

The Office of the National Coordinator for
Health Information Technology



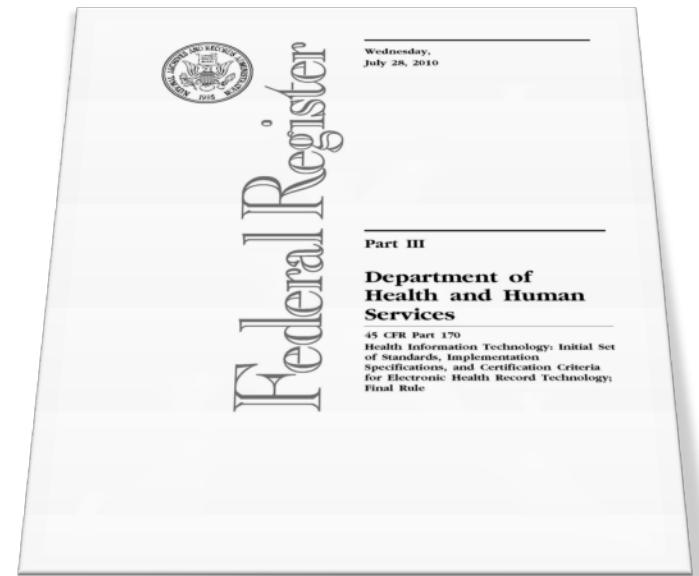
Proposed Rule Standards & Certification Criteria 2014 Edition

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Director, Federal Policy Division

- Regulatory History
- 2011 vs. 2014 Edition EHR Certification Criteria
- Major Highlights
 - Overview of the 2014 Edition
 - Redefining CEHRT Proposal
 - Permanent Certification Program Proposed Changes

Regulatory History

- Standards and Certification Criteria
- Certification Programs
- Metadata Standards



2011 Edition

S&CC July '10 final rule

- **§ 170.302** (general)
- **§ 170.304** (ambulatory)
- **§ 170.306** (inpatient)

Total = 41 + 1

VS.

2014 Edition

S&CC Feb '12 NPRM

- **§ 170.314**
 - (a) Clinical (n=18)
 - (b) Care Coordination (n=6)
 - (c) CQMs (n=3)
 - (d) Privacy and Security (n=8+1)
 - (e) Patient Engagement (n=3)
 - (f) Public Health (n=8)
 - (g) Utilization (n=4)

Total = 50 +1

“New” Certification Criteria



Ambulatory & Inpatient	Inpatient Only	Ambulatory Only
Electronic Notes	Electronic medication administration record	Secure messaging
Imaging (access to)	eRx (for discharge)	Cancer case information
Family Health History	Transmission of electronic lab tests and values/results to ambulatory providers	Transmission to cancer registries
Amendments		
View, Download, & Transmit to 3rd party		
Auto numerator recording		
Non-%-based measure use report		
Safety-enhanced design		

“Revised” Certification Criteria

Ambulatory & Inpatient		Ambulatory Only
Drug-drug, drug-allergy interaction checks	Incorporate lab tests and values/results	eRx
Demographics	CQMs	Clinical summaries
Problem list	Auditable events and tamper-resistance	
Clinical decision support		Inpatient Only
Patient-specific education resources	Encryption of data at rest	Transmission of reportable lab tests and values/results
TOC – Incorporate summary care record	Immunization Information	
TOC – Create transmit summary care record	Transmission to Immunization Registries	
Clinical information reconciliation	Automated measure calculation	

“Unchanged” Certification Criteria

Ambulatory & Inpatient	
CPOE	Drug-formulary checks
Vital signs, BMI, & growth charts	Medication list
Smoking status	Medication allergy list
Patient reminders	Patient lists
Authentication, access control, & authorization	Accounting of disclosures
Automatic log-off	Advance directives
Emergency access	Public health surveillance
Integrity	Immunization information
Reportable lab tests and values/results	Incorporate lab test results (inpatient only)

- Roughly 40% of 2014 Edition Certification Criteria Eligible for “Gap Certification”

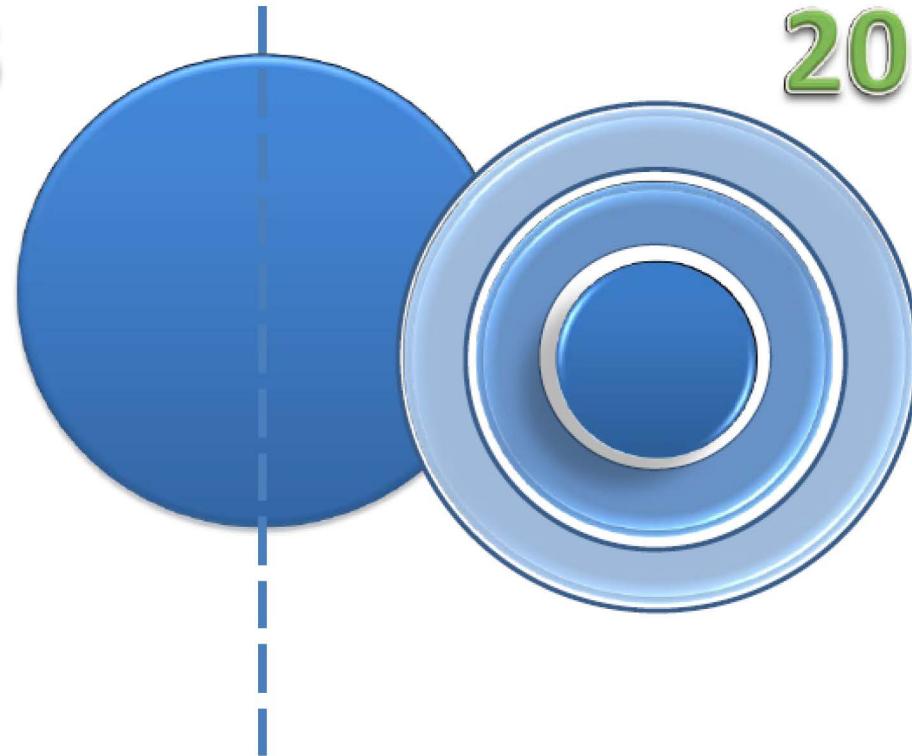
Why we think it is important...

1. Provides greater flexibility
2. Clearer definition of CEHRT and its requirements
3. Promotes continued progress towards increased interoperability requirements
4. Reduces regulatory burden (EO 13563)

Here's what we are proposing...

2011 - 13

2014



Base EHR

Base EHR

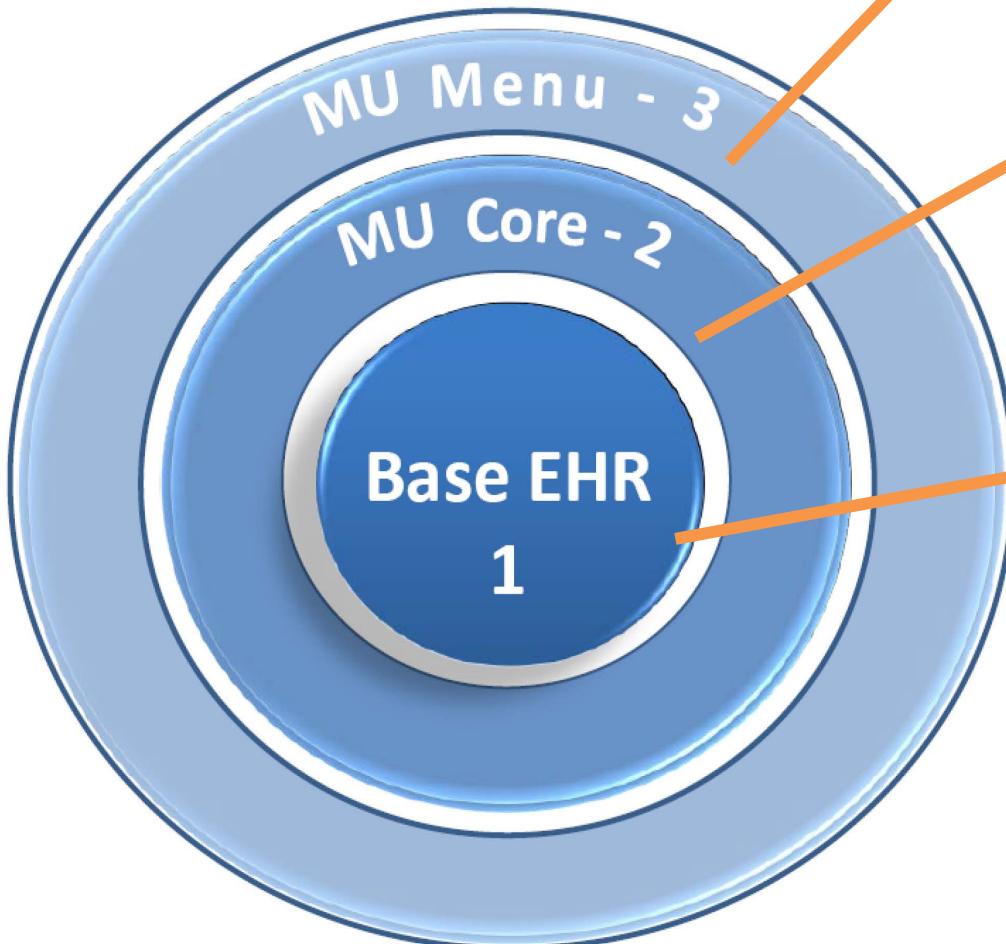
Certification Criteria Required to Satisfy the Definition of a Base EHR

Base EHR Capabilities	Certification Criteria
Includes patient demographic and clinical health information, such as medical history and problem lists	Demographics § 170.314(a)(3) Vital Signs § 170.314(a)(4) Problem List § 170.314(a)(5) Medication List § 170.314(a)(6) Medication Allergy List § 170.314(a)(7)
Capacity to provide clinical decision support	Drug-Drug and Drug-Allergy Interaction Checks § 170.314(a)(2) Clinical Decision Support § 170.314(a)(8)
Capacity to support physician order entry	Computerized Provider Order Entry § 170.314(a)(1)
Capacity to capture and query information relevant to health care quality	Clinical Quality Measures § 170.314(c)(1) and (2)
Capacity to exchange electronic health information with, and integrate such information from other sources	Transitions of Care § 170.314(b)(1) and (2) View, Download, and Transmit to 3 rd Party § 170.314(e)(1)
Capacity to protect the confidentiality, integrity, and availability of health information stored and exchanged	Privacy and Security § 170.314(d)(1)-(8)

2014 Edition CEHRT

Easy as 1, 2, 3 + C *C = CQMs

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EP/EH/CAH would only need to have EHR technology with capabilities certified for the MU menu set objectives & measures for the stage of MU they seek to achieve.

EP/EH/CAH would need to have EHR technology with capabilities certified for the MU core set objectives & measures for the stage of MU they seek to achieve unless the EP/EH/CAH can meet an exclusion.

EP/EH/CAH must have EHR technology with capabilities certified to meet the definition of Base EHR.

2014 Edition of CEHRT Policy

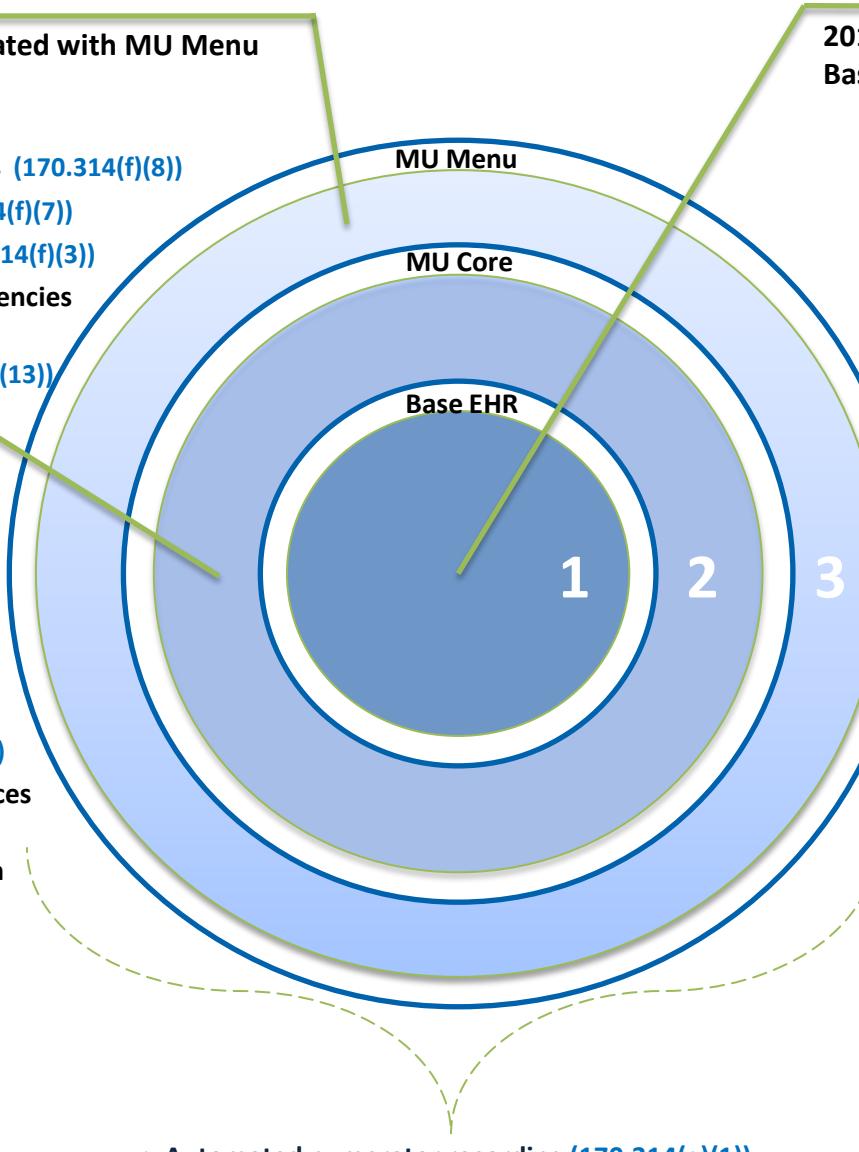
Ambulatory Setting Correlation to Proposed MU Stage 2

2014 Certification Criteria associated with MU Menu Stage 2:

- Imaging ([170.314\(a\)\(12\)](#))
- Transmission to cancer registries ([170.314\(f\)\(8\)](#))
- Cancer case information ([170.314\(f\)\(7\)](#))
- Public health surveillance ([170.314\(f\)\(3\)](#))
- Transmission to public health agencies ([170.314\(f\)\(4\)](#))
- Family health history ([170.314\(a\)\(13\)](#))

2014 Certification Criteria associated with MU Core Stage 2:

- Smoking status ([170.314\(a\)\(11\)](#))
- eRx ([170.314\(b\)\(3\)](#))
- Drug formulary checks ([170.314\(a\)\(10\)](#))
- Patient lists ([170.314\(a\)\(14\)](#))
- Patient reminders ([170.314\(a\)\(15\)](#))
- Patient-specific education resources ([170.314\(a\)\(16\)](#))
- Clinical information reconciliation ([170.314\(b\)\(4\)](#))
- Clinical summaries ([170.314\(e\)\(2\)](#))
- Secure messaging ([170.314\(e\)\(3\)](#))
- Incorporate lab test and results/values ([170.314\(b\)\(5\)](#))
- Immunization information ([170.314\(f\)\(1\)](#))
- Transmission to immunization registries ([170.314\(f\)\(2\)](#))

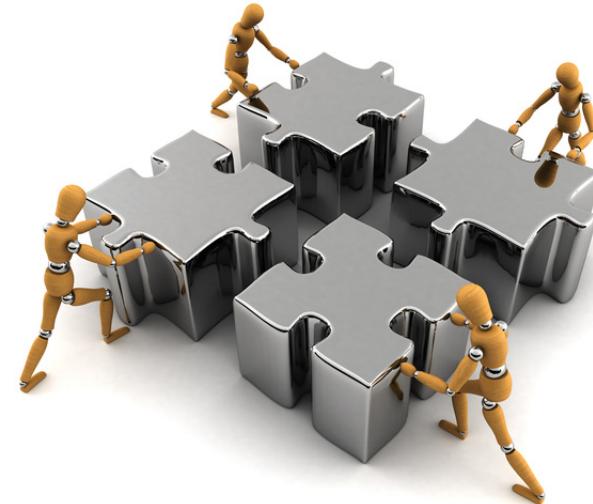


2014 Certification Criteria associated with a Base EHR:

- Demographics ([170.314\(a\)\(3\)](#))
- Vital signs, BMI, & growth charts ([170.314\(a\)\(4\)](#))
- Problem list ([170.314\(a\)\(5\)](#))
- Medication list ([170.314\(a\)\(6\)](#))
- Medication allergy list ([170.314\(a\)\(7\)](#))
- Drug-drug, drug-allergy interaction checks ([170.314\(a\)\(2\)](#))
- CPOE ([170.314\(a\)\(1\)](#))
- Clinical decision support ([170.314\(a\)\(8\)](#))
- Clinical quality measures ([170.314\(c\)\(1\)-\(2\)](#))
- Transition of Care – incorporate summary care record ([170.314\(b\)\(1\)](#))
- Transition of Care – create and transmit summary care record ([170.314\(b\)\(2\)](#))
- View, download, and transmit to 3rd Party ([170.314\(e\)\(1\)](#))
- Privacy and Security CC:
 - Authentication, Access Control, & Authorization ([170.314\(d\)\(1\)](#))
 - Auditable events & tamper resistance ([170.314\(d\)\(2\)](#))
 - Audit report(s) ([170.314\(d\)\(3\)](#))
 - Amendments ([170.314\(d\)\(4\)](#))
 - Automatic log-off ([170.314\(d\)\(5\)](#))
 - Emergency access ([170.314\(d\)\(6\)](#))
 - Encryption of data at rest ([170.314\(d\)\(7\)](#))
 - Integrity ([170.314\(d\)\(8\)](#))
 - Accounting of disclosures (optional) ([170.314\(d\)\(9\)](#))

3 proposed ways to meet CEHRT definition

- Complete EHR
- EHR Module(s) that do just enough:
 - Combination of EHR Modules
 - Single EHR Module



Proposed Revised Definition of CEHRT Compliance

EHR Reporting Period				
FY/CY 2011	FY/CY 2012	FY/CY 2013	FY/CY2014	
MU Stage 1	MU Stage 1	MU Stage 1	MU Stage 1 <u>or</u> MU Stage 2	
<p>All EPs, EHs, and CAHs must have EHR technology that has been certified to all applicable 2011 Edition EHR certification criteria <u>or equivalent 2014 Edition EHR</u> certification criteria adopted by the Secretary.</p>				All EPs, EHs, and CAHs must have EHR technology (including a Base EHR) that has been certified to the 2014 Edition EHR certification criteria that would support the objectives and measures, and their ability to successfully report the CQMs, for the MU stage that they seek to achieve.

Note: There is no such thing as being “Stage 1 Certified” or “Stage 2 Certified”

Standards...

Standards...

Standards...

Transport

2011 Edition	2014 Edition (proposed)	
N/A	Applicability Statement for Secure Health Transport	
N/A	External Data Representation and Cross-Enterprise Document Media Interchange for Direct Messaging	Direct Specifications
N/A	Simple Object Access Protocol (SOAP)-Based Secure Transport Requirements Traceability Matrix (RTM) version 1.0	NwHIN Exchange Modular Specification

Functional

Purpose	2011 Edition	2014 Edition (proposed)
Accessibility	N/A	WCAG 2.0, Level AA Conformance
Reference Source	N/A	Infobutton, International Normative Ed 2010
CQM - data capture and export	N/A	NQF Quality Data Model, 2011

Security

Purpose	2011 Edition	2014 Edition (proposed)
Auditable events	The date, time, patient identification, and user identification must be recorded when electronic health information is created, modified, accessed, or deleted; and an indication of which action(s) occurred and by whom must also be recorded.	+1: The electronic health information affected by the action(s) +2: when audit log is enabled and disabled +3: when encryption of electronic health information managed by EHR technology on end-user devices is enabled and disabled
Encryption and hashing	N/A	FIPS 140-2 Annex A
Synchronized clocks	N/A	NTPv3 or NTPv4

Content Exchange

Purpose	2011 Edition	2014 Edition (proposed)
Summary Record	HL7 CDA R2, CCD <i>HITSP Summary Doc using HL7 CCD Component HITSP/C32</i> ASTM E2369 Standard Spec for CCR and Adjunct to ASTM E2369	Consolidated CDA
eRx	NCPDP SCRIPT 8.1 / 10.6	NCPDP SCRIPT 10.6
Electronic submission of lab results to PH agencies	HL7 2.5.1 <i>HL7 2.5.1 IG electronic lab reporting to PH, R1 (US Realm)</i>	HL7 2.5.1 <i>HL7 2.5.1 IG: electronic lab reporting to PH, R1 (US Realm)</i>
Electronic submission to PH agencies for surveillance or reporting	HL7 2.3.1 / 2.5.1	HL7 2.5.1 <i>PHIN Messaging Guide for Syndromic Surveillance: Emergency Dept and Urgent Care Data HL7 Version 2.5.1.</i>

Content Exchange (continued)

Purpose	2011 Edition	2014 Edition (proposed)
Electronic submission to immunization registries	HL7 2.3.1 / 2.5.1 <i>IG for immunization Data Transactions using Version 2.3.1 of HL7 Standard Protocol Implementation Guide Version 2.2</i> <i>HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.0</i>	HL7 2.5.1 <i>HL7 2.5.1 IG for Immunization Messaging Release 1.3</i>
Quality Reporting	CMS PQRI Registry XML Spec <i>PQRI Measure Specs Manual for Claims and Registry</i>	TBD XML Spec
Cancer information	N/A	HL7 CDA, R2 <i>IG for Healthcare Provider Reporting to Central Cancer Registries, Draft, Feb 2012</i>
Imaging	N/A	DICOM PS3 – 2011
Electronic incorporation and transmission of lab results	N/A	HL7 2.5.1 <i>HL7 2.5.1 IG: S&I Framework Lab Results Interface, Release 1 (US Realm)</i>

Vocabulary/Code Sets

Data	2011 Edition	2014 Edition (proposed)
Immunizations	CVX – July 30, 2009	CVX – Aug 15, 2011
Problems	ICD-9 -CM/ IHTSDO SNOMED CT – July 2009	IHTSDO SNOMED CT – Jan 2012
Procedures	ICD-9 -CM/ CPT-4	ICD-10-PCS/HCPCS & CPT-4
Lab Tests	LOINC 2.27	LOINC 2.38
Medications	Any source vocabulary in RxNorm	RxNorm – Feb 6, 2012
Race & Ethnicity	OMB standards	OMB standards
Preferred Language	N/A	ISO 639-1:2002
Preliminary Determination of Cause of Death	N/A	ICD-10-CM
Smoking Status	N/A	Current every day; current some day; former; never; smoker, current status unknown; and unknown if ever smoked
Encounter Diagnoses	N/A	ICD-10-CM

Permanent Certification Program

Proposed Changes

- **Program Name Change**
 - “ONC HIT Certification Program”
- **Revisions to EHR Module Certification Requirements**
 - Privacy and Security Certification
 - Will not require upfront certification to P&S for the 2014 Edition CC
 - Policy outcome now reflected in Base EHR definition (which includes all P&S CC)
 - Other tweaks to make certification more efficient
 - Application of Certain New Criteria
 - § 170.314(g)(1): Automated numerator recording
 - § 170.314(g)(3): Non-percentage-based measures
 - § 170.314(g)(4): Safety-enhanced design
 - 8 Medication related certification criteria: CPOE; Drug-drug, drug-allergy interaction checks; Medication list; Medication allergy list; Clinical decision support; eMAR; e-prescribing; and Clinical information reconciliation.

- Enhancing the public comment experience
 - Word version posted
 - Comment template
 - Other useful grids/materials
- 3 ways to comment
 - Mail (snail/express)
 - Electronic through regulations.gov [preferred]
 - Hand deliver

Public Comment Template

§ 170.314(a)(13) - Family health history

Redline it if
you want to!

MU Objective

Record patient family health history as structured data.

2014 Edition EHR Certification Criterion

Family health history. Enable a user to electronically record, change, and access a patient's family health history.

FR Citation :

Specific questions in preamble? Yes

Public Comment Field:

Questions

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