

Summary of Public Health Related Aspects of Recent ONC and CMS Final Rules Version 1.0

Summary of Public Health Related Aspects of Recent ONC and CMS Final Rules Version 1.0

Table of Contents

1	Introduction	2
2	CMS and ONC 2014 CEHRT Flexibility Final Rule	3
2.1	Reasons for Changes	3
2.2	Key Aspects	3
2.2.1	Attestation Flexibility for MU Stage and Use of CEHRT in 2014	3
2.2.2	Required CEHRT Edition in 2015 and Beyond	4
2.2.3	No Change to Schedule of Participation for Providers in the Medicare EHR Incentive Program 4	
2.2.4	Stage 2 Extended Through 2016	5
2.2.5	Additional Test Message in 2014 for Public Health Objectives May Not Be Required	5
2.2.6	2014 Edition CEHRT Required to Received AUI Medicaid Payment for AUI in 2014	6
2.2.7	Additional Provisions or Changes	6
3	ONC 2014 Edition Release 2 Certification Criteria	7
3.1	Key Aspects	7
3.1.1	2014 Edition Release 2 (Optional Certification)	7
3.1.2	New EHR Certification Criteria Edition Naming Approach	7
3.2	Public Health Impact	7
3.2.1	New Optional Certification Criteria for Syndromic Surveillance – Ambulatory Setting	7
3.2.2	Syndromic Surveillance IG 1.9 Not adopted for Inpatient Certification	9

Summary of Public Health Related Aspects of Recent ONC and CMS Final Rules Version 1.0

1 Introduction

The Stage 2 Meaningful Use (MU) final rules were published in the Federal Register on September 4th, 2012. During 2014, the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) released additional final rules related to MU.

- On September 4, 2014, CMS and ONC released a final rule that grants flexibility to providers who are unable to fully implement 2014 Edition Certified Electronic Health Record Technology (CEHRT) for an EHR reporting period in 2014 due to delays in 2014 Edition CEHRT availability.

Title of Final Rule: Medicare and Medicaid Programs; Modifications to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program for 2014 and Other Changes to the EHR Incentive Program; and Health Information Technology: Revisions to the Certified EHR Technology Definition and EHR Certification Changes Related to Standards

Document Citation: 79 FR 52909

Federal Register URL: <https://www.federalregister.gov/articles/2014/09/04/2014-21021/medicare-and-medicare-programs-modifications-to-the-medicare-and-medicare-electronic-health-record>

PDF Document URL: <http://www.gpo.gov/fdsys/pkg/FR-2014-09-04/pdf/2014-21021.pdf>

- On September 11, 2014, ONC released a final rule that introduces regulatory flexibilities and general improvements for certification to the 2014 Edition EHR certification criteria (2014 Edition).

Title of Final Rule: 2014 Edition Release 2 Electronic Health Record (EHR) Certification Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange

Document Citation: 79 FR 54429

Federal Register URL: <https://www.federalregister.gov/articles/2014/09/04/2014-21021/medicare-and-medicare-programs-modifications-to-the-medicare-and-medicare-electronic-health-record>

PDF Document URL: <http://www.gpo.gov/fdsys/pkg/FR-2014-09-04/pdf/2014-21021.pdf>

This document will provide a summary of the public health related aspects of these two final rules.

Summary of Public Health Related Aspects of Recent ONC and CMS Final Rules Version 1.0

2 CMS and ONC 2014 CEHRT Flexibility Final Rule

Final Rule Summary: “This final rule changes the meaningful use stage timeline and the definition of certified electronic health record technology (CEHRT) to allow options in the use of CEHRT for the EHR reporting period in 2014. It also sets the requirements for reporting on meaningful use objectives and measures as well as clinical quality measure (CQM) reporting in 2014 for providers who use one of the CEHRT options finalized in this rule for their EHR reporting period in 2014. In addition, it finalizes revisions to the Medicare and Medicaid EHR Incentive Programs to adopt an alternate measure for the Stage 2 meaningful use objective for hospitals to provide structured electronic laboratory results to ambulatory providers; to correct the regulation text for the measures associated with the objective for hospitals to provide patients the ability to view online, download, and transmit information about a hospital admission; and to set a case number threshold exemption for CQM reporting applicable for eligible hospitals and critical access hospitals (CAHs) beginning with FY 2013. Finally, this rule finalizes the provisionally adopted replacement of the Data Element Catalog (DEC) and the Quality Reporting Document Architecture (QRDA) Category III standards with updated versions of these standards.” (79 FR 52909, page 52910)

2.1 Reasons for Changes

This final rule identified several reasons for making changes to the Medicare and Medicaid EHR Incentive Programs for 2014. Some of the reasons noted are:

- Many EHR vendors indicated there was insufficient time after the Stage 2 Final Rule was published to make the required modifications to enable their EHR products to be certified to the 2014 Edition EHR Certification Criteria.
- Due to backlogs and certification case load many EHR products were certified later than originally planned, which limited the time available for providers to deploy 2014 Edition CEHRT and prepared to demonstrate MU in 2014.
- The large number of providers required to upgrade to 2014 Edition CEHRT to meet MU in 2014 resulted in installation and implementation backlogs.

2.2 Key Aspects

2.2.1 Attestation Flexibility for MU Stage and Use of CEHRT in 2014

This final rule grants flexibility that allows eligible professionals (EPs), eligible hospitals (EHs), and critical access hospitals (CAHs) that could not fully implement 2014 Edition CEHRT for an EHR reporting period in 2014, due to delays in 2014 Edition CEHRT availability, to use 2011 Edition CEHRT or a combination of 2011 Edition and 2014 Edition CEHRT for the EHR reporting periods in 2014. These alternatives are available only for those providers that could not fully implement 2014 Edition CEHRT to meet meaningful use for an EHR reporting period in 2014 due to delays in 2014 Edition CEHRT availability. The flexibility includes options to attest to Stage 1 objectives since 2011 Edition CEHRT alone doesn't have

Summary of Public Health Related Aspects of Recent ONC and CMS Final Rules Version 1.0

the necessary functionality required to meet Stage 2 objectives and measures. The options include the requirements for clinical quality measure (CQM) reporting for providers.

The following tables show the options available to providers scheduled for Stage 1 MU in 2014 (**Table 1**) and Stage 2 MU in 2014 (

Table 2) based on their use of 2011 and/or 2014 Edition CEHRT.

Table 1 - Options for Providers Scheduled to Meet Stage 1 in 2014

Options for Providers Scheduled to Meet Stage 1 MU in 2014		
Using 2011 Edition CEHRT to do:	Using 2011 & 2014 Edition CEHRT to do:	Using 2014 Edition CEHRT to do:
<ul style="list-style-type: none"> ✓ 2013 Definition Stage 1 objectives and 2013 CQMs** 	<ul style="list-style-type: none"> ✓ 2013 Definition Stage 1 objectives and 2013 CQMs**; or ✓ 2014 Definition Stage 1 objectives and 2014 CQMs** 	<ul style="list-style-type: none"> ✓ 2014 Definition Stage 1 objectives and 2014 CQMs
<p><i>** Only providers that could not fully implement 2014 Edition CEHRT for the reporting period in 2014 due to delays in 2014 Edition CEHRT availability.</i></p>		

Table 2 - Options for Providers Scheduled to Meet Stage 2 in 2014

Options for Providers Scheduled to Meet Stage 2 MU in 2014		
Using 2011 Edition CEHRT to do:	Using 2011 & 2014 Edition CEHRT to do:	Using 2014 Edition CEHRT to do:
<ul style="list-style-type: none"> ✓ 2013 Definition Stage 1 objectives and 2013 CQMs** 	<ul style="list-style-type: none"> ✓ 2013 Definition Stage 1 objectives and 2013 CQMs**; or ✓ 2014 Definition Stage 1 objectives and 2014 CQMs**; or ✓ Stage 2 objectives and 2014 CQMs** 	<ul style="list-style-type: none"> ✓ 2014 Definition Stage 1 objectives and 2014 CQMs**; or ✓ Stage 2 objectives and 2014 CQMs
<p><i>** Only providers that could not fully implement 2014 Edition CEHRT for the reporting period in 2014 due to delays in 2014 Edition CEHRT availability.</i></p>		

The options shown in **Table 1** and

Table 2 are the provider's EHR reporting period in 2014 only.

2.2.2 Required CEHRT Edition in 2015 and Beyond

All providers must use 2014 edition CEHRT for the EHR reporting periods in 2015 and in subsequent years or until new certification requirements are adopted in subsequent rulemaking.

Summary of Public Health Related Aspects of Recent ONC and CMS Final Rules Version 1.0

2.2.3 No Change to Schedule of Participation for Providers in the Medicare EHR Incentive Program

The MU Stages and years progress consecutively for the Medicare EHR Incentive Program and this final rule does not alter the schedule of participation. Here is an excerpt from this final rule:

“The schedule of participation for a provider in the Medicare EHR Incentive Program for 2015 and subsequent years is not altered under this rule. For example, if a provider in the Medicare program first demonstrates meaningful use in 2012 that is Stage 1 Year 1 for that provider. Subsequently, the stages and years progress consecutively for the Medicare EHR Incentive Program whether or not the provider meets meaningful use; or whether or not the provider uses a different CEHRT option in 2014. So a Medicare provider who does Stage 1 Year 1 in 2012 would be in Stage 2 Year 2 in 2015 regardless of their participation in the intervening years.” (79 FR 52909, Pages: 52925-52926)

2.2.4 Stage 2 Extended Through 2016

Stage 2 is extended through CY 2016 for EPs and FY 2016 for EEs and CAHs that started MU in CY/FY 2011 or 2012. These providers will begin Stage 3 in CY or FY 2017, respectively. The Stage 3 requirements will be defined in future rulemaking. **Table 3** shows the revised MU timeline with Stage 3 starting in 2017.

Table 3 - Revised to MU Timeline

STAGE OF MEANINGFUL USE CRITERIA BY FIRST PAYMENT YEAR											
First Payment Year	Stage of Meaningful Use										
	2011	2012	2013	2014**	2015	2016	2017	2018	2019	2020	2021
2011	1	1	1	1* or 2	2	2	3	3	TBD	TBD	TBD
2012		1	1	1* or 2	2	2	3	3	TBD	TBD	TBD
2013			1	1	2	2	3	3	TBD	TBD	TBD
2014				1	1	2	2	3	3	TBD	TBD
2015					1	1	2	2	3	3	TBD
2016						1	1	2	2	3	3
2017							1	1	2	2	3

* The CMS and ONC 2014 CEHRT Flexibility Final Rule may allow some providers scheduled for Stage 2 to attest to Stage 1 objectives.
 ** 3-month quarter EHR reporting period for Medicare and continuous 90-day EHR reporting period (or 3 months at State option) for Medicaid EPs. All providers in their first year in 2014 use any continuous 90-day EHR reporting period.

Summary of Public Health Related Aspects of Recent ONC and CMS Final Rules Version 1.0

2.2.5 Additional Test Message in 2014 for Public Health Objectives May Not Be Required

If a provider sent a test message to a public health agency for one of the public health MU objectives in prior EHR reporting period, and uses of the Stage 1 flexibility options, the provider is not required to send another test message during their 2014 EHR reporting period to meet the measure (79 FR 52909, Page: 52923)

2.2.6 2014 Edition CEHRT Required to Received AUI Medicaid Payment for AIU in 2014

To receive an incentive payment in 2014 for “adopt, implement, upgrade” (AIU) under Medicaid, EPs will need to adopt, implement, or upgrade to 2014 Edition CEHRT only. This provision discourages the purchase of 2011 Edition CEHRT that could not be used to meet MU in subsequent years.

2.2.7 Additional Provisions or Changes

- The ONC regulation (45 CFR 170.102) which defined CEHRT was modified to allow for the continued use of 2011 Edition CEHRT by providers to meet MU for an EHR reporting period in 2014. This change was necessary to align with the 2014 CEHRT flexibility options.
- In the final rule the term “vendor” is expanded to include developers who create or develop health IT.

Summary of Public Health Related Aspects of Recent ONC and CMS Final Rules Version 1.0

3 ONC 2014 Edition Release 2 Certification Criteria

Final Rule Summary: “This final rule introduces regulatory flexibilities and general improvements for certification to the 2014 Edition EHR certification criteria (2014 Edition). It also codifies a few revisions and updates to the ONC HIT Certification Program for certification to the 2014 Edition and future editions of certification criteria as well as makes administrative updates to the Code of Federal Regulations.” (79 FR 54429, page 54430)

3.1 Key Aspects

3.1.1 2014 Edition Release 2 (Optional Certification)

The 2014 Edition Release 2 EHR Certification Criteria (2014 Edition Release 2) are designated as “optional”. Therefore, EHR technology for the in-patient and ambulatory settings would not need to be certified to optional criteria to be issued a Complete EHR Certification. EHR technology developers are not required to update and recertify their products to the 2014 Edition Release 2 and eligible providers (EPs, EHS, and CAHs) are not required to upgrade to 2014 Edition Release 2 CEHRT. However, ONC encourages EHR technology developers and eligible providers to consider whether the 2014 Edition Release 2 offers any opportunities or advantages that they may want to pursue.

The 2014 Edition Release 2 final rule adopted ten optional 2014 Edition EHR certification criteria and two revised 2014 Edition EHR certification criteria that provide flexibility, clarity, and enhance health information exchange. The adopted criteria include a subset from the Proposed Rule for a Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria issue by ONC on February 26, 2014

3.1.2 New EHR Certification Criteria Edition Naming Approach

Previous editions of EHR certification criteria were named for the first year when ONC would expect compliance to support the EHR Incentive Programs (e.g., 2011 and 2014 Editions). Going forward, ONC will editions of certification criteria by the year in which the final rule is released.

Other rulemakings like the 2014 Edition Release 2 final rule, which include additional criteria or alternatives to previously adopted certification criteria but do not adopt an edition of certification criteria, would be added to the most current edition of certification criteria (e.g., [current edition year] Release #X).

3.2 Public Health Impact

3.2.1 New Optional Certification Criteria for Syndromic Surveillance – Ambulatory Setting

The 2014 Edition criterion required the use of the HL7 2.5.1 standard. At the time, ONC expected the industry to develop an HL7 2.5.1 Implementation Guide (IG) for ambulatory (and non-urgent care)

Summary of Public Health Related Aspects of Recent ONC and CMS Final Rules Version 1.0

syndromic surveillance. However to date the industry has not developed HL7 2.5.1 Implementation Guide (IG) for syndromic surveillance in ambulatory and non-urgent care settings.

To promote providers' ability to achieve the MU syndromic surveillance objective for Stage 2 in ambulatory and non-urgent care settings, ONC is permitting EHR technology to certify to an optional criterion that allows any electronic method of transmission.

- ONC has adopted an optional 2014 Edition "syndromic surveillance" certification criterion (§ 170.314(f)(7)) for the ambulatory setting.
- This optional certification criterion on "syndromic surveillance" permits EHR technology designed for the ambulatory setting to simply demonstrate that it can electronically create syndrome-based public health surveillance information for electronic submission (using any method or standard) to be certified to this criterion.

This provides certification flexibility and potential EP flexibility, while also providing a path forward.

Because there is no current IG that supports ambulatory syndromic surveillance data submission using query-based standards, ONC 2014 Ed. Release 2.0 Certification criteria included an optional set of data elements within this optional certification criterion to provide some additional specificity and to which EHR technology developers may choose to have their EHR technology certified. These data elements are:

- Patient demographics
- Provider specialty
- Provider address
- Problem list
- Vital signs
- Laboratory results
- Procedures
- Medications
- Insurance

While the aforementioned data elements are optional for the purposes of demonstrating compliance to this certification criterion, if an EHR technology developer wishes to certify its EHR technology to this criterion as a whole, including the optional data set, the EHR technology would need to demonstrate that it can electronically produce syndromic surveillance information that contains all of the data elements.

Summary of Public Health Related Aspects of Recent ONC and CMS Final Rules Version 1.0

3.2.2 Syndromic Surveillance IG 1.9 Not adopted for Inpatient Certification

ONC has not adopted the IG Release 1.9 for inpatient certification to either the current “syndromic surveillance” certification criterion or the optional “syndromic surveillance” certification. Release 2.0 of the IG, will be considered for future rulemaking.