

The Office of the National Coordinator for
Health Information Technology



2014 Edition Standards & Certification Criteria Final Rule

[HIT Standards Committee Special Edition]

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Putting the **I** in **HealthIT**
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S&CC 2014 Edition Final Rule

Major Themes

- Enhancing standards-based exchange
- Promoting EHR technology safety and security
- Enabling greater patient engagement
- Introducing greater transparency
- Reducing regulatory burden

S&CC and Meaningful Use

Complementary but Different Scopes

- S&CC scope = “technical”
 - Specifies the capabilities EHR technology must include and how they need to perform in order to be certified.
 - It does not specify how the EHR technology needs to be used.
- Meaningful use scope = “behavioral”
 - Specifies how eligible providers need to use Certified EHR Technology in order to receive incentives.

2014 Edition (NPRM) VS. 2014 Edition (Final)

S&CC February '12

§ 170.314

- (a) Clinical (n=18)
- (b) Care Coordination (n=6)
- (c) CQMs (n=3)
- (d) Privacy and Security (n=9*)
- (e) Patient Engagement (n=3)
- (f) Public Health (n=8)
- (g) Utilization (n=4)

S&CC August '12

§ 170.314

- (a) Clinical (n=17)
- (b) Care Coordination (n=7)
- (c) CQMs (n=3)
- (d) Privacy and Security (n=9*)
- (e) Patient Engagement (n=3)
- (f) Public Health (n=6*)
- (g) Utilization (n=4)

* = includes optional
certification criteria ³

“New” Certification Criteria



Ambulatory & Inpatient	Inpatient Only	Ambulatory Only
Electronic Notes	Electronic medication administration record	Secure messaging
Image results	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		
Quality management system		
Data Portability		

“Revised” Certification Criteria

Ambulatory & Inpatient		Ambulatory Only
Drug-drug, drug-allergy interaction checks	Vital signs, body mass index, and growth charts	eRx
Demographics	CQMs (3 criteria)	Clinical summaries
Clinical information reconciliation	Incorporate lab tests and values/results	
Problem list	End-user device encryption	
Clinical decision support	Auditable events and tamper-resistance	Inpatient Only
Drug-formulary checks	Audit report(s)	
TOC – receive, display, and incorporate toc/referral summaries	TOC – create and transmit toc/referral summaries	Transmission of reportable lab tests and values/results
Patient list creation	Patient-specific education resources	
Smoking status	Automated measure calculation	
Transmission to Immunization Registries	Transmission to public health agencies – syndromic surveillance	

“Unchanged” Certification Criteria

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

- These certification criteria would be “eligible” for “gap certification.”

Common MU Data Set

(1) Patient name	(9) Medications – RxNorm
(2) Sex	(10) Medication allergies – RxNorm
(3) Date of birth	(11) Laboratory test(s) – LOINC
(4) Race – OMB Standard	(12) Laboratory value(s)/result(s)
(5) Ethnicity – OMB Standard	(13) Vital signs – height, weight, blood pressure, BMI
(6) Preferred language – ISO 639-2 constrained	(14) Care plan field(s), including goals and instructions
(7) Smoking status – 8 SNOMED CT[®] codes.	(15) Procedures – (i) SNOMED CT[®] or CPT/HCPCS. (ii) <u>Optional</u>. ICD-10-PCS (iii) <u>Optional</u>. CDT
(8) Problems – SNOMED CT[®].	(16) Care team member(s).

45 CFR 170.314(a)

Clinical

Certification Criterion	Changes from Proposed Version to Final Version
(3) Demographics	<ul style="list-style-type: none">• Clarified that the standard for preferred language is ISO 639-2 constrained to those languages represented in ISO 639-1• Removed the reference to a vocabulary standard (ICD -10) for preliminary cause of death
(4) Vital signs, body mass index, and growth charts	Clarified that only numerical values can be recorded
(5) Problem list	Adopted the most recent version of SNOMED CT® and US extension
(8) Clinical decision support	<ul style="list-style-type: none">• Specified that the use of the HL7 Context-Aware Knowledge Retrieval (“Infobutton”) standard would be optional as part of the linked referential decision support capability (and adopted IGs)• Limited configuration variations to be just based on a user’s role
(11) Smoking status	Adopted an 8-code list of SNOMED CT® codes for smoking status
(13) Family health History	Adopted as alternatives, the most recent version of SNOMED CT® and the HL7 Pedigree standard for recording family health history
(15) Patient-specific education resources	Adopted HL7 Infobutton standard and the URL and SOAP-based implementation guides

45 CFR 170.314(b)

Care Coordination

Certification Criterion	Changes from Proposed Version to Final Version
(1) TOC – receive, display, and incorporate toc/referral summaries	<ul style="list-style-type: none">• Require receipt according to the same transport standards we adopted for transmit• Require the capability to display previously adopted summary care record standards: CCD/C32 and CCR• Clarified that incorporate meant that problems, medications, and medication allergies data could be processed and stored for subsequent use• Included a general patient matching capability with the incorporation capability• Require that EHR technology would be able to individually display all of the other CCDA section templates that were not incorporated
(2) TOC – create and transmit toc/referral summaries	Revised the transport standards referenced to require certification to the primary Direct Project specification and to permit two optional approaches in addition [(1) Secure App Statement + XDR/XDM for Direct Msg'n; (2) SOAP RTM +XDR/XDM for Direct Msg'n]
(3) Electronic prescribing	NCPDP SCRIPT 10.6 and RxNorm

45 CFR 170.314(b)

Care Coordination

Certification Criterion	Changes from Proposed Version to Final Version
(5) Incorporate lab tests and values/results	<ul style="list-style-type: none">• Removed the erroneous reference to the main HL7 2.5.1 standard• Adopted an updated version of the LRI implementation guide and the most recent version of LOINC®• <u>Note</u>: This certification criterion remains “unchanged” for the inpatient setting
(6) Transmission of electronic lab tests and values/results to ambulatory providers <i>Inpatient setting only</i>	Adopted an updated implementation guide and the most recent version of LOINC®
(7) Data portability	<ul style="list-style-type: none">• New certification criterion• Focuses on the most current clinical information about each patient for which an export summary can be created using the Consolidated CDA

45 CFR 170.314(c)

Clinical Quality Measures

Certification Criterion	Changes from Proposed Version to Final Version
(1) Clinical quality measures—capture and export	<ul style="list-style-type: none">• Revised to a per CQM approach• Adopted QRDA Category I for export
(2) Clinical quality measures—import and calculate	Adopted QRDA Category I for import to create a link between the two capabilities
(3) Clinical quality measures—electronic submission	<ul style="list-style-type: none">• Included the electronic submission certification criterion in the Base EHR definition• Adopted QRDA Category I and III as electronic reporting formats

45 CFR 170.314(d)

Privacy and Security

Certification Criterion	Changes from Proposed Version to Final Version
(2) Auditable events and tamper-resistance	<ul style="list-style-type: none">• Adopted the ASTM standard “for audit and disclosure logs for use in health information systems” and point to specific sections within that standard that mirrored the data/actions that were explicitly referenced in the proposed version• Clarified language
(7) End-user device encryption	<ul style="list-style-type: none">• Changed the certification criterion’s name• Modified the first part of the certification criterion to more clearly express a technical capability that could be tested and certified

45 CFR 170.314(e)

Patient Engagement

Certification Criterion	Changes from Proposed Version to Final Version
(1) View, download, and transmit to 3rd party	<ul style="list-style-type: none">• Included a requirement that the online access must be done through secure channel• Specified that only the primary Direct Project transport specification is required for certification• Adopted SNOMED CT® and CPT/HCPCS as alternative required vocabularies for procedures, but also permit additional (optional) certification to ICD-10-PCS and CDT (dental terminology)• Changed the accessibility requirement from WCAG Level AA to Level A• Removed the requirement to enable images to be downloaded and transmitted to a 3rd party• Adopted the use of RxNorm for medication allergies

Certification Criterion	Changes from Proposed Version to Final Version
(2) Transmission to Immunization Registries	Adopted an updated implementation guide and the most recent version of CVX codes
(3) Transmission to public health agencies – syndromic surveillance	Adopted an updated implementation guide and addendum
(4) Transmission of reportable lab tests and values/results <i>Inpatient setting only</i>	Adopted a supplement to the implementation guide and the most recent versions of LOINC® and SNOMED CT®
(5) Cancer case information <i>Optional - ambulatory setting only</i>	Designated as “optional”
(6) Transmission to cancer registries <i>Optional - ambulatory setting only</i>	Designated as “optional” and adopted an updated/final implementation guide and the most recent versions of LOINC® and SNOMED CT®

45 CFR 170.314(g) Utilization

Certification Criterion	Changes from Proposed Version to Final Version
(1) Auto numerator recording	Modified to require that EHR Modules be able to create a report or file that enables a user to review the patients or actions that would make the patient or action eligible to be included in the measure's numerator
(2) Automated measure calculation	No change
(3) Safety-enhanced design	No change
(4) Quality management system	<ul style="list-style-type: none">• New certification criterion• Requires the disclosure of whether and what QMS was used in for EHR technology development . Acceptable approaches are: 1) a single QMS; 2) multiple QMS'; or 3) no QMS.

Standards Applicability

Purpose	Vocabulary & Code Sets	Content Exchange / Utilization	Transport
Demographics	OMB Race/Ethnicity ISO 639-2 (constrained)		
Problems	SNOMED CT [®] + US ext		
CDS		HL7 Infobutton + IGs	
Smoking Status	SNOMED CT [®] + US ext		
Family Health History	SNOMED CT [®] + US ext HL7 Pedigree		
Patient Ed Resources		HL7 Infobutton + IGs	
ToC – receive, display, & incorporate	SNOMED CT [®] + US ext RxNorm	CCD/C32	Applicability Statement for Secure Health Transport
		CCR	AppState + XDR/XDM
		Consolidated CDA	SOAP RTM + XDR/XDM

Standards Applicability (cont.)

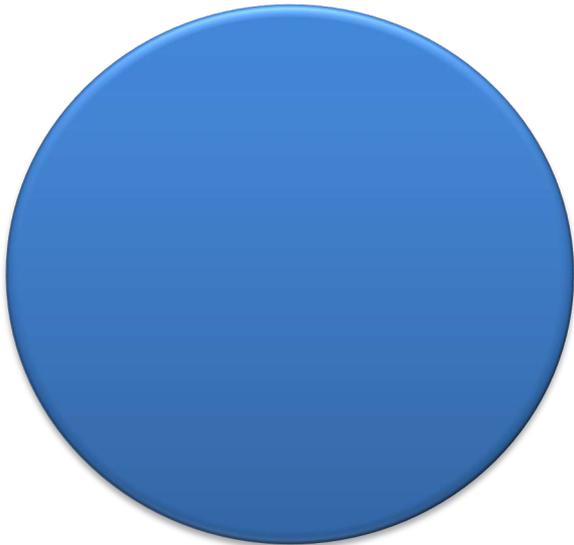
Purpose	Vocabulary & Code Sets	Content Exchange / Utilization	Transport
ToC – Create & Transmit	[Common MU Data Set] ICD-10-CM CVX	Consolidated CDA	Applicability Statement for Secure Health Transport
			AppState + XDR/XDM
			SOAP RTM + XDR/XDM
e-Rx	RxNorm	NCPDP SCRIPT 10.6	
Incorporate Labs (ambulatory)	LOINC	HL7 S&I LRI Spec	
Data Portability	[Common MU Data Set] ICD-10-CM CVX	Consolidated CDA	

Standards Applicability (cont.)

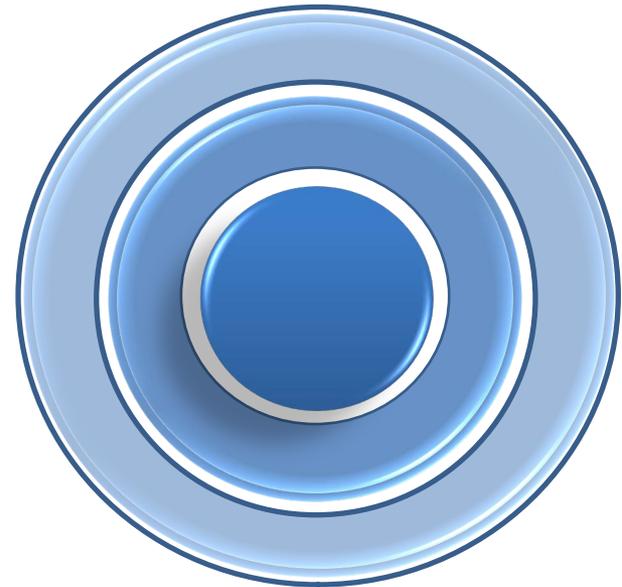
Purpose	Vocabulary & Code Sets	Content Exchange / Utilization	Transport
CQM Export		QRDA Category I	
CQM Import		QRDA Category I	
CQM e-Submit		QRDA Category I & III	
View, download, transmit to 3 rd party	[Common MU Data Set]	Consolidated CDA	Applicability Statement for Secure Health Transport
		WCAG Level A	
Clinical Summary	[Common MU Data Set]	Consolidated CDA	
Immz Reporting	CVX	HL7 2.5.1 + IGs	
Syndromic Surveillance		HL7 2.5.1 +IG (inpatient only)	
ELR	SNOMED CT [®] + US ext LOINC	HL7 2.5.1 + IG	
Cancer Registry	SNOMED CT [®] + US ext LOINC	CDA R2 + IG	

Revised Certified EHR Technology (CEHRT) Definition

July 2010 Final Rule Policy
Static Definition
Driven by Certification Criteria



August 2012 Final Rule Policy
Dynamic Definition
Driven by Meaningful Use



Big picture

- The new regulatory framework provides more flexibility.
- The potential number of 2014 Edition certification criteria to which EHR technology would need to be certified (for an eligible provider to have EHR technology that meets the CEHRT definition) could be limited to the MU stage needs of an EHR technology developer's customer.

CEHRT Interdependence – Two views of the CEHRT Definition

- For eligible providers:
 - It is about having EHR technology(ies) certified to meet the Base EHR definition and just enough of 2014 Edition certification criteria to support their achievement of the MU stage they seek to meet.
- For EHR technology developers:
 - This new definition presents the opportunity to rethink the scope of EHR technology certifications sought.
 - Now able to seek “right size certifications” for their EHR technology based on their customers scope of practice and/or the MU stage that their customers will be seeking to achieve.

- Two types of certifications can be issued:
 - “Complete EHR” (i.e., EHR tech certified to all mandatory cert. criteria)
 - “EHR Module” (i.e., EHR tech certified to less than all mandatory cert. criteria)
- The scope of a certification issued to EHR technology represents only the capabilities for which the certification was sought/granted.
- EHR technology developers get to choose the type of certification sought for EHR technology and its **scope** (i.e., for EHR Modules, the number of cert. criteria to which it would be certified).
 - Additional capabilities beyond those for which certification criteria have been adopted are not within the scope of ONC’s regulatory framework and reflect a business decision made by the EHR technology developer if they are included with an EHR technology to which a certification is issued.

So what? What's to be excited about?

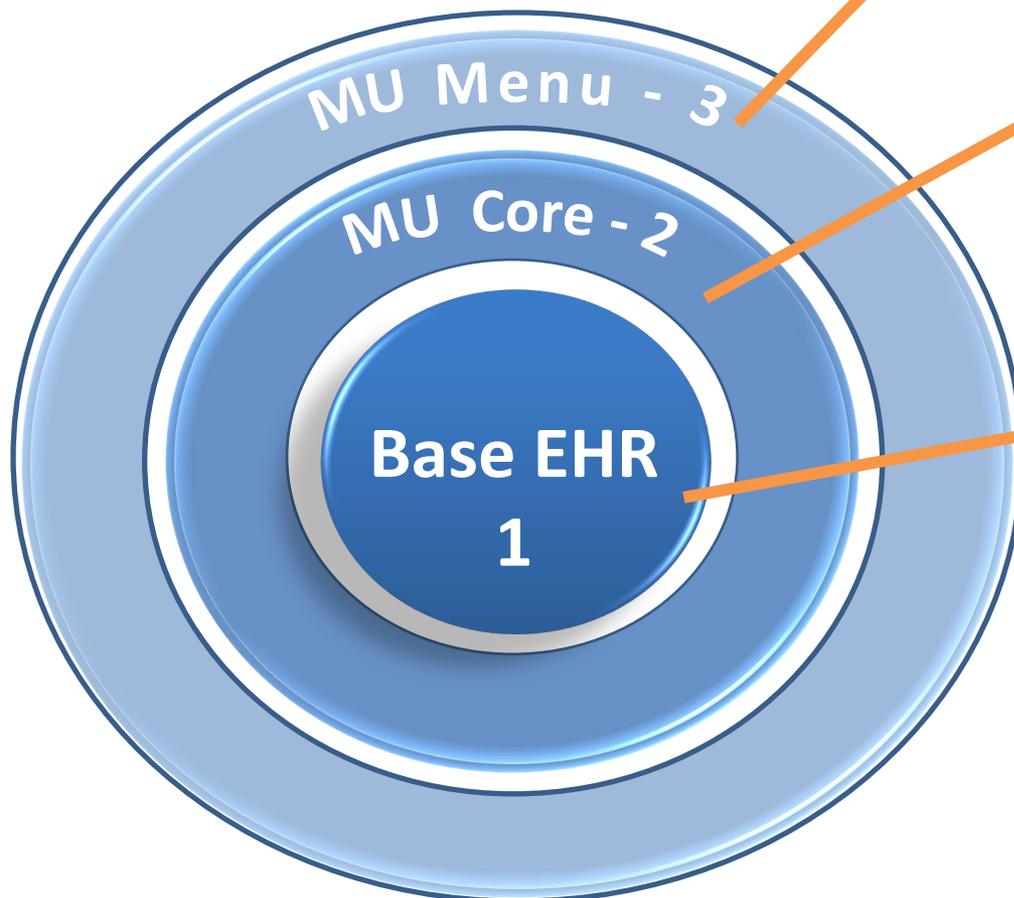
Now 3 ways to meet CEHRT definition

- Complete EHR
 - Generally provides overall assurance.
 - EPs would still need EHR technology certified to cancer registry certification criteria if they seek to meet that MU objective.
- EHR Module(s):
 - Combination of EHR Modules
 - *Single EHR Module* **NEW**
- In the case of EHR Modules, it is now possible for an eligible provider to have just enough EHR technology certified to the 2014 Edition EHR certification criteria to meet the CEHRT definition.



2014 Edition CEHRT

Easy as 1, 2, 3 + C*



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 Base EHR definition.

*C = CQMs

Certification Criteria Assigned to Final Base EHR Definition

- It is a definition. It is meant to be used like a checklist to meet the CEHRT definition.
- It is not “a Base EHR” or a singular type of EHR technology that has these capabilities.
- The Base EHR definition includes CQM requirements not specified in this table.

2014 Edition EHR Certification Criteria Required to Satisfy the Base EHR Definition		
EHR technology that:	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)	N/A
	Problem List § 170.314(a)(5)	☑
	Medication List § 170.314(a)(6)	☑
	Medication Allergy List § 170.314(a)(7)	☑
Has the capacity to provide clinical decision support	Drug-Drug and Drug-Allergy Interaction Checks § 170.314(a)(2)	N/A
	Clinical Decision Support § 170.314(a)(8)	☑
Has the capacity to support physician order entry	Computerized Provider Order Entry § 170.314(a)(1)	☑
Has the capacity to capture and query information relevant to health care quality	Clinical Quality Measures § 170.314(c)(1) through (3)	☑
Has the capacity to exchange electronic health information with, and integrate such information from other sources	Transitions of Care § 170.314(b)(1) and (2)	☑
	Data Portability § 170.314(b)(7)	☑
	View, Download, and Transmit to 3rd Party § 170.314(e)(1)	N/A
Has the capacity to protect the confidentiality, integrity, and availability of health information stored and exchanged	Privacy and Security § 170.314(d)(1) through (8)	☑

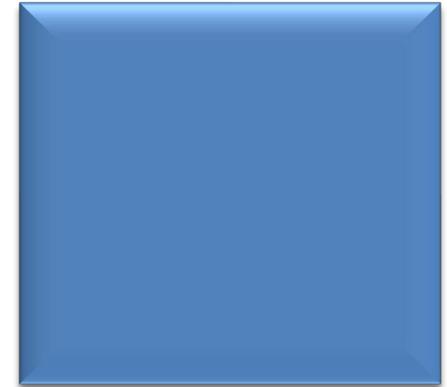
CEHRT: Show and Tell

EP MUS1 min = 27 CC

- *No MU core exclusions*
- ** 5 MU menu deferral*

Ambulatory CEHRT = 32 CC

**2010 Final
Rule Policy**

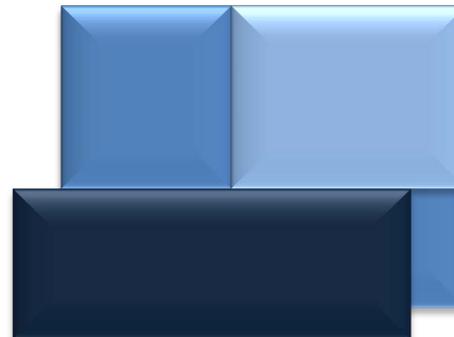


EP min = variable

**2012 Final
Rule Policy**



**Reality sized
"Right sized"
certified EHR Module(s)**



**Ambulatory CEHRT =
CC required by Base EHR def
+ those to meet MU stage**



Revised CEHRT Definition

Effective Dates and Options

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>EPs, EHs, and CAHs have 3 options:</p> <ol style="list-style-type: none"> 1) EHR technology that has been certified to all applicable 2011 Edition EHR certification criteria. 2) EHR technology that has been certified to all applicable 2011 Edition or equivalent 2014 Edition EHR certification criteria 3) EHR technology certified to the 2014 Edition EHR certification criteria that meets the Base EHR definition and would support ability to achieve MU stage 1 and successfully report the CQMs. 			<p>All EPs, EHs, and CAHs must have EHR technology certified to the 2014 Edition EHR certification criteria that meets the Base EHR definition and would support the objectives, measures, and their ability to successfully report the CQMs, for the MU stage that they seek to achieve.</p>

Same Policy

- 2014 Edition EHR technology supports the achievement of either meaningful use stage.
- Certification is not tied to MU stages.
- No “Stage 1 Certified” or “Stage 2 Certified” in perpetuity.

Illustrated: Two Types of Certifications Issued

“Complete EHR” or “EHR Module”

1 Universe of EHR technology capabilities
(e.g., all of what XYZ’s EHR technology includes)

2 2014Ed Complete EHR definition
Generally supports MUS1 or MUS2 achievement
Certified to all mandatory 2014Ed CC for setting

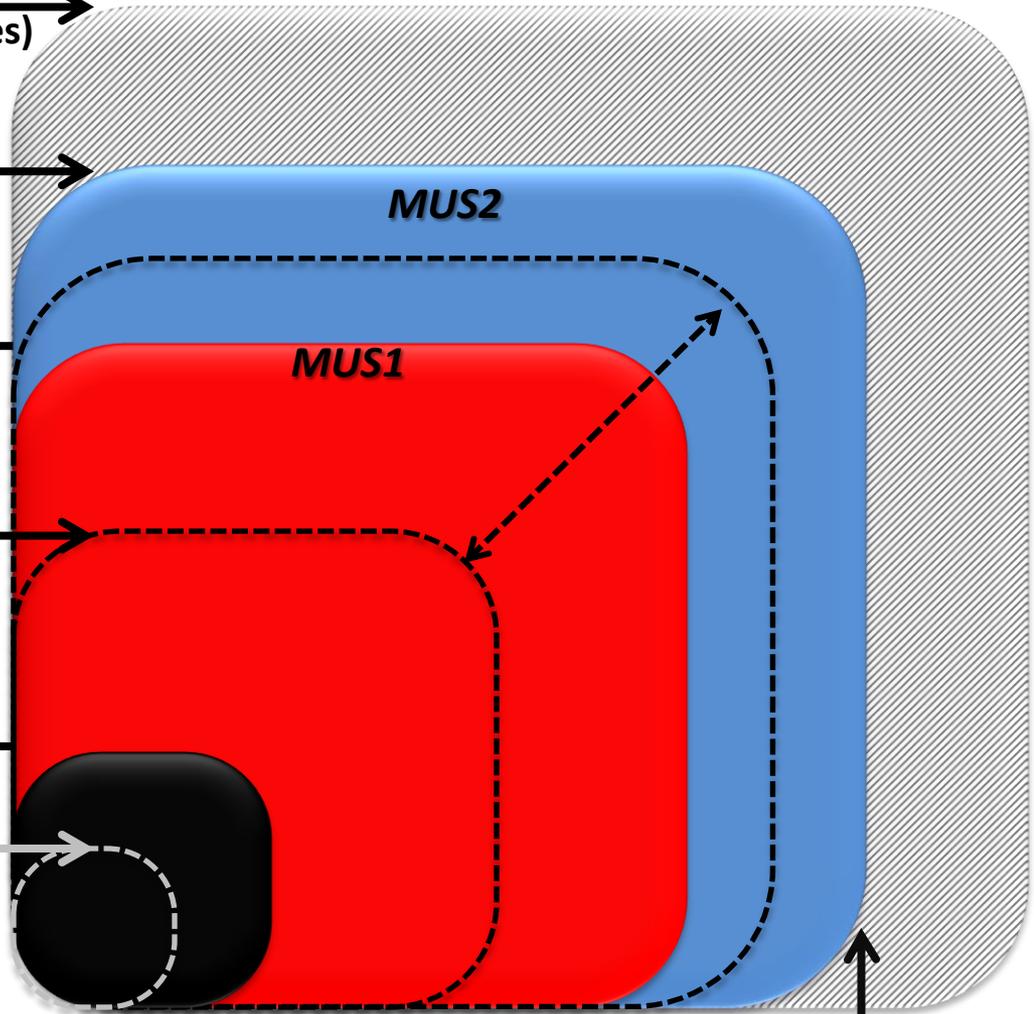
3 EHR Module certified to number of 2014Ed necessary to support MUS1

4 Inner square = EHR Module certified to number of 2014Ed CC less than MUS1 (or MUS2)

Outer square = EHR Module certified to number of 2014Ed CC necessary to support MUS2

5 Base EHR definition = certified EHR Module

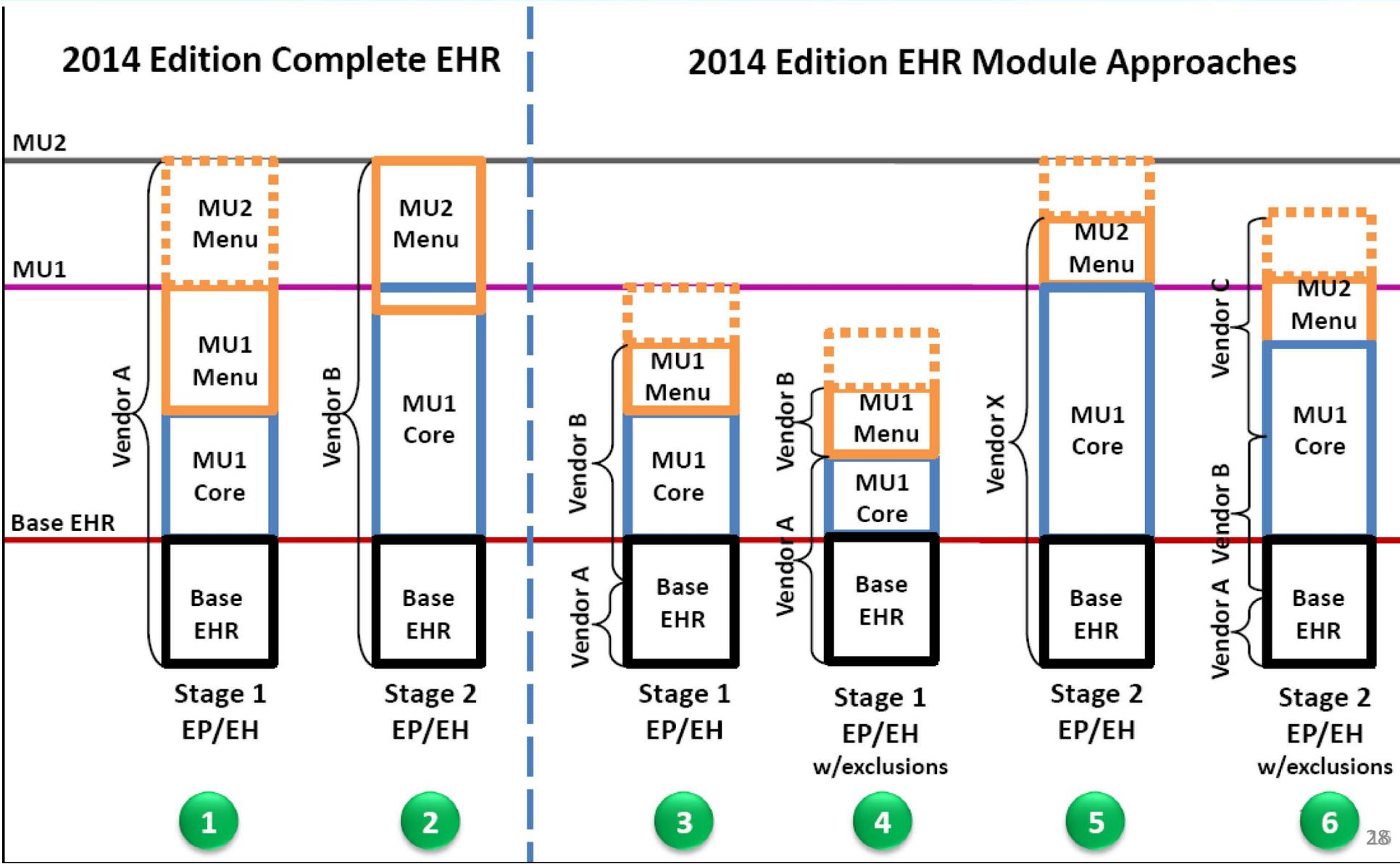
6 EHR Module certified to less than Base EHR definition



Point to remember:
Certification’s scope does **NOT** address all capabilities included in EHR technology

2014 Edition Scope Stops Here

A Different Look: Understanding the CEHRT Definition and the Minimum Number of Certification Criteria to which EHR Technology would need to be certified



- **Temporary Certification Program Sunsets**
 - Upon 2014 Edition final rule effective date
- **Program Name Change**
 - “ONC HIT Certification Program”
- **Revisions to EHR Module Certification Requirements**
 - Privacy and Security Certification Policy
 - 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

ONC HIT Certification Program

Final Changes (cont.)

- **Application of certain new certification criteria to EHR technology**
 - § 170.314(g)(1): Automated numerator recording
 - § 170.314(g)(3): 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.
 - § 170.314(g)(4): Quality management system
- **Price Transparency:** ONC-ACBs are required to ensure that EHR technology developers notify eligible providers about additional types of costs (i.e., one-time, ongoing, or both) that affect a certified Complete EHR or certified EHR Module's total cost of ownership for the purposes of achieving meaningful use.
- **Test Result Transparency:** The final rule requires that ONC-ACBs submit a hyperlink of the test results used to issue a certification to a Complete EHR or EHR Module.

What's Next?

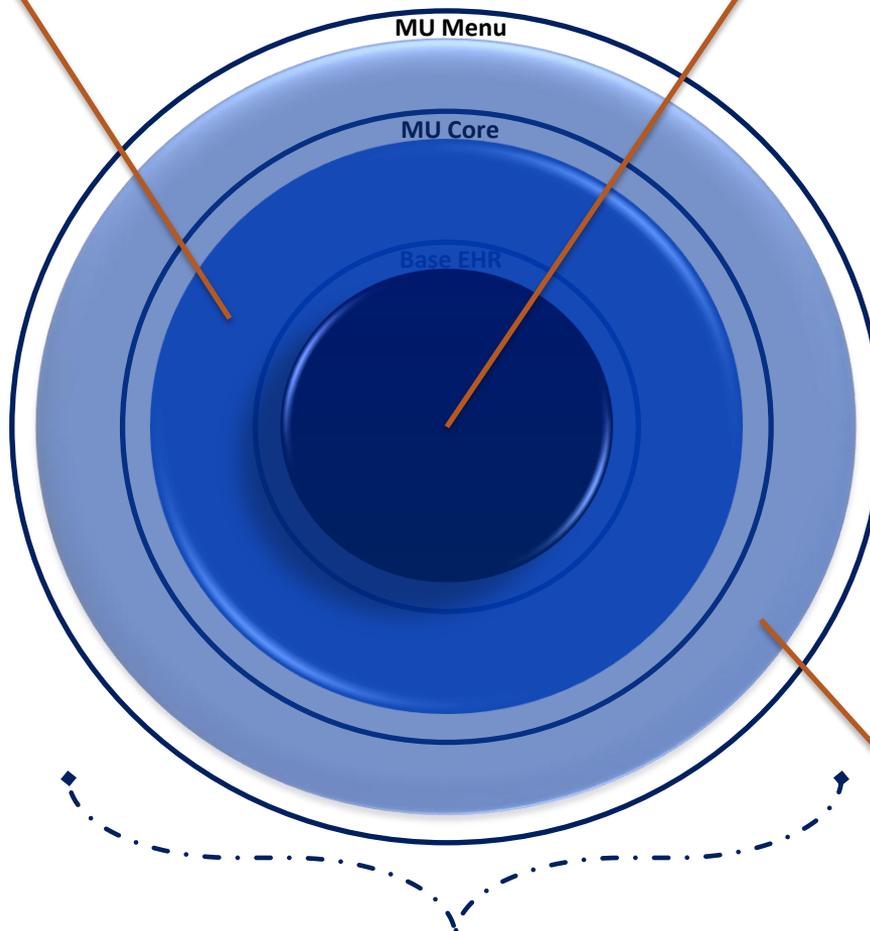
Anticipated Timeline

- Aug 2012
 - Final rule issued
- Sept 2012 – Oct 2012
 - Weekly waves of test procedures and electronic test tools published
 - Test Procedures and tools available for comment
- Nov 2012 – Dec 2012
 - Testing workshop
 - National Coordinator approves 2014Ed test procedures
- Testing and certification to 2014 Edition available early 2013.

2014 Edition EHR Certification Criteria Mapped to the 2014 CEHRT Definition for EHRs & CAHs Seeking to Achieve MU Stage 2 in and after CY 2014

2014 Certification Criteria associated with MU Core Stage 2:

- Drug-drug, drug-allergy interaction checks (170.314(a)(2))
- Vital signs, BMI, & growth charts (170.314(a)(4))
- Smoking status (170.314(a)(11))
- Patient list creation (170.314(a)(14))
- Patient-specific education resources (170.314(a)(15))
- eMAR (170.314(a)(16))
- Clinical information reconciliation (170.314(b)(4))
- Incorporate lab tests & values/results (170.314(b)(5))
- View, download, & transmit to 3rd Party (170.314(e)(1))
- Immunization information (170.314(f)(1))
- Transmission to immunization registries (170.314(f)(2))
- Transmission to PH agencies – syndromic surveillance (170.314(f)(3))
- Transmission of reportable lab tests & values/results (170.314(f)(4))



2014 Certification Criteria associated with a Base EHR:

- CPOE (170.314(a)(1))
- Demographics (170.314(a)(3))
- Problem list (170.314(a)(5))
- Medication list (170.314(a)(6))
- Medication allergy list (170.314(a)(7))
- Clinical decision support (170.314(a)(8))
- Transitions of care (170.314(b)(1) & (2))
- Data portability (170.314(b)(7))
- Clinical quality measures (170.314(c)(1) - (3))
- 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))
 - End-user device encryption (170.314(d)(7))
 - Integrity (170.314(d)(8))
 - Accounting of disclosures* (170.314(d)(9))

2014 Certification Criteria associated with MU Menu Stage 2:

- Electronic notes (170.314(a)(9))
- Drug-formulary checks (170.314(a)(10))
- Image results (170.314(a)(12))
- Family health history (170.314(a)(13))
- Advance directives (170.314(a)(17))
- eRx (170.314(b)(3))
- Transmission of e-lab tests & values/results to providers (170.314(b)(6))

2014 ed. certification criteria for which certification may be required:

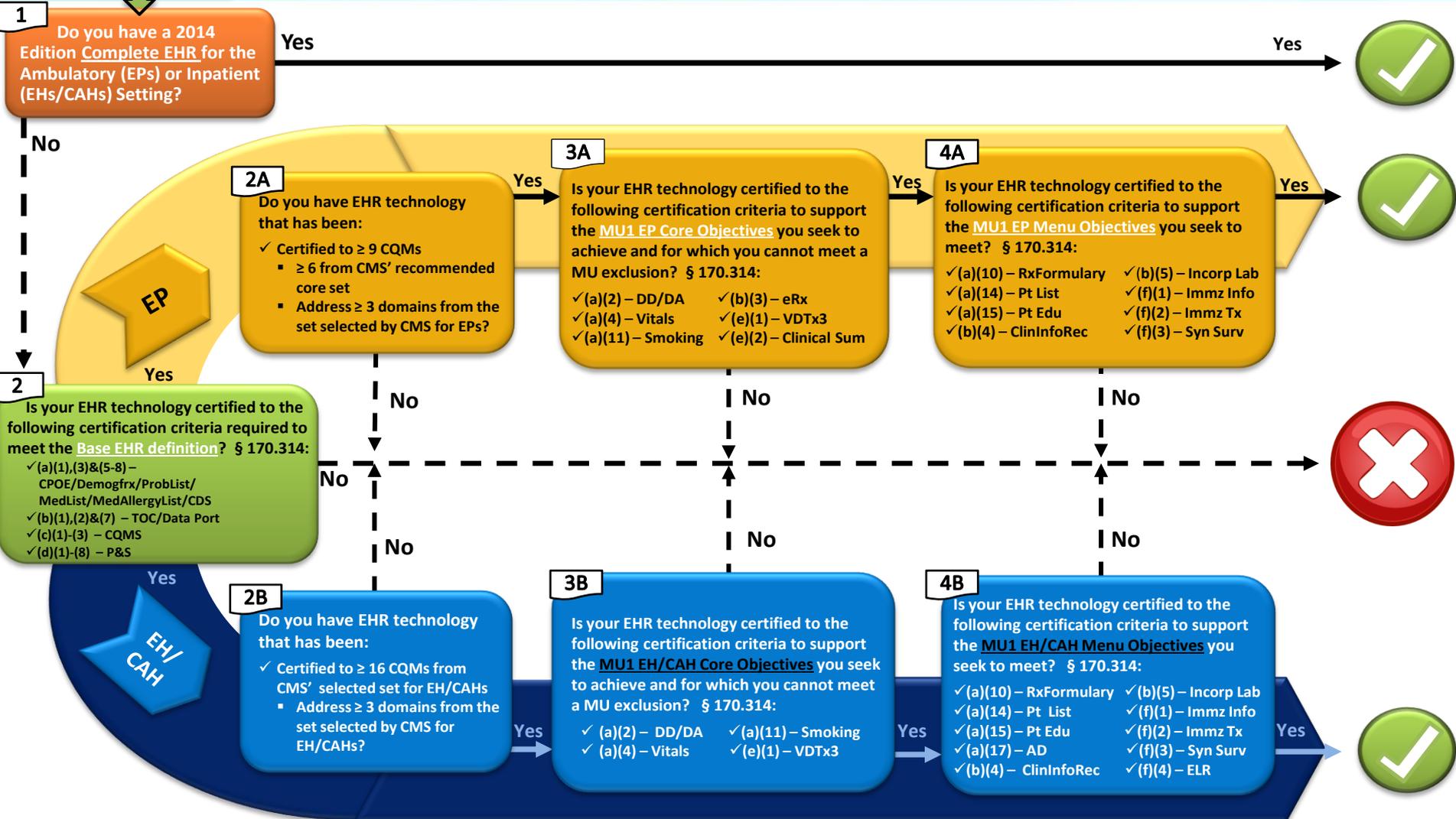
- Automated numerator recording (170.314(g)(1))
- Automated measure calculation (170.314(g)(2))
- Safety-enhanced design (170.314(g)(3))
- Quality management system (170.314(g)(4))

*= optional

Do you have EHR Technology that meets the new Certified EHR

Technology definition for Meaningful Use Stage 1?

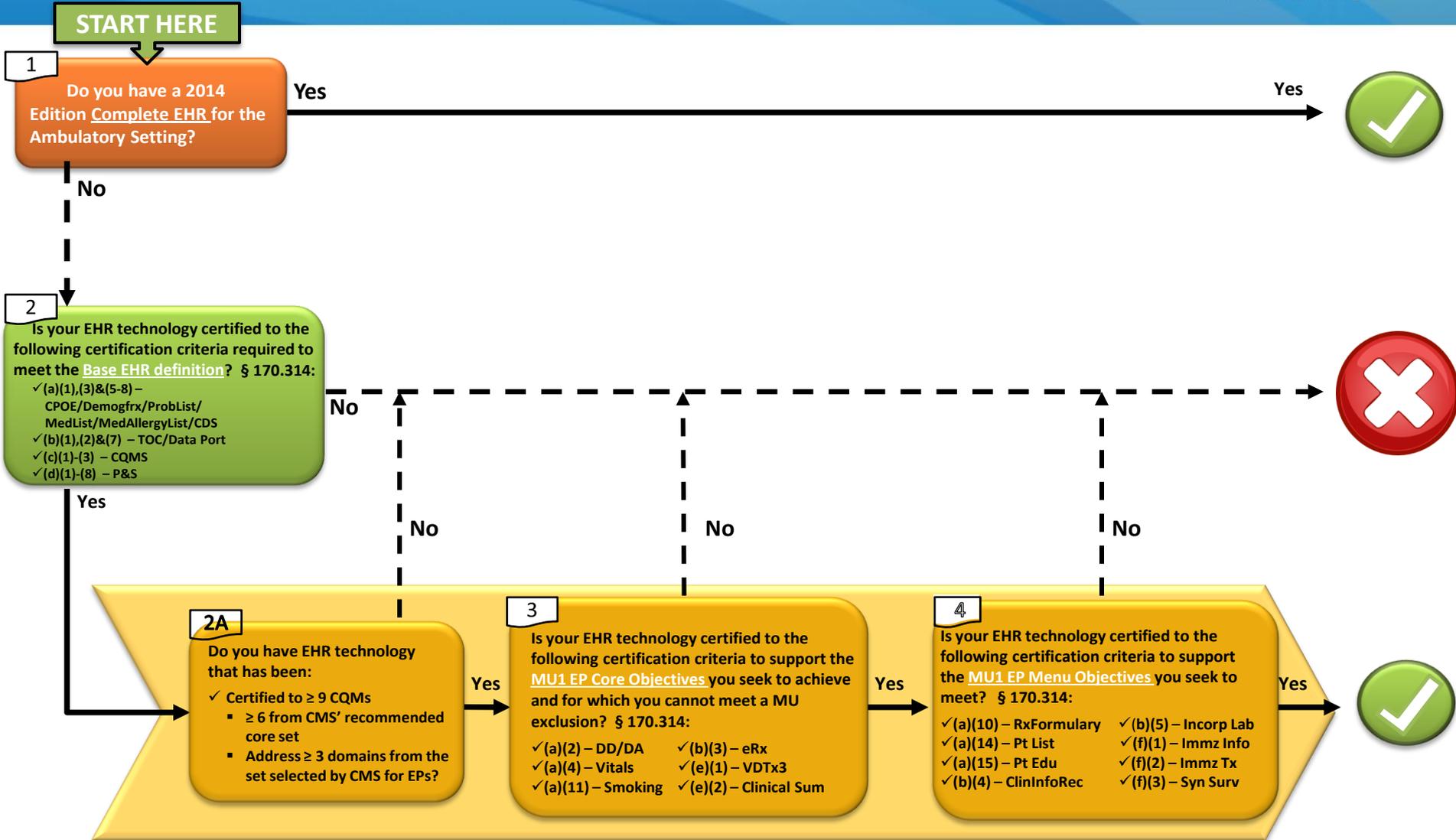
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Note: To meet the CEHRT definition, EHR technology will need to have been certified to:

- Automated numerator recording (170.314(g)(1)) or Automated measure calculation (170.314(g)(2));
- Safety-enhanced design (170.314(g)(3)); and
- Quality management system (170.314(g)(4))

EPs: Do you have EHR Technology that meets the new Certified EHR Technology definition for Meaningful Use Stage 1?



Note: To meet the CEHRT definition, EHR technology will need to have been certified to:

- Automated numerator recording (170.314(g)(1)) or Automated measure calculation (170.314(g)(2));
- Safety-enhanced design (170.314(g)(3)); and
- Quality management system (170.314(g)(4))

But wait, there's more!

- Check back to:

<http://www.healthit.gov/policy-researchers-implementers/meaningful-use-stage-2-0>

Now:

- CEHRT Infographic flows and Bull's eye diagrams

Coming soon:

- Grids comparing MU1 and MU2 w/ 2014 Ed.
- Standards resource page where all the adopted standards as part of the 2014 Edition EHR Certification Criteria will be listed with URLs to where you can find/access them.

Questions

