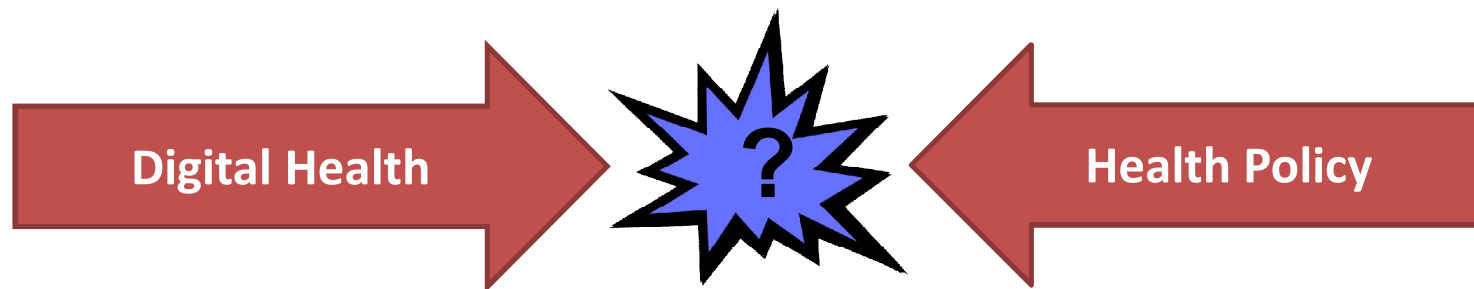


When Digital Health and Policy Collide

HIPAA Summit

March 30, 2017

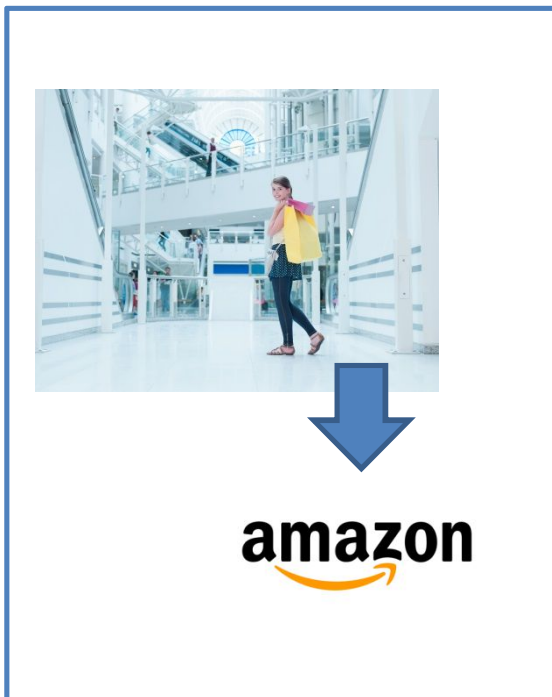
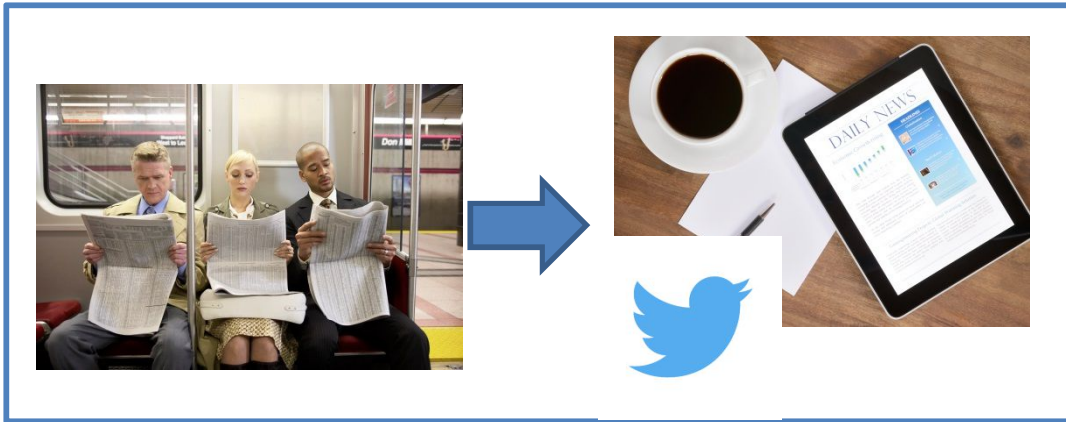
Jodi G. Daniel, JD, MPH
Partner
Crowell & Moring, LLP



What we will cover

- Overview of digital technology and health care
- Government influence over digital health
- Promises and challenges
- How policy is adapting to support digital health progress
- Where we are headed

Technology Changing the World Around Us

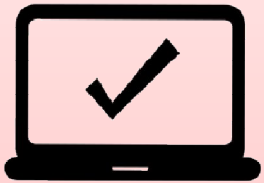




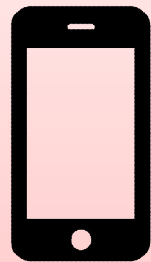
HEALTH CARE

ALL OTHER INDUSTRIES

Digital Health



**Electronic
Health
Records**



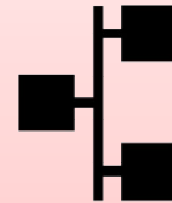
**Mobile
Health**



**Remote
Monitoring,
Wearables,
Ingestables**



Telehealth



**Big Data
and Data
Analytics**



**Precision
Medicine**

Interoperability

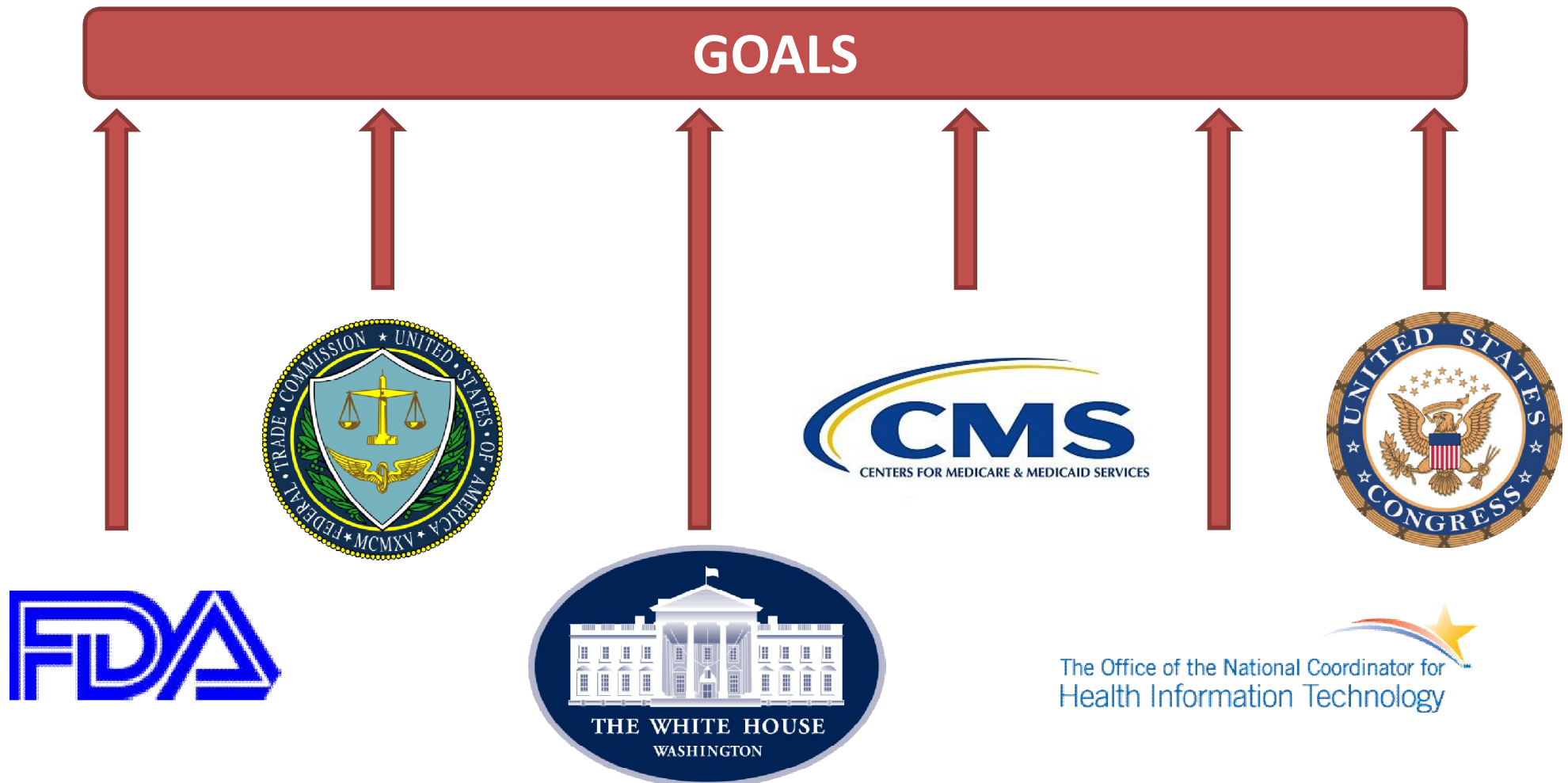
Government Influence Over Digital Health

Federal Policy Levers

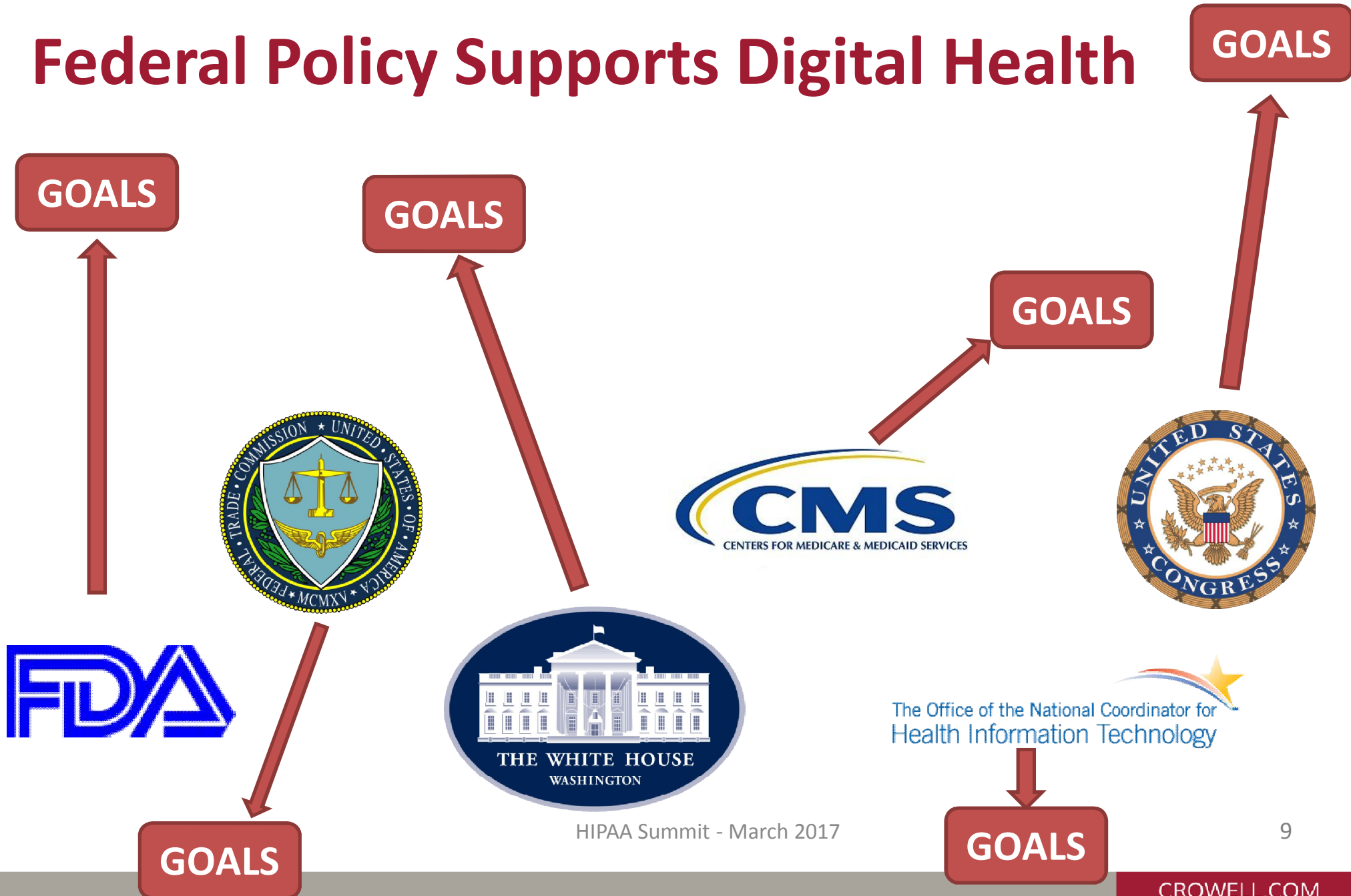
- Legislation
 - Regulation
 - Guidance
 - Government programs as a model
 - Requirements to participate in government programs
 - Government spending and conditions
 - Public/Private Partnerships
 - Convenor
 - Bully Pulpit
- **Need money and authority**



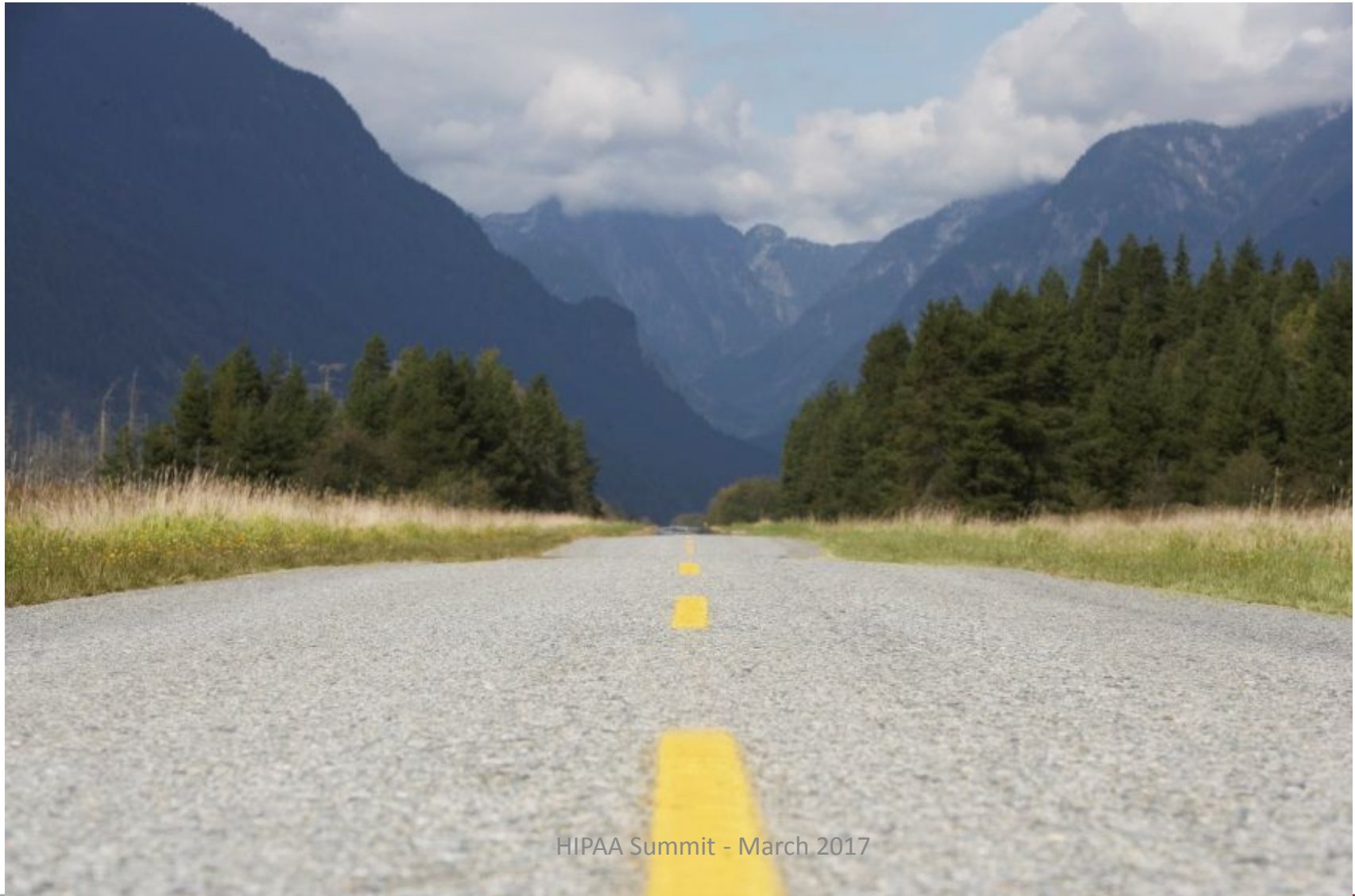
Federal Policy Supports Digital Health



Federal Policy Supports Digital Health

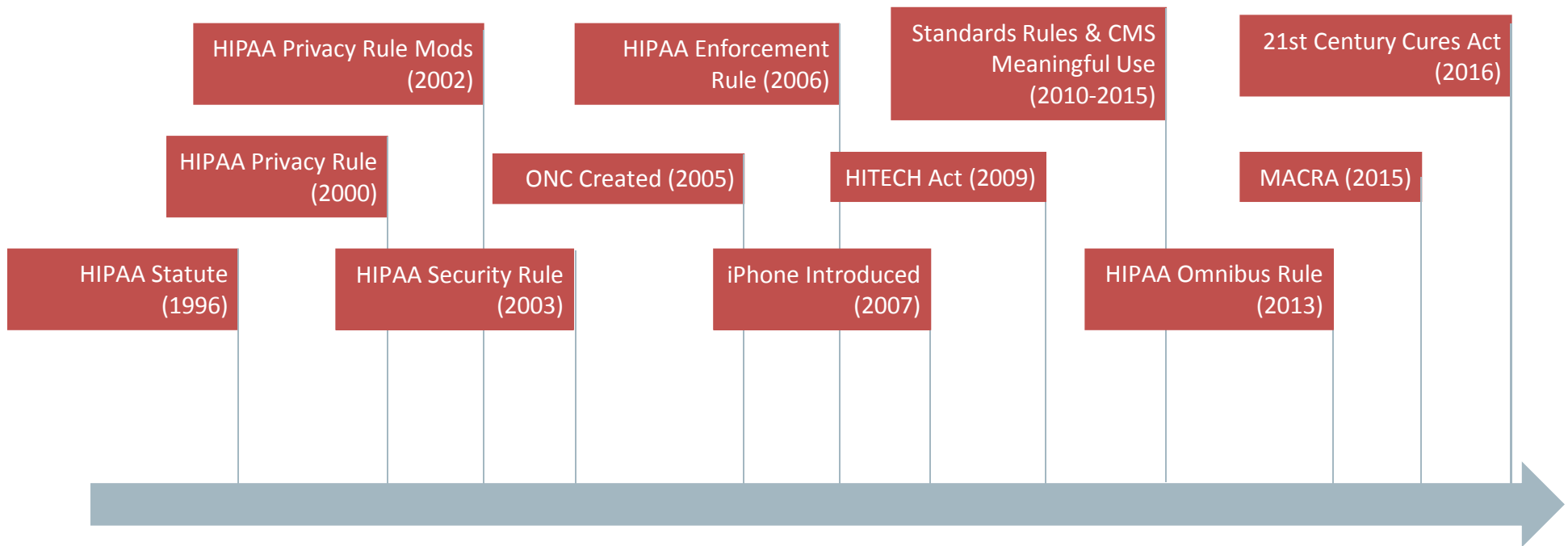


Health IT Journey



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HIPAA and Health IT

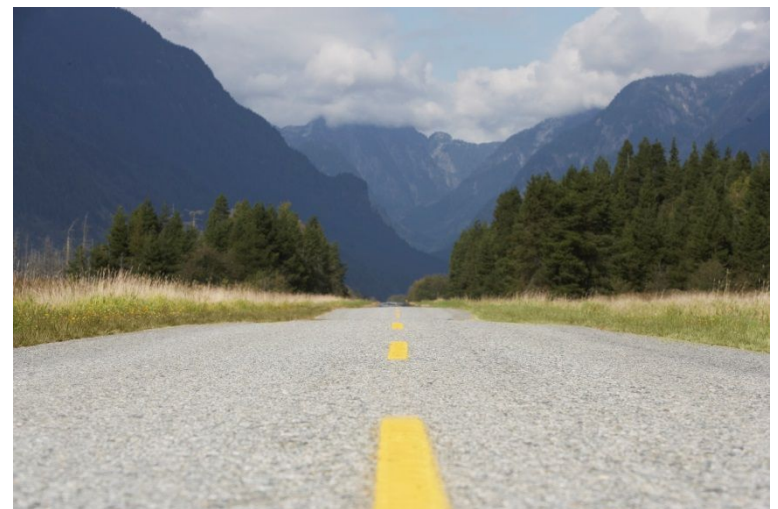


Health IT Journey Begins

“By computerizing health records, we can avoid dangerous medical mistakes, reduce costs, and improve care.”

--President George W. Bush, State of the Union Address
January 20, 2004

President Bush outlined a plan to ensure that most Americans have electronic health records within the next 10 years.

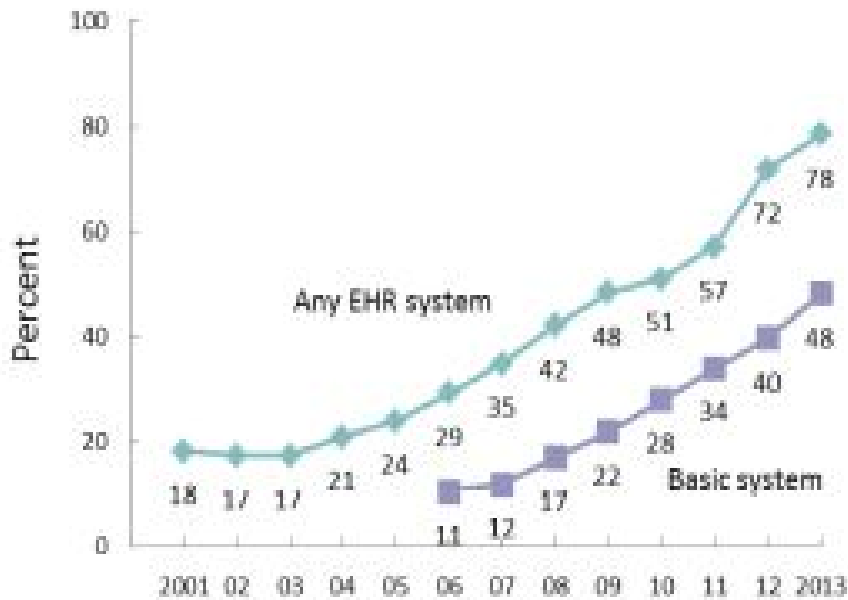


Incentives for Adoption of Health IT

- Meaningful Use Program
 - HITECH Act (2009)
 - CMS Electronic Health Record (EHR) Incentives Program
 - Health IT Standards and Certification Program
 - About \$35 Billion in incentives
- MACRA (2015)

Electronic Health Record Adoption

Office-Based Physicians



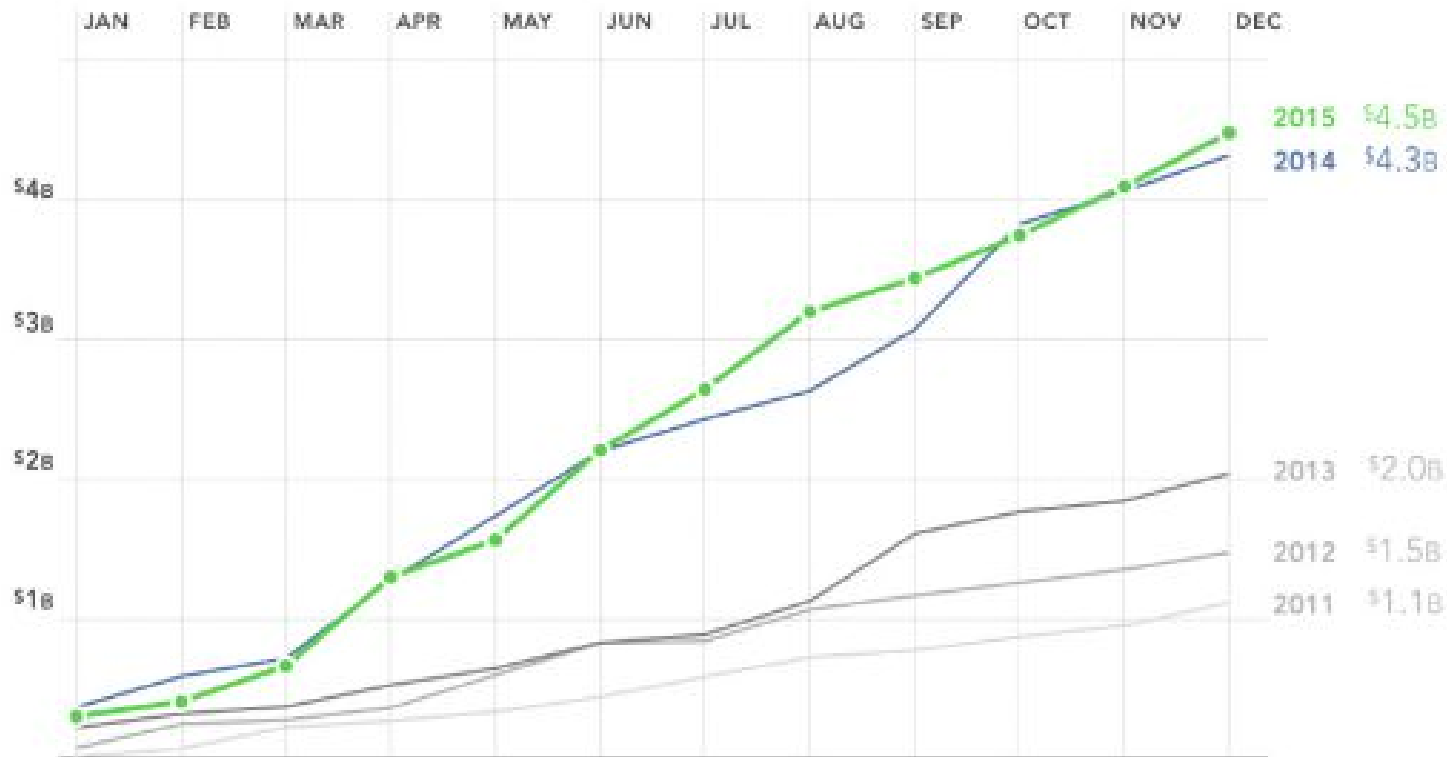
Non-Federal Acute Care Hospitals



Source: ONC Data Brief
April 2015

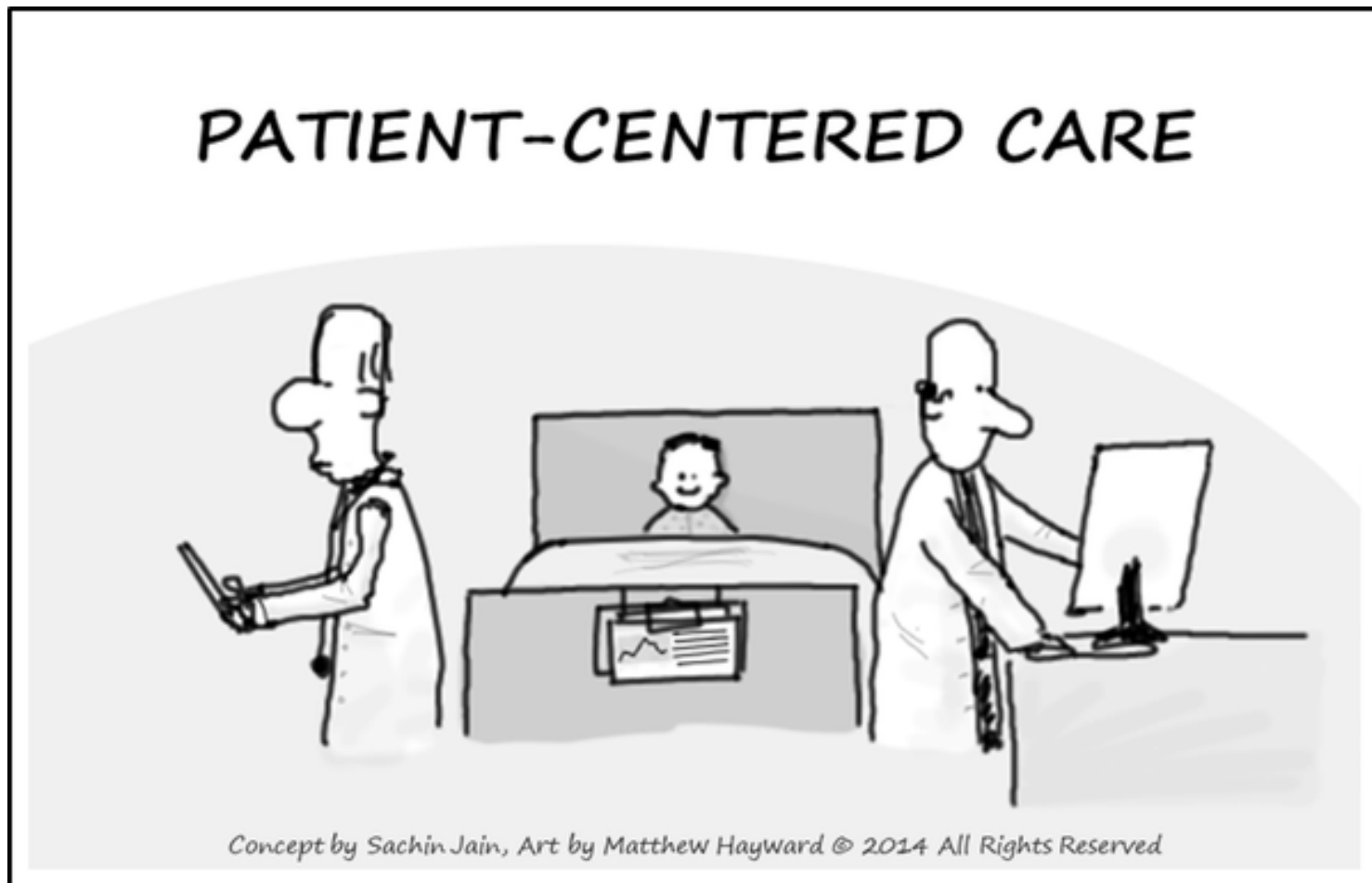
Investment in Health IT Innovation

DIGITAL HEALTH FUNDING
2011-2015



Source: Rock Health Funding Database

Interoperability?

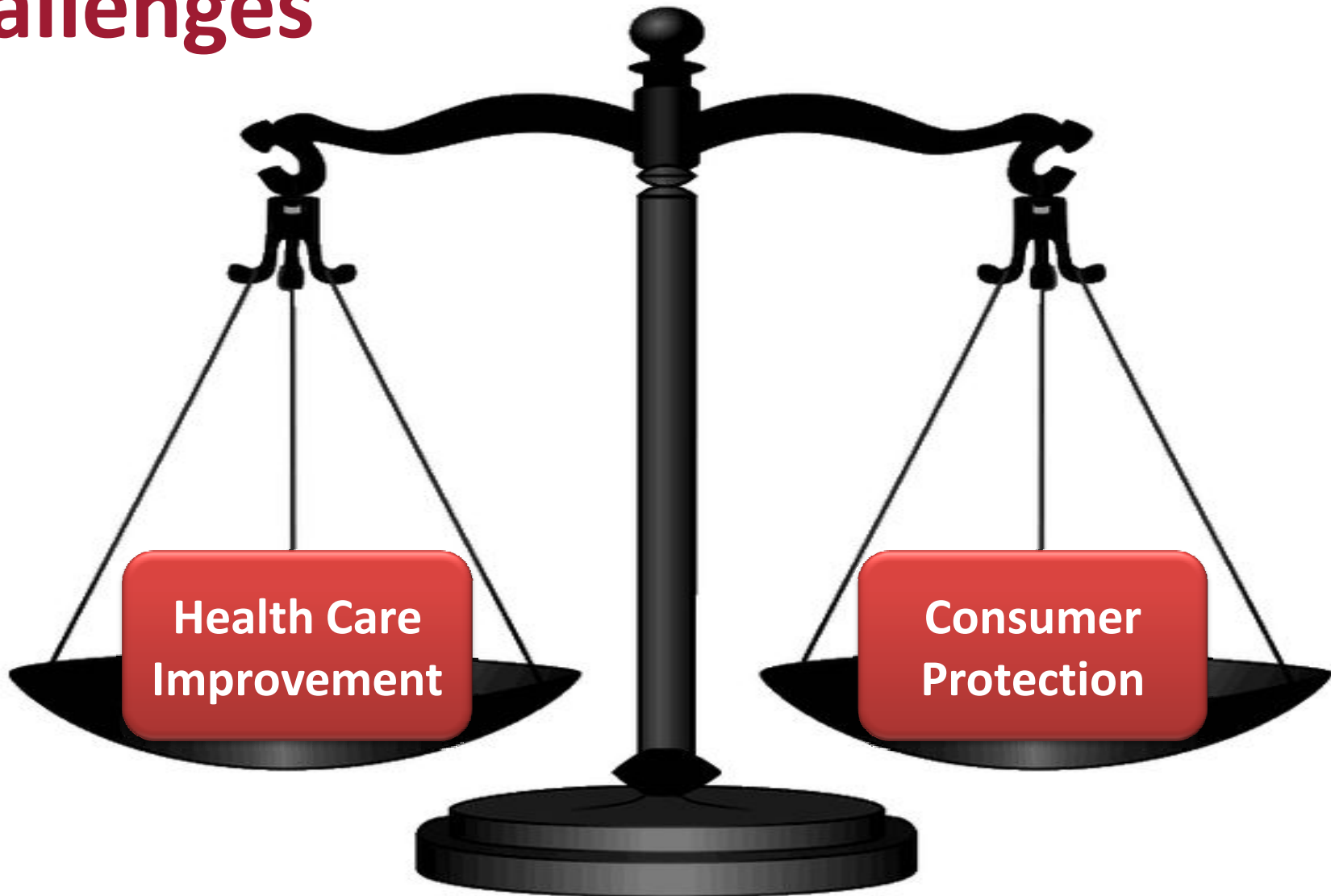


The Promise of Digital Health

- The electronic data can support:
 - Value-based payment
 - Research
 - Consumer engagement in health care
 - Improved efficiency in health care
 - Improved health care outcomes



Challenges



Challenges:

Health Security In the News

Premier Healthcare Reports Possible Data Breach that Could Affect More than 200,000 Patients
-Fox, 3/8/16

Hackers' Ransom Attack On California Hospital More Proof Healthcare Cybersecurity Is Floundering
-International Business Times, 2/17/16

Another Healthcare Data Breach
-USA Today, 7/25/15

Private Sector Concerns: HIPAA Enforcement

Penalties

- Federal criminal penalties:
 - Knowing Violation: Fines up to \$50,000 & 1 year
 - False Pretenses: Fines up to \$100,000 & 5 years
 - Intent to Sell: \$250,000 & 10 years
- Federal civil penalties:
 - OCR Enforcement (max \$1.5M per violation)
 - Penalty depends on culpability and other factors
 - Count multiple violations of identical provision (per person, per day, per act/omission)
- State AGs also have enforcement power



➔ HIPAA Enforcement on the Rise ➔

Challenges: PRIVACY DIVIDE



Health Care Sector
HIPAA Regulated
Environment

Health Care Sector
Non-Regulated
Environment

How Policy is Adapting to Support Digital Health Progress

Connecting HIPAA and Health IT

- HITECH Act Modifications and Omnibus HIPAA Rule
- HIPAA Guidance Tools
 - Developer Portal
 - Health app scenarios guidance
 - BA Access FAQ
 - Ransomware & Cyber Security Crosswalk
 - Patient Access Guidance
 - Cloud Guidance
 - Text Messaging Guidance Upcoming
 - The “Real HIPAA” Series

Helping innovators and those using digital health tools comply with HIPAA

- Health App Scenario Guidance
 - Helps answer questions about when are health app developers subject to HIPAA
- The Real HIPAA Series
 - Explains how uses of health information and leveraging electronic health information can occur consistent with treatment, payment, and health care operations under HIPAA.
- Cloud Guidance
 - Addresses questions about covered entities and business associates using cloud service providers to store health data

Promoting Patient Access

- OCR set rules and provided guidance on individuals' access to their protected health information under the Privacy Rule
 - Form and Format and Manner of Access – including electronic
 - Timeliness
 - Fees
 - Directing Copy to a Third Party, and Certain Other Topics
- ONC sets technical requirements for EHRs, including:
 - Ability to view, download and transmit (VDT) and to have data available through APIs.
- CMS sets health care provider requirements, including:
 - Enable VDT and patient access to data through an API
- AND... 21st Century Cures...

21st Century Cures Act



**** Health IT Provisions Focus on Interoperability and Access ****

21st Century Cures Act

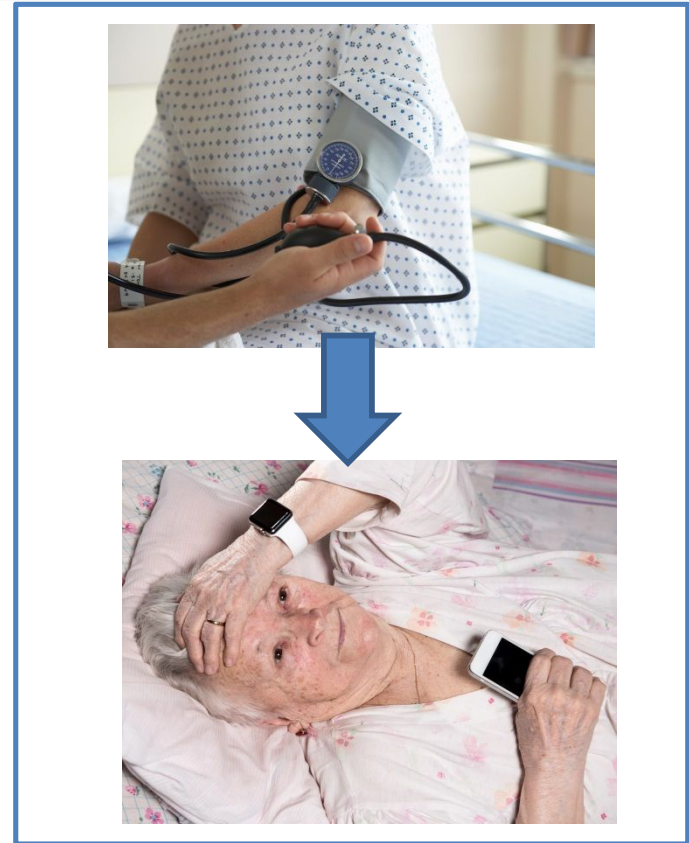
- Focus: Interoperability and Access
 - Redefines “interoperability”
 - Creates new legal prohibition regarding “information blocking”
 - Expands certification provisions beyond EHR incentive program
 - Focuses on a governance framework for networks
 - Promotes patient access

Where are we headed...



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Technology Changing Health



Trends in Health Care

- Shift in payment models
- Shift on focus from services to outcomes
- Shift to care closer to home and community
- Shift from clinician direction to patient engagement
- Growing focus on data from outside clinical setting
- Growing interest in leveraging data to improve health of individuals and populations

What's Going on in Washington?



"HOLD STILL. WE'RE GOING TO REPEAL YOUR KIDNEYS AND REPLACE THEM WITH SOMETHING GREAT WE THINK OF LATER."

What is likely...

- 21st Century Cures Act Implementation
 - Push toward interoperability
 - Push toward patient access and creation of a longitudinal patient record
 - Reducing reporting/regulatory burden on doctors
- Continued focus on reducing costs
- Continued focus on outcomes-based payment



HEALTH CARE

ALL OTHER INDUSTRIES ³³

Contact

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