Stage 3/2015 Edition Health IT Certification Criteria Proposed Rules Overview
May 11, 2015

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- CMS cannot address any comment suggestion or statement made by anyone attending the presentation or consider any such comment or suggestion in the rule writing process.

- Please submit comments through the formal process outlined in the Federal Register.

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Elisabeth Myers

STAGE 3 MEANINGFUL USE PROPOSED RULE OVERVIEW

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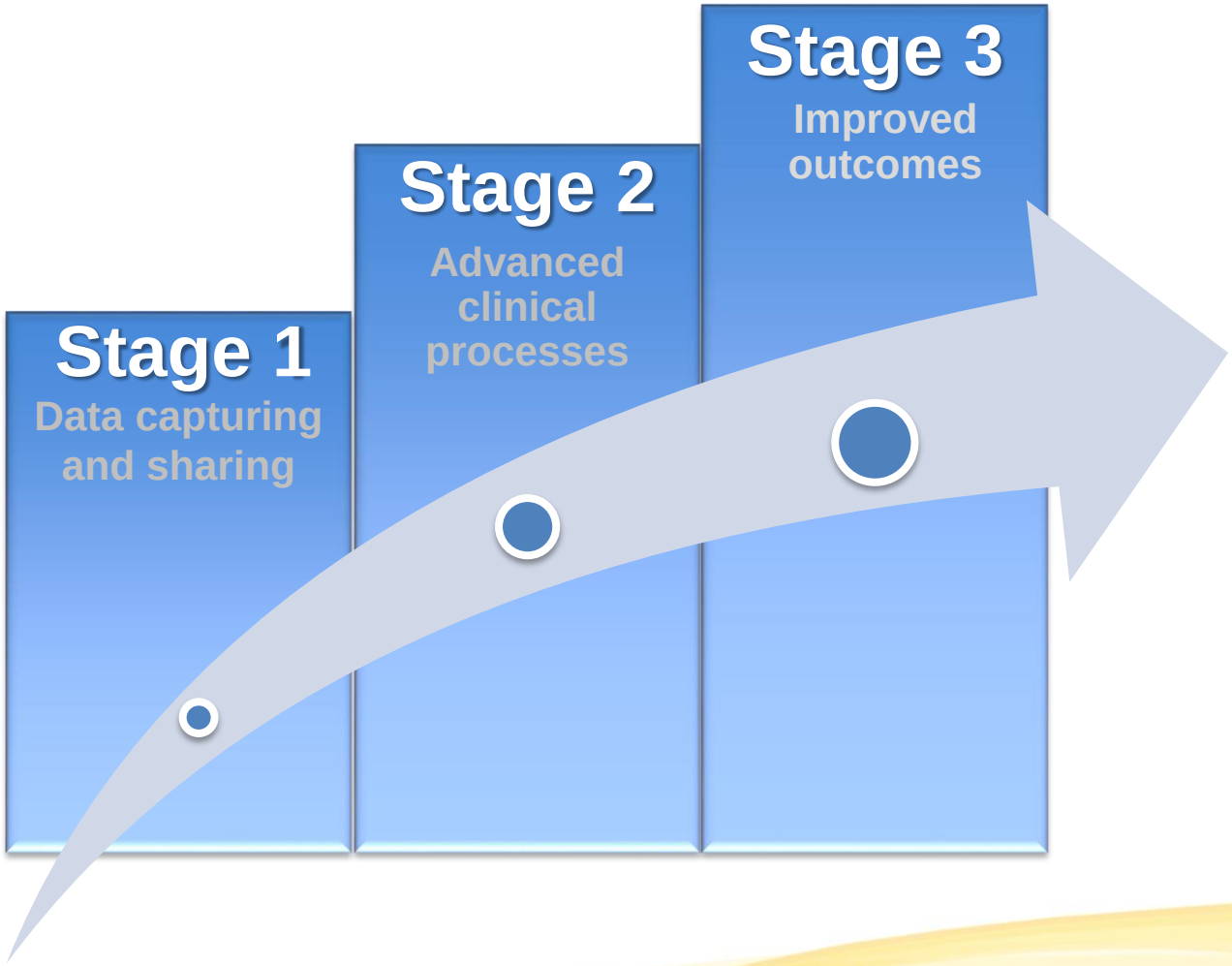
Learning Objectives

1. Understand approach for Stage 3
2. Explain Stage 3 proposed requirements
3. Differentiate between previous requirements and Stage 3


Stage 3
Improved outcomes
Stage 2
Advanced clinical processes
Stage 1
Data capturing and sharing

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Stage 3
NPRM Requirements

Goals of Proposed Provisions

1. Provide a flexible, clear framework to simplify the meaningful use program and reduce provider burden
2. Ensure future sustainability of Medicare and Medicaid EHR Incentive Programs
3. Advance the use of health IT to promote health information exchange and improved outcomes for patients

Stage 3 NPRM Streamlines Programs

Streamlining

- Synchronizing on single stage and single reporting period

Stage 3 NPRM Streamlines Programs

Streamlining

- Reducing burden by removing objectives that are:
  - Redundant paper based versions of now electronic functions
  - Duplicative of other more advanced measures using same certified EHR technology function
  - Topped out and have reached high performance

Stage 3 NPRM Streamlines Programs

Streamlining

- 8 advanced use objectives

Stage 3 NPRM Improves Outcomes

Stage 3 NPRM focuses on objectives which support advanced use of EHR technology and quality improvement

Health information exchange objectives improve outcomes by:

- Ensuring providers caring for same patient are sharing info with one another
- Providing patients with easy access to health info
- Fostering data collection in sharable format across multiple health care organizations
- Supporting learning health system through sharing of common clinical dataset and expanding types of registries to which hospitals and providers can report

Stage 3 NPRM Provides Flexibility

The Stage 3 proposed rule makes the meaningful use program more flexible:

- Have option to report on Stage 3 criteria in 2017
- Required to report on Stage 3 beginning in 2018 regardless of prior participation/stage of meaningful use

Stage 3 NPRM Provides Flexibility

The Stage 3 proposed rule makes the meaningful use program more flexible:

- Simplifying meaningful use objectives and measures and allowing flexible measures for:
  - health information exchange
  - consumer engagement
  - public health reporting
- Providing enhanced flexibility and options for public health reporting

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Stage 3 Requirements, Objectives & Measures

Reporting Period

- Full calendar year reporting period beginning in 2017
- CQM reporting in coordination with quality reporting programs

Stage 3 Proposed Objectives

1. Protect Electronic Health Information
2. Electronic Prescribing (eRx)
3. Clinical Decision Support
4. Computerized Provider Order Entry (CPOE)
5. Patient Electronic Access to Health Information
6. Coordination of Care through Patient Engagement
7. Health Information Exchange
8. Public Health Reporting

Retained Stage 2 objectives with modifications

Objective	Measure(s)
Protect Electronic Health Information	Conduct or review a security risk analysis including addressing the encryption/security of data stored in CEHRT, and implement security updates as necessary and correct identified security deficiencies as part of the EP's, EH's, or CAH's risk management process.
Electronic Prescribing (eRx)	EP Measure: More than 80% of all permissible prescriptions, or all prescriptions, written by the EP are queried for a drug formulary and transmitted electronically using CEHRT. EH/CAH Measure: More than 25% of hospital discharge medication orders for permissible prescriptions (for new, changed, and refilled prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.
Clinical Decision Support	EPs, EHs, and CAHs must satisfy both measures in order to meet the objective: • Measure 1: Implement at least 5 CDS interventions tied to clinical quality measures or key high-priority health conditions. • Measure 2: Enable and implement the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.
Computerized Provider Order Entry (CPOE)	More than 80% of medication, 60% of laboratory, and 60% of "diagnostic imaging" orders are recorded using CPOE. EPs, eligible hospital, or CAH must meet all 3 measures.

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Objectives with expanded scope:

1. Patient Electronic Access to Health Information
2. Coordination of Care through Patient Engagement
3. Health Information Exchange
4. Public Health Reporting

Objective	Measure(s)
Patient Electronic Access to Health Information	EPs/EHs/CAHs must satisfy both measures in order to meet the objective. **Measure 1** • More than 80% of all unique patients seen by the EP or discharged from the hospital during the EHR reporting period are provided access to new information within 24 hours of its availability to the EP/EH/CAH, subject to the provider's discretion to withhold certain information. **Measure 2** • Use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to 35% of patients.

Objective	Measure(s)
Coordination of Care through Patient Engagement	EPs/EHs/CAHs must attest to 3 measures, but meet 2 out of 3 thresholds: **Measure 1** • More than 25% of all unique patients (or authorized representatives) under the care of the EP/EH/CAH during the EHR reporting period (1) view, (2) download, or (3) transmit to a third party their health information. Or enable API and meet Measure 1 of Patient Electronic Access Objective. **Measure 2** • EP/EH/CAHs communicate with patients electronically through secure messaging for 35% of patients encountered during the reporting period. In patient-to-provider communication, provider must respond to patient to receive credit under this objective. “Communicate” means when a provider sends a message to patients OR when a patient sends a message to the provider and the provider responds. **Measure 3** • EP/EH/CAH must use health information received electronically from a non-physician source for 15% of patients encountered by EP/EH/CAH in the reporting period and must use health information received from a patient or from the patient’s caregiver for 5% of patients encountered by the EP/EH/CAH in the reporting period.

Objective	Measure(s)
Health Information Exchange	EPs/EHs/CAHs must attest to 3 measures, but meet 2 out of 3 thresholds: **Measure 1** • The EP/EH/CAH that transitions or refers their patient to another setting of care or to another provider of care creates and exchanges an electronic summary of care record for 50% of such transitions of care and referrals. The electronic summary of care must be sent in accordance with the standards for transitions of care set by ONC. **Measure 2** • The EP/EH/CAH must receive, request or query for a patient's electronic summary of care record that has been created by another setting of care or provider of care for 40% of all new patient encounters during the reporting period. The electronic summary of care must be accessed in accordance with the standards for transitions of care set by ONC. **Measure 3** • Clinical Information Reconciliation (CIR) – Providers perform clinical information reconciliation for more than 80% (percent will be the same as Measure 1) of transitions of care in which the patient is transitioned into the care of the EP/EH/CAH. Provider may choose to reconcile 2 out of 3 of the following: meds, problems, and allergies.

Objective	Measure(s)

Public Health Reporting	Providers must report data on an ongoing basis to established public health registries. *Registry options: Immunization, syndromic surveillance, ELR, specialized (PDMP, cancer, etc.)*
	
	• **EP Objective: Report 3 measures from #1-5**
	
	• **EH/CAHs Objective: Report 4 measures from #1-6**
	
	  • **Measure 1-** Immunization Registry Reporting
	  • **Measure 2**- Syndromic Surveillance Reporting
	  • **Measure 3**- Case Reporting
	  • **Measure 4**- Public Health Registry Reporting*
	  • **Measure 5**- Clinical Data Registry Reporting**
	  • **Measure 6**- Electronic Reportable Laboratory Results
	
	**Providers may choose to report to more than one public health registry to meet the number of measures.*
	**Providers may choose to report to more than one clinical data registry to meet the number of measures required to meet the objective*.

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Modifications to Meaningful Use in 2015-2017 NPRM

Goals of Proposed Provisions

1. Align with Stage 3 proposed rule to achieve overall goals of programs
2. Synchronize reporting period objectives and measures to reduce burden
3. Continue to support advanced use of health IT to improve outcomes for patients

Changes to Participation Timeline

2015	Attest to modified version of Stage 2 with accommodations for Stage 1 providers
2016	Attest to modified version of Stage 2
2017	Attest to either modified version of Stage 2 **or** full version of Stage 3
2018	Attest to full version of Stage 3

Alignment of Meaningful Use NPRMs

The Stage 1 and 2 Modification NPRM reconciles measures to align criteria for 2015 to 2017 with Stage 3 to:

- Prepare providers to report Stage 3 criteria in 2018
- Reduce provider burden and create a single set of sustainable objectives that promote best practices for patients
- Enable providers to focus on objectives which support advanced use of health IT, such as:
  - health information exchange
  - consumer engagement
  - public health reporting

Submitting Comments

1. **Electronically:**

- You may submit electronic comments on this regulation to: http://www.regulations.gov/#!submitComment;D=CMS-2015-0033-0002
- Follow the "Submit a comment" instructions.

2. **By regular mail**

3. **By express or overnight mail**

4. **By hand or courier**

CMS Help Desks

- **EHR Information Center Help Desk**
  - (888) 734-6433 / TTY: (888) 734-6563
  - Hours of operation: Monday-Friday 8:30 a.m. – 4:30 p.m. in all time zones (except on Federal holidays)

- **NPPES Help Desk**
  - Visit https://nppes.cms.hhs.gov/NPPES/Welcome.do
  - (800) 465-3203 - TTY (800) 692-2326

- **PECOS Help Desk**
  - Visit https://pecos.cms.hhs.gov/
  - (866)484-8049 / TTY (866)523-4759

- **Identification & Access Management System (I&A) Help Desk**
  - PECOS External User Services (EUS) Help Desk Phone: 1-866-484-8049
  - TTY 1-866-523-4759
  - E-mail: EUSSupport@cgi.com

The Office of the National Coordinator for Health Information Technology

2015 Edition Proposed Rule

Modifications to the ONC Health IT Certification Program and the 2015 Edition Health IT Certification Criteria

Elise Sweeney Anthony, Deputy Director, Office of Policy
Michael L. Lipinski, Director, Division of Federal Policy and Regulatory Affairs

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2015 Edition Health IT Goals

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INTEROPERABILITY

ACCESS

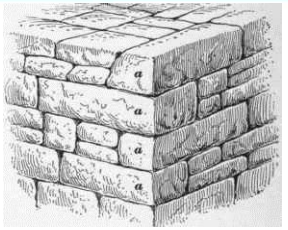
USER/MARKET RELIABILITY

SUPPORTING THE CARE CONTINUUM

INTEROPERABILITY

- New and updated vocabulary and content standards for the structured recording and exchange of health information (including the 2015 Base EHR Definition and the Common Clinical Data Set)
- Transitions of Care
  - ❑ Both versions of the Consolidated CDA (Release 1.1 and Release 2.0) + Edge Protocol
  - ❑ Rigorously testing C-CDA creation, templates, vocabulary codes; and XDM processing
  - ❑ Patient matching data with constraints

2015 Base EHR Definition



Focuses on the functionalities that all users of certified Health IT should minimally possess consistent with the HITECH Act requirements.

Base EHR Capabilities	Certification Criteria
Includes patient demographic and clinical health information, such as medical history and problem lists	Demographics, Problem List, Medication List, Medication Allergy List, Smoking, and Implantable Device List
Capacity to provide clinical decision support	Clinical Decision Support
Capacity to support physician order entry	Computerized Provider Order Entry
Capacity to capture and query information relevant to health care quality	Clinical Quality Measures (CQMs)- record and export
Capacity to exchange electronic health information with, and integrate such information from other sources	Transitions of Care, Data Portability, Application Access to Common Clinical Data Set, and ["Direct" or "Direct, Edge Protocol, and XDR/XDM"]

The Common Clinical Data Set includes key health data that should be exchanged using specified vocabulary standards and code sets as applicable

Patient name	Lab tests
Sex	Lab values/results
Date of birth	Vital signs
Race	Procedures
Ethnicity	Care team members
Preferred language	Immunizations
Problems	Unique device identifiers for implantable devices
Smoking Status	Assessment and plan of treatment
Medications	Goals
Medication allergies	Health concerns

ONC Interoperability Roadmap Goal

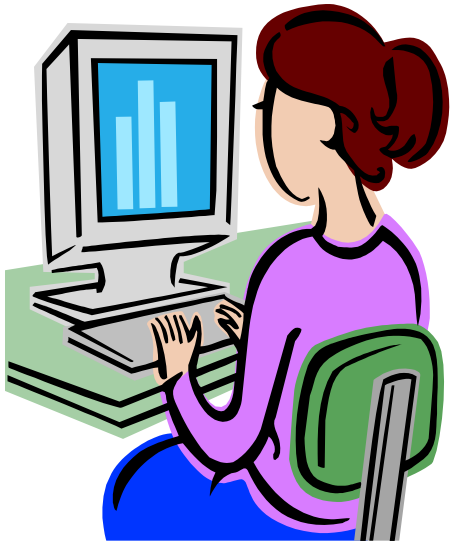
2015-2017

Send, receive, find and use a common clinical data set to improve health and health care quality.

ACCESS

- **The 2015 Edition also proposes that Common Clinical Data Set be available for additional use cases, including data portability, VDT and API.**

Data Portability



View, download, and transmit to 3rd Party

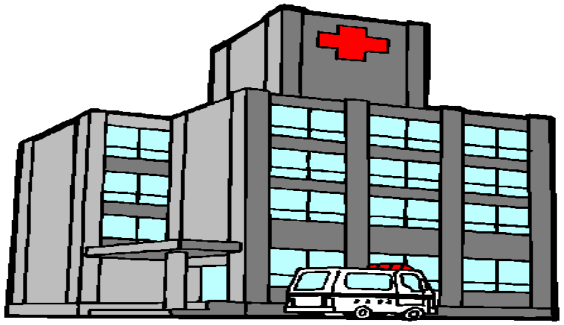
Respond to application programming interface (API) requests for data

USER/MARKET RELIABILITY

- **Privacy and Security**

- **Patient Safety**

- **Surveillance and Certification Maintenance**



- **Transparency**

SUPPORTING THE CARE CONTINUUM

- **Current:** Prior editions were adopted with a specific focus on the EHR Incentive Programs
- **Proposed:** A more accessible ONC Health IT Certification Program supportive of:
  - ❑ Diverse health IT systems, including but not limited to EHR technology ("Health IT Module" instead of "EHR Module")
    - Remember that there is no "Complete EHR" certification to the 2015 Edition or future editions
  - ❑ Health IT across the care continuum, including long-term and post acute care settings
- **"Available/Optional" certification criteria, including supporting health disparities:**
  - ❑ Exchange of sensitive health information (data segmentation for privacy)
  - ❑ Record of social, psychological, and behavioral data
  - ❑ Laboratory exchange
  - ❑ Care plan

SUPPORTING THE CARE CONTINUUM

A number of programs currently use or are proposing to use the ONC Health IT Certification Program. Here are a few:

- Physician Self-Referral Law exception and Anti-kickback Statute safe harbor for certain EHR donations
- CMS chronic care management services
- Department of Defense Healthcare Management System Modernization Program
- The Joint Commission for participation as ORYX vendor – eCQMs for hospitals

Certification to the 2015 Edition Use Cases (MU & Beyond)

Certification Program Requirements

Criteria proposed as always required for 2015 Edition certification (n=2)	Criteria proposed as conditional for 2015 Edition certification depending on capabilities in scope (n= 10)	Proposed 2015 Edition criteria pointed to by CMS for MU 3 & to implement statute (Base EHR definition) (n=37)		Available proposed 2015 Edition criteria for certification (n=19)
Quality Management System - (g)(4)	Authentication, Access Control, Authorization- (d)(1)	CPOE Medications (a)(1)	Patient-specific Education Resources - (a)(17)	Vital Signs, BMI, and Growth Charts - (a)(6)
Accessibility-Centered Design-(g)(8)	Auditable Events and Tamper-resistance- (d)(2)	CPOE Laboratory (a)(2)	Patient Health Information Capture – (a)(19)	Image results - (a)(13)
	Audit Report(s) - (d)(3)	CPOE Diagnostic Imaging (a)(3)	Implantable Device List - (a)(20)	Patient List Creation - (a)(16)
	Amendments - (d)(4)	Drug-drug, Drug-allergy Interaction Checks for CPOE – (a)(4)	Transitions of Care – (b)(1)	eMAR- (a)(18)
	Automatic Access Time-out - (d)(5)	Demographics -- (a)(5)	Clinical Information Reconciliation and Incorporation – (b)(2)	Social, Psychological, and Behavioral Data - (a)(21)
	Emergency Access-(d)(6)	Problem List – (a)(7)	E-Rx - (b)(3)	Decision Support – knowledge artifact - (a)(22)
	End-User Device Encryption-(d)(7)	Medication list – (a)(8)	Data Portability – (b)(6)	Decision Support – service - (a)(23)
	Integrity - (d)(8)	Medication Allergy List – (a)(9)	CQM – record and export - (c)(1)	Incorporate Laboratory Tests and Values/Results – (b)(4)
	Safety Enhanced Design - (g)(3)	CDS – (a)(10)	CQM – import and calculate – (c)(2)	Transmission of Laboratory Test Reports – (b)(5)
	Consolidated CDA Creation Performance – (g)(6)	Drug-formulary and Preferred Drug List Checks –(a)(11)	CQM – report (c)(3)	DS4P – send (b)(7)
		Smoking Status - (a)(12)	VDT - (e)(1)	DS4P – receive (b)(8)
		Family Health History (a)(14); or Family Health History – Pedigree (a)(15)	Secure messaging - (e)(2)	Care Plan - (b)(9)
		Transmission to Immunization Registries (f)(1)	Transmission to PHA – case reporting (f)(5)	CQM filter - (c)(4)
		Transmission to PHA – syndromic surveillance (f)(2)	Transmission to PHA – antimicrobial use and resistance reporting (f)(6)	Accounting of Disclosures – (d)(9)
		Transmission to PHA – reportable laboratory tests and values/results (f)(3)	Transmission to PHA – health care surveys (f)(7)	Accessibility technology compatibility (g)(5)
		Transmission to Cancer Registries (f)(4)	Automated Numerator Recording - (g)(1) or Automated Measure Calculation - (g)(2)	SOAP Transport and Security Specification and XDR/XDM for Direct Messaging – (h)(3)
		Application Access to Common Clinical Data Set – (g)(7)	Direct Project (h)(1) or Direct Project, Edge Protocol, and XDR/XDM (h)(2)	Healthcare Provider Directory – query request (h)(4)
				Healthcare Provider Directory – query response (h)(5)
				Electronic Submission of Medical Documentation– (i)(1)

Green = new to the 2015 Edition

Light Blue = criteria in the "available" column previously adopted in an edition to support MU1/MU2

Red Font = "unchanged" criteria (eligible for gap certification)

Blue Font = "minimally revised" criteria

Black Font/Gray Background = "revised" criteria

Certification Responsibilities for Health IT Developers

IF you seek product certification to the following:	THEN your product will always need to be certified to:	AND will also need to be certified to:
Any clinical criterion in 45 CFR 170.315(a)	• The privacy & security (P&S) criteria at § 170.315(d)(1)-(d)(7) • Quality management system (QMS) at § 170.315(g)(4) • Accessibility-centered design (ACD) at § 170.315(g)(8)	Safety-enhanced design (SED) at § 170.315(g)(3) if you seek certification to any one of the following criteria: • § 170.315(a)(1)-(10), (18), (20), (22), and (23)
Any care coordination criterion in 45 CFR 170.315(b)	• The P&S criteria at § 170.315(d)(1)-(d)(3) and (d)(5) - (d)(8) • QMS at § 170.315(g)(4) and ACD at (g)(8)	SED at § 170.315(g)(3) if you seek certification to any one of the following criteria: • § 170.315(b)(2)-(b)(4) Consolidated CDA performance at § 170.315(g)(6) if you seek certification to any one of the following criteria: • § 170.315(b)(1), (2), (6), (7), and (9)
Any clinical quality measures criterion in 45 CFR 170.315(c)	• The P&S criteria at § 170.315(d)(1)-(d)(3) • QMS at § 170.315(g)(4) and ACD at (g)(8)	N/A
Any privacy and security criterion in 45 CFR 170.315(d)	• QMS at § 170.315(g)(4) • ACD at § 170.315(g)(8)	N/A
Any patient engagement criterion in 45 CFR 170.315(e)	• The P&S criteria at § 170.315(d)(1)-(d)(3), (d)(5), and (d)(7) • QMS at § 170.315(g)(4) and ACD at (g)(8)	Consolidated CDA performance at § 170.315(g)(6) if you seek certification to § 170.315(e)(1)
Any public health criterion in 45 CFR 170.315(f)	• The P&S criteria at § 170.315(d)(1)-(d)(3) and (d)(7) • QMS at § 170.315(g)(4) and ACD at (g)(8)	N/A
45 CFR 170.315(g)(1) or (2)	• QMS at § 170.315(g)(4)	N/A
45 CFR 170.315(g)(7)	• QMS at § 170.315(g)(4) and ACD at (g)(8)	Consolidated CDA performance at § 170.315(g)(6)
Any transport methods and other protocols criterion in 45 CFR 170.315(h)	• The P&S criteria at § 170.315(d)(1)-(d)(3) • QMS at § 170.315(g)(4) and ACD at (g)(8)	Transitions of care at § 170.315(b)(1) if you seek certification to § 170.315(h)(1)
Any administrative criterion in 45 CFR 170.315(i)	• The P&S criteria at § 170.315(d)(1)-(d)(3) and (d)(5)-(d)(8) • QMS at § 170.315(g)(4) and ACD at (g)(8)	Consolidated CDA performance at § 170.315(g)(6) if you seek certification to § 170.315(i)(1)

Proposed EHR Incentive Programs
Stage 3 Meaningful Use Objectives

- **Objective 1:** Protect Patient Health Information
- **Objective 2:** Electronic Prescribing
- **Objective 3:** Clinical Decision Support
- **Objective 4:** Computerized Provider Order Entry
- **Objective 5:** Patient Electronic Access to Health Information
- **Objective 6:** Coordination of Care through Patient Engagement
- **Objective 7:** Health Information Exchange
- **Objective 8:** Public Health and Clinical Data Registry Reporting

Certified Health IT Module(s) to Support the EHR Incentive Programs Stage 3

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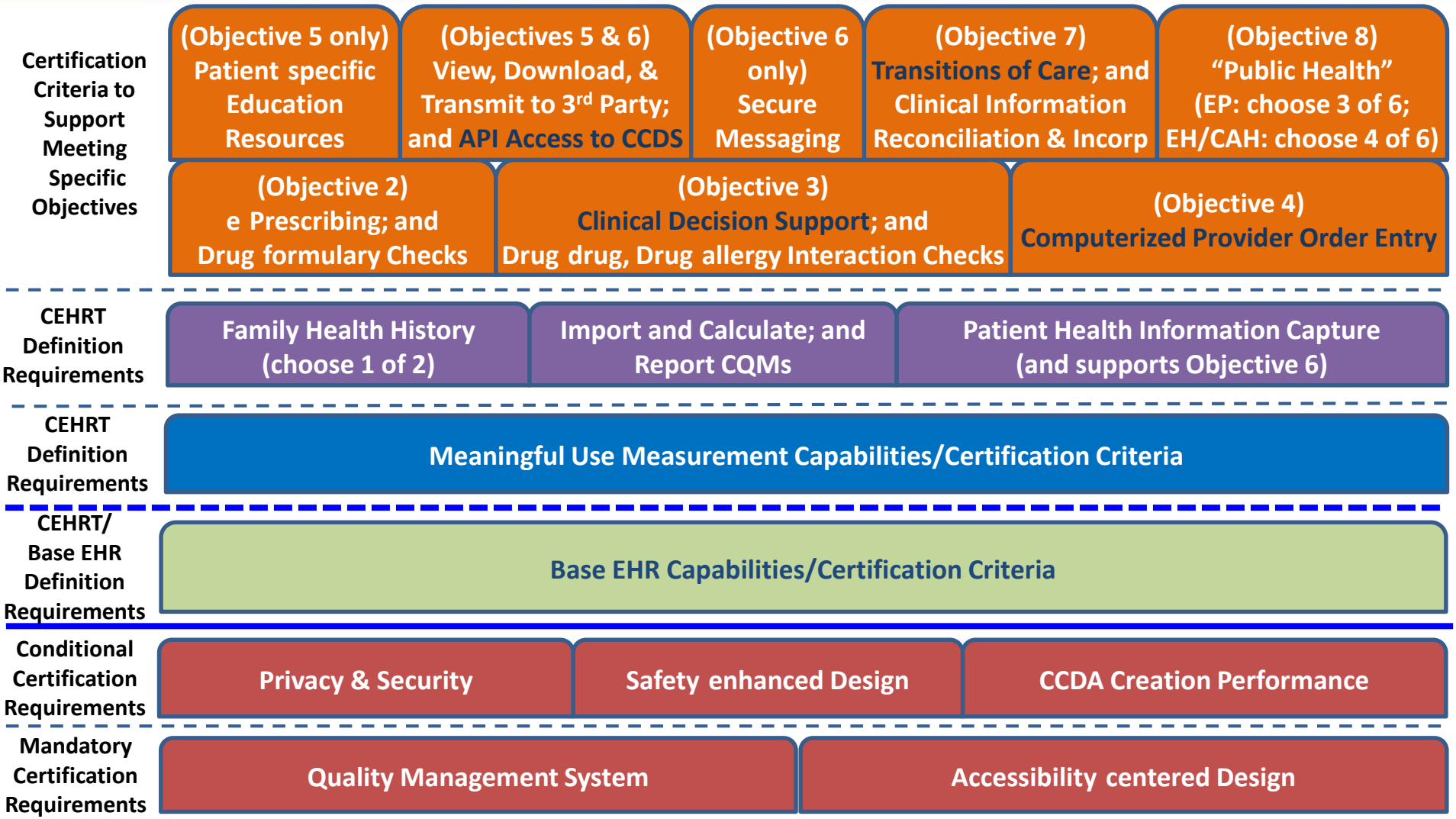

Support Stage 3 of the EHR Incentive Programs

What is Minimally Required for Stage 3?

2014 Edition vs. Proposed 2015 Edition

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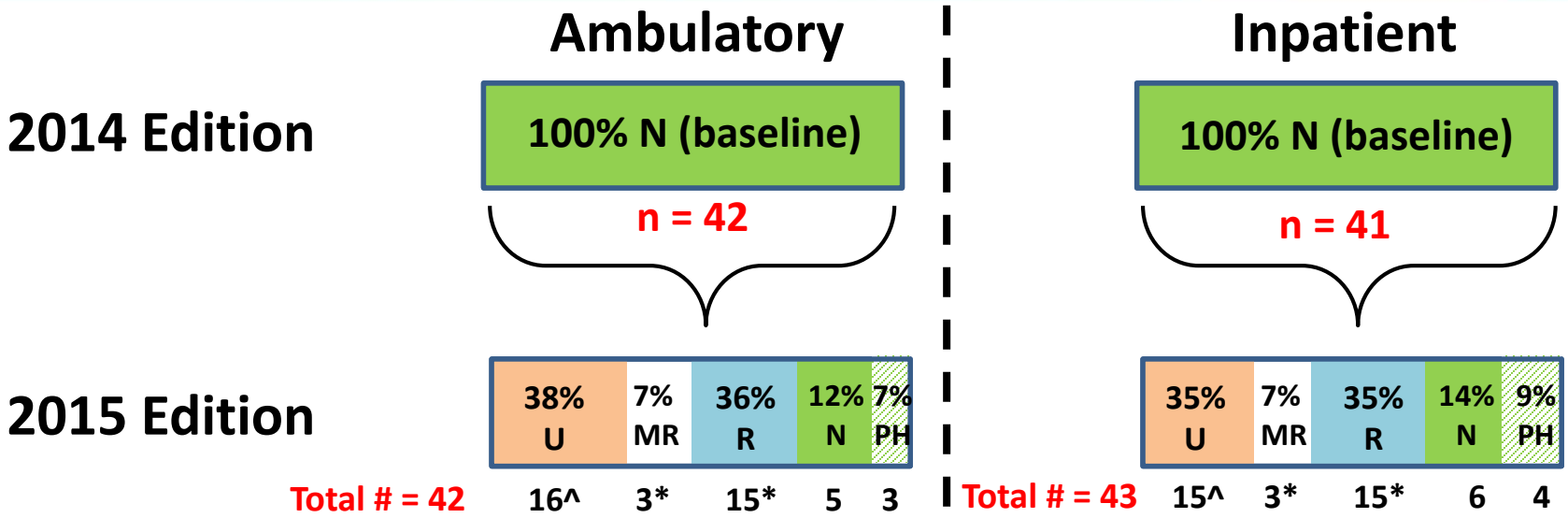

Bottom Line

- 45% of criteria are unchanged or minimally revised for the ambulatory setting.
- 42% of criteria are unchanged or minimally revised for the inpatient setting.
- Only need to do ~60% of the proposed 2015 Edition criteria to participate in Stage 3.
- The total minimum number of criteria needed to participate in Stage 3 remains the same for EPs and almost the same for EHs/CAHs as compared to Stage 2.
  - **Note:** This analysis does not account for potential exclusions

U = Unchanged criteria
MR = Minimally revised criteria
R = Revised criteria
N = New criteria

PH = Public health criteria (new and revised. EPs choose 3 of 6 measures and EHs/CAHs choose 4 of 6 measures.
^ Includes the "QMS" criterion, which may be revised for some health IT developers
* Depends on which family health history criterion is chosen (SNOMED CT or pedigree)

Certified Health IT Module(s) to Support Other Health Care Settings (LTPAC Example)

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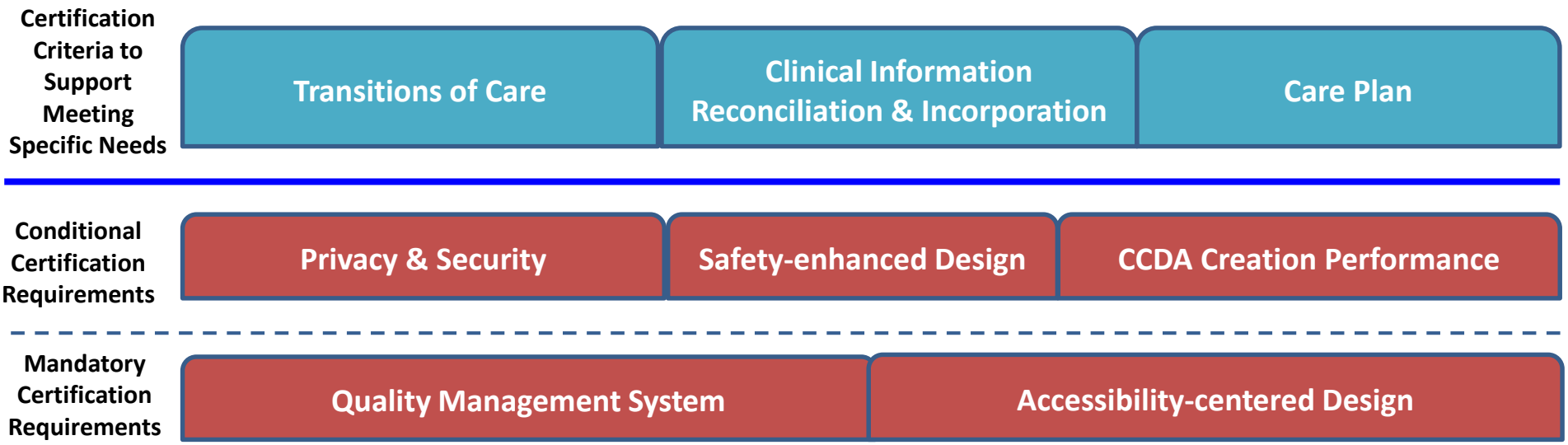
Long-Term Post-Acute Care Certification (example only)



Use of the ONC Health IT Certification Program to Support the Care Continuum

Certified Health IT Module(s) to Support Other Health Care Settings (Behavioral Health Example)

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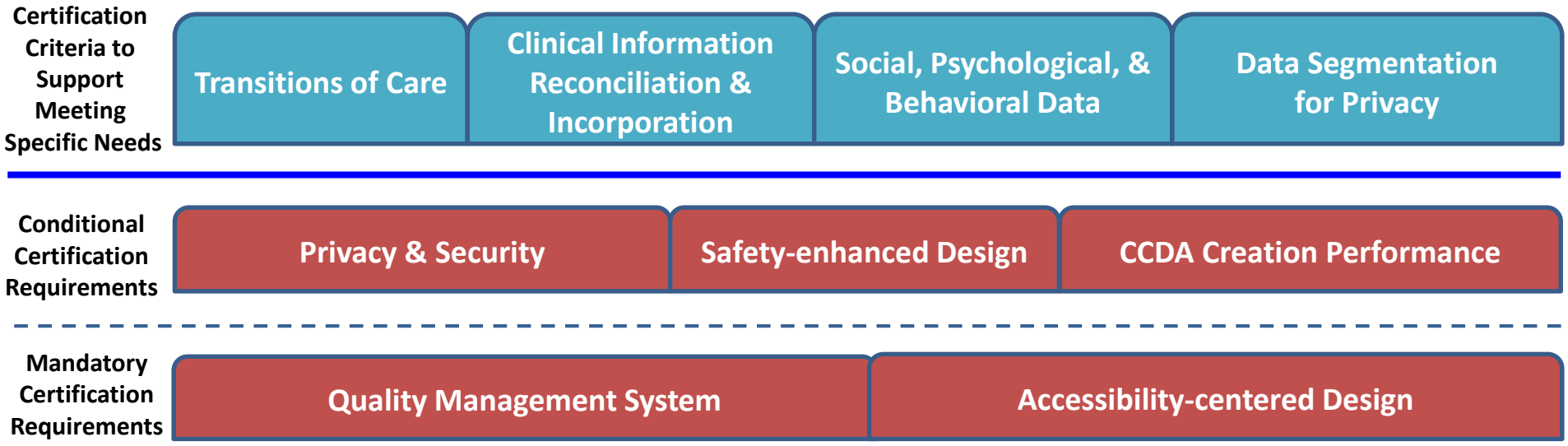
Behavioral Health Certification (example only)



Use of the ONC Health IT Certification Program to Support the Care Continuum

When and How to Comment

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- ONC published the 2015 Edition Proposed Rule in the Federal Register on **March 30, 2015**
- The comment period is open until **May 29, 2015**
- You can review the proposed rule and comment here: http://www.regulations.gov/#!documentDetail;D=HHS_FRDOC_0001-0572
- To assist in commenting on the rule, ONC provides a:
  - ❑ Microsoft Word version of the rule (http://www.healthit.gov/sites/default/files/2015_editionnprm_ofr_disclaimer_3-20-15.docx); and
  - ❑ Public Comment Template (http://www.healthit.gov/sites/default/files/2015editionnprm_public_comment_template_4-1-15_final508_.docx)