



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

### 45 CFR Part 170

### RIN 0991-AB92

### Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements; Correction

**AGENCY:** Office of the National Coordinator for Health Information Technology (ONC),  
Department of Health and Human Services.

**ACTION:** Proposed rule; correction.

**SUMMARY:** This notice makes the following corrections to the proposed rule that appeared in the February 26, 2014 Federal Register entitled “Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements”:  
corrects the preamble text and gap certification table for four certification criteria that were omitted from the list of certification criteria eligible for gap certification for the 2015 Edition EHR certification criteria; and provides information on inactive web links that appear in the proposed rule.

**DATES:** Comments on the proposed rule published February 26, 2014, at 79 FR 10880, continue to be accepted until no later than 5 p.m. on April 28, 2014.

**FOR FURTHER INFORMATION CONTACT:** Steven Posnack, Director, Federal Policy Division, Office of Policy and Planning, Office of the National Coordinator for Health Information Technology, 202-690-7151.

### SUPPLEMENTARY INFORMATION:

#### I. Background

In FR Doc. 2014-03959, the proposed rule entitled “Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements” (79 FR 10880) (hereinafter referred to as the 2015 Edition proposed rule), four 2015 Edition EHR certification criteria were omitted from the list of certification criteria eligible for gap certification. There are also inactive web links included in the preamble. These errors are identified and corrected in this correction notice.

## **II. Summary of Errors**

We define “gap certification” at 45 CFR 170.502 as “the certification of a previously certified Complete EHR or EHR Module(s) to: (1) [a]ll applicable new and/or revised certification criteria adopted by the Secretary at subpart C of [part 170] based on the test results of a NVLAP-accredited testing laboratory; and (2) [a]ll other applicable certification criteria adopted by the Secretary at subpart C of [part 170] based on the test results used to previously certify the Complete EHR or EHR Module(s)” (for further explanation, see 76 FR 1307-1308). Our gap certification policy focuses on the differences between certification criteria that are adopted through rulemaking at different points in time. This allows EHR technology to be certified to only the differences between certification criteria editions rather than requiring EHR technology to be fully retested and recertified to certification criteria that remain “unchanged” from one edition to the next and for which previously acquired test results are sufficient. Under our gap certification policy, “unchanged” certification criteria (see 77 FR 54248 for further explanation) are eligible for gap certification, and each ONC-Authorized Certification Body (ONC-ACB) has discretion over whether it will provide the option of gap certification.

In the 2015 Edition proposed rule, we noted whether a proposed 2015 Edition EHR certification criterion was “eligible” or “ineligible” for gap certification at the beginning of each

section of the preamble that discussed each certification criterion. We also provided a table that cross-walked “unchanged” 2015 Edition EHR certification criteria to the corresponding 2014 Edition EHR certification criteria (79 FR 10916, Table 4). In the preamble section for each certification criterion and in the gap certification table (Table 4), we omitted four certification criteria that are eligible for gap certification because they are “unchanged” based on our description of what constitutes an “unchanged” criterion. These criteria are:

- For the inpatient setting only § 170.315(a)(2) Computerized provider order entry – laboratory (79 FR 10887);
- § 170.315(h)(1) Transmit – Applicability Statement for Secure Health Transport (79 FR 10914);
- § 170.315(h)(2) Transmit – Applicability Statement for Secure Health Transport and XDR/XDM for Direct Messaging (79 FR 10914);
- § 170.315(h)(3) Transmit – SOAP Transport and Security Specification and XDR/XDM for Direct Messaging (79 FR 10914).

In addition, some of the web links in the preamble have become inactive since the proposed rule was published.

### **III. Correction of Errors**

In FR Doc. 2014-03959 of February 26, 2014 (79 FR 10880), make the following corrections:

1. On page 10887, first column, line 15, “Ineligible.” is corrected to read “Eligible for the inpatient setting. Ineligible for the ambulatory setting.”
2. On page 10914, second column, line 24, “Ineligible” is corrected to read “Eligible.”
3. On page 10914, second column, line 50, “Ineligible” is corrected to read “Eligible.”

4. On page 10914, third column, line 12, “Ineligible” is corrected to read “Eligible.”

5. On page 10916, Table 4 – Gap Certification Eligibility for 2015 Edition EHR Certification

Criteria is revised to read as follows:

<b>Table 4. Gap Certification Eligibility for 2015 Edition EHR Certification Criteria</b>			
<b>2015 Edition</b>		<b>2014 Edition</b>	
<b>Regulation Section</b>	<b>Title of Regulation Paragraph</b>	<b>Regulation Section</b>	<b>Title of Regulation Paragraph</b>
§ 170.315(a)(1)	Computerized physician order entry - medications	§ 170.314(a)(1)	Computerized Provider Order Entry
§ 170.315(a)(2) Inpatient setting only	Computerized physician order entry – laboratory		
§ 170.315(a)(3)	Computerized physician order entry – radiology/imaging		
§ 170.315(a)(4)	Drug-drug, drug-allergy interaction checks	§ 170.314(a)(2)	Drug-drug, drug-allergy interaction checks
§ 170.315(a)(6)	Vital signs, BMI, & growth charts	§ 170.314(a)(4)	Vital signs, BMI, & growth charts
§ 170.315(a)(7)	Problem list	§ 170.314(a)(5)	Problem list
§ 170.315(a)(8)	Medication list	§ 170.314(a)(6)	Medication list
§ 170.315(a)(9)	Medication allergy list	§ 170.314(a)(7)	Medication allergy list
§ 170.315(a)(12)	Drug-formulary checks	§ 170.314(a)(10)	Drug-formulary checks
§ 170.315(a)(13)	Smoking status	§ 170.314(a)(11)	Smoking status
§ 170.315(a)(14)	Image results	§ 170.314(a)(12)	Image results
§ 170.315(a)(16)	Patient list creation	§ 170.314(a)(14)	Patient list creation
§ 170.315(a)(18)	Electronic medication administration record	§ 170.314(a)(16)	Electronic medication administration record
§ 170.315(a)(19)	Advance directives	§ 170.314(a)(17)	Advance directives
§ 170.315(b)(3)	Electronic prescribing	§ 170.314(b)(3)	Electronic prescribing
§ 170.315(c)(1) – (3)	Clinical quality measures	§ 170.314(c)(1) – (3)	Clinical quality measures
§ 170.315(d)(1)	Authentication, access control, & authorization	§ 170.314(d)(1)	Authentication, access control, & authorization
§ 170.315(d)(3)	Audit report(s)	§ 170.314(d)(3)	Audit report(s)
§ 170.315(d)(4)	Amendments	§ 170.314(d)(4)	Amendments
§ 170.315(d)(5)	Automatic log-off	§ 170.314(d)(5)	Automatic log-off
§ 170.315(d)(6)	Emergency access	§ 170.314(d)(6)	Emergency access
§ 170.315(d)(7)	End-user device encryption	§ 170.314(d)(7)	End-user device encryption
§ 170.315(d)(8)	Integrity	§ 170.314(d)(8)	Integrity
§ 170.315(d)(9)	Accounting of disclosures	§ 170.314(d)(9)	Accounting of disclosures
§ 170.315(e)(3)	Secure messaging	§ 170.314(e)(3)	Secure messaging
§ 170.315(f)(1)	Immunization information	§ 170.314(f)(1)	Immunization information
§ 170.315(f)(3) <sup>#</sup>	Transmission to public health agencies – syndromic surveillance	§ 170.314(f)(3) <sup>#</sup>	Transmission to public health agencies – syndromic surveillance
§170.315(f)(5)	Cancer case information	§170.314(f)(5)	Cancer case information
§ 170.315(g)(4)	Quality management system	§ 170.314(g)(4)	Quality management system
§ 170.315(h)(1)	Transmit – Applicability Statement for Secure Health Transport	§ 170.314(b)(2)(ii)(A)	Transitions of care – create and transmit transition of care/referral summaries.

§ 170.315(h)(2)	Transmit – Applicability Statement for Secure Health Transport and XDR/XDM for Direct Messaging	§ 170.314(b)(2)(ii)(B)	Transitions of care – create and transmit transition of care/referral summaries.
§ 170.315(h)(3)	Transmit – SOAP Transport and Security Specification and XDR/XDM for Direct Messaging	§ 170.314(b)(2)(ii)(C)	Transitions of care – create and transmit transition of care/referral summaries.

# If certified to the revised 2014 Edition version of this criterion after the effective date of the 2015 Edition Final Rule. For further information on this distinction, please see the gap certification discussion under the “Transmission to Public Health Agencies – Syndromic Surveillance” in section III.A of this preamble.

Inactive Web links

Inactive web links included in the 2015 Edition proposed rule are identified on ONC’s Standards and Certification Regulations page with an explanation and/or corrected link (<http://www.healthit.gov/policy-researchers-implementers/standards-and-certification-regulations>).

Dated: March 13, 2014

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Jennifer M. Cannistra,  
Executive Secretary to  
the Department.

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