Clinical Engineering Symposium – AAMI2010
Tampa FL June 26, 2010

Keynote Presentation
Clinical Engineering Symposium

Meaningful Use Update for the US Electronic Health Record Programs

Elliot B. Sloane, PhD, CCE, FHIMSS
Drexel University Health Systems Engineering Director
Founder, Center for Healthcare Information Research and Policy

Co-Chair, IHE International
Board of Directors, Delaware Valley HIMSS
Board of Directors, ANSI Healthcare Technology Standards Panel
Sponsor, IEEE 11073 Medical Informatics Standards
Past Chair, HIMSS Security and Privacy Steering Committee

Elliot Sloane's Bio Brief

- 35+ years in the medical technology and IT/HIT fields, as a technology/engineering expert and consumer/safety advocate
  - Biomedical and Clinical Engineering core
  - Information Systems and Sciences doctorate
- 25 years as a CIO, COO, CTO, CRO in the medical technology industry (ECRI Institute & MEDIQ, Inc)
- 10+ years in business schools, MIS, CS, and,
- Finally, ***Health Systems Engineering*** at Drexel University
  - Also, founder and board member/chair with multiple non-profits
  - Consultant to US gov't and World Health Organization
    - Specializations: medical devices, privacy, security, patient safety (and related technical standards and policies)

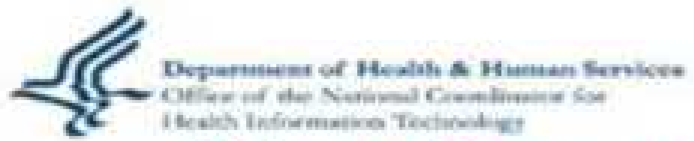
© 2010 Elliot Sloane, all rights reserved.

Meaningful Use Presentation Overview

- HHS Office of the National Coordinator (ONC) of Health IT's most up to date MU interpretation
- ONC's new "final temporary" mandatory MU software standards, certification, and testing
- Where do medical devices intersect the MU roadmap
- What are our opportunities and challenges?

© 2010 Elliot Sloane, all rights reserved.

Let’s use a few of ONC’s own slides from last month:



Getting to Meaningful Use

This was presented to PAeHI, 11 May 2010

Excerpted by Elliot Sloane, Drexel University for AAMI 2010 Conference

Available at http://www.paehi.org/ehealth/resources/

Joshua Seidman, PhD
Acting Director, Meaningful Use
Office of Provider Adoption Support
Office of the National Coordinator for HIT

A Seasonal View of Meaningful Use

Grass

Meaningful Use of Grass

© 2010 Elliot Sloane, all rights reserved.

Why?

"We'll be on our way to computerizing all of America's medical records, which won't just eliminate inefficiencies, save billions of dollars and create tens of thousands of jobs – but will save lives by reducing deadly medical errors."

– President Barack Obama, February 4, 2009

President Obama's rationale for the roughly $30 Billion earmarked in the ARRA HITECH legislation.

© 2010 Elliot Sloane, all rights reserved.

How HITECH Addresses Barriers to Adoption

Obstacle	Intervention	Funds Allocated
Market Failure, Need for Financial Resources	• Medicare and Medicaid EHR Incentive Programs for "Meaningful Use"	• $27.3 B*
Addressing Adoption Difficulties	• Regional Extension Centers • Health IT Research/Resource Center	• $643 M • $50 M
Workforce Training	• Workforce Training Programs	• $84 M
Addressing Technology Challenges and Providing Breakthrough Examples	• Strategic Health Information Technology Advanced Research Projects (SHARP) • Beacon Communities Programs	• $60 M • $250 M
Privacy and Security	• Policy Framework • New Privacy and Security Policies	Addressed across all Programs
Need for Platform for Health Information Exchange	• NHIN, Standards and Certification • State Cooperative Agreement Program	• $64.3 M • $548 M

*$27.3 B is high scenario

HIT as a tool and foundation for delivery system improvement

Improved Quality & Efficiency

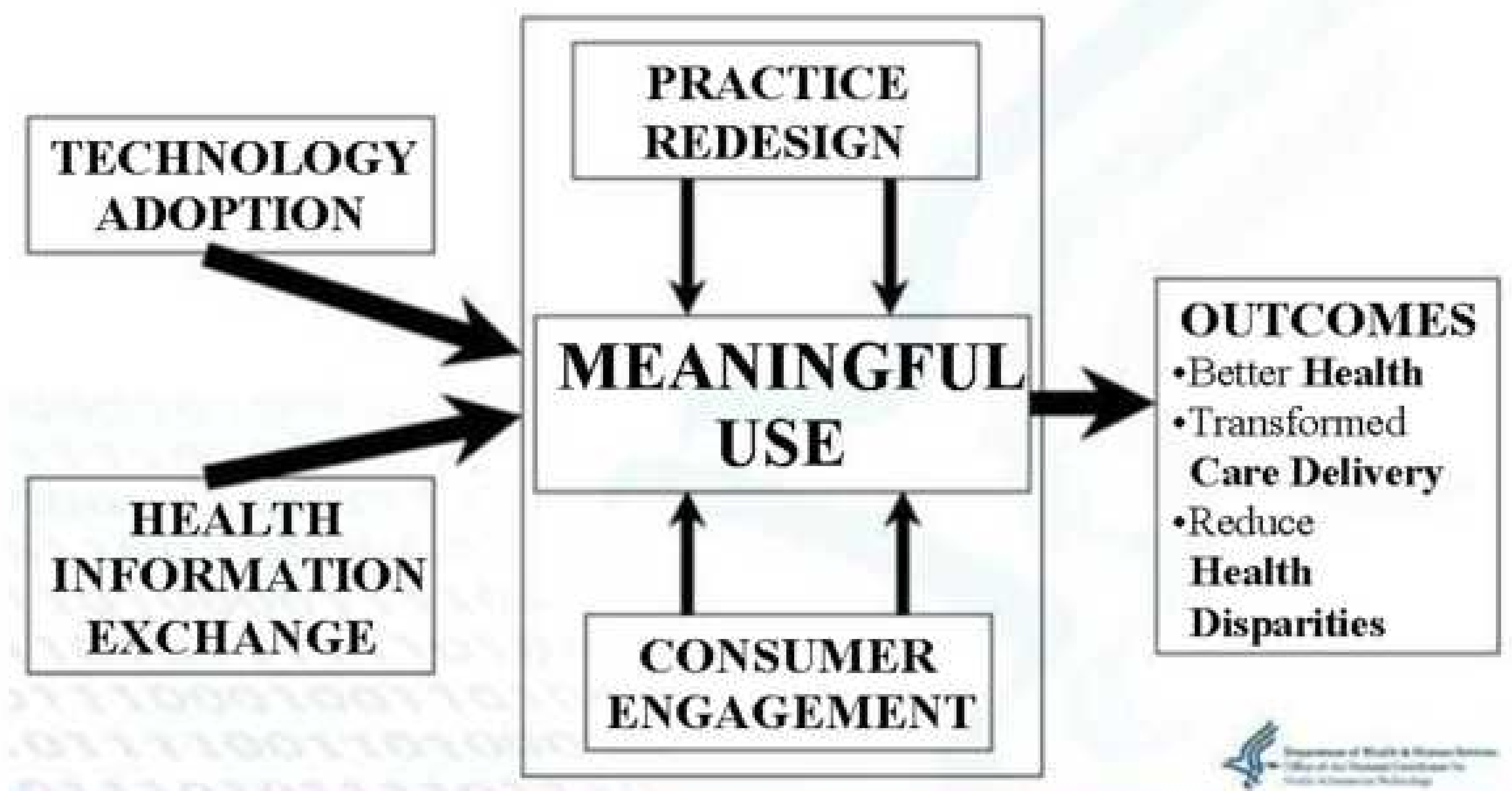
Care Delivery Innovations

Provider Feedback & Measurement

Payment Reform

HIT Foundation
Meaningful Use of EHRs

Getting to Meaningful Use…
…To Improve Health & Health Care



Making Meaning of "Meaningful Use"

- HITECH goals
  - Not about technology
  - Improving health and transforming health care through meaningful use of HIT

Data capture and sharing

Advanced clinical processes

Improved outcomes

Where Does "Health Care Reform" Fit In?

- HIT-enabled quality improvement
  - Expectations regarding data collection
  - E-specifications for quality measures
- Center for Medicare & Medicaid Innovation
  - Success of value-based purchasing demos & pilots measured by HIT-generated data
- Re-admissions reimbursement
- PQRI and RHQDAPU
- Health-Associated Infections
- Evolution of the patient-centered medical home

Meaningful Use Presentation Outline

- HHS Office of the National Coordinator (ONC) of Health IT's most up to date MU interpretation
- ONC's new "final temporary" mandatory MU software standards, certification, and testing
- Where do medical devices intersect the MU roadmap
- What are our opportunities and challenges?

© 2010 Elliot Sloane, all rights reserved.

New "final temporary" EHR certification rules were posted June 18, 2010

Health Care Providers: Key Points

In order to qualify for Medicare and Medicaid EHR incentive payments, providers must use EHR technology that has been certified by an Office of the National Coordinator for Health Information Technology-Authorized Testing and Certification Body (ONC-ATCB, or ATCB). The temporary certification program provides assurances that the EHR technology adopted by health care providers is technically capable of supporting their efforts to achieve meaningful use.

Developers of EHR Technology: Key Points

The temporary certification program provides a way for developers of EHR Technology to have their EHR technology tested and certified so that it can be subsequently adopted by health care providers who seek to achieve meaningful use.

A1. What is the temporary certification program final rule?

The Secretary of Health and Human Services (the Secretary) issued the temporary certification program final rule to establish a process through which organizations may become ONC-ATCBs. An ONC-ATCB is authorized by the National Coordinator to test and certify EHR technology (Complete EHRs and/or EHR Modules).

© 2010 Elliot Sloane, all rights reserved.

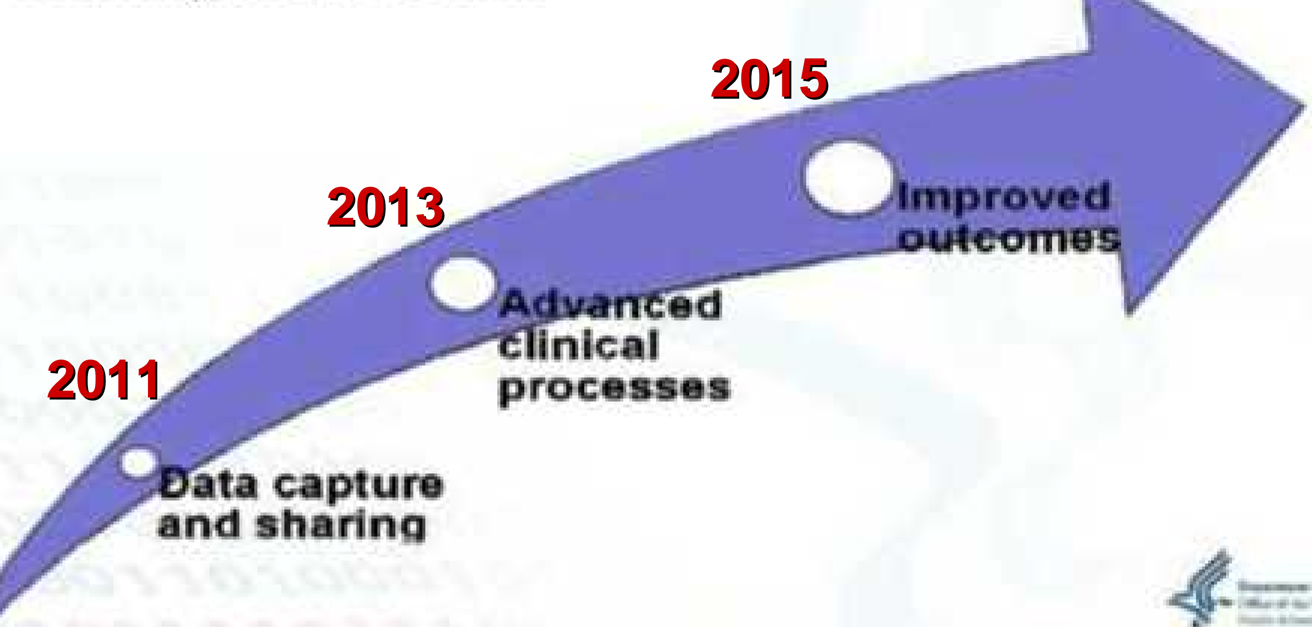
What makes it "final temporary?"

- This Final Rule for ***Authorized Testing and Certifying Bodies ATCB*** (and the testing and certification criteria) will SUNSET on December 31, 2011
  - – May be deferred slightly if NIST is not ready to institute the "final permanent" ATCB program!
- Why December 31, 2011?
  - – The Meaningful Use criteria (and testing and certification) are MANDATED to be revised by CMS in 2012 and 2014, for deployment by Meaningful Users in 2013 & 2015!

© 2010 Elliot Sloane, all rights reserved.

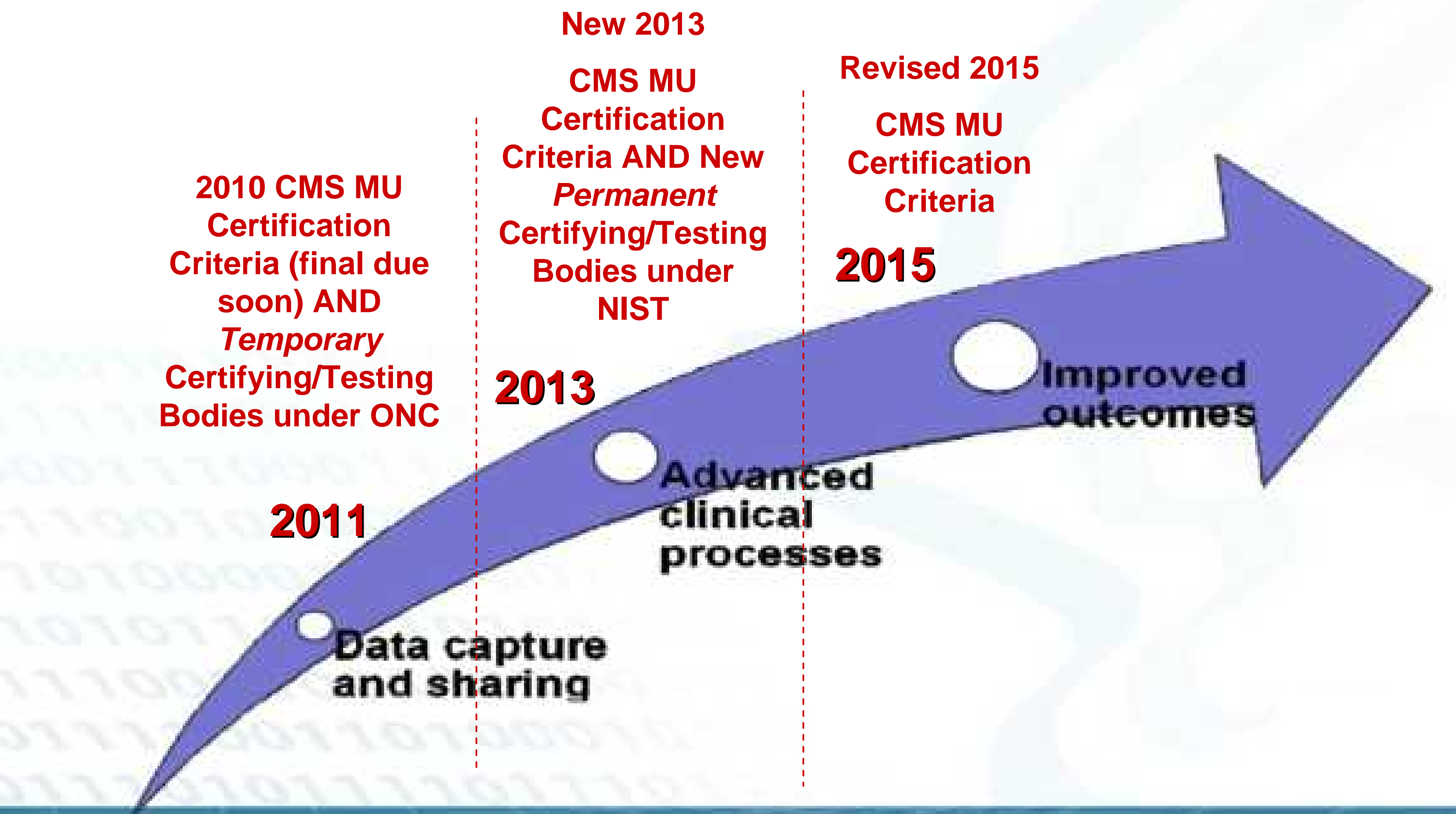
Making Meaning of "Meaningful Use"

- **HITECH goals**
  - Not about technology
  - Improving health and transforming health care through meaningful use of HIT



The "Certification" of software for Meaningful Use will LAPSE every two years according to ONC's June 18 Final rule.

i.e., each hospital or physician will have to be able to prove they are "meaningfully using" software certified to the 2013 and 2015 Meaningful Use Criteria in order to receive the CMS incentives!



ONC's Meaningful Use Matrix – Page 1 of 7

Health Outcomes Policy Priorities	Care Goals	2011 Objectives *Goal is to electronically capture in coded format and to report health information and to use that information to track key clinical conditions*	2011 Measures	2013 Objectives *Goal is to guide and support care processes and care coordination*	2013 Measures	2015 Objectives *Goal is to achieve and improve performance and support care processes and on key health system outcomes*	2015 Measures
Improve quality, safety, efficiency, and reduce health disparities	• Provide access to comprehensive patient health data for patient's health care team • Use evidence-based order sets and CPOE • Apply clinical decision support at the point of care • Generate lists of patients who need care and use them to reach out to patients (e.g., reminders, care instructions, etc) • Report to patient registries for quality improvement, public reporting, etc	• Use CPOE for all order types including medications [OP, IP] • Implement drug-drug, drug-allergy, drug-formulary checks [OP, IP] • Maintain an up-to-date problem list [OP, IP] • Generate and transmit permissible prescriptions electronically (eRx) [OP] • Maintain active medication list [OP, IP] • Maintain active medication allergy list [OP, IP] • Record primary language, insurance type, gender, race, ethnicity [OP, IP] • Record vital signs including height, weight, blood pressure [OP, IP] • Incorporate lab-test results into EHR [OP, IP] • Generate lists of patients by specific condition to use for quality improvement, reduction of disparities, and outreach [OP] • Send reminders to patients per patient preference for preventive /follow up care [OP, IP]	• Report quality measures, including: - % diabetics with A1c under control [OP] - % hypertensive patients with BP under control [OP] - % of patients with LDL under control [OP] - % of smokers offered smoking cessation counseling [OP, IP] • % of patients with recorded BMI [OP] • % eligible surgical patients who received VTE prophylaxis [IP] • % of orders entered directly by physicians through CPOE • Use of high-risk medications in the elderly [OP, IP] • % of patients over 50 with annual colorectal cancer screenings [OP]	• Use evidence-based order sets [OP, IP] • Record clinical documentation in EHR [IP] • Generate and transmit permissible prescriptions electronically [IP] • Manage chronic conditions using patient lists and decision support [OP, IP] • Provide clinical decision support at the point of care (e.g., reminders, alerts) [OP, IP] • Report to external disease (e.g., cancer) or device registries [OP (esp. specialists) IP] • Conduct medication administration using bar coding [IP]	• Additional quality reports using HIT-enabled NQF-endorsed quality measures [OP, IP] • % of all orders entered by physicians through CPOE [OP, IP] • Potentially preventable Emergency Department Visits and Hospitalizations [IP] • Inappropriate use of imaging (e.g. MRI for acute low back pain) [OP, IP] • Other efficiency measure (TBD) [OP, IP]	• Achieve minimal levels of performance on quality, safety, and efficiency measures • Implement clinical decision support for national high priority conditions [OP, IP] • Medical device interoperability [OP, IP] • Multimedia support (e.g. x-rays) [OP, IP]	• Clinical outcome measures (TBD) [OP, IP] • Efficiency measures (TBD) [OP, IP] • Safety measures (TBD) [OP, IP]

ONC sets the MU Goals, CMS translates them into incentive dollars, NIST ensures the software is Certified and Tested to ONC's MU Goals

Other Important EHR certification AND TESTING rules June 18, 2010

- All prior certifications (CCHIT) are void
- Certification requires actual testing
  - Hospitals MAY choose to have their self-written or heavily customized software tested and certified separately
- NIST is custom-writing a suite of NEW, open source test tools (HITSP has been deferred)

http://xw2k.nist.gov/healthcare/use_testing/index.html

The NIST tools MUST be used; no “substantial equivalent tests” allowed!!

© 2010 Elliot Sloane, all rights reserved.

Test Method Rollout Schedule

General criteria (302); Ambulatory (304); Inpatient (306)

Wave 1

§170.302 (b)
Maintain up-to-date problem list

§170.302 (c)
Maintain active medication list

§170.302 (d)
Maintain active medication allergy list

§170.302 (e)
Record and chart vital signs

§170.302 (f)
Smoking status

§170.304 (a)
Computerized provider order entry

Wave 2

§170.302 (h)
Generate patient lists

§170.304 (c)
Record demographics

§170.304 (d)
Generate patient reminder list

§170.304 (g)
Timely access

§170.306 (a)
Computerized provider order entry

§170.306 (b)
Record demographics

§170.306 (e)
Electronic copy of discharge information

Wave 3

§170.302 (a) Drug-drug, drug-allergy, drug formulary checks

§170.302 (l) Medication reconciliation

§170.302 (o) Access control

§170.302 (p) Emergency access

§170.302 (q) Automatic log-off

§170.302 (r) Audit log

§170.302 (s) Integrity

§170.302 (t) Authentication

§170.302 (u) Encryption

§170.302 (v) Accounting of disclosures

§170.304 (e) Clinical decision support

§170.304 (f) Electronic copy of health information

§170.304 (h) Clinical summaries

§170.304 (i) Exchange clinical information and patient summary record

§170.306 (c) Clinical decision support

§170.306 (d) Electronic copy of health information

§170.306 (f) Exchange clinical information and summary record

Wave 4

§170.302 (g)
Incorporate laboratory test results

§170.302 (i)
Report quality measures

§170.302 (j)
Check insurance eligibility

§170.302 (k)
Submit claims

§170.302 (m)
Submission to immunization registries

§170.302 (n)
Public health surveillance

§170.304 (b)
Electronically exchange prescription information

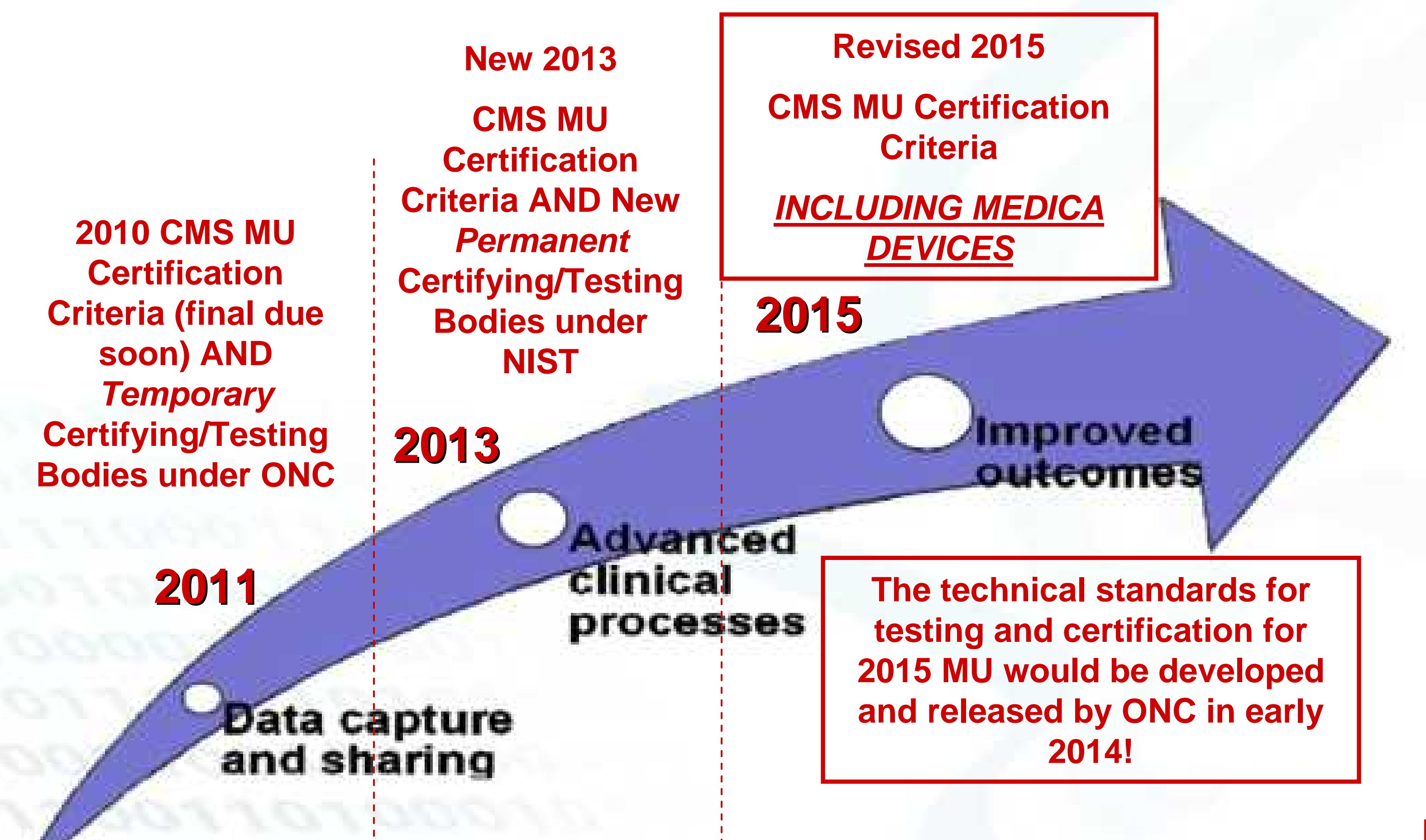
§170.306 (g)
Reportable lab results

Meaningful Use Presentation Outline

- HHS Office of the National Coordinator (ONC) of Health IT's most up to date MU interpretation
- ONC's new "final temporary" mandatory MU software standards, certification, and testing
- Where do medical devices intersect the MU roadmap
- What are our opportunities and challenges?

© 2010 Elliot Sloane, all rights reserved.

According to a January 2011 presentation by Dr. Charles Friedman, ONC's Scientific Director at a meeting at the FDA, the mandatory deployment of medical devices for "Meaningful Use" certification will be in the 2015 wave.



BUT…

Wasn't the question "when will medical devices" be part of Meaningful Use?

- According to the FDA, EHRs are already medical devices!

FDA Discusses Oversight, Regulation of HIT at ONC Workgroup Hearing on Patient Safety

A key medical device regulator from the Food and Drug Administration discussed a range of oversight and regulatory approaches that would categorize electronic health record systems as medical devices during a Feb. 25 informational hearing held by a workgroup of the Office of the National Coordinator for Health Information Technology's Policy Committee.

The certification and adoption workgroup heard from vendors, physicians, and government officials as to the impact EHR systems have had on patient safety.

According to Jeffrey Shuren, director of FDA's Center for Devices and Radiological Health, under the Federal Food, Drug, and Cosmetic Act, health information technology software is a medical device. However, "to date, FDA has largely refrained from enforcing our regulatory requirements with respect to HIT devices," Shuren said.

Things that make you go hmmmm…

- If the FDA drops the "regulated medical device shoe" now, that will be one more HUGE factor in the midst of a "perfect storm" already embedded within Meaningful Use
- But, none of the HIPAA, HITECH, or MU regulations, certification, or testing really speak to patient safety
  - I believe the FDA will eventually have to take the plunge…

© 2010 Elliot Sloane, all rights reserved.

Meaningful Use Presentation Outline

- HHS Office of the National Coordinator (ONC) of Health IT's most up to date MU interpretation
- ONC's new "final temporary" mandatory MU software standards, certification, and testing
- Where do medical devices intersect the MU roadmap
- What are our opportunities and challenges (and obligations?)

© 2010 Elliot Sloane, all rights reserved.

For efficiency, accuracy, safety, and timeliness, Patient Care Devices must *directly* feed real-time clinical data into the EHR. (This includes classical medical devices and "personal health" devices.

Workstation

Modality

© 2010 Elliot Sloane, all rights reserved.

Get yourself ready for interoperable medical devices

- Use your purchasing programs to insist that YOUR vendors offer a no/low cost evolutionary path that they can and will make compatible with ONC's 2014 standards

- Put EHR (and software engineering) topics on your reading list.
  - www.HIMSS.org and HealthIT.HHS.gov

© 2010 Elliot Sloane, all rights reserved.

IHE-PCD is not the ***only*** standard. It is one of several other emerging standards, such as the Continua Alliance work for personal/home health devices and the CIMIT/MDPnP architecture being developed under an ASTM standard, which is explained in a HITSP TN905 document.
(get it for free at www.HITSP.org)

© 2010 Elliot Sloane, all rights reserved.

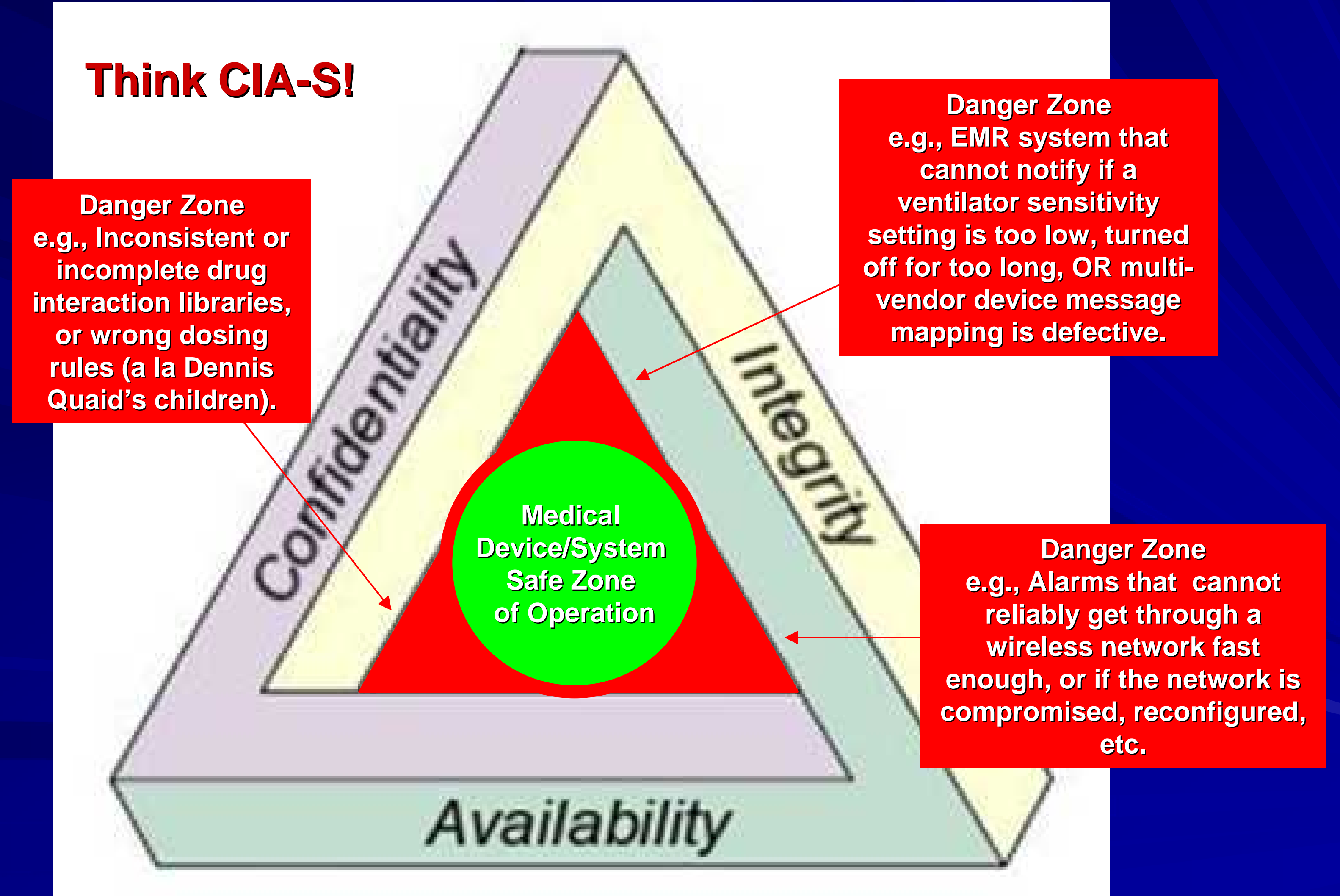
Get ready for HIPAA 2.0
HIPAA is aging; circa '96, rooted in '94
HITECH is the "Son of HIPAA"

Health Information Technology for Economic and Clinical Health

Act of January '09

© 2010 Elliot Sloane, all rights reserved.

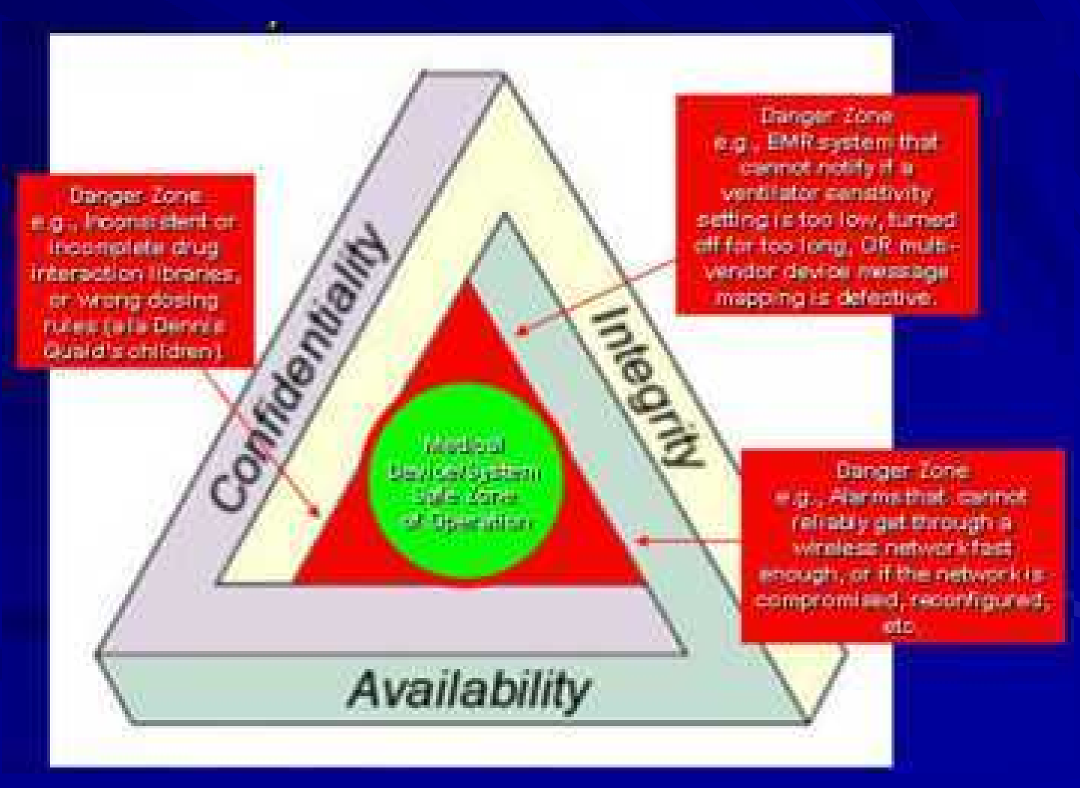
The good old CIA Triad is NOT enough for healthcare; Need SAFETY zones!



© 2010 Elliot Sloane, all rights reserved.

My suspicion and hope: CIAS could become the framework for “HIPAA 2.0”

- – **Confidentiality**
- – **Integrity**
- – **Availability**
- – **Safety**



That would take some of the pressure off of the FDA, too!

© 2010 Elliot Sloane, all rights reserved.

Let's ask for support to address and manage EHR Safety

- AAMI, ACCE, HIMSS, and IEEE should be our advocates for an improved CAIS structure for HIPAA 2.0
- All should advocate for IEC 80001, which at least exposes "risk" so that it can be proactively identified and managed

© 2010 Elliot Sloane, all rights reserved.

Keep the faith: we have friends in high places!

Healthcare Business News

REPRINTS PRINT BOOKMARK & SHARE

Siemens names Glaser CEO of health business unit

By Shawn Rhea / HITS staff writer
Posted: June 25, 2010 - 3:30 pm ET

Glaser

Siemens Healthcare, Malvern, Pa., has appointed Partners HealthCare System Chief Information Officer John Glaser as CEO of Siemens' Health Services business unit, effective Aug. 16.

Glaser, 55, replaces Janet Dillione, who is now executive vice president and general manager of healthcare business at Nuance Communications, Burlington, Mass.

In his new role, Glaser will be responsible for leading Siemens' global healthcare IT business. He will spearhead product development, strategy, portfolio management and financial performance.

The Future of HealthCare IT: Synergy with Biomedical Engineering

John P. Glaser, PhD
Vice President and CIO
Partners HealthCare

AAMI
June 2004

Our AAMI Keynote Speaker from 2004, Dr. John Glaser, was named Siemens' CEO yesterday!

© 2010 Elliot Sloane, all rights reserv

So, LEAD Meaningfully!

OUR TIME IS NOW.

We may never have a chance like this again…

As General George Patton said:

"Lead, follow, or get out of the way!"

Become a Meaningful Leader of Meaningful Users!

© 2010 Elliot Sloane, all rights reserved.

For further information:

Elliot B. Sloane, PhD, CCE, FHIMSS

www.ebsloane.org

ebsloane@drexel.edu, and

ebsloane@ any of:

gmail.com, ieee.org, drexel.edu, ebsloane.org, yahoo.com, hotmail.com, etc.

or just Google™ me!!

Thanks for sharing this time with me!

The floor is open for Q&A!!!

© 2010 Elliot Sloane, all rights reserved.