

**Implementation, Certification and Testing (ICT) Workgroup**

**Certification NPRM Comment Template – Group 1**

**Proposed 2015 Edition Electronic Health Record (EHR) Certification Criteria, 2015 Edition Base EHR Definition, and ONC Health IT Certification Program Modifications**

| [**C. Costs and Benefits**](https://www.federalregister.gov/articles/2015/03/30/2015-06612/2015-edition-health-information-technology-health-it-certification-criteria-2015-edition-base#p-117)  **p. 14** |
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| Our estimates indicate that this proposed rule is an economically significant rule as its overall costs for health IT developers may be greater than $100 million in at least one year. We have, therefore, projected the costs and benefits of the proposed rule. The estimated costs expected to be incurred by health IT developers to develop and prepare health IT to be tested and certified in accordance with the 2015 Edition health IT certification criteria (and the standards and implementation specifications they include) are represented in monetary terms in Table 1 below. (continued on pp.15) |
| **Public Comment Field: While it is entirely plausible that increased use of standards and the adherence to such tested criteria would result in the qualitative benefits enumerated by the proposed rule, it would be more appropriate to enumerate the quantitative benefits with hard evidence in the level of quality outcomes these new criteria aim to improve. For example, the level of care coordination could be expected to improve as a result of improved interoperability amongst EHRs and thus reduce the number of potentially avoidable hospital admissions that result in overall total cost reduction of XX.X% by XX date (2020).** |

| [**1. Applicability**](https://www.federalregister.gov/articles/2015/03/30/2015-06612/2015-edition-health-information-technology-health-it-certification-criteria-2015-edition-base#p-144)  **p. 28** |
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| Section 170.300 establishes the applicability of subpart C – Certification Criteria for Health Information Technology. We propose to revise paragraph (d) of § 170.300 to add in a reference to § 170.315 and revise the parenthetical in the paragraph to say “i.e., apply to any health care setting” instead of “i.e., apply to both ambulatory and inpatient settings.” These proposed revisions would clarify which specific capabilities within a certification criterion included in § 170.315 have general applicability (i.e., apply to any health care setting) or apply only to an inpatient setting or an ambulatory setting.. (continued on pp.128) |
| **Public Comment Field: This is an important step in noting that EHR technologies (and capabilities) are setting-specific in terms of the pieces and parts used at each type of setting across the continuum of care. The initial intent of “complete” certification was most likely intended to help protect or signal to potential buyers that the “complete” package of capabilities to achieve MU was contained within that certified system. It would be prudent for ONC to communicate clearly to vendors that they have an ethical and legal obligation to clearly signal to potential buyers the precise attributes of MU that the purchased system will facilitate achievement. So, it is with great caution that ONC should proceed down this path with the foresight that there is now a greater potential for providers to misunderstand the true capabilities they may be purchasing in each of the modular pieces of the certified technologies and most likely impossible to understand which pieces would be needed to achieve the MU and subsequent incentive payment for participation in the program.** |

| [**Gap Certification Eligibility Table for 2015 Edition Health IT Certification Criteria**](https://www.federalregister.gov/articles/2015/03/30/2015-06612/2015-edition-health-information-technology-health-it-certification-criteria-2015-edition-base#p-1143) **p.234** |
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| **Preamble FR Citation**: 80 FR 16867 | **Specific questions in preamble?** *No* |
| **Public Comment Field: This section only provides what appears to be a naming convention crosswalk. There are no “gaps” identified at this time and is stated us such in the paragraph. However, when the gap certification criteria are proposed, the ONC should take note of the significant burden that a change in standards will have on the vendor and the industry. There must be precautions taken to ensure forward and backward compatibility amongst these standards/criteria transitions. So, to the extent possible, the ONC should address the specifics of those transitional requirements and note the increased testing and cost burden placed on the vendor. If these precautions are not taken, there could be the unintended consequence of currently “working systems” that break as a result of new implementations of the new criteria.** |

| [**Common Clinical Data Set Definition**](https://www.federalregister.gov/articles/2015/03/30/2015-06612/2015-edition-health-information-technology-health-it-certification-criteria-2015-edition-base#p-1181)  **p.245** |
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| **Preamble FR Citation**: 80 FR 16871 | **Specific questions in preamble?** *No* |
| **Public Comment Field: This change does not appear substantial because it only signifies a name change as written. However, as noted in comments above and implicit in the proposed rule, the ONC should be clear as to how it will handle 2014 certified MU technologies with 2015 certified technologies. The central problem to solve in policy may be as simple as stating that the vendors must ensure backward and forward compatibility with any of its certified MU technologies. But that may be an oversimplification of a very complex issue.** |

| [**§ 170.315(g)(6) Consolidated CDA creation performance**](http://www.federalregister.gov/a/2015-06612/p-933) **p. 202** |
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| **Included in 2015 Edition Base EHR Definition?**No, but a conditional certification requirement  |
| **Stage 3 MU Objective** N/A |
| **2015 Edition Health IT Certification Criterion**(6) Consolidated CDA creation performance. The following technical and performance outcomes must be demonstrated related to Consolidated CDA creation. The capabilities required under paragraphs (g)(6)(i) through (iii) of this section can be demonstrated in tandem and do not need to be individually addressed in isolation or sequentially. (i) Reference C-CDA match. Upon the entry of clinical data consistent with the Common Clinical Data Set, the technology must be able to create a data file formatted in accordance with each of the standards adopted in § 170.205(a)(3) and (4) that matches a gold-standard, reference data file.(ii) Document-template conformance. Upon the entry of clinical data consistent with the Common Clinical Data Set, the technology must be able to create a data file formatted in accordance with each of the standards adopted in § 170.205(a)(3) and (4) that demonstrates a valid implementation of each of the following document templates (as applicable to the adopted standard):(A) Generally applicable. CCD; Consultation Note; History and Physical; Progress Note; Care Plan; Transfer Summary; and Referral Note.(B) Inpatient setting only. Discharge Summary. (iii) Vocabulary conformance. Upon the entry of clinical data consistent with the Common Clinical Data Set, the technology must be able to create a data file formatted in accordance with each of the standards adopted in § 170.205(a)(3) and (4) that demonstrates the required vocabulary standards (and value sets) are properly implemented. |
| **Preamble FR Citation:** 80 FR 16859 | **Specific questions in preamble**? *Yes* |
| **Public Comment Field: It is entirely plausible that testing for the correct syntax of a C-CDA created in a system once would tend to signify that the system is capable of such performance and is only repetitive and possibly unnecessary to require testing of that capability for each functional capability test requiring a C-CDA. However, the ONC should be cautious in attempting to ensure interoperability. Syntax checking is only one part of the interoperability issue. The semantic check would require the production and testing of each C-CDA. So, while it may appear to lessen the burden by only testing the syntax once, it may have unintended consequences with regards to achieving semantic interoperability if the ONC does not require that the vendor produce each interoperability check to include the correctly formatted message with each test. It is not an undue burden to have the vendor simply repeat the “performance” of creating a C-CDA. The real issue here is ensuring that the ONC has clearly minimized the “vagueness” of the interoperability requirement by clearly specifying the “exact” requirement for each interoperable exchange. Such specificity would require the ONC to detail the expected option used for each message. Without such specificity, the simple creation of a C-CDA and its validation of performance would be meaningless in achieving interoperability.****\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*****In order to ensure interoperability, ONC must ensure the optionality in C-CDAs is removed by specifying any optional fields. And, after passing certification, ONC should have in place some sort on on-going “interoperability” testing for vendors to prove they are maintaining conformance (occasional send of C-CDA to a test system) . Also, the certified system is usually not the exact system that is deployed, e.g., at minimum new certificates, ONC should consider a quick “on-boarding” test to ensure the deployed systems is compliant by sending a test C-CDA (to same test system).** |

| [**Open Data Certified Health IT Product List (CHPL)**](http://www.federalregister.gov/a/2015-06612/p-1313) **p. 288** |
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| **Preamble FR Citation:** 80 FR 16883 | **Specific questions in preamble?** *Yes* |
| **Public Comment Field: No Comment** |

| [**“Removal” of Meaningful Use Measurement Certification Requirements**](http://www.federalregister.gov/a/2015-06612/p-1199) **p. 253** |
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| **Preamble FR Citation:** 80 FR 16873 | **Specific questions in preamble?** *No* |
| **Public Comment Field: It is unclear how this proposed change affects the testing requirement for reporting CQMs. It may be implicit that ONC is not intending to change the CQM reporting and testing requirements with this rule, but just the non-clinical MU measurements. Suggest that ONC make this proposed change more clear.** |

| [**The ONC Health IT Certification Program and Health IT Module**](http://www.federalregister.gov/a/2015-06612/p-112) **p. 12** |
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| **Preamble FR Citation**: 80 FR 16873 | **Specific questions in preamble?** *No* |
| **Public Comment Field: As stated in previous comment, the proposed rule to remove the automated numerator and denominator calculations does not apply to CQM reporting, as those reporting requirements are covered by different standards. With regards to requiring “field surveillance” of a deployed system … the ONC should clearly articulate what such a surveillance would entail. It is a step in the right direction that recognizes the fact that deployed or implemented versions of a lab-tested system could vary greatly in performance from site to site. However, much of that variation is a result of site-specific configuration issues. So, it is understandable that the ONC is requesting the vendor to document “deviation” from the “standard” implementation. However, the alterations to the standard implementation should only require documentation is such an alteration affects the achievement of the MU program. If the ONC does not limit with specificity what is meant by the audit and/or the requirement to document and report changes to the “standard” deployment of the “lab-tested” system, there will most certainly by undue burden on the vendor, the site, and that may threaten the forward progress of the MU program.** |