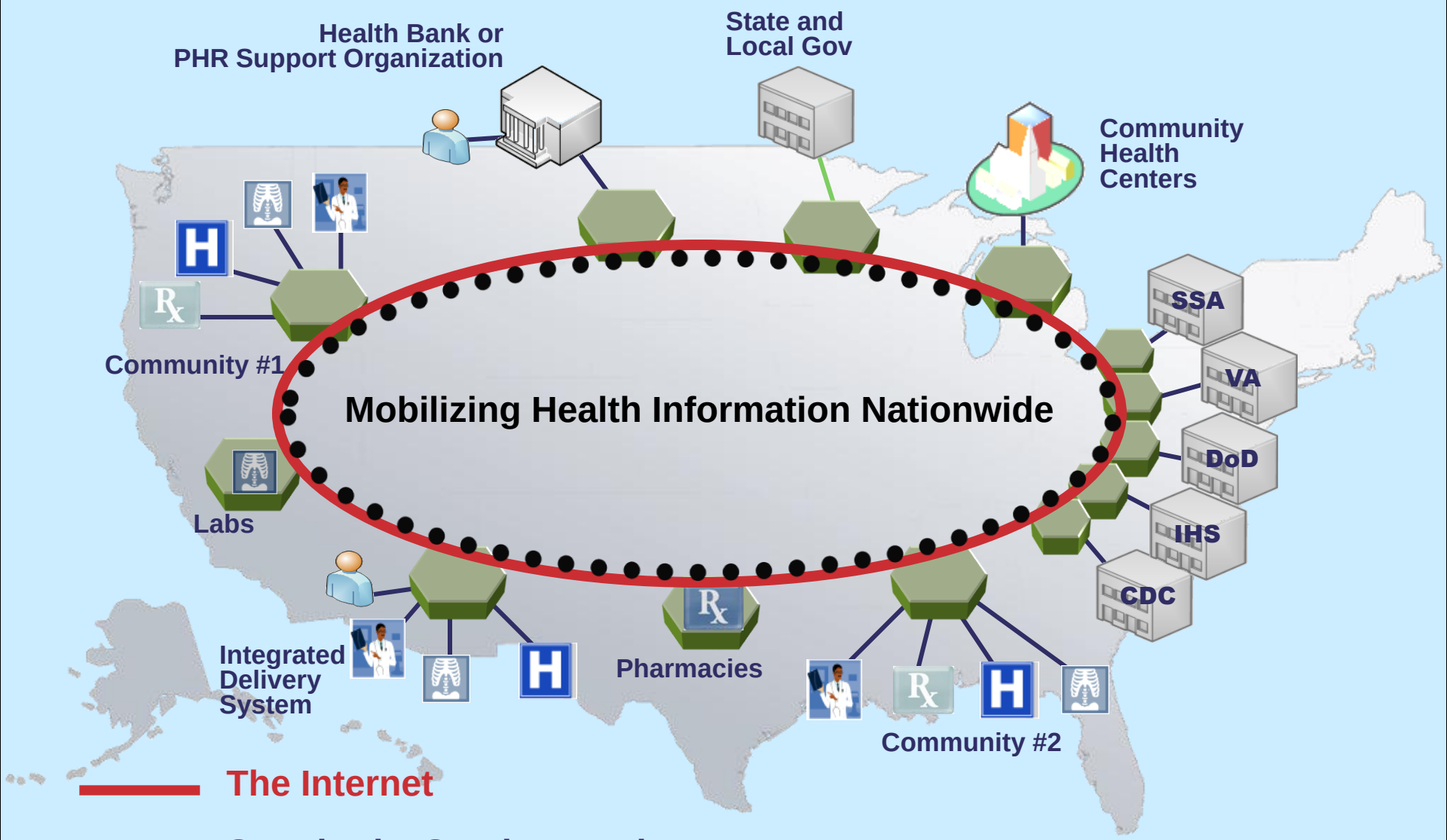
* These hospitals reported that they were either beginning to implement the specified functionality in at least one unit or had identified the resources required for implementation in the next year.

A slightly different way to look at the hospital data

Percent of hospitals fully implementing:

- Laboratory and radiology reports: 77%-78%
- Drug allergy/interaction alerts: 45%-46%
- Medication lists: 45%

The Nationwide Health Information Network



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HITECH Component View: Based on the Law

1. National coordination through an ONC in statute
2. Payment incentives to providers and hospitals who achieve *meaningful use* of certified EHRs (one estimate of net cost: $17.2 Billion)
   - Beginning 2011
   - Through (government) Medicare or Medicaid
3. Supportive grant programs authorized
4. Enhanced privacy and security provisions

1. National Coordination

- ONC becomes a permanent organization
- Two Federal Advisory Committees
  - Policy
  - Standards
- Strategic plan to be revised
- Standards and certification criteria to be formally adopted
- Establish certification process
- Governance of Nationwide Health Information Network

2. Payment Incentives and Meaningful Use

- *A hospital or eligible provider must be a meaningful user to receive payment incentives (up to $44,000 per provider)*
- Changes the focus from technology potential to clinician behavior
- By law, a "meaningful user" must:
  1. Use a *certified* EHR
  2. Exchange health information
  3. Report quality measures

3. Grant Programs

- Implementation assistance (Extension Program)
- Grants to states to promote health IT, emphasizing health information exchange
- Education: building health IT workforce
  - Community college consortia
  - Curriculum development centers
  - University-based training
  - Competency examination
- Beacon Community Program
- Health IT Research (“SHARP”)

4. Privacy Provisions

- Appoint a Chief Privacy Officer
- Breach notifications – for protected health information
- Prohibition on the sale of EHR data or protected health information without authorization
- Patient's right of access to information in electronic form

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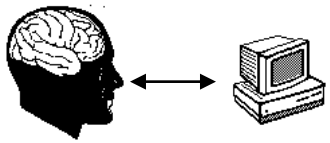
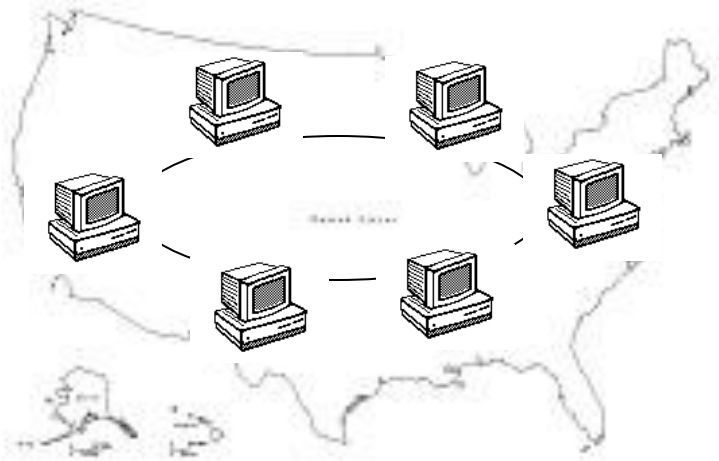
The “Two Element” View

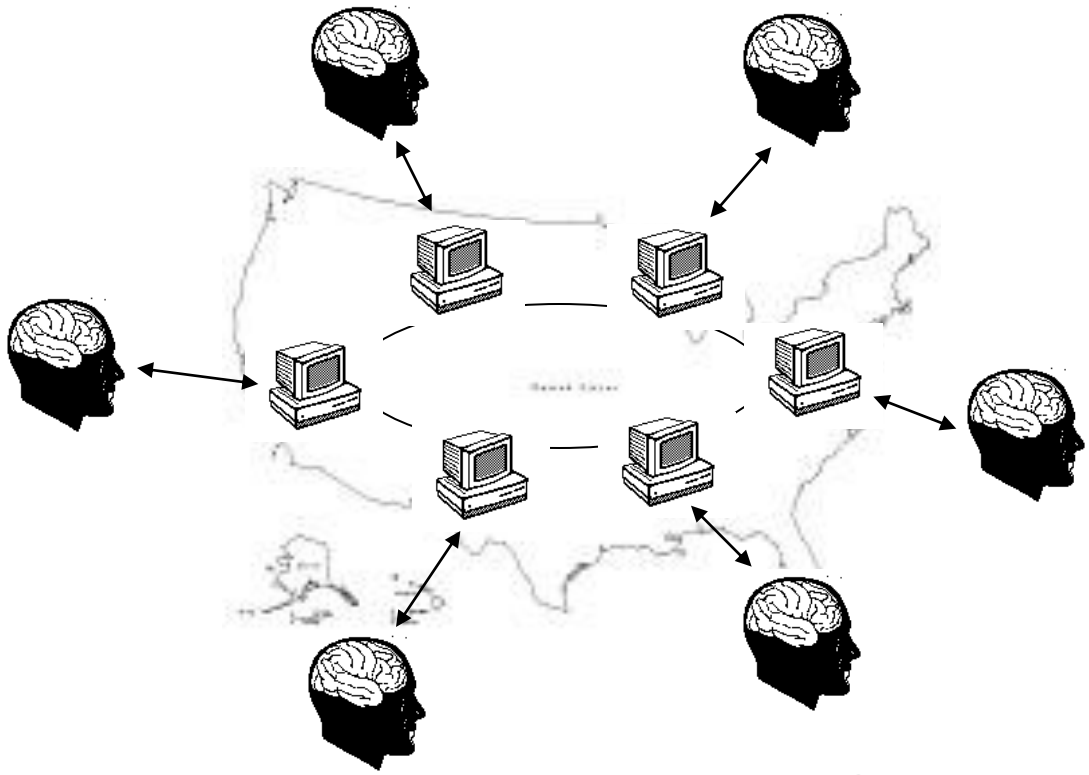
Element 1: Adopted Health IT Systems



Element 2: A Trusted Pathway to Exchange Information



Combining the Elements Enables Meaningful Use

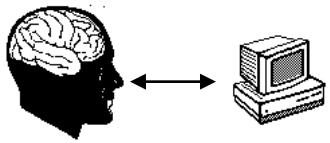


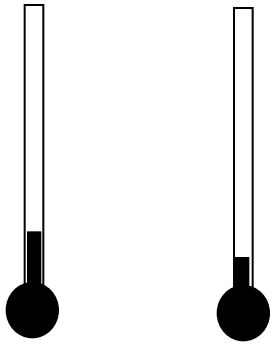
Statutory Components of MU

1. Adoption of certified EHRs
2. Health information exchange
3. Quality reporting

Building Element 1

Adopted Health IT Systems





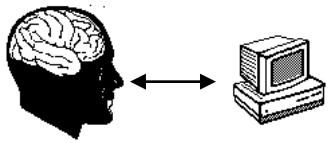
Progress 2009

Primary Initiatives:

- Payment Incentives for MU
- Regional Extension Centers Grants
- Health IT Workforce Grants
- Certification

Element 1: Progress

Adopted Health IT Systems



- Incentives for MU
- Regional Extension Centers Grants
- Health IT Workforce Grants
- Certification

Proposed Regulation defining MU released Dec 30

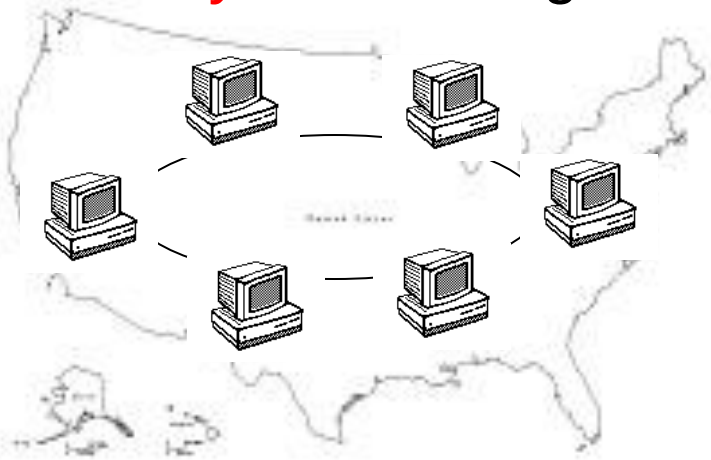
Funding Opportunity Issued August 20

"Interim final rule" expressing criteria issued December 30

Funding Opportunities Issued Nov/Dec

Building Element 2

A Trusted Pathway to Exchange Information

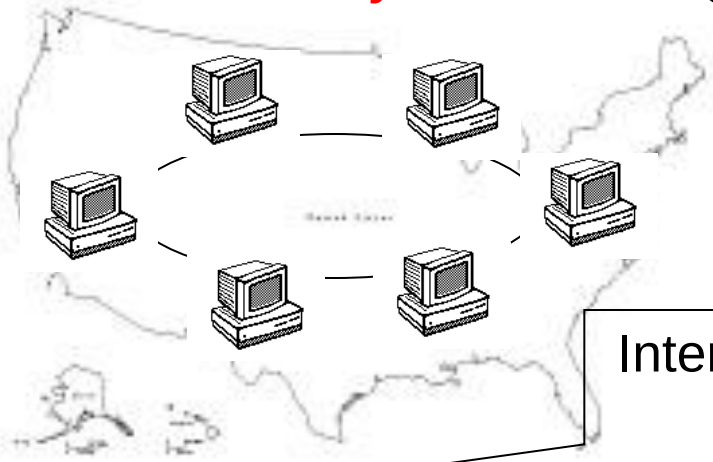


Primary Initiatives:

- Standards
- Grants to States
- Nationwide Health Information Network
- Privacy and Security

Element 2: Progress

Element 2: A Trusted Pathway to Exchange Information



- Standards
- Grants to States
- Nationwide Health Information Network
- Privacy and Security

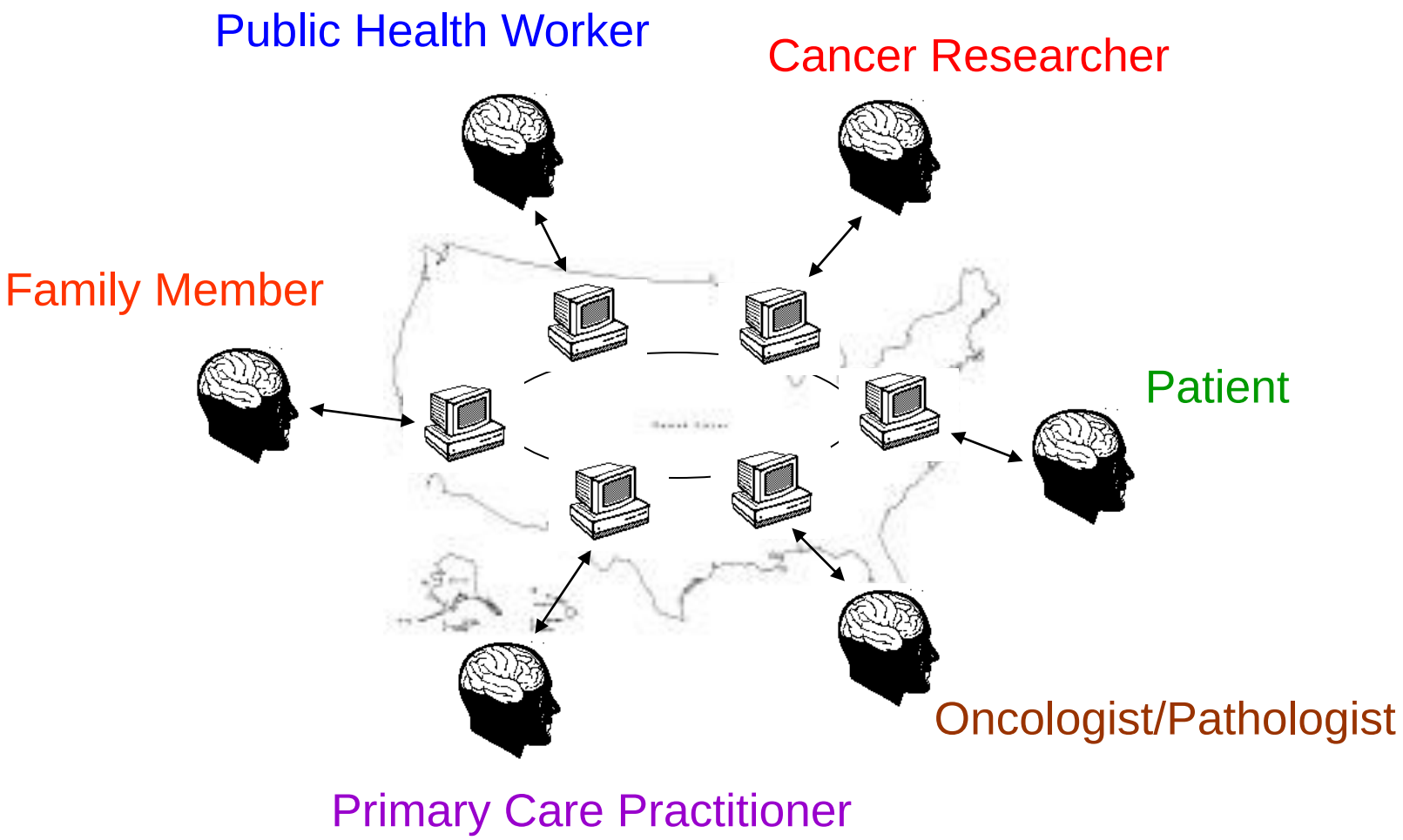
Interim final rule issued December 30

Funding Oppy Issued August 20

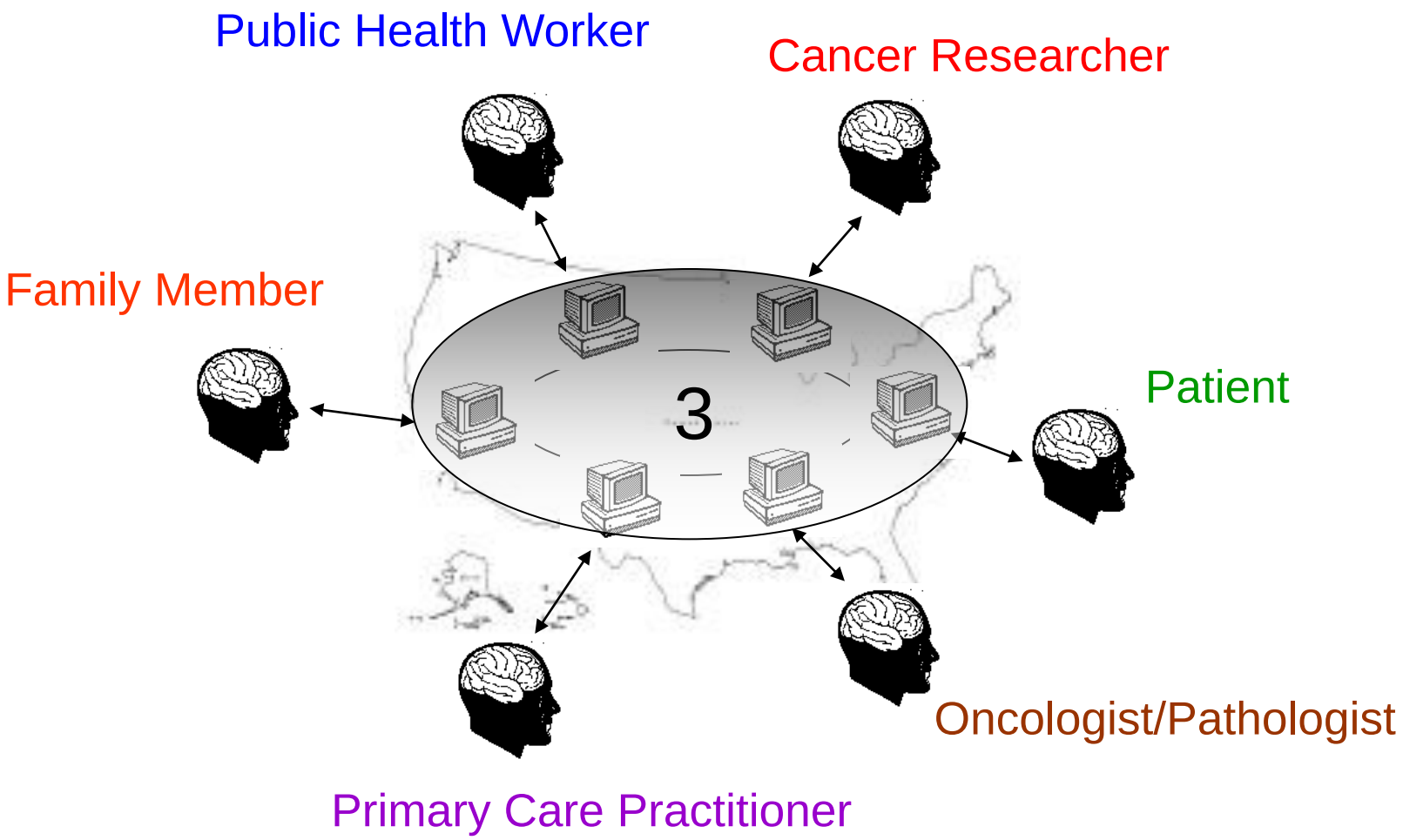
CPO, new regulations, State activities

Redesign and limited production

Elements 1 and 2 Are Necessary but Not Sufficient for System Transformation

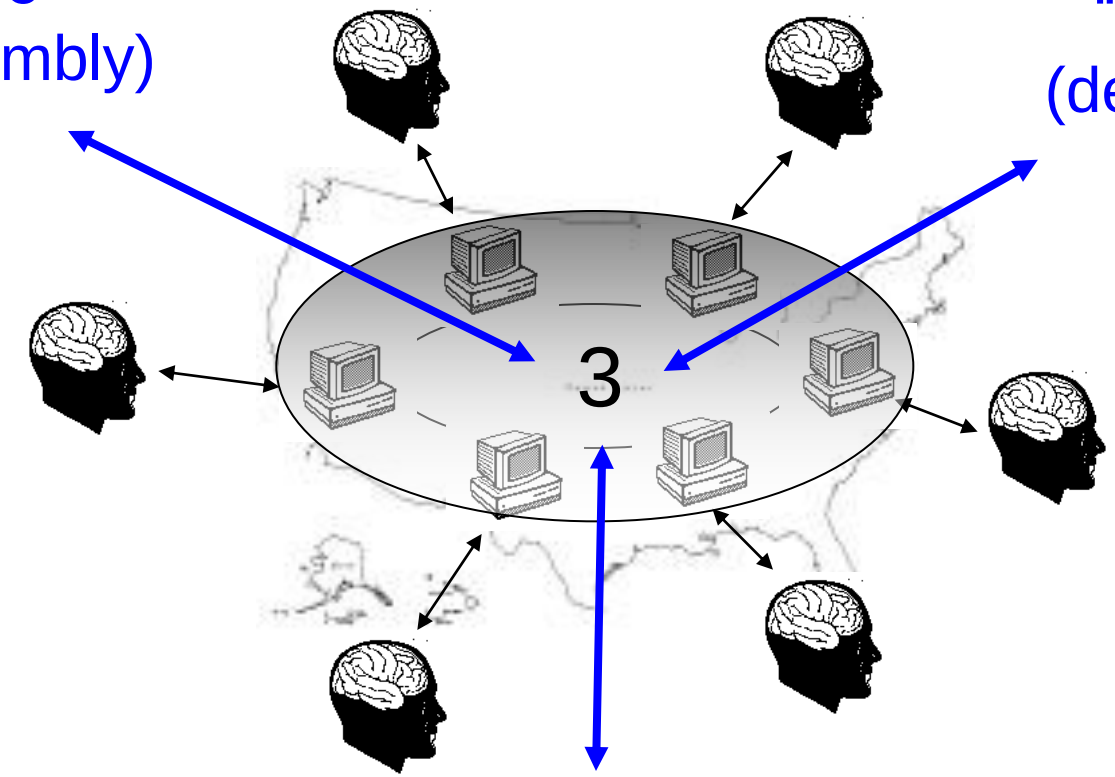


Need an Element 3!



Element 3 Enables a Learning Health Care System and Population Health

"Gridware"
(smart assembly)



"Cool Apps"
(deliver value to end-users)

"Learningware"
(discover new knowledge)

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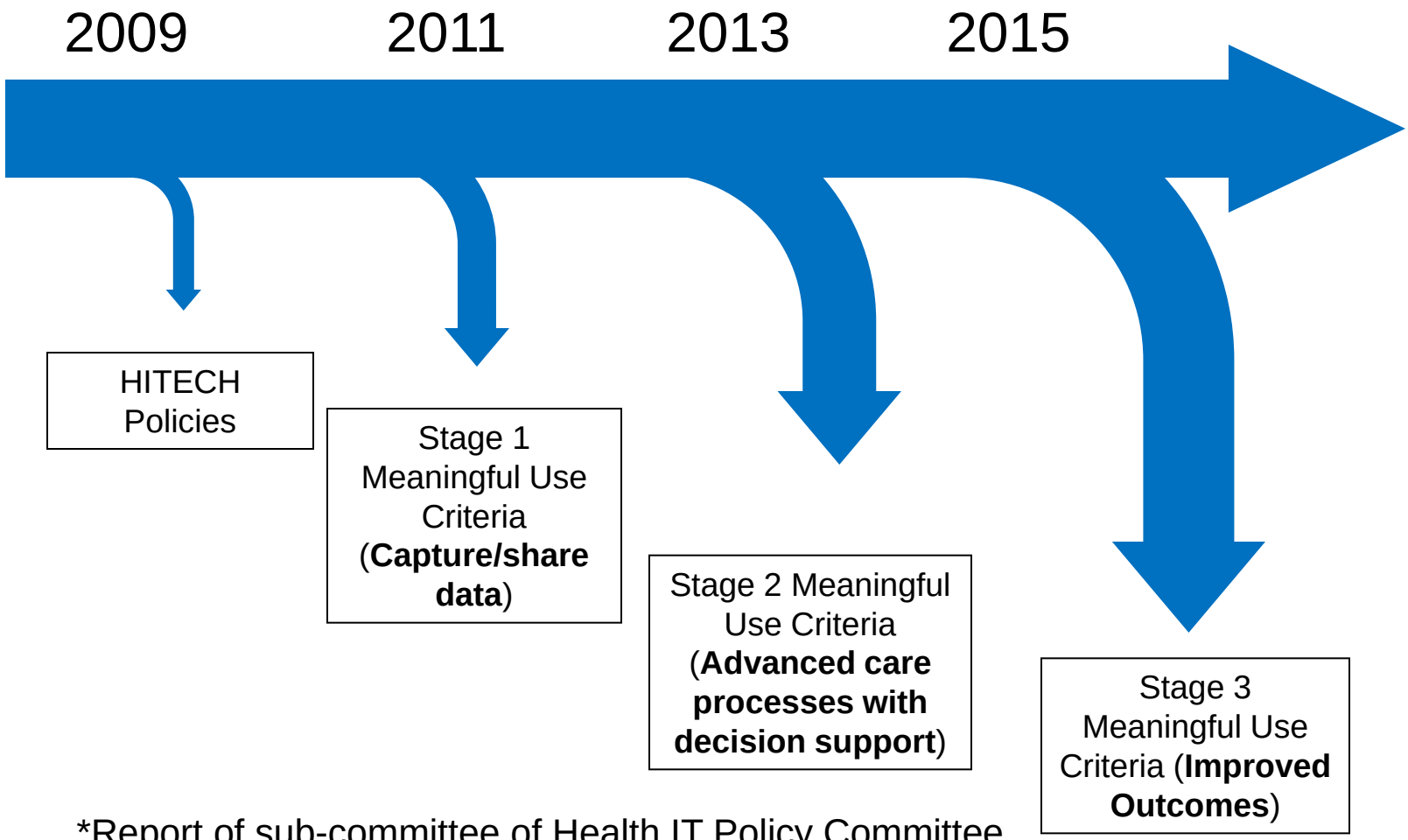
Meaningful Use is Being Defined

- See http://healthIt.hhs.gov/meaningfuluse
  - Recommendations: August 14, 2009
  - Stage 1 Proposed Rule: December 30, 2009

- *Policy priorities for MU*
  - Improve quality, safety, efficiency and reduce disparities
  - Engage patients and families
  - Improve care coordination
  - Improve population and public health
  - Ensure adequate privacy and security

Meaningful Use Will Follow an "Escalation Path" *



*Report of sub-committee of Health IT Policy Committee

Crosswalking MU Policy Priorities and Device Interoperability

- Improve quality, safety, efficiency and reduce disparities
  - *Accurate, complete, automated data capture is necessary to achieve these goals.*
- Engage patients and families
  - *Home-based medical device data acquisition will engage patient and family participation in care.*
- Improve care coordination
  - *Also requires accurate, complete, automated data capture*
- Improve population and public health
  - *National infrastructure that supports interoperable devices will support comprehensive population medical surveillance*
- Ensure adequate privacy and security
  - *A device data security model should be part of modern medical device development, regulation, and certification.*

“Interoperability” and “Device” in MU Documents

- In HIT Policy Committee Recommendations, “interoperability” appears once, and “device” 4 times
  - Medical device interoperability envisioned for 2015
  - Data feeds from home monitoring devices envisioned for 2013

- In CMS’ proposed rule, “interoperability” appears 18 times, and “device” 2 times

Finale: MU and Device Interoperability

- The conceptual connection between MU and interoperability is illustrated by the proposed rule
- Interoperable devices, as a domain, have significant potential to advance the policy priorities of MU

Thanks and Write to Me:

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