

ONC Fact Sheet: Voluntary 2015 Edition EHR Certification Criteria (“2015 Edition”) Proposed Rule

Background

The Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) have announced a new timeline for meaningful use (MU) Stage 3’s expected start date.

This timeline provides ONC the opportunity to begin to shift its regulatory approach to a more incremental and frequent approach of publishing rules (every 12 to 18 months) that would benefit the industry and enable ONC to:

- A) **Adapt** certification regulations to more effectively and efficiently respond to stakeholder feedback and support HHS delivery of reform and clinical transformation programs that may seek to leverage health IT certification.
- B) **Better** ONC’s regulations by making “bug fixes” and other regulatory improvements as part of a more frequent rulemaking cycle.
- C) **Chart** a course toward enhanced interoperability, information exchange, quality improvement, patient engagement, and patient safety that gives health IT developers more ability to predict ONC’s potential next steps.
- D) **Deliver** smaller, incremental regulatory requirements that are easier to integrate into software development cycles.

The proposed new capabilities, standards-based requirements, and public comment solicitations on potential future certification criteria included in this proposed rule provide all stakeholders, including EHR technology developers, with advance visibility and time to react to the potential requirements ONC may consider for the 2017 Edition in support of MU Stage 3.

Specific Highlights

The ONC 2015 Edition proposed rule proposes:

- New certification criteria representing new functionality such as a certification criterion to support patient population filtering of clinical quality measures;
- To enhance interoperability with new or updated implementation specifications for several certification criteria, including transitions of care, clinical decision support, and a few related to public health reporting;
- To improve interoperable exchange with policy revisions that changes the certification approach for transitions of care;
- A path for the certification of “non-MU” EHR technology;
- To codify ONC regulatory guidance provided in Frequently Asked Questions issued since the 2014 Edition Final Rule;
- A revision to the 2014 Edition syndromic surveillance certification criterion to better support the ability of EPs’, EHS’, and CAHs’ to meet the corresponding MU objectives and measures;
- Closer alignment with other HHS program policies (e.g., CLIA and clinical quality measure reporting) and to address Office of the Inspector General (OIG) recommendations;
- To discontinue the “Complete EHR” definition and the issuance of Complete EHR certifications starting with the 2015 Edition; and
- To solicit comment on new capabilities and standards-based requirements for potential future certification criteria (2017 Edition in support of MU Stage 3) to provide EHR technology developers advance visibility and time to react.

Transitions of Care Enhanced Interoperability Functionality

Interoperability to support transitions of care (ToC) and increased options for interoperable exchange are two of ONC's top priorities. To further these goals, we propose to:

1. Separate the 2014 Edition's ToC requirement to demonstrate both "content" and "transport" capabilities together. This revision in the 2015 Edition will enable those distinct capabilities to be separately tested and certified and separately implemented by EPs, EHs, and CAHs as a means to meet the Certified EHR Technology (CEHRT) definition. This should create more opportunities for health information exchange entities to certify transport capabilities as EHR Modules and potentially more exchange services choices for providers; and
2. Adopt a new "performance standard" for the receipt of electronic documents formatted in the Consolidated Clinical Document Architecture (CCDA) standard as part of the 2015 Edition ToC certification criterion. The proposed "performance standard" would require EHR technology to successfully electronically process validly formatted CCDAs no less than 95% of the time. This proposal is aimed at enhancing EHR technology's reliability upon receipt of summary care records.

Non-MU Technology Certification

The rule proposes to increase the flexibility in ONC's regulatory structure to more easily accommodate health IT certification for other purposes beyond MU. EHR technology is often designed for other types of health care settings where individual or institutional health care providers are not typically eligible to qualify for MU incentive payments under Medicare or Medicaid, such as behavioral health or long-term post-acute care settings. EHR technology is also designed, for example, primarily to support health information exchange and is agnostic to whether the health care provider is using the technology to achieve MU. However, under ONC's current requirements EHR technology developers have to design their EHR technology to meet MU-specific measure calculation requirements even though the EHR technology may not be used for MU. We want to avoid such situations and instead make our regulatory structure more flexible and extensible such that it can more easily accommodate health IT certification for other purposes beyond MU. Accordingly, we propose to establish an "MU EHR Module" and "non-MU EHR Module" for certification.

Discontinuation of the Complete EHR Definition

The rule proposes to discontinue the regulatory use of the Complete EHR definition beginning with the 2015 Edition. The original CEHRT definition required an EP, EH, or CAH to have EHR technology that met all the certification criteria adopted for a setting (ambulatory or inpatient). By definition, if an EP, EH, or CAH adopted a 2011 Edition Complete EHR they also satisfied the CEHRT definition. Since publication of the 2014 Edition Final Rule, some stakeholders incorrectly believe their only option to meet the CEHRT definition is to adopt a 2014 Edition Complete EHR. Stakeholders have also indicated that some EHR technology developers have continued to seek only a Complete EHR certification and, thus, only plan to offer a certified Complete EHR as a solution to customers. However, under the CEHRT definition for FY/CY 2014 and subsequent years, stakeholders only need EHR technology (EHR Modules) certified to the 2014 Edition that:

1. Meets the Base EHR definition (a finite set of capabilities); and
2. Includes only the other capabilities that they need for the MU Stage they are attempting to achieve.

Complete EHR certification no longer aligns verbatim with the CEHRT definition or the MU needs of most EPs, EHs, and CAHs. Further, an EHR technology issued a Complete EHR certification is not necessarily "complete" or sufficient for an EP's, EH's, or CAH's to achieve MU. For example, based on the 2014 Edition Complete EHR definition, it may not be certified to the clinical quality measures on which a particular provider intends to report and it may not have been certified to capabilities included in optional certification criteria that a provider needs for MU.

Gap Certification between the 2014 and 2015 Editions

"Gap certification" focuses on the differences between certification criteria editions. Gap certification enables EHR technology developers to use test results from a prior edition's certification toward a new edition's

certification when the criteria in both editions are the same. By not having to fully retest an entire set of capabilities, updated and improved EHR technologies could more efficiently complete the testing and certification processes and, ultimately, more quickly reach the market.

What matters most for gap certification is how an edition’s “new,” “revised,” and “unchanged” certification criteria are distributed. The more “unchanged” certification criteria there are in an edition, the more criteria are available for gap certification and therefore the more streamlined new certifications to that edition can be (i.e., less of a “big lift” for developers). The following table shows how the 2011 and 2014 Editions criteria were distributed and how the 2015 Edition would be distributed as proposed. As the table illustrates, the 2015 Edition provides developers with the opportunity for significant gap certification efficiencies.

	Ambulatory Criteria	Inpatient Criteria
2011 Edition	<div style="border: 1px solid black; padding: 5px; text-align: center;"> 100% N (baseline) </div> n = 33	<div style="border: 1px solid black; padding: 5px; text-align: center;"> 100% N (baseline) </div> n = 32
2014 Edition	<div style="display: flex; justify-content: space-around; align-items: center;"> <div style="border: 1px solid black; padding: 2px; text-align: center;"> 20% U </div> <div style="border: 1px solid black; padding: 2px; text-align: center;"> 50% R </div> <div style="border: 1px solid black; padding: 2px; text-align: center;"> 30% N </div> </div> n = 9 22 13	<div style="display: flex; justify-content: space-around; align-items: center;"> <div style="border: 1px solid black; padding: 2px; text-align: center;"> 22% U </div> <div style="border: 1px solid black; padding: 2px; text-align: center;"> 51% R </div> <div style="border: 1px solid black; padding: 2px; text-align: center;"> 27% N </div> </div> n = 10 23 12
2015 Edition	<div style="display: flex; justify-content: space-around; align-items: center;"> <div style="border: 1px solid black; padding: 2px; text-align: center;"> 52% U </div> <div style="border: 1px solid black; padding: 2px; text-align: center;"> 33% R </div> <div style="border: 1px solid black; padding: 2px; text-align: center;"> 15% N </div> </div> n = 28 18 8	<div style="display: flex; justify-content: space-around; align-items: center;"> <div style="border: 1px solid black; padding: 2px; text-align: center;"> 53% U </div> <div style="border: 1px solid black; padding: 2px; text-align: center;"> 32% R </div> <div style="border: 1px solid black; padding: 2px; text-align: center;"> 15% N </div> </div> n = 28 17 8

U = Unchanged; R= Revised; N=New

2015 Edition Certification

Compliance with the 2015 Edition would be voluntary. **No** EHR technology developer who has certified its EHR technology to the 2014 Edition would need to recertify to the 2015 Edition for its customers to participate in the Medicare and Medicaid EHR Incentive Programs. Correspondingly, EPs, EEs, and CAHs that participate in the Medicare and Medicaid EHR Incentive Programs **would not** need to “upgrade” to EHR technology certified to 2015 Edition criteria to have EHR technology that meets these programs’ Certified EHR Technology (CEHRT) definition.

As a result, EHR technology developers and EPs, EEs, and CAHs would have the opportunity to move ahead to the 2015 Edition at their own pace and on their own terms. However, if EHR technology developers were to certify EHR technology to the 2015 Edition, eligible providers would be able to use such EHR technology to meet the Certified EHR Technology definition for purposes of participating in the Medicare and Medicaid EHR Incentive Programs, either in combination with EHR technology certified to the 2014 Edition or instead of 2014 Edition EHR technology.