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

Interim Final Rule on Standards, Implementation Specifications, and Certification Criteria

NIST/OCR Conference

Safeguarding Health Information:

Building Assurance through HIPAA Security

Steven Posnack, ONC

How Does All This Work?

“Meaningful User of Certified EHR Technology”

Meaningful Use Regulations

HIT Certification Programs Regulations

Correlated

HIT Standards & Certification Criteria Regulations

ONC Interim Final Rule

- **Initial Set of Standards, Implementation Specifications, and Certification Criteria**
  - Definitions
  - Standards and Certification Criteria
  - Relationship to Meaningful Use Proposed Rule
  - Relationship to HIPAA Security Rule

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Acronym Check

- CFR: Code of Federal Regulations
- EHR: Electronic Health Record
- FACA: Federal Advisory Committee Act
- IFR: Interim Final Rule
- ONC: Office of the National Coordinator for Health IT
- PHSA: Public Health Service Act

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IFR – The Basics

- **Statutory Authority**
  - American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5)
  - Title XIII of Division A and Title IV of Division B
    - Health Information Technology for Economic and Clinical Health Act (HITECH Act)
  - The HITECH Act amended the Public Health Service Act (PHSA) and created "Title XXX – Health Information Technology and Quality"
    - Section 3004(b) – required the Secretary to adopt an initial set of standards, implementation specifications, and certification criteria by 12/31/2009
    - Created 45 CFR Part 170

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Principles that Guide Certification Criteria and Standards

- **Certification Criteria**
  - Assure providers that Certified EHR Technology can support achievement of Meaningful Use
  - Key capabilities that can be tested objectively
  - Minimal set – supports innovation
- **Standards**
  - Incrementally build capacity
  - Establish the foundation for greater interoperability

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IFR – Definitions (1)

- Certified EHR Technology (Statutory)
  - [A] qualified electronic health record that is certified pursuant to section 3001(c)(5) as meeting standards adopted under section 3004 that are applicable to the type of record involved (as determined by the Secretary, such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals)

IFR – Definitions (2)

- Certified EHR Technology (Regulatory)
  - Complete EHR or a combination of EHR Modules, each of which:
    - (1) Meets the requirements included in the definition of a Qualified EHR; and
    - (2) Has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary.

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IFR – Definitions (3)

- Complete EHR (Regulatory)
  - EHR technology that has been developed to meet all applicable certification criteria adopted by the Secretary.
- EHR Module (Regulatory)
  - any service, component, or combination thereof that can meet the requirements of at least one certification criterion adopted by the Secretary.

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IFR – Standards

- **Organized into four categories:**
  - Content Exchange Standards
  - Vocabulary Standards
  - Transport Standards
  - Privacy and Security Standards

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IFR – Certification Criteria

Certification criteria are aligned with the meaningful use objectives for eligible professionals and eligible hospitals

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IFR – Certification Criteria Deatils

- **General Certification Criteria**
  - applicable to all Complete EHRs or EHR Modules
  - Includes privacy and security certification criteria
- **Ambulatory Certification Criteria**
  - applicable to Complete EHRs or EHR Modules designed for ambulatory settings
- **Inpatient Certification Criteria**
  - applicable to Complete EHRs or EHR Modules designed for inpatient settings

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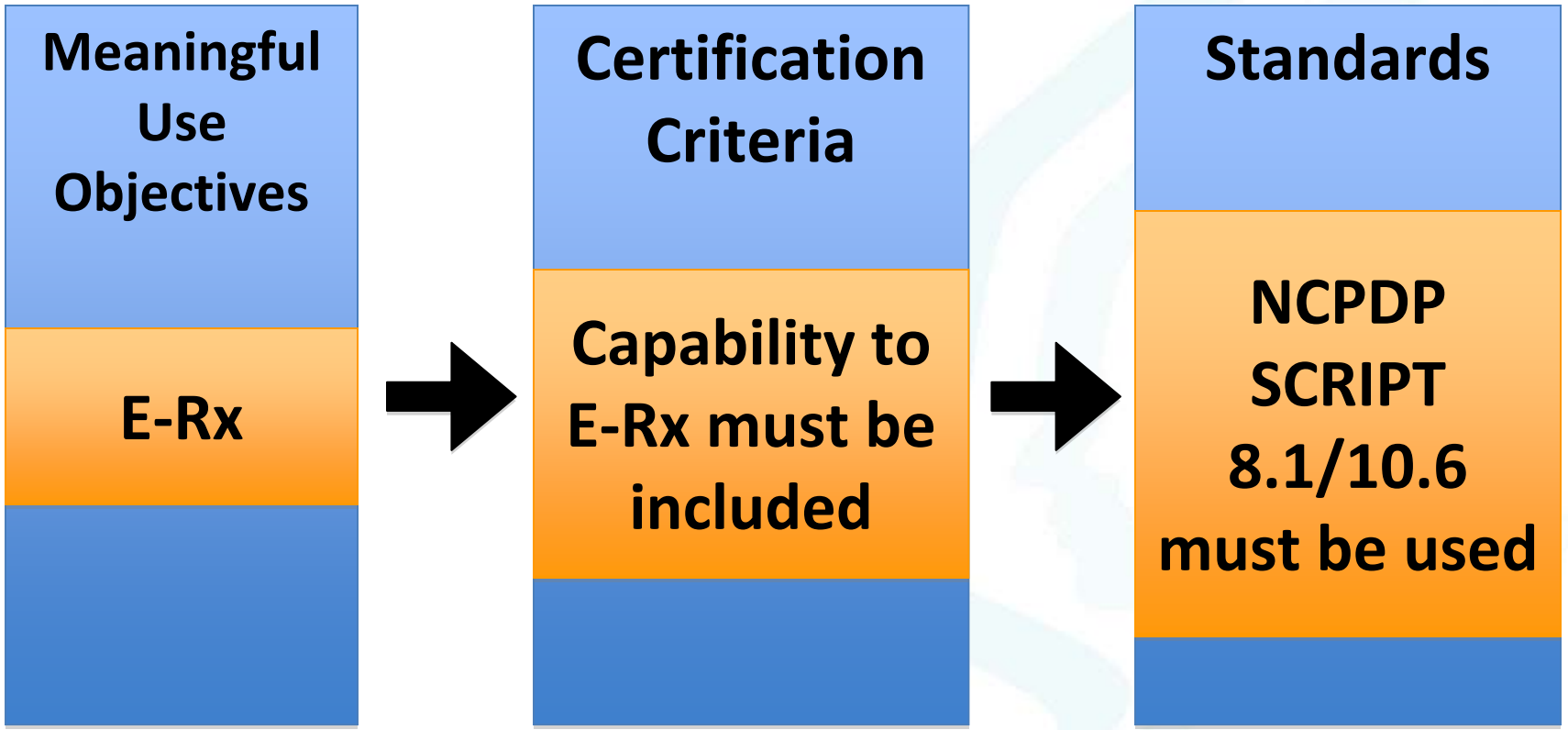
IFR – Relationship to Meaningful Use

Illustrative Crosswalk



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HIPAA Security Rule & Certification Criteria

- **HIPAA Security Rule**
  - Focuses on: administrative, physical, and technical safeguards
  - Sets standards for all e-PHI created, received, maintained, or transmitted by HIPAA Covered Entities
- **Certification Criteria**
  - Focus on technical safeguards
  - Establish requirements for capabilities
  - Apply to Complete EHRs and EHR Modules
  - Do not set organizational policy

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HIPAA Security Rule & Certification Criteria

45 CFR 164.312

- (a)(1) – Access control
- (a)(2)(i) – User identification (r)
- (a)(2)(ii) – Emergency access (r)
- (a)(2)(iii) – Automatic logoff (a)
- (a)(2)(iv) – Encryption/decryption (Data at Rest) (a)
- (b) – Audit Controls
- (c)(1) – Integrity
- (c)(2) – Authenticate ePHI (a)
- (d) Person or entity authentication
- (e)(1) – Transmission security
- (e)(2)(i) – Integrity controls (a)
- (e)(2)(ii) – Encryption (transmission) (a)

45 CFR 170.302

- (o) – Access control
- (p) – Emergency access
- (q) – Automatic logoff

- (u) – Encryption
- (r) – Audit log
- (s) – Integrity

- (t) – Authentication

- (s) – Integrity
- (u) – Encryption

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What's next?

- **IFR Comment Period Closed**
  - March 15, 2010
- **Working with CMS to align Standards and Certification Criteria Final Rule with Meaningful Use Final Rule**
- **To view comments go to: http://www.regulations.gov**
  - Keyword "health IT standards"

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