The Office of the National Coordinator for
Health Information Technology

2014 Edition Release 2 EHR Certification Criteria Final Rule

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Overview

- Background
- Edition Naming Approach
- 2014 Edition Release 2 Criteria and Provisions
- 2014 Edition Framework with Release 2
- What's Next?

Background

Proposed Rule and Comments

- Proposed a Voluntary Proposed Edition on February 26, 2014
- Goals were to provide regulatory flexibility, clarify policy, improve interoperability, and make administrative changes to the ONC HIT Certification Program
- Stakeholders provided feedback that the full set of proposals in the proposed rule was too expansive
- Support for incremental rule making was mixed

Final Rule Overview

- Adopts a small subset of the proposals as optional and revised 2014 Edition Release 2 certification criteria that provide flexibility, clarity, and enhance health information exchange
- Provides more choices for health IT developers and their customers, including new interoperable ways to securely exchange health information
- Adopts proposals make our program more effective and less burdensome
- Provides gradual rulemaking that serves as a model for ONC to update its rules as technology and standards evolve to support innovation

Edition Naming Approach

Edition Naming Change

- Previous editions of EHR certification criteria were named for the first year when we would expect compliance to support the EHR Incentive Programs. e.g., 2011 and 2014 Editions.

- Stakeholder feedback on our most recent February NPRM noted that this naming approach creates unrealistic expectations that certified products will be available by the edition year.

- ONC determined that editions should not have any additional implied meaning and will therefore name editions of certification criteria by the year in which the final rule is released.

- Other rulemakings similar to the 2014 Edition Release 2 final rule would be added to the most current edition of certification criteria (e.g., 201X Edition Release 2).

Edition Naming Visual
Past vs Future (Illustrative Only)

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Past		Future
2010 CY Final Rule "Initial Set"	**MU S1** **2011 Ed = 2011** **1st Year Compliance**	**2010 CY Final Rule** "Initial Set"
2012 CY Final Rule "2014 Edition" & Initial Set now "2011 Edition"	**MU S1 & S2** **2014 Ed (was) = 2014** **1st Year Compliance**	**2012 CY Final Rule** "2014 Edition" & Initial Set now "2011 Edition'
2014 CY Final Rule Proposed Voluntary Edition "2015 Edition"	**MU S1 & S2 Supportive** **No Compliance Year**	**2014 CY Final Rule** **"2014 Edition Release 2"**
2015 CY Final Rule "2017 Edition"	**MU and beyond supportive**	**2015 CY Final Rule** **"2015 Edition"**
	MU and beyond supportive	**201X?|201X? CY Final Rule** **"2015 Edition Release 2"**

2014 Edition Release 2 Criteria and Provisions

2014 Edition Release 2
EHR Certification Criteria

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Optional Certification Criteria		Revised Certification Criteria	
Regulation Section	Title of Regulation Paragraph	Regulation Section	Title of Regulation Paragraph
§ 170.314(a)(18)	Optional – computerized provider order entry – medications	§ 170.314(e)(1)	View, download, and transmit to 3rd party
§ 170.314(a)(19)	Optional – computerized provider order entry – laboratory	§ 170.314(g)(3)	Safety-enhanced design
§ 170.314(a)(20)	Optional – computerized provider order entry – diagnostic imaging		
§ 170.314(b)(8)	Optional – transitions of care		
§ 170.314(b)(9)	Optional – clinical information reconciliation and incorporation		
§ 170.314(f)(7)	Optional – ambulatory setting only – Transmission to public health agencies – syndromic surveillance		
§ 170.314(g)(1)	Optional – automated numerator recording		
§ 170.314(h)(1)	Optional – Applicability Statement for Secure Health Transport		
§ 170.314(h)(2)	Optional – Applicability Statement for Secure Health Transport and XDR/XDM for Direct Messaging		
§ 170314(h)(3)	Optional – SOAP Transport and Security Specification and XDR/XDM for Direct		

Alternative Certification Criteria and Certification Approaches

Computerized Provider Order Entry (CPOE)

- Divides CPOE into three separate certification criteria:
  - Medications (same requirements remain)
  - Laboratory (same requirements remain)
  - Diagnostic imaging (formerly radiology)

- **Why?**
  - Allows an EHR technology developer to create adaptations, such as mobile apps for one of the three capabilities **OR** certify to just one capability
  - Provides eligible professionals flexibility for the EHR Incentive Programs based on practice needs

Transitions of Care (ToC) & View, Download, and Transmit to 3rd Party (VDT)

- New ToC criterion
  - Decoupled the "content" portion of the 2014 Edition "transitions of care" (ToC) criterion from the "transport" capabilities and adopted a new set of transport criteria (see next slide).
  - Adopted the Implementation Guide (IG) for Direct Edge Protocols v1.1 to promote interoperability and an EHR's ability to reliably connect to a HISP.

- Revised VDT criterion
  - Revised the VDT criterion to include the same decoupling of transport made to the new ToC criterion as optional for certification (i.e., use of the Edge Protocols IG v1.1)

- **Why?** Allows health information service providers (HISPs) and other health IT developers to certify to either **content** capabilities or **transport** capabilities.

  Note: Developers do not have to seek certification to both criteria.

Transmission Method Certification Criteria

- Adopted three certification criteria for transmission methods as part of decoupling "content" and "transport" for ToC and VDT:
  1. Direct
  2. Direct and XDR/XDM for Direct Messaging
  3. SOAP RTM and XDR/XDM for Direct Messaging

- **Why?** Allows for flexibility in the certification and use of transmission methods

Clinical Information Reconciliation and Incorporation (CIRI)

- CIRI certification criterion "moves" incorporation capabilities from the ToC certification criterion.

- **Why?** Moves incorporation to a more appropriate criterion which better reflects the clinical workflow associated with incorporation.

Syndromic Surveillance

- Applicable to ambulatory setting/eligible professionals
- Permits any electronic method of creating syndromic surveillance information for exchange
- **Why?**
  - The industry has not developed an implementation guide (IG) for the adopted standard (HL7 2.5.1 IG) and providers are sending syndromic surveillance data to public health using alternate standards (such as CDA and QRDA III) without developed, consensus IGs for syndromic surveillance.
  - Promotes flexibility and providers' ability to achieve the MU syndromic surveillance objective for Stage 2 using certified EHR technology.

Utilization Certification Criteria

- Safety-enhanced design (SED) criterion
  - Revised to include the optional three CPOE criteria and optional CIRI criterion.
  - **Why?** Provides regulatory clarity.

- Automated numerator recording criterion
  - Designated as "optional" for the purposes of excluding it from the 2014 Edition Complete EHR definition.
  - **Why?** Provides regulatory clarity.
  - **Note:** EHR Modules **must** be certified to the automated numerator recording criterion or the automated measure calculation criterion.

Gap Certification Eligibility

- **How does it work?** Allows the use of test results from a previous certification for certification to functionalities that have not changed in Release 2, subject to the discretion of an ONC-Authorized Certification Body (ONC-ACB).

- Seven Release 2 criteria are eligible for gap certification if EHRs were certified to the 2014 Edition versions of these functionalities or, **in some cases**, the 2011 Edition:
  - Three optional CPOE criteria
  - Optional syndromic surveillance criterion
  - Three optional transmission criteria

Certification Program Improvements

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- Discontinued the "Complete EHR" definition and Complete EHR certification beginning with the next adopted edition of certification criteria.
  - **Why?** Adds regulatory clarity, supports flexibility & reduces burden
  - **Note:** This does not affect prior or future 2014 Edition certifications.

- Adopted the "ONC Certified HIT" certification and design mark for required use by ONC-ACBs.
  - **Why?** Provides clarity for the market as it relates to health IT certified under the program.
  - **Note:** Health IT developers do **not** have to use the mark.

- Adopted an updated standard (ISO/IEC 17065) for the accreditation of ONC-ACBs.
  - **Why?** Maintains alignment with industry practices.

Administrative Updates

- Finalized a proposal to remove 2011 Edition-specific EHR certification criteria and related standards, terms, and requirements from the Code of Federal Regulations (CFR) effective March 1, 2015.
  - **Why?**
    - EHR technology certified to 2011 Edition will no longer meet the CEHRT definition starting in 2015
    - Keeps criteria editions current for the purposes of Stark/Anti-Kickback EHR donation rules
- Finalized a proposal to remove the temporary certification program (TCP) regulations from the CFR on the effective date of this final rule.
  - **Why?** TCP sunset on October 4, 2012, and is no longer in existence

2014 Edition Framework With Release 2

2014 Edition CEHRT
Easy as 1, 2, 3 + C*

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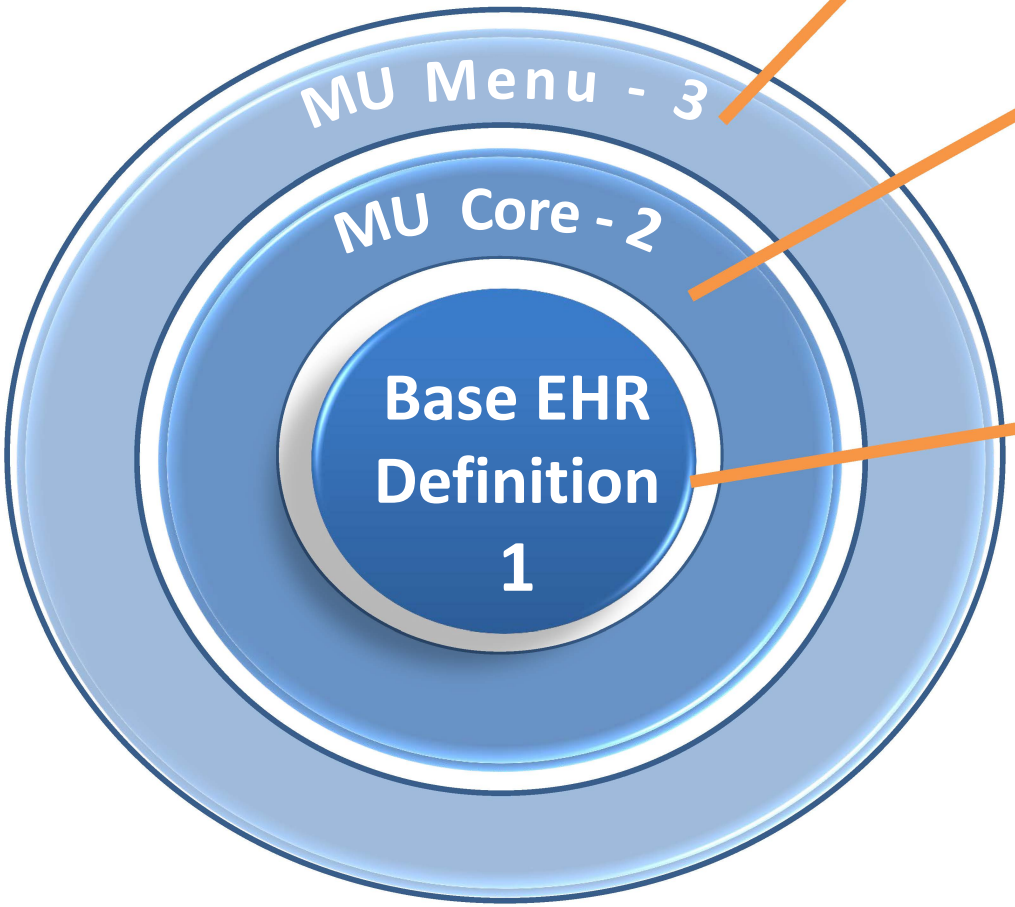

EP/EH/CAH would only need to have EHR technology with capabilities certified for the MU menu set objectives & measures for the stage of MU they seek to achieve.

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 Base EHR definition.

***C = CQMs**

Certification Criteria Included in the Base EHR Definition

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- **It is a definition. It is meant to be used like a checklist to meet the CEHRT definition.**
- **It is <u>not</u> "*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)	☑
	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	Clinical Decision Support § 170.314(a)(8)	☑
Has the capacity to support physician order entry	Computerized Provider Order Entry For at least one of the four criteria at § 170.314(a)(1), **(a)(18), (a)(19) or (a)(20)**	☑
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); **or (b)(8) and (h)(1); or (b)(1) and (b)(2) combined with either (b)(8) or (h)(1), or both (b)(8) and (h)(1)**	☑
	Data Portability § 170.314(b)(7)	☑
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)	☑

Release 2 Relationship to Meaningful Use Eligible Professionals Core and Menu Examples

- Core - CPOE Example
  - Stage 2 has separate % measure requirements for medications, laboratory, and radiology orders, but exclusions *may* apply (i.e., writing fewer than 100 of each order type during an EHR reporting period)
  - Stage 1 does not include measures for laboratory and radiology orders
- Menu - Syndromic Surveillance Example
  - Stage 2 Measure: Successful ongoing submission of electronic syndromic surveillance data from CEHRT to a public health agency for the entire reporting period

Two Types of Certifications

"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)

Why do we designate certification criteria optional?

Answer: The designation of "optional" for certification criteria (in this case, the 2014 Edition) was developed to accommodate the Complete EHR definition. If a certification criterion is not designated as "optional," an EHR technology designed for the ambulatory setting or inpatient setting would need to be certified to the criterion in order to satisfy the Complete EHR definition and be issued a Complete EHR certification.

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

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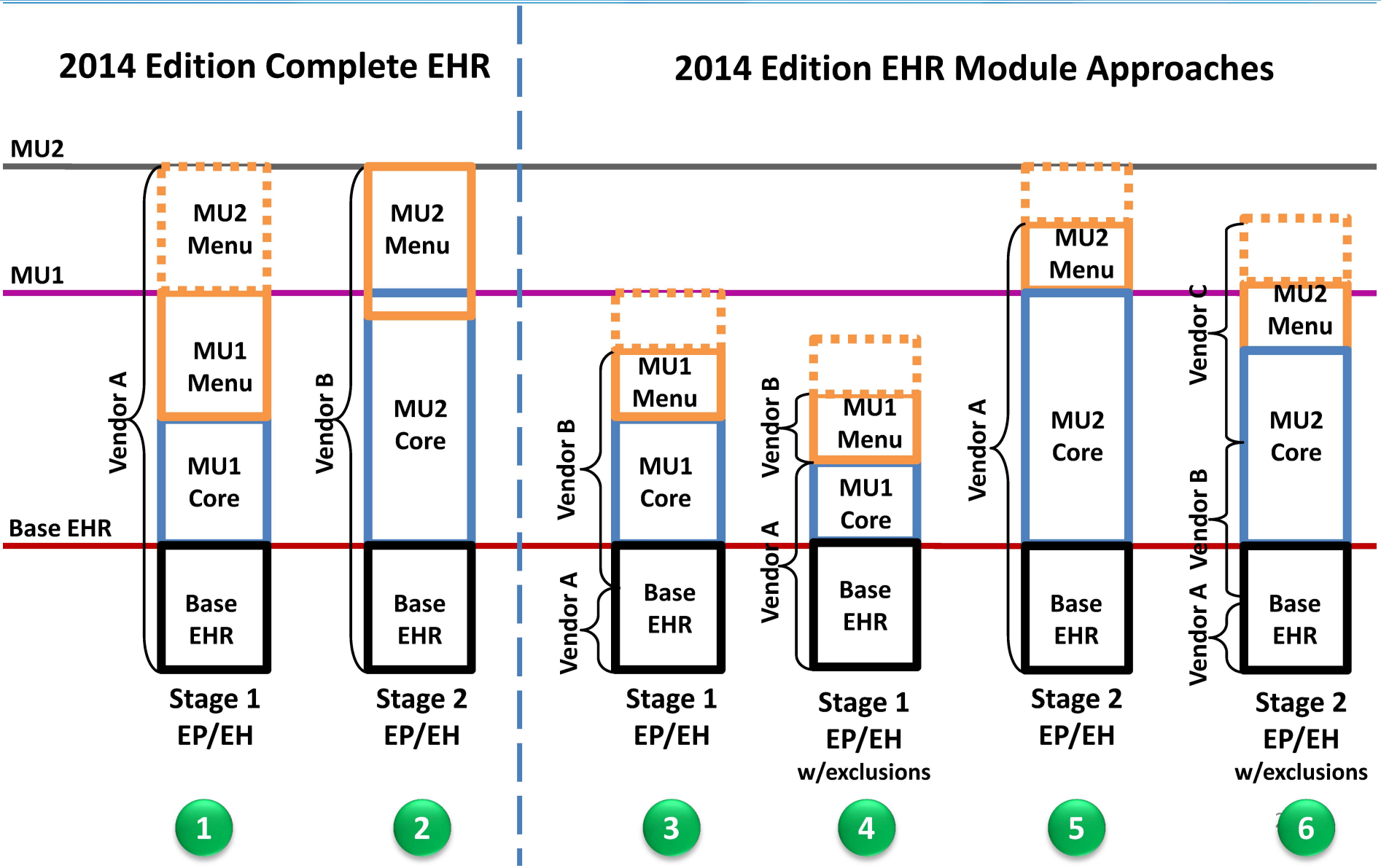

What's Next?

Next Steps

- ONC will be publishing a proposed rule for the next edition of EHR certification criteria jointly with the next CMS EHR Incentive Programs proposed rule. We anticipate these rules will be published this winter.

- We anticipate that the next edition of certification criteria will contain functionalities that will be required for the next stage of the EHR Incentive Programs.

- The public comments we received on the proposed rule will help inform our proposals for the next edition of certification criteria.

Resources

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- Press Release: http://www.hhs.gov/news/press/2014pres/09/20140910a.html
- Fact Sheet: http://www.healthit.gov/sites/default/files/2014-r2-ehr-certification-final-rule-onc-factsheet.pdf
- Final Rule: http://www.gpo.gov/fdsys/pkg/FR-2014-09-11/pdf/2014-21633.pdf
- Health IT Regulations: http://www.healthit.gov/policy-researchers-implementers/health-it-regulations
- My Contact: Michael.Lipinski@hhs.gov