

The Office of the National Coordinator for  
Health Information Technology



# 2014 Edition Standards & Certification Criteria Final Rule

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Putting the **I** in **HealthIT**  
[www.HealthIT.gov](http://www.HealthIT.gov)



# 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 <sup>3</sup>

# “New” Certification Criteria



Ambulatory & Inpatient	Inpatient Only	Ambulatory Only
<b>Electronic Notes</b>	<b>Electronic medication administration record</b>	<b>Secure messaging</b>
<b>Image results</b>	<b>eRx (for discharge)</b>	<b>Cancer case information</b>
<b>Family Health History</b>	<b>Transmission of electronic lab tests and values/results to ambulatory providers</b>	<b>Transmission to cancer registries</b>
<b>Amendments</b>		
<b>View, Download, &amp; Transmit to 3<sup>rd</sup> party</b>		
<b>Auto numerator recording</b>		
<b><del>Non-% based measure use report</del></b>		
<b>Safety-enhanced design</b>		
<b>Quality management system</b>		
<b>Data Portability</b>		

# “Revised” Certification Criteria

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

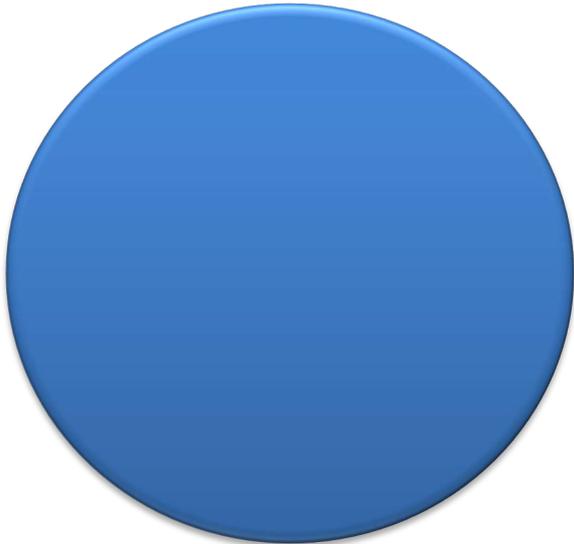
# “Unchanged” Certification Criteria

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

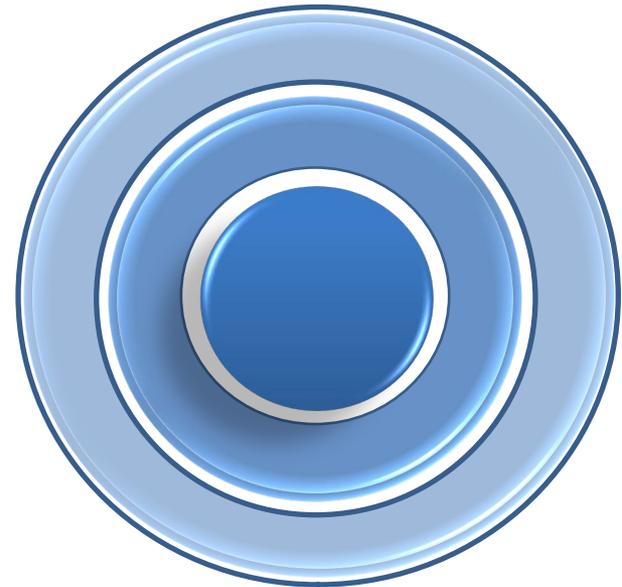
- These certification criteria would be “eligible” for “gap certification.”

# 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?

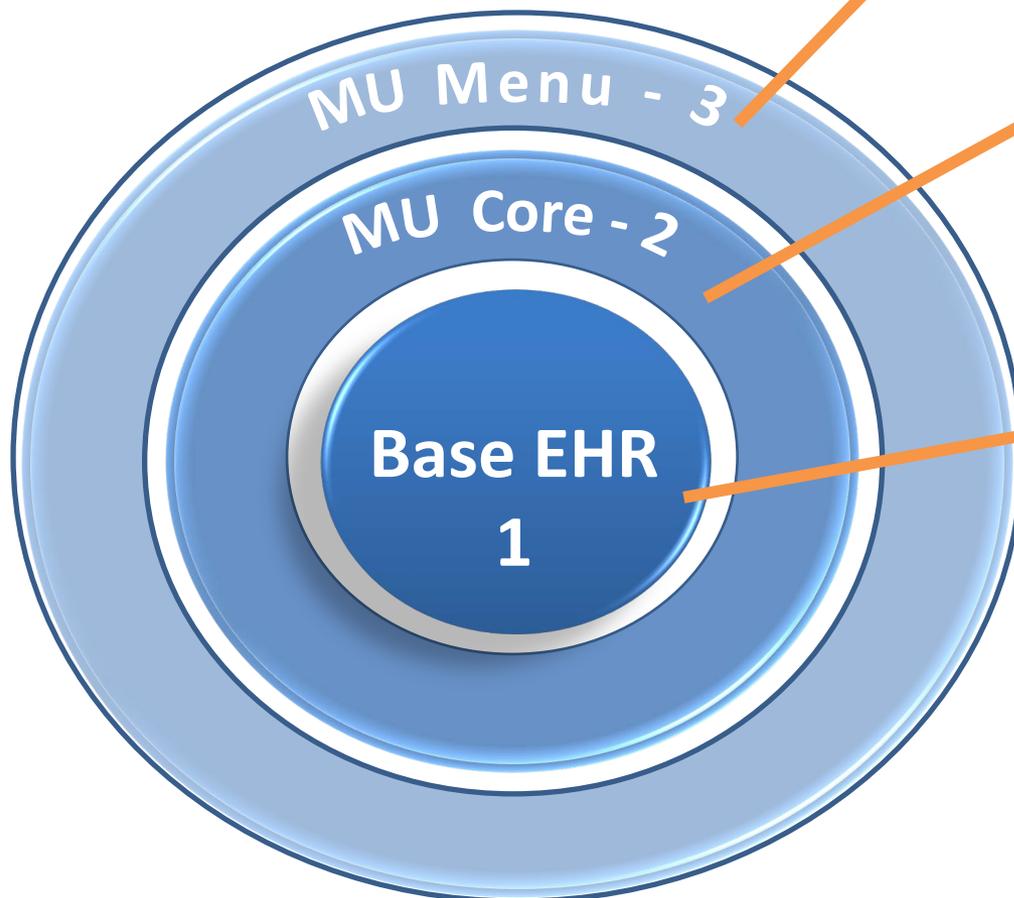
## Now 3 ways to meet CEHRT definition

- 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)	☑
	<del>Vital Signs § 170.314(a)(4)</del>	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	<del>Drug-Drug and Drug-Allergy Interaction Checks § 170.314(a)(2)</del>	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)	☑
	<del>View, Download, and Transmit to 3rd Party § 170.314(e)(1)</del>	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**

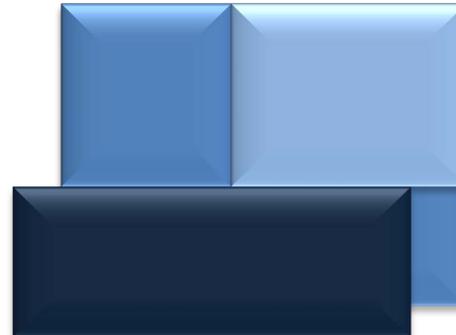


**EP min = variable**

**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
<b>MU Stage 1</b>	<b>MU Stage 1</b>	<b>MU Stage 1</b>	<b>MU Stage 1 <u>or</u> MU Stage 2</b>
<p><b>EPs, EHs, and CAHs have 3 options:</b></p> <ol style="list-style-type: none"> <li>1) EHR technology that has been certified to all applicable 2011 Edition EHR certification criteria.</li> <li>2) EHR technology that has been certified to all applicable 2011 Edition or equivalent 2014 Edition EHR certification criteria</li> <li>3) <b>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.</b></li> </ol>			<p><b>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.</b></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

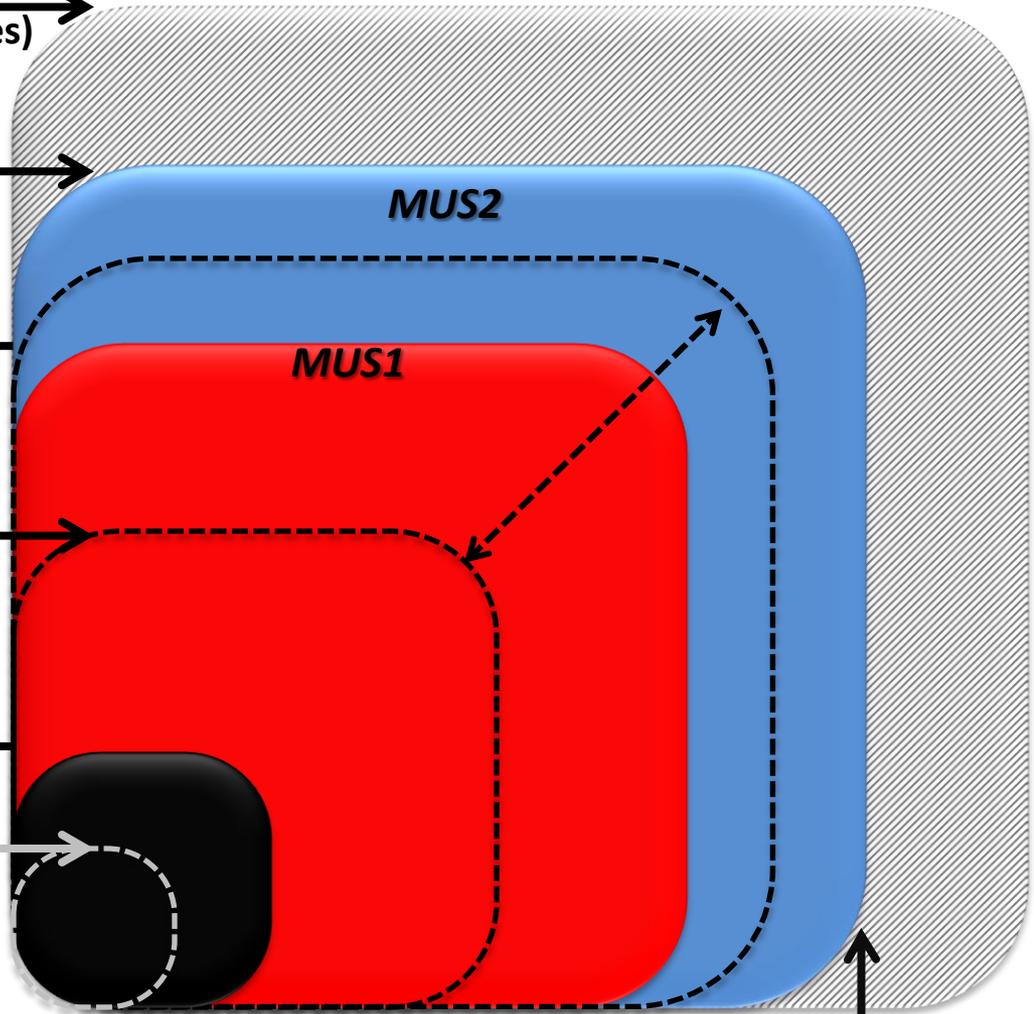
**3** EHR Module certified to number of 2014Ed necessary to support MUS1

**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

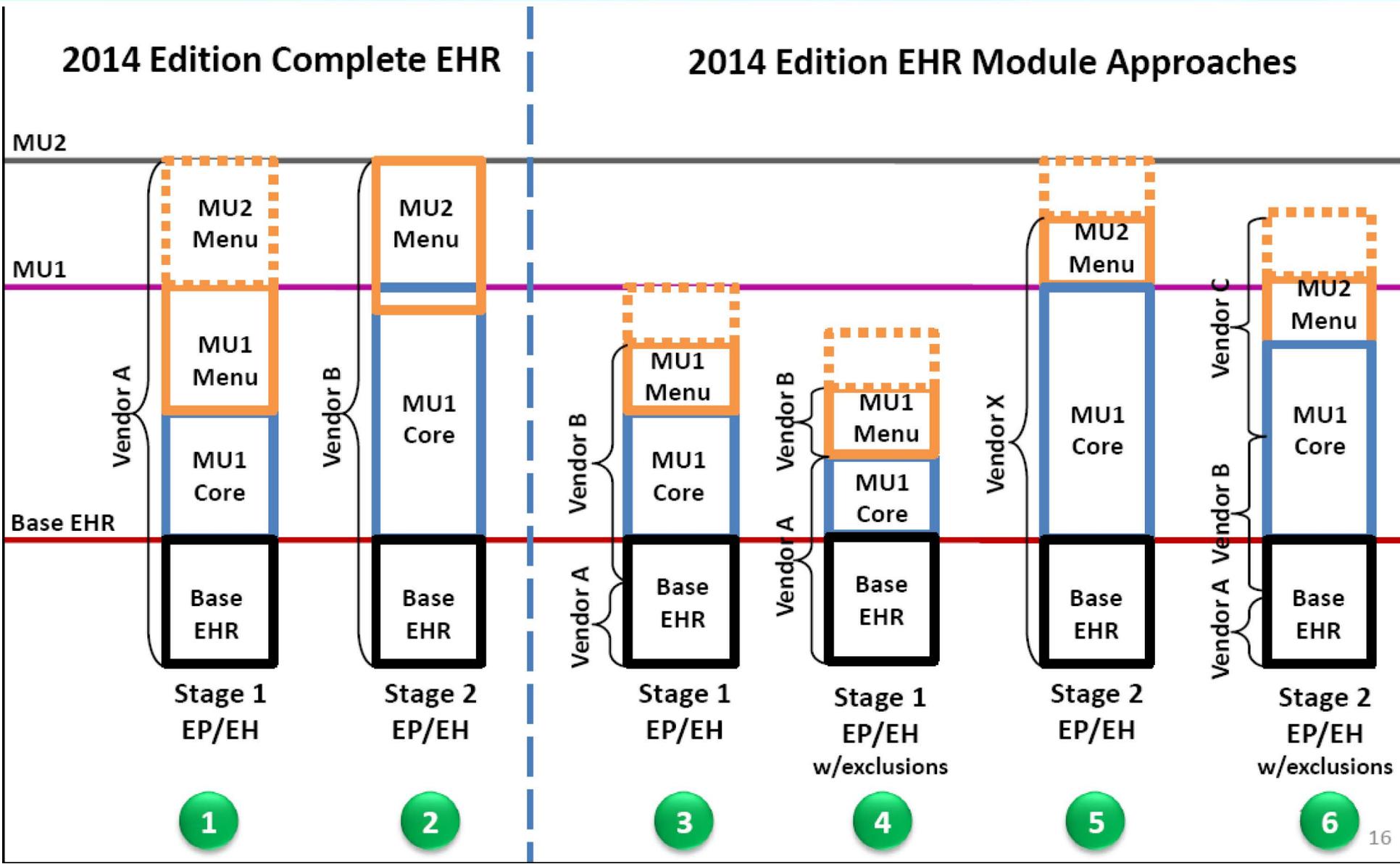
**6** EHR Module certified to less than Base EHR definition



*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?

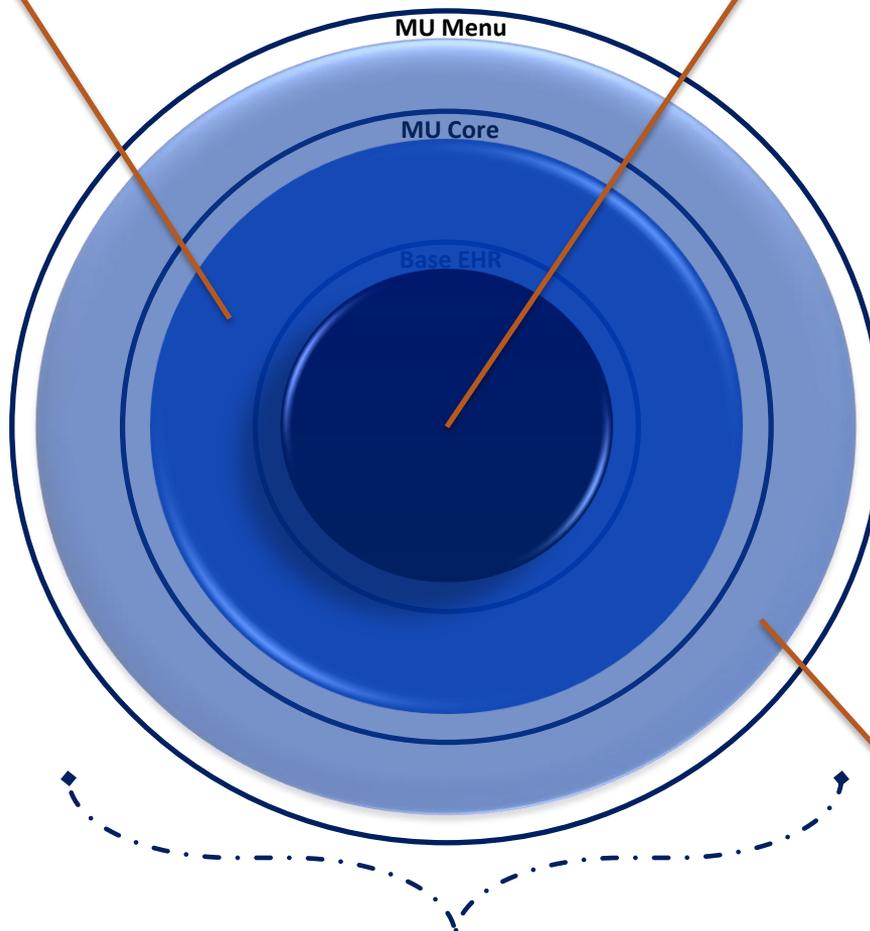
## Anticipated Timeline

- 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 EHs & 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 3<sup>rd</sup> 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))

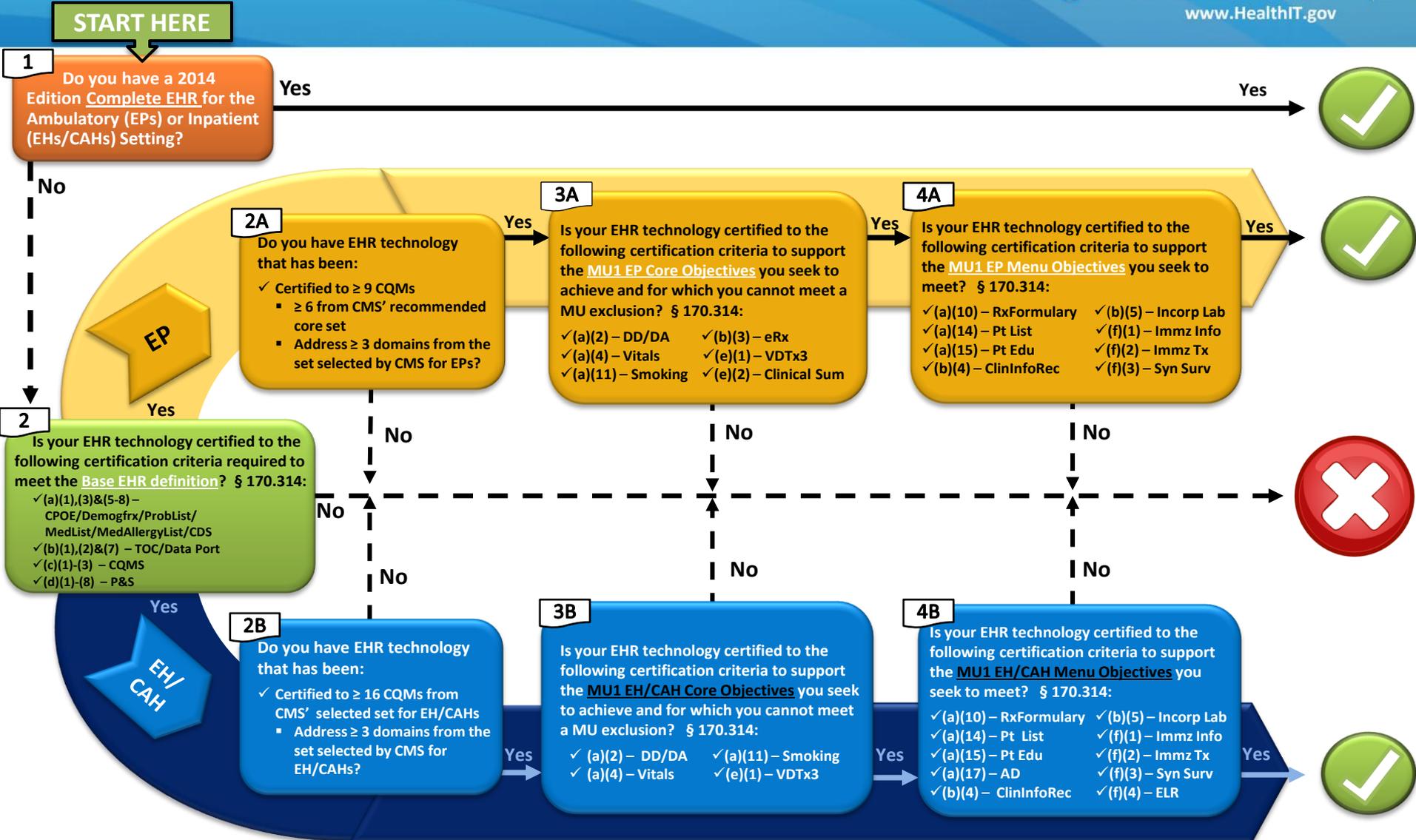
## 2014 ed. certification criteria for which certification may be required:

- 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

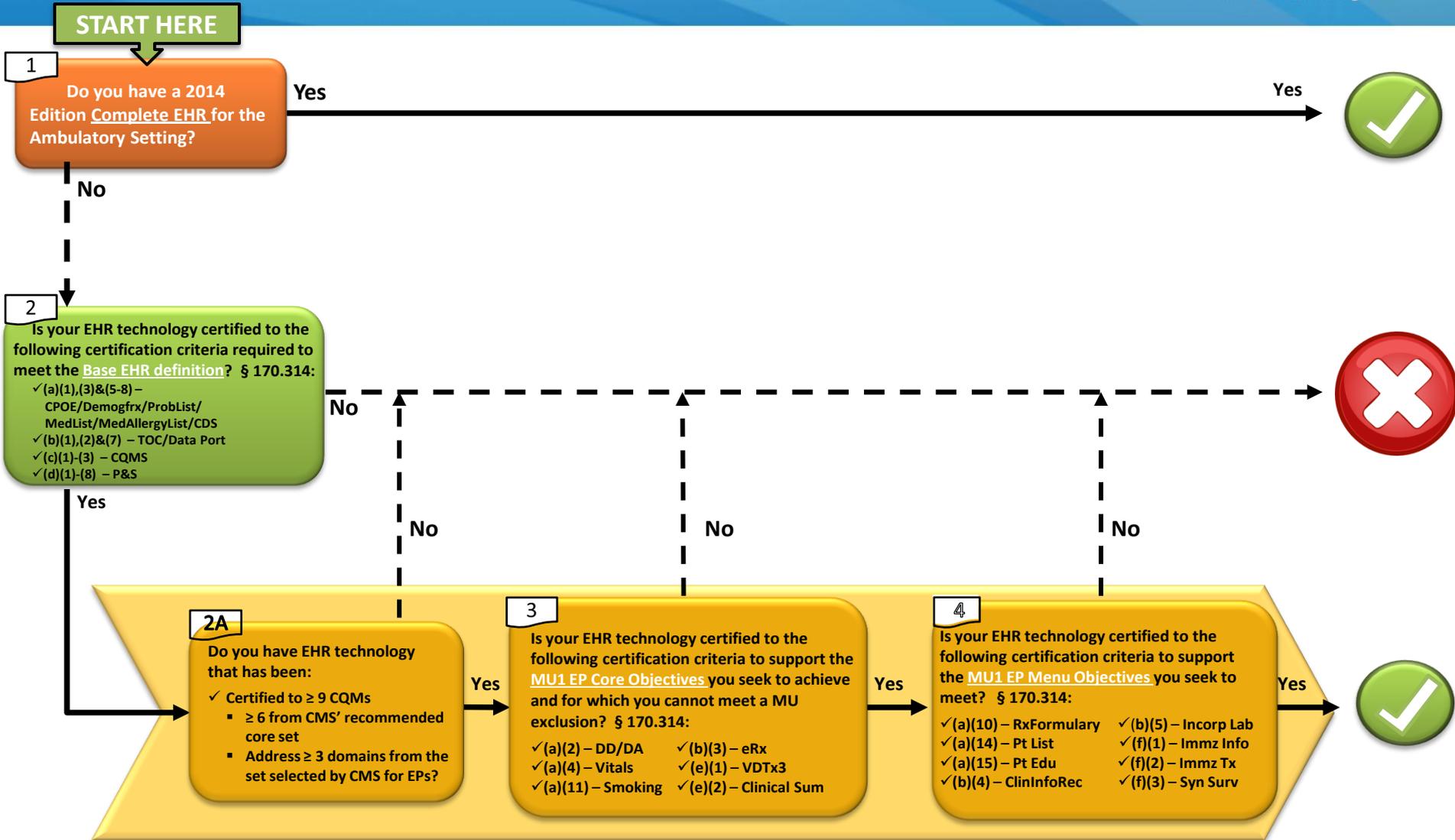
## Technology definition for Meaningful Use Stage 1?



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

