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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; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 495

[CMS–0046–F and CMS–0052–F]

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Office of the Secretary

45 CFR Part 170

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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

ACTION: Final rule.

AGENCY: Centers for Medicare & Medicaid Services (CMS), and Office of the National Coordinator for Health Information Technology (ONC), HHS.

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.

DATES: These regulations are effective on October 1, 2014.

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SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory Basis

1. Standards, Implementation Specifications, and Certification Criteria

The Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5) was enacted on February 17, 2009. The HITECH Act amended the Public Health Service Act (PHSA) and created ''Title XXX—Health Information Technology and Quality'' to improve health care quality, safety, and efficiency through the promotion of health IT and electronic health information exchange.

Section 3004(b)(3) of the PHSA titled ''Subsequent Standards Activity'' provides that the ''Secretary shall adopt additional standards, implementation specifications, and certification criteria as necessary and consistent'' with the schedule published by the HIT Standards Committee. We consider this provision in the broader context of the HITECH Act to grant the Secretary the authority and discretion to adopt standards, implementation specifications, and certification criteria that have been recommended by the HIT Standards Committee and endorsed by the National Coordinator, as well as other appropriate and necessary health IT standards, implementation specifications, and certification criteria.

In the September 4, 2012 **Federal Register** (77 FR 54163), the Secretary issued a final rule (the ''2014 Edition EHR certification criteria final rule'') that adopted the 2014 Edition EHR certification criteria and a revised Certified EHR Technology (CEHRT) definition. The standards, implementation specifications, and certification criteria adopted by the Secretary in the final rule established the capabilities that CEHRT must include in order to, at a minimum, support the achievement of meaningful use by eligible professionals (EPs), eligible hospitals, and CAHs under the Medicare and Medicaid EHR Incentive Programs beginning with the EHR reporting periods in FY/CY 2014.

2. Health IT Certification Programs

Section 3001(c)(5) of the PHSA provides the National Coordinator with the authority to establish a certification program or programs for the voluntary certification of health IT. Specifically, section 3001(c)(5)(A) specifies that the ''National Coordinator, in consultation with the Director of the National Institute of Standards and Technology, shall keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted under this subtitle'' (that is, certification criteria adopted by the Secretary under section 3004 of the PHSA). The certification program(s) must also ''include, as appropriate, testing of the technology in accordance with section 13201(b) of the [HITECH] Act.''

Section 13201(b) of the HITECH Act requires that with respect to the development of standards and implementation specifications, the Director of the National Institute of Standards and Technology (NIST), in coordination with the HIT Standards Committee, ''shall support the establishment of a conformance testing infrastructure, including the development of technical test beds.'' The HITECH Act also indicates that ''[t]he development of this conformance testing infrastructure may include a program to accredit independent, non-Federal laboratories to perform testing.'' ONC has established the ONC HIT Certification Program for the purpose of testing and certifying health information technology, related to the compliance of health IT with adopted standards, implementation, and certification criteria. (see 76 FR 1262 and 77 FR 54268). EHR technology capabilities certified through the ONC HIT Certification Program are required for use with the EHR Incentive Programs (see 76 FR 1262).

3. Medicare and Medicaid EHR Incentive Programs

The American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5) amended Titles XVIII and XIX of the Social Security Act (the Act) to authorize incentive payments to EPs, eligible hospitals, CAHs, and Medicare Advantage (MA) organizations to promote the adoption and meaningful use of certified electronic health record (EHR) technology. Sections 1848(o), 1853(l) and (m), 1886(n), and 1814(l) of the Act provide the statutory basis for the Medicare incentive payments made to meaningful EHR users. These statutory provisions govern EPs, MA

organizations (for certain qualifying EPs and hospitals that meaningfully use CEHRT, subsection (d) hospitals, and CAHs, respectively. Sections 1848(a)(7), 1853(l) and (m), 1886(b)(3)(B), and 1814(l) of the Act also establish downward payment adjustments, beginning with calendar or fiscal year 2015, for EPs, MA organizations, subsection (d) hospitals, and CAHs that are not meaningful users of CEHRT for certain associated reporting periods. Sections 1903(a)(3)(F) and 1903(t) of the Act provide the statutory basis for Medicaid incentive payments.

II. Provisions of the December 7, 2012 Interim Final Rule With Comment Period and Analysis of and Responses to Public Comments

In the December 7, 2012 **Federal Register** (77 FR 72985), CMS and ONC jointly published an interim final rule with comment period (IFC) titled ''Health Information Technology: Revisions to the 2014 Edition Electronic Health Record Certification Criteria; and Medicare and Medicaid Programs; Revisions to the Electronic Health Record Incentive Program'' (the ''December 7, 2012 IFC''). The Department of Health and Human Services (HHS) issued the December 7, 2012 IFC to replace the Data Element Catalog (DEC) standard and the Quality Reporting Document Architecture (QRDA) Category III standard adopted in the final rule published on September 4, 2012 in the **Federal Register** with updated versions of those standards. The December 7, 2012 IFC also revised the Medicare and Medicaid EHR Incentive Programs by: adding an alternative measure for the Stage 2 meaningful use objective for hospitals to provide structured electronic laboratory results to ambulatory providers; correcting 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 making the case number threshold exemption for CQM reporting applicable for eligible hospitals and CAHs beginning with FY 2013. This December 7, 2012 IFC also provided notice of CMS's intention to issue technical corrections to the electronic specifications for CQMs released on October 25, 2012.

In this final rule, we discuss the provisions of the December 7, 2012 IFC and describe our final policy. No comments within the scope of the IFC were timely received. However, we received some comments outside the scope of the December 7, 2012 IFC which provided recommendations for potential standards and policies to adopt in rulemaking for future stages of meaningful use. We are not addressing these comments in this rule. However, we will retain these comments for consideration in future rulemaking for the EHR Incentive Programs.

A. Adoption and Incorporation by Reference of Newer Versions of the DEC and QRDA III Standards

In the 2014 Edition EHR certification criteria final rule (77 FR 54163), we adopted the Data Element Catalog (DEC), August 2012 version, standard at 45 CFR 170.204(c) and incorporated the standard by reference at 45 CFR 170.299(m)(5). The DEC is included in the certification criterion at 45 CFR 170.314(c)(1), which requires EHR technology presented for certification to be able to electronically record all of the data identified in the DEC that would be necessary to calculate each CQM.

Prior to the December 7, 2012 IFC (77 FR 72987), we performed a gap analysis to determine whether the August 2012 version of DEC (now referred to as ''DEC version 1.0'') still appropriately specified all of the data that EHR technology would need to capture to support the final 2014 CQM e-specifications. Based on that analysis, we determined that the version of the DEC we adopted in the final rule needed to be updated in order to correctly align with data capture expectations expressed by numerous 2014 CQM e-specifications. Therefore, we provisionally adopted replacing Version 1.0 of the DEC incorporated by reference at 45 CFR 170.299(m)(5) with the updated version (DEC, Version 1.1 (October 2012)) as the standard referenced by the 2014 Edition EHR certification criterion at 45 CFR 170.314(c)(1).

We also replaced the version of the Quality Reporting Document Architecture (QRDA) Category III (QRDA III) standard incorporated by reference at 45 CFR 170.299(f)(14) with the November 2012 balloted version of QRDA III as the standard referenced by the 2014 Edition EHR certification criterion at 45 CFR 170.314(c)(3). The November 2012 balloted version of QRDA III clarifies ambiguities in the August version we had previously adopted in the 2014 Edition EHR certification criteria final rule (77 FR 54232); specifically, certain data that would need to be included in any QRDA III file submitted to CMS, such as a provider's National Provider Identifier (NPI) or Taxpayer Identification Number (TIN) in order for the electronic submission to be properly processed. Additionally, some of the required components have been changed to optional in the November 2012 balloted version of the standard, which may reduce the burden for EHR technology developers.

While ONC is not required by statute to publish a final rule based on the previous publication of an interim final rule, we are using this joint rulemaking as an opportunity to respond to comments received on the December 7, 2012 IFC provisions concerning 45 CFR 170.299.

We received no comments on the provisions concerning the DEC and QRDA III standards. For the reasons stated in the December 7, 2012 IFC, we are finalizing these provisions without modification.

B. Revisions to the Medicare and Medicaid EHR Incentive Programs

1. Meaningful Use Criteria

a. Stage 2 Hospital Objective for Providing Electronic Lab Results to Ambulatory Providers

In the Stage2 final rule (77 FR 54041 through 54043), we included an objective and measure in the Stage 2 menu set for eligible hospitals and CAHs at 42 CFR 495.6(m)(6)(i) and (ii) to provide structured electronic lab results to ambulatory providers for more than 20 percent of electronic lab orders received.

In the December 7, 2012 IFC we added an alternative measure allowing a method for calculating the denominator using all lab orders received rather than only those received electronically. This change was provisionally adopted to accommodate cases where hospitals send a large number of lab results electronically in response to orders they receive through non-electronic means or where a hospital receives a very small percentage of its total lab orders electronically and therefore could have difficulty meeting the measure threshold regardless of the number of lab results it sends electronically to ordering providers.

We received no comments on this provision and are finalizing this provision without modification for the reasons previously stated.

b. Stages 1 and 2 Hospital Objective for View, Download, and Transmit

In the Stage 2 final rule (77 FR 54041 through 54043), we included the following objective in the Stage 2 core set for eligible hospitals and CAHs at 42 CFR 495.6(l)(8)(i) and (ii). We also included the objective in the Stage 1 core set for eligible hospitals and CAHs at 42 CFR 495.6(f)(12)(i)(B) and (ii)(B).

Objective: Provide patients the ability to view online, download, and transmit information about a hospital admission.

In the Stage 2 final rule (77 FR 53968), we inadvertently omitted the word ''unique'' from the regulation text for the denominators of the measures associated with this objective.

In the December 7, 2012 IFC we made corrections to § 495.6(f)(12)(ii)(B), (l)(8)(ii)(A), and (l)(8)(ii)(B) to clarify that the measures for that objective for eligible hospitals and CAHs are based on the number of unique patients discharged from a hospital's inpatient or emergency department during the EHR reporting period.

We received no comments on this provision and are finalizing this provision without modification for the reasons previously stated.

2. Case Number Threshold Exemption for CQM Reporting for Hospitals

In the Stage 2 proposed rule, we solicited comments on whether a case number threshold would be appropriate for hospital CQM reporting, given the apparent burden on hospitals that very seldom have the types of cases addressed by certain measures. As we stated in the Stage 2 final rule (77 FR 54080), many commenters noted that the implementation of a case number threshold for hospital CQM reporting would help reduce the burden placed on hospitals that very seldom have cases that would be counted in the denominator of certain CQMs.

In the December 7, 2012 IFC we provisionally adopted a case threshold exemption applicable for eligible hospitals and CAHs in all stages of meaningful use beginning with FY 2013. Eligible hospitals and CAHs that demonstrate meaningful use for the first time and submit their CQMs using attestation would be able to qualify for the exemption. Eligible hospitals and CAHs with 5 or fewer discharges during the relevant EHR reporting period (if attesting to a 90-day EHR reporting period), or 20 or fewer discharges during the year (if attesting to a full year EHR reporting period) as defined by the CQM's denominator population could claim an exemption for that CQM.

To be eligible for the exemption, Medicare-eligible hospitals and CAHs must use the same process outlined in the Stage 2 final rule (see 77 FR 54080). This process includes submitting aggregate population and sample size counts for Medicare and non-Medicare discharges as defined by the CQM's denominator population for the EHR reporting period no later than November 30 after the end of the fiscal year containing the EHR reporting period (for example, November 30, 2013 for the hospital's EHR reporting period that occurs in FY 2013). Medicaid-only hospitals, including children's hospitals, must report this same information to the state to which they attest, in a manner specified by that state.

We received no comments on this provision and we are finalizing this provision without modification for the reasons previously stated.

3. Technical Corrections to CQM Electronic Specifications

In the interim final rule with comment period, we announced our intent to issue technical corrections to the electronic specifications for the 2014 CQMs on or around December 21, 2012.

We received no comments on this provision and we are finalizing this provision without modification for the reasons previously stated.

III. Provisions of the May 23, 2014 Proposed Rule and Analysis of and Responses to Public Comments

In the May 23, 2014 **Federal Register** (79 FR 29732), we published a proposed rule titled ''Medicare and Medicaid Programs; Modifications to the Medicare and Medicaid Electronic Health Record Incentive Programs for 2014; and Health Information Technology: Revisions to the Certified EHR Technology Definition.'' In this final rule, we discuss the provisions of that proposed rule, summarize and respond to the public comments timely received, and describe our final policy.

In sections 1848(o)(2)(A) and 1886(n)(3)(A) of the Act, the Congress identified the broad goal of expanding the use of EHRs through the concept of meaningful use. Section 1903(t)(6)(C) of the Act also requires Medicaid providers adopt, implement, upgrade, or meaningfully use CEHRT if they are to receive incentives under Title XIX of the Act. CEHRT used in a meaningful way is one piece of the broader health information technology infrastructure needed to reform the health care system and improve health care quality, efficiency, and patient safety. This vision of reforming the health care system and improving health care quality, efficiency, and patient safety should inform the definition of meaningful use.

Certified EHR technology is defined for the Medicare and Medicaid EHR Incentive Programs at 42 CFR 495.4, which references the Office of the National Coordinator for Health Information Technology's (ONC) definition of CEHRT under 45 CFR 170.102. For Stages 1 and 2 of meaningful use, CMS and ONC worked closely to ensure that the definition of meaningful use of CEHRT and the standards and certification criteria for CEHRT were coordinated. The definition of CEHRT under 45 CFR 170.102 requires, beginning with Federal fiscal year (FY) and calendar year (CY) 2014, EHR technology certified to the 2014 Edition EHR certification criteria. Therefore, all EPs, eligible hospitals, and CAHs must use 2014 Edition CEHRT to meet meaningful use under the Medicare and Medicaid EHR Incentive Programs beginning with FY 2014 and CY 2014.

On September 4, 2012, we published in the **Federal Register** (77 FR 53968 through 54162) a final rule titled ''Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2,'' that established, among other final policies, the timeline for the stages of meaningful use through 2021 and the EHR reporting periods in 2014, as shown in Table 1 (77 FR 53973 through 53975).

TABLE 1—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	*2	2	3	3	TBD	TBD	TBD	TBD
2012	.....	1	1	*2	2	3	3	TBD	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

TABLE 1—STAGE OF MEANINGFUL USE CRITERIA BY FIRST PAYMENT YEAR—Continued

First payment year	Stage of meaningful use										
	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
2017	.....	.....	.....	.....	.....	.....	1	1	2	2	3

*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.

EPs, eligible hospitals, and CAHs that attest to meaningful use for an EHR reporting period in 2014 for their first year of Stage 2 or their second year of Stage 1 have a 3-month quarter EHR reporting period in CY 2014 (EPs) or FY 2014 (eligible hospitals and CAHs). For the Medicaid incentive payments for meaningful use, EPs have an EHR reporting period of any continuous 90-day period in CY 2014 as defined by the state Medicaid program, or, if the state so chooses, any 3-month CY quarter in 2014. EPs, eligible hospitals, and CAHs that demonstrate meaningful use for the first time in 2014 have an EHR reporting period of any continuous 90-day period in CY 2014 or FY 2014, respectively.

A. Proposed Changes to Meaningful Use Stage Timeline and the Use of CEHRT

1. Reporting in 2014

We are revisiting some of the requirements for the Medicare and Medicaid EHR Incentive Programs for 2014. Many EHR vendors have indicated, through letters to CMS, public forums, listening sessions, survey data, and information related to the certification and testing process, that the amount of time available after the publication of the Stage 2 final rule was too short to make the required coding changes to enable their EHR products to be certified to the 2014 Edition of EHR certification criteria. We understand, based on information gained from EHR technology developers and ONC-Authorized Certification Bodies on timing, backlogs, and the certification case load, that many EHR products were certified later than anticipated. These late certifications impacted the corresponding time available to providers to effectively deploy 2014 Edition CEHRT and to make the necessary patient safety, staff training, system testing and workflow revisions in order to be prepared to demonstrate meaningful use in 2014. The availability of 2014 Edition CEHRT is further limited by the large number of providers needing to upgrade to 2014 Edition CEHRT. By the end of February 2014, over 350,000 providers received an EHR incentive payment for adopting, implementing, upgrading, or successfully demonstrating meaningful use with 2011 Edition CEHRT. In 2014, in order for providers to successfully demonstrate meaningful use for Stages 1 or 2, all eligible providers needed to adopt, implement, or upgrade to 2014 Edition CEHRT. However, through letters to CMS, public forums, listening sessions, and public comment at CMS meetings, many provider associations expressed concern that, although 2014 Edition CEHRT may be available for adoption, a several month backlog exists for the updated version to be installed and implemented so providers can successfully demonstrate meaningful use for an EHR reporting period in 2014. We also understand that the delay in availability may limit a provider's ability to fully implement 2014 Edition CEHRT across the facility. For example, a hospital may have different systems in multiple settings, which all require an update and integration. Alternatively, a provider may have certain 2014 Edition CEHRT functionality that, once implemented in a live setting, requires software patches or workflow changes.

Accordingly, in an effort to grant more flexibility to providers who experienced 2014 Edition CEHRT product availability issues that impact the ability to fully implement 2014 Edition CEHRT to meet meaningful use, we proposed some changes for the Medicare and Medicaid EHR Incentive Programs for 2014. We proposed to allow EPs, eligible hospitals, and 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 continue to use 2011 Edition CEHRT or a combination of 2011 Edition and 2014 Edition CEHRT for the EHR reporting periods in CY 2014 and FY 2014, respectively. These proposed 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.

We proposed these options for the use of CEHRT to meet meaningful use for an EHR reporting period in 2014 only. We will maintain the existing policy that all providers must use 2014 Edition CEHRT for the EHR reporting periods in CY 2015, FY 2015, and in subsequent years, or until new certification requirements are adopted in subsequent rulemaking.

Furthermore, in order to avoid inadvertently incentivizing the purchase of an outdated product that cannot be used to demonstrate meaningful use in a subsequent year, we proposed that to qualify for an incentive payment under Medicaid for 2014 for adopting, implementing, or upgrading CEHRT, a provider must adopt, implement, or upgrade to 2014 Edition CEHRT only. A provider would not be able to qualify for a Medicaid incentive payment for 2014 for adopting, implementing, or upgrading to 2011 Edition CEHRT or a combination of 2011 and 2014 Edition CEHRT. We proposed to revise the definition of ''Adopt, Implement or Upgrade'' under 42 CFR 495.302 to reflect this proposal.

The edition of certified EHR technology available to a provider dictates the stage and version of the meaningful use objectives and measures the provider will be able to meet. For example, 2011 Edition CEHRT alone does not have the necessary functionality required to meet the Stage 2 objectives and measures. In addition, the edition of CEHRT determines which CQMs a provider calculates and reports because calculations are part of the software programming within the CEHRT system.

The 3 options for the use of CEHRT editions and the available Stage of meaningful use objectives and measures associated with each option are as follows:

a. Using 2011 Edition CEHRT Only

We proposed that all EPs, eligible hospitals, and CAHs that use only 2011 Edition CEHRT for their EHR reporting period in 2014 must meet the meaningful use objectives and associated measures for Stage 1 under 42 CFR 495.6 that applied for the 2013 payment year, regardless of their current stage of meaningful use. We note that in the Stage 2 final rule (77 FR 53975 through 53979), we finalized certain changes to the Stage 1 objectives and associated measures, with some changes applying beginning with 2013, while other changes applying beginning with

2014. For ease of reference, we refer to the Stage 1 objectives and associated measures under 42 CFR 495.6 applicable for 2013 as the ''2013 Stage 1 objectives and measures,'' and refer to the Stage 1 objectives and associated measures under 42 CFR 495.6 applicable for 2014 as the ''2014 Stage 1 objectives and measures.'' Providers who choose this option must attest that they are unable to fully implement 2014 Edition CEHRT because of issues related to 2014 Edition CEHRT availability delays when they attest to the meaningful use objectives and measures.

b. Using a Combination of 2011 and 2014 Edition CEHRT

We proposed that all EPs, eligible hospitals, and CAHs using a combination of 2011 Edition CEHRT and 2014 Edition CEHRT for their EHR reporting period in 2014 may choose to meet the 2013 Stage 1 objectives and measures or the 2014 Stage 1 objectives and measures, or if they are scheduled to begin Stage 2 in 2014 under the timeline shown in Table 1, they may choose to meet the Stage 2 objectives and associated measures under 42 CFR 495.6. Providers who choose this option must attest that they are unable to fully implement 2014 Edition CEHRT because of issues related to 2014 Edition CEHRT availability delays when they attest to the meaningful use objectives and measures.

c. Using 2014 Edition CEHRT for 2014 Stage 1 Objectives and Measures in 2014 for Providers Scheduled to Begin Stage 2

A provider's ability to fully implement all of the functionality of 2014 Edition CEHRT may be limited by the availability and timing of product installation, deployment of new processes and workflows, and employee training. This effect is compounded for providers in Stage 2 as some providers may not be able to fully implement all of the functions included in 2014 Edition CEHRT necessary to meet the Stage 2 objectives and measures in time to complete the EHR reporting period in 2014. Therefore, under our proposal, providers scheduled to begin Stage 2 for the EHR reporting period in 2014 who cannot fully implement all the functions of their 2014 Edition CEHRT required for Stage 2 objectives and measures due to issues related to 2014 Edition CEHRT availability delays could use 2014 Edition CEHRT to attest to the 2014 Stage 1 objectives and measures for the EHR reporting period in 2014. Providers scheduled to begin Stage 2 in 2014 who choose this option must attest that they are unable to fully implement 2014 Edition CEHRT because of issues related to 2014 Edition CEHRT availability delays when they attest to the meaningful use objectives and measures.

The EHR reporting periods in 2014 already have been established, and we did not propose any changes. Under the current timeline shown in Table 1, providers that first demonstrated meaningful use Stage 1 in 2011 or 2012 must begin Stage 2 in 2014. We proposed that the options regarding use of the various editions of CEHRT outlined earlier applies only to the EHR reporting periods in 2014 for the EHR Incentive Program. Providers scheduled to begin Stage 2 in 2014 that instead meet the Stage 1 criteria in 2014 must begin Stage 2 in 2015 as noted in Table 3. In 2015, all providers, except those in their first year of demonstrating meaningful use, must report based on a full year EHR reporting period. In addition, in 2015, all providers must have 2014 Edition CEHRT in order to successfully demonstrate meaningful use.

TABLE 2—PROPOSED CEHRT SYSTEMS AVAILABLE FOR USE IN 2014

If you were scheduled to demonstrate:	You would be able to attest for Meaningful Use:		
	Using 2011 Edition CEHRT to do:	Using 2011 & 2014 Edition CEHRT to do:	Using 2014 Edition CEHRT to do:
Stage 1 in 2014	2013 Stage 1 objectives and measures*.	2013 Stage 1 objectives and measures* —OR— 2014 Stage 1 objectives and measures*	2014 Stage 1 objectives and measures.
Stage 2 in 2014	2013 Stage 1 objectives and measures*.	2013 Stage 1 objectives and measures* —OR— 2014 Stage 1 objectives and measures* —OR— Stage 2 objectives and measures*	2014 Stage 1 objectives and measures* —OR— Stage 2 objectives and measures.

* Only providers that could not fully implement 2014 Edition CEHRT for the EHR reporting period in 2014 due to delays in 2014 Edition CEHRT availability.

The following are example scenarios under our proposal.

Example A: An EP initiated participation in the Medicare EHR Incentive Program in 2011. The EP successfully demonstrated meaningful use and received incentive payments for 2011, 2012, and 2013. Based on the timeline in the Stage 2 final rule, the EP is required to use 2014 Edition CEHRT and demonstrate Stage 2 of meaningful use in 2014. Under our proposal, this EP who is scheduled to begin Stage 2 in 2014 would have the following options:

- Attest to the Stage 2 objectives and measures of meaningful use using 2014 Edition CEHRT in 2014 as scheduled.
- Attest to the Stage 2 objectives and measures of meaningful use using a combination of 2011 and 2014 Edition CEHRT in 2014 if they are unable to fully implement 2014 Edition CEHRT due to delays in 2014 Edition CEHRT availability.
- Attest to the 2014 Stage 1 objectives and measures using 2014 Edition CEHRT or a combination of 2011 and 2014 Edition CEHRT in 2014 if they are unable to fully implement 2014 Edition CEHRT due to issues related to 2014 Edition CEHRT availability delays.
- Attest to the 2013 Stage 1 objectives and measures using 2011 Edition CEHRT or a combination of 2011 and 2014 Edition CEHRT in 2014 if they are unable to fully implement 2014 Edition CEHRT due to issues related to 2014 Edition CEHRT availability delays. Clinical quality measures must be submitted through attestation if attesting to the 2013 Stage 1 objectives and measures as discussed in section III.B. of this final rule.

Example B: An EP initiated participation in the Medicare EHR Incentive Program in 2013. The EP successfully demonstrated meaningful use and received an incentive payment for 2013. Based on the timeline in the Stage 2 final rule, the EP is required to use 2014 Edition CEHRT and demonstrate Stage 1 of meaningful use in 2014. Under our proposal, this EP would have 1 of the following options:

- Attest using 2014 Edition CEHRT to the 2014 Stage 1 objectives and measures of meaningful use in 2014 as scheduled.
- Attest using a combination of 2011 and 2014 Edition CEHRT and meet the 2014 Stage 1 objectives and measures of meaningful use in 2014 if they are unable to fully implement

2014 Edition CEHRT due to delays in 2014 Edition CEHRT availability.

• Attest using 2011 Edition CEHRT or a combination of 2011 and 2014 Edition CEHRT and meet the 2013 Stage 1 objectives and measures of meaningful use in 2014 if they are unable to fully implement 2014 Edition CEHRT due to delays in 2014 Edition CEHRT availability. Clinical quality measures must be submitted through attestation if attesting to the 2013 Stage 1 objectives and measures as discussed in section II.B. of this rule.

Comment: The majority of commenters supported the proposals presented. Commenters explained that a wide range of EHR vendor and developer issues impeded successful implementation of 2014 Edition CEHRT. These issues include software installation difficulties, testing delays, repeated updates, and software issues that required costly and time-consuming manual corrections. Commenters also raised patient safety concerns about the potential for errors stemming from software glitches and crashes associated with 2014 Edition CEHRT. Some commenters explained that these software installation and implementation problems had a negative effect on productivity, record accuracy, and overall EHR operations because essential functions were not ready on time. Commenters stated that these EHR software delays and other problems have rendered it impossible for providers to adequately implement 2014 Edition CEHRT, train their staff, and test all the required functions in time to demonstrate meaningful use for an EHR reporting period in 2014. Other commenters, many with several years of Stage 1 experience, further point out their EHR vendors do not even have 2014 Edition CEHRT available for them to install so they have been unable to upgrade their CEHRT edition.

Many commenters added that waiting until 2015 to require the use of 2014 Edition CEHRT for an EHR reporting period will give everyone enough time to get their EHRs stabilized. This stabilization would allow providers to implement additional features, products, and workflows to successfully meet the objectives and measures of meaningful use. Accordingly, the overwhelming majority of commenters welcome the changes proposed.

Response: We appreciate the commenters and all stakeholders for the suggestions provided on the EHR Incentive Program. The large number of public comments received is a testament to the continued commitment among the health care and health IT industry to improving access to quality care for patients. We understand the changes required to move the EHR Incentive Program forward take time; and we have heard your concerns over the challenges of successfully implementing 2014 Edition CEHRT in time for an EHR reporting period in 2014. It is for this reason we proposed to offer providers options for the use of certified EHR technology in 2014. As confirmed by the overwhelming number of comments received in support of these proposals, we believe the changes proposed give providers the flexibility and time needed to adequately upgrade and fully implement 2014 Edition CEHRT. We look forward to working further with stakeholders as the next stages of the EHR Incentive Programs evolve, cognizant that stakeholder involvement remains critical to the continued success of this program.

We also note that throughout this final rule, as in the proposed rule, we use the term ''vendor.'' We have added the term developer to this reference as some commenters used this term, and we note that in some cases, the developer and the vendor may be different entities. In other cases, products may be developed by the provider which means that the products were not purchased from an external vendor. For purposes of this final rule, we clarify that the term ''vendor'' shall include developers who create or develop health IT.

Comment: Some commenters opposed the options for the use of CEHRT outlined in the proposed rule. These commenters explained that they successfully tested, upgraded, and implemented 2014 Edition CEHRT and characterized the proposals as unfair to those providers and EHR vendors who worked hard to ensure all Stage 2 requirements and software were ready on time. Some categorized these proposals as unfair to early adopters of EHR technology. These commenters believed the changes as proposed may provide a free pass to those who waited until the last minute to implement 2014 Edition CEHRT, and provide no benefit to those who are ready to move forward. Some commenters requested that we do not finalize this rule in any form, stating that although they acknowledge the EHR Incentive Programs presents some challenges, they believe some difficulties stem from stakeholders being simply unwilling to put in any effort.

Other commenters stated that we should not finalize the proposals because they believe the EHR Incentive Programs are already too complicated given the different stages and requirements. These commenters believed adding more changes only further complicates a program already in need of simplification.

Other commenters explained that the proposed rule should not be finalized because it does not support the effort to move the health care system forward, which is a clear goal of the EHR Incentive Programs and the meaningful use objectives and measures. These commenters expressed concern that the proposed changes might hinder the expansion of health information exchange; limit patients' access to their health care information; or delay the momentum of the EHR Incentive Program. These commenters stated that the changes supported by meaningful use, like providing beneficiaries with online access to their health information, represent a monumental achievement in health IT; and they expressed concern that the options for the use of CEHRT in 2014 may result in delays in this effort. Similarly, commenters were concerned that this would delay forward progress in interoperability, which would be contrary to Congress' intent in passing the HITECH Act and would limit the exchange of health care data between providers which supports the coordination of care.

Response: We appreciate those stakeholders who fully implemented 2014 Edition CEHRT and are able to meet the objectives and measures of meaningful use for an EHR reporting period in 2014. We understand the challenges faced in accomplishing that goal and wish to recognize the tremendous amount of work from providers and EHR vendors in meeting these objectives and helping to move health IT forward.

However, we disagree with these commenters to the extent the changes proposed somehow give providers that waited until the last minute a ''free pass'', or punish those providers who were early adopters. We received numerous comments, and verified through internal research on implementation and readiness, that EHR development and implementation delays caused many providers to be unable to fully implement 2014 Edition CEHRT. Our analysis further showed no identifiable correlation between a provider's efforts to prepare to demonstrate meaningful use—including successful past participation—and the ability to obtain and implement CEHRT in a practice setting. Many providers had no control over their position in their vendor's queue for CEHRT installation, no influence on a product's development timeline, and no participation in the product's movement through the certification process. All of

which may have also contributed to the overall delay in 2014 Edition CEHRT availability. It is for these reasons we proposed these changes. Our intent in proposing these options was not to further complicate the program, to provide a benefit to certain providers, or to penalize other providers. Rather, we sought to be responsive to stakeholder concerns by proposing options for providers who were unable to fully implement 2014 Edition CEHRT for an EHR reporting period in 2014 because of issues related to 2014 Edition CEHRT availability delays.

We note that several commenters raised concerns about the potential impact of these proposals on health IT interoperability. However, we believe that the proposed options for the use of CEHRT in the short term will support moving interoperability forward over the long term. Allowing providers additional time to fully implement the 2014 Edition CEHRT required for health information exchange will support efforts to expand the use of this technology on the whole and continue providers' efforts to incorporate electronic health information exchange and care coordination into their practices.

We also recognize the concerns expressed by commenters about how our proposals may affect patients and their families if progress on patient engagement initiatives is slowed. We understand that patients' electronic access to health information, supported by the meaningful use of EHR technology, comprises an integral part of improving patient-provider engagement and patient health literacy. Again, we believe that the short-term delay will allow for more providers to continue forward progress and begin providing essential health information to their patients through certified EHR technology.

In addition, we cannot ignore the overwhelming concern from providers, or the supporting data showing that many providers cannot successfully meet meaningful use for an EHR reporting period in 2014 using 2014 Edition CEHRT because of issues related to 2014 Edition CEHRT availability delays. We believe that giving additional time to providers who have not otherwise been able to fully implement 2014 Edition CEHRT in their practice will help them continue to make progress toward more advanced use of EHRs including the health information exchange and patient engagement objectives.

In addition, requiring providers to rush implementation despite significant obstacles does not improve health care outcomes or best serve patient safety as a whole. Rather, we believe that the options proposed will allow providers and EHR vendors sufficient time to upgrade and safely and effectively implement the 2014 Edition CEHRT, which, in turn, will result in better health outcomes for patients.

Finally, the actions involved in meeting the objectives and measures of meaningful use are not simply part of a reporting program, they are also based on changing behaviors and setting standards that drive toward improved clinical process and better outcomes for patients. For providers who could not otherwise participate because of a lack of 2014 Edition CEHRT, the allowance of flexibility in the use of CEHRT Editions means they may continue to be actively engaged in the processes and actions required by the program. For the 2013 Stage 1 objectives and measures, this includes providing important information to patients about their care, implementing patient safety measures like automated drug interaction and drug allergy checks, and reporting on public health data. These objectives help to move the EHR Incentive Programs forward and to support delivery system transformation efforts through health IT.

Comment: While most commenters support the proposal to provide options for providers using CEHRT to meet meaningful use in 2014, some commenters expressed concern about the cost and time required to modify state Medicaid EHR attestation systems to accommodate the program changes specified in the proposed rule. Some commenters requested that CMS allow states the flexibility to decline the changes proposed, or to make additional changes within state Medicaid EHR Incentive Programs beyond those proposed by CMS.

Response: We recognize the potential burden that these changes may have on state system development and enhancement activity, and are aware that the changes specified in the proposed rule may have implications for cost, timing, and system changes. In order to accommodate these changes, we are committed to working with individual states to update contracts and funding requests in Implementation-Advance Planning Documents (I–APDs) to enact the systems changes needed to support these policy changes. We remind states that enhanced Federal financial participation is available for EHR Incentive Program administration costs. We do not believe these concerns outweigh the benefits of the proposed options for the use of CEHRT, which we believe would enable providers who would otherwise be unable to meet meaningful use, to be able to do so in 2014.

Comment: Several commenters reported that the proposed rule would increase the complexity of an already difficult transition from Stage 1 to Stage 2 for many Medicaid EPs, and requested that we provide guidance to clarify any changes to the program that result from this final rule. Commenters requested clarification on whether this change is limited to the use of CEHRT for an EHR reporting period in 2014 for Medicaid given that state Medicaid programs must make administrative, system, and operational changes in response to the changes proposed, which may take significant time to complete.

Response: We recognize the additional complexity introduced under these proposals for providers participating in the Medicaid EHR Incentive Program, but we believe that the benefits of giving providers option for using CEHRT in 2014 to meet meaningful use will outweigh any additional confusion that may occur. We will provide ongoing technical assistance and appropriate materials to state staff and providers to help them understand how the changes in this rule affect participation in the Medicaid EHR Incentive Program. We stress that the changes regarding the options for using CEHRT are limited to the EHR reporting period in 2014 for both Medicare and Medicaid. For 2015 and subsequent years, we proposed no changes regarding the use of CEHRT or the stage of meaningful use a provider must attest to, except for the change in the Stage 3 start date.

Comment: Several commenters encouraged CMS to not adopt any changes or exclusions which affect the ability of providers serving patients residing in correctional facilities to meet the requirements of meaningful use.

Response: We appreciate the commenters' feedback. However, we did not propose any changes that would uniquely affect providers serving patients in correctional facilities.

Comment: We received numerous comments during this public comment period that were either unrelated to the EHR Incentive Program or outside the scope of the proposed rule. These comments included changes to Stage 2, requests for revisions to EHR reporting periods in years other than 2014, and suggestions for implementation of Stage 3.

Response: We thank all the commenters for their suggestions and feedback on the EHR Incentive Programs. However, comments

unrelated to the proposals fall outside the scope of the proposed rule and are not be addressed in this final rule.

Instead, we urge readers, especially those who provided comments pertaining to Stage 3, to wait until the release of the Stage 3 proposed rule to provide comments on this particular area.

Comment: We received multiple comments from providers on the delays in service and a perceived lack of communication from EHR vendors. Commenters stated that some vendors are still unable to provide them with 2014 Edition CEHRT, or that products they have in place have not yet been certified. Another provider requested that CMS compel EHR vendors to better communicate with their clients, especially in cases where they are not actively pursuing certification. These commenters stressed the need to be able to rely on EHR vendors, and the perceived lack of communication often inhibits trust in a business relationship. However, another commenter believed the proposed rule forced providers to blame vendors and system developers, in order to take advantage of the options for using CEHRT. This commenter added that such behavior did not foster a cooperative relationship between vendor and provider.

Response: We recognize the concern and need for effective and timely communication with EHR vendors during the EHR certification process. We are committed to working with our federal partners at the ONC and industry stakeholder groups representing EHR vendors to create and disseminate meaningful use related resources for use in supporting providers.

We stress that in this proposed rule, we did not intend to attribute fault to any stakeholder, including EHR vendors, always recognizing the success of this program hinges upon the cooperation of all stakeholders. Rather, the options we proposed recognize the overall difficulties and delays in the industry as a whole in getting 2014 Edition CEHRT fully certified and implemented in time for providers to use for an EHR reporting period in 2014.

Comment: Several commenters requested that we finalize this rule as quickly as possible and questioned the public comment period. A commenter stated that we did not specify the end of the comment period in the proposed rule. Other commenters requested that CMS either shorten or eliminate the public comment period entirely, or provide a definitive date for final rule implementation. In general, these commenters expressed concern that the comment period ending on July 21, 2014 would delay the implementation of the rule and effectively limit providers to using the 4th quarter as their EHR reporting period. These commenters expressed concern that this timeframe is not feasible for eligible hospitals because the fourth quarter of FY 2014 began on July 1, 2014, prior to the end of the comment period.

Response: We thank the commenters for their suggestions but respectfully disagree with the concerns raised. First, we disagree with the commenter that stated that we did not specify the end of the public comment period. The proposed rule, as pointed out by other commenters, specified that the comment period ended on July 21, 2014. The comment period allows us to receive invaluable feedback on the proposals and gain a better understanding of the impact they may have on providers and the health care industry.

Second, we acknowledge a perceived concern that the timing of this final rule effectively limits a provider's EHR reporting period in 2014 to the fourth quarter. However, we believe this concern stems largely from a misunderstanding of the EHR reporting periods and the time allowed for attestation. There are two related actions required to report on the objectives and measures to demonstrate meaningful use. The first is to capture data for an EHR reporting period, the second is to attest to that data in the EHR Incentive Programs Registration and Attestation System. First, providers may capture data for any EHR reporting period of a three-month quarter within 2014 (CY for EPs, FY for eligible hospitals and CAHs) using the options in this final rule. For example, a provider may meet the meaningful use objectives and measures using the options in this final rule during the first quarter EHR reporting period in 2014 (October 2013 through December 2013 for eligible hospitals and CAHs, January 2014 through March 2014 for EPs). Second, a provider may submit their data and attest to meaningful use at any point from the end of the selected EHR reporting period through the end of the attestation period. The attestation period does not open and close after each reporting period. The attestation period opens at the end of the first reporting period of the year and is open the remainder of the year and finally closes 2 months after the end of the year (CY for EPs, FY for eligible hospitals and CAHs), not at the end of any given EHR reporting period.

Therefore if an eligible hospital were unable to fully implement 2014 Edition CEHRT for an EHR reporting period in 2014 because of issues related to 2014 Edition CEHRT availability delays, the options provided in this rule would allow that eligible hospital to use 2011 Edition CEHRT, or a combination of 2011 and 2014 Edition CEHRT to meet meaningful use during any 3-month quarter EHR reporting period in FY 2014. That eligible hospital could select the first, second, third, or fourth quarter of FY 2014 as its EHR reporting period and attest to meeting the meaningful use objectives and measures at the end of the year. Therefore, the last quarter of the year is not the only available quarter which a provider may use for their EHR reporting period in 2014.

Comment: Some commenters wanted us to extend the options for the use of CEHRT we proposed for 2014 into 2015. These commenters stated the additional flexibility would allow time for providers and EHR vendors to adequately implement the technology. Another commenter suggested extending the options for using CEHRT into 2015 in order to align the program with the upcoming ICD–10 transition.

Response: The options detailed in the proposed rule apply to the use of CEHRT for the EHR reporting period in 2014 and do not extend to 2015 or subsequent years. We believe the options proposed for 2014 allow providers to continue moving forward with the meaningful use of certified EHR technology. However, to extend the proposed options for using CEHRT beyond the EHR reporting period in 2014 puts ongoing program goals at risk. We set the new standards for 2014 Edition CEHRT to achieve more advanced functionalities and drive toward enhanced information exchange and interoperability. We acknowledged in previous comment and response discussion that even these proposed options for the use of CEHRT represent some delay to forward progress. However, we believe our proposals would mitigate that delay by enabling more providers to participate in the program in 2014 while maintaining the requirement to use 2014 Edition CEHRT in 2015. But, allowing any further extension compounds the potential risk to health information exchange infrastructure and may detrimentally affect the alignment with related CMS programs such as PQRS and IQR. For these reasons, we did not propose extending the options for the use of CEHRT beyond 2014.

Comment: A few commenters questioned whether providers ready to move forward with attestations should still do so. These commenters questioned whether providers who have adopted and are live with 2014 Edition

CEHRT should use one of the CEHRT options proposed for the EHR reporting period in 2014. Some commenters further questioned if they should delay active installation of their 2014 Edition CEHRT to accommodate these changes.

Response: Providers who have fully implemented 2014 Edition CEHRT must attest to the objectives and measures for their stage of meaningful use for an EHR reporting period in 2014. The proposed options for using CEHRT are available only to those providers who are unable to fully implement 2014 Edition CEHRT for an EHR reporting period in 2014 because of issues related to 2014 Edition CEHRT availability delays.

We stated in the proposed rule that we strongly recommend EPs, eligible hospitals, and CAHs that have not yet purchased EHR technology to obtain 2014 Edition CEHRT as these providers will still need to use 2014 Edition CEHRT for their EHR reporting period in 2015. This also applies for providers in the process of installing or implementing 2014 Edition CEHRT. These providers should continue the implementation process as 2014 Edition CEHRT will be required for use for an EHR reporting period in 2015.

In addition, we proposed that a Medicaid provider must adopt, implement, or upgrade to only 2014 Edition CEHRT if they wish to qualify for the adopt, implement, or upgrade incentive payment under Medicaid for their first participation year. This was proposed in order to avoid inadvertently incentivizing the purchase of an outdated product that cannot be used to demonstrate meaningful use in a subsequent year.

Comment: A commenter requested clarification of what we meant by requiring Medicaid EPs to adopt, implement, or upgrade 2014 Edition CEHRT. The commenter questioned whether documentation of a plan to upgrade from older technology is sufficient.

Response: We proposed that to receive an incentive payment for ''adopt, implement, upgrade'' under Medicaid, EPs will need to adopt, implement, or upgrade (AIU) to 2014 Edition CEHRT only. As mentioned in the proposed rule, this requirement discourages the purchase of an outdated product that could not be used to meet meaningful use in subsequent years. We do not consider a plan to upgrade from older technology sufficient. We further note that Medicaid EPs who qualify for a first year incentive payment for AIU may be subject to the Medicare payment adjustment under section 1848(a)(7) of the Act if they do not demonstrate meaningful use for an applicable EHR reporting period.

Comment: We received multiple comments on the proposed options for the use of CEHRT. Generally, the majority of commenters supported the proposed options, and several commenters requested clarification on one or more of the options. A few commenters generally objected to one or more of the options, finding the options for the use of CEHRT time consuming, complicated, confusing, or inconvenient.

Some commenters requested that CMS clarify how the edition of CEHRT would dictate the stage of Meaningful Use under the CEHRT options. Specifically, commenters requested clarification on how the proposed options for the use of CEHRT would work with objectives, associated measures, and CQMs. Commenters questioned whether the options for the use of CEHRT extended to allowing options for measure selection. A few commenters suggested that we allow additional options for the use of CEHRT regardless of the Edition of CEHRT the provider has implemented. These options included: allowing providers to attest to Stage 2 with exclusion of one or more core objectives; allowing providers to report on either Stage 1 or 2, using either the 2011 or 2014 Edition CEHRT; allowing providers to choose between 2014 Stage 1 objectives and measures and the 2013 Stage 1 objectives and measures; and allowing providers to report on any version of CQMs.

Many commenters wanted additional explanation of what we meant by a combination of 2011 and 2014 Edition CEHRT. These commenters requested that we clarify if the combination referred to set amounts of time, or whether a specific ratio between CEHRT editions was required, or whether a specific CEHRT edition needed to be used for each objective or measure. These commenters were also concerned that the coding differences between the software editions would make it difficult to use a combination of the two as proposed in the options for the use of CEHRT. Other commenters requested clarification if the combined 2011/2014 option for the use of CEHRT could be used for providers practicing in multiple locations equipped with different editions of CEHRT.

In addition, many commenters requested that guidance on the documentation requirements for the related reporting requirements be provided to program auditors for each potential option.

Response: We appreciate the supportive comments regarding the options for the use of CEHRT proposed for meeting meaningful use for an EHR reporting period in 2014. Our priority is to promote the meaningful use of certified EHR technology and support the successful implementation of 2014 Edition CEHRT including the functionalities required to support enhanced patient engagement, interoperability, and health information exchange. We recognize clinical workflows, business procedures, and maintaining documentation may require modifications upon implementation of 2014 Edition CEHRT. In addition, we recognize that affected providers will need to consider multiple factors in determining the option for which they may be eligible. However, we believe the proposals outlined for the use of CEHRT in 2014 will allow affected providers the flexibility to choose the option which applies to their particular circumstances. Upon attestation, providers may select one of the options proposed and the EHR Incentive Program Registration and Attestation System will prompt the provider to attest to meeting the applicable objectives, measures, and CQMs based on their Edition of CEHRT. Furthermore, we note, as suggested by some commenters, that auditors will be provided guidance related to reviewing attestations associated with the options for using CEHRT.

While we understand it may be cumbersome for providers to use a combination of 2011 and 2014 Edition CEHRT to meet meaningful use in 2014, we expect the benefit of ultimately demonstrating meaningful use outweighs the complexity of using two CEHRT editions. We do not specify whether a provider must use 2011 Edition CEHRT or 2014 Edition CEHRT for a certain amount of time during the EHR reporting period, whether a certain amount of modules in one CEHRT edition or another is required, or whether a certain number of provider settings must have one CEHRT edition over another. This is because we expect there will be significant variation among practices based on the type of software used, the complexity of a provider's total systems, and the overall implementation timeline for 2014 Edition CEHRT installation.

Providers who use a combination of 2011 Edition and 2014 Edition CEHRT will enter a certification number into the Registration and Attestation System, and they will be presented with a choice of 2013 Stage 1 objectives and measures, or 2014 Stage 1 objectives and measures (and Stage 2 objectives and measures if

they were previously scheduled to begin Stage 2). Providers using a combination of 2011 Edition and 2014 Edition CEHRT who choose to attest to the 2013 Stage 1 meaningful use objectives and measures will report on only those objectives and measures and attest to the CQMs that were applicable for 2013. Providers using a combination of 2011 and 2014 Edition CEHRT who choose to attest to the 2014 Stage 1 meaningful use objectives and measures will report on only those objectives and measures and submit the 2014 CQMs through attestation or electronic reporting. Providers using a combination of 2011 Edition and 2014 Edition CEHRT who choose to attest to Stage 2 objectives and measures will attest to only the Stage 2 objectives and measures and submit the 2014 CQMs through attestation or electronic reporting.

Comment: We received numerous comments on the EHR reporting periods for both 2014 and 2015. For 2014, some commenters wanted us to allow providers to skip attestation entirely. Some commenters requested clarification regarding the EHR reporting period for providers employing the options outlined in the rule. Another commenter questioned whether it was possible to attest based on a 3rd quarter (April through June) instead of 4th quarter (July through September) EHR reporting period in FY 2014 using the CEHRT options proposed. Some commenters suggested that eligible hospitals should attest using any one quarter of the fiscal year, while others disagreed with using a 3-month period by quarter.

Another commenter suggested that CMS should generally allow a 90-day reporting period for Stage 2, year 1, in order to allow ample time to test and meet the measures in Stage 2.

However, the majority of commenters, focused on the 2015 reporting period and made suggestions regarding the length of the EHR reporting period. Several commenters requested that CMS consider 2015 a transition period with the use of 2014 Edition CEHRT. Many of these commenters suggested a 90-day attestation period for 2015, citing that providers and EHR vendors do not have enough time in 2014 to fully integrate 2014 Edition CEHRT. The majority of these commenters then requested a flexible 90-day period, explaining that the rule will not be finalized prior to the beginning of the last EHR reporting period. Commenters added reporting for a full year in 2015 is impossible if providers had to switch systems on the first of the year.

Other commenters explained that a 90-day reporting period is needed for 2015 because the proposed extension is not enough given the time needed to adopt, implement, and operationalize a 2014 Edition CEHRT and all of the changes that accompany it. These commenters noted such a short extension does not adequately serve the purpose of the proposed rule. Finally, some commenters wanted a 90-day reporting period because of the delay in ICD–10 implementation, or because they believed Stage 2 measures fell outside their control. Many commenters requested clarification regarding the ramifications of not being able to implement 2014 Edition CEHRT by January 1, 2015.

Response: The special 3-month quarter EHR reporting period in 2014 was established in the Stage 2 final rule and does not apply to 2015 or subsequent years. In the proposed rule, we did not propose to change the EHR reporting periods that were established in the Stage 2 final rule for 2014 or any subsequent year with regard to the incentive payments or payment adjustments. The purpose of the proposed rule was to provide options for the use of CEHRT to allow providers to meet meaningful use within the existing EHR reporting periods using the technology available to them. We are not considering changes to the EHR reporting periods for 2015 or subsequent years in this final rule for the same reasons we are not considering changing the edition of CEHRT required for 2015 or subsequent years. Changes to the EHR reporting period would put the forward progress of the program at risk, and cause further delay in implementing effective health IT infrastructure. In addition, further changes to the reporting period would create further misalignment with the CMS quality reporting programs like PQRS and IQR, which would increase the reporting burden on providers and negatively impact quality reporting data integrity.

However, as stated previously in this final rule, providers may attest based on an EHR reporting period of any quarter in 2014 using the options specified in this final rule. We believe the options for using CEHRT proposed, as well as the ability for a provider to attest based on any quarter in 2014, strike a balance between being responsive to those providers unable to fully implement 2014 Edition CEHRT because of issues related to 2014 Edition CEHRT availability delay and continuing to move the EHR Incentive Program forward.

Comment: Commenters questioned how states will verify that eligible providers are ''unable to fully implement 2014 Edition CEHRT because of issues related to 2014 Edition CEHRT availability delays'' when they attest to meaningful use objectives and measures for the Medicaid EHR Incentive Program. Commenters stated that without having detailed guidance on how states should capture and verify this new attestation requirement that states would be at a greater risk of making improper payments to providers.

Response: We recognize the potential difficulties in adding this requirement for both providers and state Medicaid agencies, but still believe that it is necessary to ensure that this final rule is tailored to those providers who were unable to fully implement 2014 Edition CEHRT.

Comment: Several commenters sought clarification on the circumstances under which providers could use the proposed options for the use of CEHRT outlined in the proposed rule. Commenters requested that CMS clarify or further define the terms ''unable to fully implement'' and ''2014 Edition CEHRT availability delays.''

The comments pertaining to this particular area fell into several categories. The largest commenter group wanted precise definitions because they believed the proposed rule was not sufficiently clear. Several commenters remarked that we provided limited examples in the proposed rule. These commenters explained these terms, so critical to determining available options for using CEHRT, could encompass an endless number of scenarios. Other commenters wanted to know if providers retained the discretion to determine what these terms meant, and if not, who would ultimately decide what they meant. Some commenters suggested that the use of the proposed options should be based on a provider's determination that it could not effectively deploy 2014 Edition CEHRT. Other commenters wanted the options for using CEHRT expanded to more than just issues with 2014 CEHRT availability delays.

Some commenters expressed concern that the language we used was too broad; while others stated that the language was too restrictive. Several commenters wanted us to either substitute or add to ''fully implement'' with a host of other terms, including deployment, operationalize, work, establish, institute, initiate, place, or execute. Several commenters expressed confusion about whether they could use the options for CEHRT when they have 2014 Edition CEHRT available, but could not train new personnel or establish new workflows because of late software installations.

Many commenters requested timeframes or deadlines for when these terms would be applicable. For example, a commenter questioned what would be considered an adequate amount of time to complete all of the transitional processes (training, workflow, validation of reporting) post 2014 Edition CEHRT deployment.

Other commenters suggested expanding the circumstances where an inability to fully implement or 2014 Edition CEHRT availability delays could be used. Specifically, many commenters remarked delays with implementation of 2014 Edition CEHRT consisted of more than just vendor related availability issues and added that we should clarify that many issues could be involved. A commenter noted that the time period to be considered for the option to report on Stage 1 should consist of not only the time for the vendor to obtain 2014 edition certification, but also should extend to all subsequent vendor and health care provider tasks required to fully operationalize Stage 2. Other commenters wanted us to consider an inability to fully test 2014 Edition CEHRT an appropriate circumstance under which to use the CEHRT options. Other commenters noted a lack of training on the new technology changes and requested that this be considered a valid reason for using the CEHRT options.

Commenters explained that EHR vendors did not train providers in time, thereby resulting in an inability to attest to meaningful use. Other commenters stated that cost and staff turnover and changes caused their inability to fully implement 2014 Edition CEHRT, and wanted clarification on whether that qualified them to use the CEHRT options. Another commenter suggested we consider a financial hardship as a reason to be unable to fully implement 2014 Edition CEHRT because of issues related to 2014 Edition CEHRT availability delays.

Some commenters stated problems associated with the 2014 Stage 1 objectives and measures or the Stage 2 objectives and measures themselves should be considered as a suitable reason for using the CEHRT options. A commenter remarked that his vendor only released the capability for the lab result measure in June, and he still is waiting for the upgrade to be able to report on the measure.

Many commenters expressed concern over attesting to Stage 2 because of a lack of 2014 Edition CEHRT availability associated with the Stage 2 transitions of care measure requiring transmission of an electronic summary of care document using 2014 Edition CEHRT. This measure requires providers to send an electronic summary of care document for more than 10 percent of transitions or referrals. EPs especially expressed this concern because their 2014 implementation timeline may be 3 months behind eligible hospitals and CAHs given fiscal and calendar year differences. Commenters explained that even those EPs who did fully implement their own 2014 Edition CEHRT systems may still be unable to meet Stage 2 requirements due to other EPs and community hospitals lacking 2014 Edition CEHRT. Since Stage 2 requires electronic summary of care records for more than 10 percent of transitions of care to be electronically transmitted by the referring or transitioning EP using 2014 Edition CEHRT or facilitated by an eHealth Exchange participant, commenters indicated that the EP cannot guarantee receipt if the recipient or intermediary does not have the 2014 Edition CEHRT functionality required to receive the electronic document. These commenters suggested we allow an EP under these circumstances to attest to the Stage 1 objectives when insufficient opportunities exist to send summary of care records electronically because recipients did not fully implement 2014 Edition CEHRT.

Other commenters raised concerns over other measures under the EHR Incentive Program, some requiring the specific use of 2014 Edition CEHRT. Many commenters wanted to know whether issues with direct messaging, portal non-use by patients, mapping problems, or other similar measure issues could be considered an inability to fully implement 2014 Edition CEHRT because of issues related to a 2014 CEHRT availability delay. A commenter explained that Stage 2's focus on cooperation among providers makes implementation difficult when not all providers are at the same capability level. Commenters maintained these issues fell outside the provider's control and should be considered suitable reasons to use the CEHRT options. Some commenters added that providers should be allowed to meet less than the required thresholds and still be considered to meet meaningful use for the EHR reporting period in 2014.

Other commenters remarked that although they had no issues with 2014 Edition CEHRT availability, providers could not meet several measure requirements because of late code releases on a short time frame. Therefore, these commenters suggested that all providers be allowed to use the CEHRT options. Similarly, many commenters wanted all restrictions for using the CEHRT options eliminated completely, and instead, allow all providers to use the options for CEHRT regardless of the reason.

Response: We agree that some clarification is necessary regarding what we meant by ''not able to fully implement'' and ''delays in 2014 Edition CEHRT availability'' in the proposed rule. We begin by addressing those commenters who pointed out that we did not provide examples which fully encompass every scenario where an inability to fully implement or a 2014 Edition CEHRT availability delay was possible, as well as those commenters who stated the terminology generally was vague and unclear. We did not provide an exhaustive list of every possible scenario in the proposed rule in recognition of the many different scenarios where a provider may not be able to fully implement 2014 Edition CEHRT for an EHR reporting period in 2014 due to delays in 2014 Edition CEHRT availability. We also did not propose alternate terminology for ''implement'', such as operationalize, institute, or initiate, as suggested by commenters because we wanted to use consistent terminology in the proposed rule.

Next, we clarify what we meant by a delay in 2014 Edition CEHRT availability. As stated previously, we proposed the options for using CEHRT due to the overwhelming number of providers who informed us they could not meet the objectives and measures of meaningful use with 2014 Edition CEHRT because, for example, they did not have the product installed, or were waiting for EHR vendor certification or for necessary software updates from the EHR vendor. Such delays then gave the provider little to no time to get the necessary training, system testing and workflow revisions in place to fully implement their 2014 Edition CEHRT in time for an EHR reporting period in 2014. Thus, the delay in the 2014 Edition CEHRT availability resulted from one or more delays related to the development, certification, testing, and release of an EHR product by the EHR vendor which then results in the inability for a provider to fully implement 2014 Edition CEHRT for an EHR reporting period in 2014. In stating that the delays are attributable to the development, certification, testing, and release of an EHR product by the EHR vendor, we do not intend to infer that the EHR vendor is culpable. We recognize that vendors themselves may have experienced unexpected delays during the development process because of the compressed timeline between receipt of final requirements to the

deadline for implementation. This could include delays within the certification process as well. For example, if a vendor's actions were timely but the ONC Authorized Certification Body experienced a backlog due to a high volume of certification requests, a delay in the testing and certification of a product may have occurred. Further, as reflected in the special shortened EHR reporting period in 2014 established in the Stage 2 final rule, we anticipated potential delays from the volume of providers requiring a simultaneous software upgrade. Rather, we proposed the options for the use of CEHRT to alleviate provider and vendor burden in light of our research and analysis demonstrating that the scale of the problem was greater than anticipated when the Stage 2 final rule was published. Accordingly, a provider's ability to use these flexible options for CEHRT is based on the provider's inability to fully implement 2014 Edition CEHRT based on these types of issues related to software development, certification and release of the product by the EHR vendor which affected 2014 CEHRT availability.

We did not intend, as suggested by some commenters, to allow reasons such as a provider waiting too long to purchase the software or, as explained later in this section, a lack of staff or resources to constitute a ''delay'' for purposes of using one of the proposed CEHRT options. Therefore, we stress the delay in 2014 Edition CEHRT availability must be attributable to the issues related to software development, certification, implementation, testing, or release of the product by the EHR vendor which affected 2014 CEHRT availability, which then results in the inability for a provider to fully implement 2014 Edition CEHRT.

Next, we clarify what we meant by an inability to fully implement 2014 Edition CEHRT. It is in this area where we intended to provide the broadest application. We start with examples of what does not constitute an inability to fully implement 2014 Edition CEHRT. We believe that beginning with what is not permissible, rather than what is, represents a far smaller set of circumstances that will both quell providers' concerns about audits and provide additional parameters on the use of the CEHRT options generally.

Accordingly, we clarify that the following situations would not be permissible reasons to use the options for CEHRT because they do not constitute an inability to fully implement 2014 Edition CEHRT. First, providers that did not fully implement 2014 Edition CEHRT due to financial issues, such as the costs associated with implementing, upgrading, installing, testing, or other similar financial issues, would not be able to use the options for CEHRT for the EHR reporting period in 2014. Although we understand cost is a factor for health care providers, as it is with any other business, we proposed the options for CEHRT to address delays in the availability of 2014 Edition CEHRT, and not the costs associated with it. Therefore, we do not find cost to be a permissible reason for using one of the options for CEHRT. Rather, we point out that providers facing significant cost concerns relating to such things as insufficient internet access and insurmountable barriers to obtaining infrastructure (broadband access) have the option to file an application for a hardship exception.

Second, with limited exception discussed later in this section, issues related to the meaningful use objectives and measures do not constitute an inability to fully implement 2014 Edition CEHRT. Several commenters mentioned that although 2014 Edition CEHRT was available, fully functioning, and implemented, they wanted to attest with one of the CEHRT options because of issues relating to one or more Stage 2 objectives and measures, such as the inability to meet certain measure thresholds which increased from Stage 1 to Stage 2, an overall objection to Stage 2 measures generally, or concerns with measures believed to be outside a provider's control—such as an inability to obtain a beneficiary's email address. Again, we proposed alternate options only for those providers who could not fully implement 2014 Edition CEHRT for a full EHR reporting period in 2014 because of issues related to 2014 Edition CEHRT availability delays. We did not propose these options in order for providers to be exempted from meeting Stage 2 measure requirements. We do not find that an inability to meet one or more measures, as in the examples cited previously, fits within the rationale we proposed for using one of the CEHRT options. Rather, overall concerns and comments requesting changes or exemptions to one or more of the Stage 2 measures and objectives fall outside the scope of this rule, and will not be discussed with any further detail here. Accordingly, for the reasons stated previously, those providers who have fully implemented 2014 Edition CEHRT and cannot meet one or more measures for reasons unrelated to the inability to fully implement 2014 Edition CEHRT due to delays in the product availability cannot use the options for the use of CEHRT and must attest to their stage of meaningful use using 2014 Edition CEHRT as originally intended.

However, we recognize the concern raised by commenters, stated previously, that in the Stage 2 meaningful use objective for provision of a summary of care document during for more than 10 percent of transitions of care, the second measure requires electronic transmission using CEHRT, which implies that the recipient or intermediary is able to receive the summary of care document in the standard required for transmission. As mentioned by commenters, the sending provider may experience significant difficulty meeting the 10 percent threshold, despite the referring provider's ability to send the electronic document, if the intermediary or the recipient of the transition or referral is experiencing delays in the ability to fully implement 2014 Edition CEHRT. We acknowledge referring providers may not be able to meet the summary of care measure in 2014, if receiving providers they frequently work with have not upgraded to 2014 Edition CEHRT. We therefore believe a limited exception is warranted for providers who could not meet the threshold for the Stage 2 summary of care measure requiring the transmission of an electronic summary of care document for more than 10 percent of transitions or referrals because the recipients of the transitions or referrals were impacted by issues related to 2014 Edition CEHRT availability delays and therefore could not implement the functionality required to receive the electronic summary of care document. Therefore, we consider the inability to fully implement to extend to those providers for the summary of care document measure at 42 CFR 495.6 (d)(14)(ii)(B) for EPs and (l)(11)(ii)(B) for eligible hospitals and CAHs. A referring provider under this circumstance may attest to the 2014 Stage 1 objectives and measures for the EHR reporting period in 2014. However, the referring provider must retain documentation clearly demonstrating that they were unable to meet the 10 percent threshold for the measure to provide an electronic summary of care document for a transition or referral for the reasons previously stated.

We stress that other issues related to objectives and measures, such as a failure to meet a measure threshold, or failure to conduct the activities required to meet a measure, will not be considered a suitable basis to use the CEHRT options outlined in this final rule.

Next, we find staff changes and turnover to be an insufficient rationale

for a provider to use the CEHRT options. Some commenters explained that circumstances such as the termination or attrition of staff rendered them unable to train new staff in time to implement 2014 Edition CEHRT. However, we did not intend such rationale to be permissible. Rather, references we made in the proposed rule regarding the inadequate amount of time to train staff stemmed, again, from the fact that EHR vendors were delayed in installing 2014 Edition CEHRT, which, in turn, gave providers little to no time to train their staff on the new software. We consider staff turnover and changes, as well as any other similar situations, to be issues frequently encountered in the normal course of business and therefore insufficient grounds for a provider to use the CEHRT options.

Finally, we do not find situations stemming from a provider's inaction or delay in implementing 2014 Edition CEHRT sufficient to use one of the CEHRT options. These situations include providers waiting too long to engage a vendor or a provider's inability or refusal to purchase the requisite software update. Such circumstances would not be permissible reasons to use the CEHRT options because they did not stem from a 2014 Edition CEHRT availability delay.

We again stress that the proposed rule was intended to allow options for providers that were unable to fully implement 2014 Edition CEHRT for an EHR reporting period in 2014 due to issues relating to 2014 Edition CEHRT availability delays. Therefore, we will not remove the requirement that a provider's inability to fully implement 2014 Edition CEHRT was based on issues related to 2014 Edition CEHRT availability delays, because this requirement comprises the primary reason for the proposed rule.

In deciding whether a provider can use a CEHRT option, we stress that the installation of 2014 Edition CEHRT alone is not the sole factor. Obviously, those providers still waiting for installation of 2014 Edition CEHRT represent the most concrete example of those able to use the CEHRT options because it represents the clearest illustration of both a 2014 Edition CEHRT availability delay and lack of full implementation. However, those providers with 2014 Edition CEHRT installed may also be able to use the options for the use of CEHRT. Again, we stress that an availability delay is not based solely on whether the software is certified and then installed or not, as many commenters questioned. Rather, providers with 2014 Edition CEHRT installed may nonetheless face a 2014 CEHRT availability delay because they are waiting for vendor software updates, or the software itself is presenting problems with functionality, or when the software does not yet contain all required components. This also may include situations where a problem with the software presents a safety issue, such as when a drug allergy or drug interaction clinical decision support does not function properly, or cases where the vendor identified a functionality problem and sends out patches to fix the problem, requiring the provider to wait until the issue is resolved to use the software. We recognize these issues take time to resolve, and the overall delay in 2014 Edition CEHRT availability may have constrained that time for many providers. So, although we cannot list every possible scenario, installed 2014 Edition CEHRT with delayed or missing software updates, or cases where the software itself renders a provider unable to reliably use the software would be permissible reasons to use the CEHRT options because such issues are considered to be a 2014 Edition CEHRT availability delay. We stress that this does not include, as explained earlier, circumstances where the software functions properly but the provider cannot meet one or more requirements of the measure or the increased thresholds on measures common to both stages. The basis for using one of the CEHRT options stems from a problem with first getting the software installed because of EHR vendor delays, and then fully implementing (including training, workflows, and related activities) 2014 Edition CEHRT in time for a full EHR reporting period in 2014. We note that being able to implement 2014 Edition CEHRT for a part of the reporting period is not considered full implementation of 2014 Edition CHERT. Providers who are only able to implement 2014 Edition CEHRT for part of a reporting period would be permitted to use the CEHRT options in this rule.

Along this vein, we received requests to define what is allowable for staff training, system testing and workflow revision under the proposed options for providers who are unable to fully implement 2014 Edition CEHRT. An inability to train staff, test the updated system, or put new workflows in place because of delays associated with the installation of 2014 Edition CEHRT constitutes a failure to fully implement, and provides sufficient rationale to use the options for the use of CEHRT. We note several commenters wanted us to specify cutoff dates for training or workflows where we would find it suitable to allow using the CEHRT options. However, such limits would be impossible for us to adequately capture. Because the number and types of providers involved with the EHR Incentive Program vary greatly, we cannot simply state a hard date or exact time because a large hospital chain would possess different time and workflow requirements, for example, than a single EP. However, we can clarify that in order to use one of the options for the use of CEHRT, the provider must not have had enough time to fully implement 2014 Edition CEHRT, including training of staff, perform system testing, and establishing revised workflows in order to report for a full EHR reporting period. If a large hospital, for example, had their CEHRT installed in August, we expect that this hospital would not have enough time to be able to report for an EHR reporting period in 2014 because the hospital would not be able to train staff or establish the necessary changes in workflow. However, if a hospital had 2014 Edition CEHRT installed in January 2014 and decided to wait until August 2014 to begin training, testing and workflow activities, for example, then this rationale would not be sufficient to establish that the provider could not fully implement 2014 Edition CEHRT due to a delay in 2014 Edition CEHRT availability, because the delay was on the part of the hospital.

Again, we note that we cannot capture every scenario where a provider can use an option for the use of CEHRT and understand a number of providers will likely choose to attest under one of the options proposed in this final rule. Given the number of stakeholders who raised problems with getting 2014 Edition CEHRT fully implemented and running, we expected a fairly wide use of the options for the use of CEHRT, which is why we proposed these provisions. However, as explained earlier, we also proposed the requirement that a provider must attest to an inability to fully implement 2014 Edition CEHRT due to issues relating to 2014 Edition CEHRT availability delays in order to use the CEHRT options. Although we understand the broad application that will likely ensue, we believe the parameters set forth earlier will provide further guidance to stakeholders in determining whether to use the options, while at the same time, continue to move the program forward toward the overall goal of the meaningful use of certified EHR technology.

Comment: A number of commenters raised fairness concerns around those providers who met all requirements and

can report using 2014 Edition CEHRT in 2014. These commenters explained that such providers and EHR vendors were not being provided with any benefit from the options outlined in the proposed rule, or with meeting requirements as originally created. Some even suggested that we provide additional incentives to those providers who can report as scheduled, as an award for meeting all requirements in 2014. Other commenters requested that all providers be allowed to use the options for the use of CEHRT regardless of the reason.

Response: We appreciate the commenters' feedback. However, the proposed rule was not intended to unfairly favor any stakeholder. Rather, we proposed this rule to provide relief to those providers who could not meet meaningful use for an EHR reporting period in 2014 using 2014 Edition CEHRT because of vendor delays with software implementation. These providers were caught in situations where their vendors did not have 2014 Edition CEHRT ready, and therefore would be unable to meet meaningful use for an EHR reporting period in 2014. These providers would otherwise not be participating in the program which would weaken the overall momentum and diminish essential program goals such as continuing to build health information exchange infrastructure, increasing participation in essential public health reporting programs, and capturing and reporting data on clinical standards and quality.

We applaud those providers and EHR vendors who met all requirements and upgraded in time for the EHR reporting period in 2014. We understand the time and effort that such a task entailed and continue to appreciate the work these pioneers accomplish in moving the EHR Incentive Program forward. But, allowing all providers, including those who have fully implemented 2014 Edition CEHRT, to use an alternate edition of CEHRT would simply be counterintuitive. If we allowed such a step, we expect many providers would choose the alternate options and continue to report on Stage 1, which would thereby leave us, as also noted by some commenters, with little to no data to review on Stage 2. Such circumstances, we fear, would later prove problematic in implementing Stage 3 and would go against our rationale to review Stage 2 data in order to mold Stage 3. The entire overarching purpose of the EHR Incentive Program is to move providers towards advanced use of health IT to support reductions in cost, increased access, and improved outcomes for patients. However, allowing all providers—including those who can meet meaningful use using 2014 Edition CEHRT—to delay their forward progress would put these goals at significant risk. Therefore, providers must be able to show an inability to fully implement 2014 Edition CEHRT because of delays in 2014 Edition CEHRT availability in order to use one of the options for the use of CEHRT.

In addition, although we again applaud those providers who can meet meaningful use for an EHR reporting period in 2014 using 2014 Edition CEHRT as originally intended, we do not believe that an extra incentive for these providers is warranted. The dollar amounts of the incentive payments are established by statute, and we do not have authority to award additional amounts.

Comment: Many commenters raised objections to the Stage 2 objectives and measures. Some commenters stated the measure requirements for meeting meaningful use in 2014 are unreasonable. Other commenters suggested that the resources and costs required to meet the Stage 2 objectives and measures are substantial.

A commenter stated that although EHR vendors do not have 2014 Edition CEHRT ready, CMS and ONC continue to set requirements ahead of the pace of the market. Some commenters stated that the rush results in hurried check box measures, which vendors cannot have ready on time and which simply do not work. Other commenters cited general issues with 2014 Edition CEHRT measures including lab interfaces, patient portals, and direct messaging functions.

Many commenters took objections to the Stage 2 measures themselves. Some commenters stated it was unrealistic to expect the Medicare beneficiary population to be computer savvy or use email. Other commenters objected that labs, prescriptions, and radiology orders must be initiated electronically by a licensed clinician. These commenters stated that the lack of hand writing for such orders requires a great deal of changes in workflows for most practices and affects the staffing choices providers make in their practices.

Many commenters objected to the data that needed to be entered for one or more of the Stage 2 measures themselves, finding them time consuming, intrusive, costly, and difficult to implement.

Response: We appreciate the thoughtful input commenters provided regarding the Stage 2 meaningful use objectives and measures, including challenges in meeting certain measures and the number of objectives to report. The flexibility in this final rule recognizes the difficulties in meeting measures and objectives specifically due to the inability to fully implement 2014 Edition CEHRT based on delays in availability. However, modifications to the Stage 2 meaningful use objectives and measures were not included in the scope of the proposed rule and will not be considered in this final rule. We urge readers to wait until the release of the Stage 3 proposed rule to provide comments on ways to improve the meaningful use requirements.

Comment: Some commenters requested clarity on how this will affect public health reporting with respect to HL7 version 2.3.1 and version 2.5.1, and the effect on how providers will meet the measures or claim exclusions.

Response: We proposed no changes to specific measures or to the exclusions related to the measures where exclusions apply. We expect providers will continue the process of enrolling with and reporting to public health agencies as per the requirements of the meaningful use objectives related to public health reporting. In addition, if a provider sent a test message to a public health agency in a previous EHR reporting period and chooses to report to 2013 Stage 1 objective and measures or 2014 Stage 1 objectives and measures for the 2014 reporting period with one of the alternate options for the use of CEHRT, the provider is not required to send another test message to meet the public health measure for the 2014 reporting period.

Comment: Some commenters requested that CMS clarify how the flexible CEHRT options would be applicable for a provider who practices in multiple locations. These commenters questioned how an EP should attest to meaningful use if 2014 Edition CEHRT is fully implemented in one location, but not in other locations. These providers seek clarification as to whether they can attest to meaningful use using patient data from only the location with the most encounters during an EHR reporting period, and exclude patient data from other locations.

Response: EPs who practice in multiple locations which have been unable to fully implement 2014 Edition CEHRT for an EHR reporting period in 2014 due to CEHRT availability delays may attest using the options outlined in this final rule. If an EP uses different editions of CEHRT at multiple locations, he or she may choose to use the alternate CEHRT option that is best applied for his or her patient encounters across all locations during the EHR reporting period. However, these EPs

should then use the data from all patient encounters which occur at a location equipped with any edition of certified EHR technology, just as the EP would use the patient data from all locations equipped with CEHRT to meet meaningful use in any other year.

However, if over 50 percent of the EP's patient encounters during the EHR reporting period occur at locations equipped with 2014 Edition CEHRT which has been fully implemented, the EP would not be eligible to use the flexibility options in this final rule and should therefore limit their denominators to only those patient encounters in locations equipped with fully implemented 2014 Edition CEHRT.

Comment: Several commenters noted that it is unreasonable to expect first time providers to attest by October 1, 2014. These commenters suggested that providers who are attesting for the first time in 2014 should be allowed to do so through the end of the calendar year.

Response: It should be noted that new participants in the EHR Incentive Programs may choose any 90 days up to the end of the year to complete and EHR reporting period, and they have until the close of the attestation period (February 28, 2015 for EPs and November 30, 2014 for CAHS and eligible hospitals) to attest to meaningful use and receive an incentive payment for the EHR reporting period in 2014. Successfully demonstrating meaningful use for any reporting period in 2014 would allow these providers to avoid the 2016 payment adjustment. The October 1, 2014 deadline is the date by which EPs who have not demonstrated meaningful use in a prior year must attest in order to also avoid the 2015 payment adjustment. First time participants would otherwise be subject to the 2015 payment adjustment because they did not meet meaningful use in 2013. This does not apply to brand new providers who have an automatic 2 year exemption from the payment adjustments.

However, we reiterate all new participants in 2014 may earn an incentive payment for 2014 and avoid the 2016 payment adjustment by successfully demonstrating meaningful use for an EHR reporting period of any continuous 90 days in 2014. Even if these providers do not meet the early attestation deadline and therefore receive a payment adjustment in 2015, they may still earn an incentive payment for meeting meaningful use for an EHR reporting period in 2014.

Comment: Several commenters questioned whether they could attest for 2014 using a prior quarter in 2014 using 2011 Edition CEHRT and 2013 Stage 1 objectives and measures, or whether they can only use the fourth quarter for an EHR reporting period. Other commenters stated generally whether any earlier reporting period could be used and requested clarification on the attestation deadlines for each quarterly reporting period.

Response: Given commenter feedback, we recognize that some confusion exists in this area. We wish to reiterate the attestation deadline to attest for an EHR reporting period is not 60 days after the end of any given reporting period (3-month quarter or 90 days for new participants). The deadline is 2 months after the end of the federal fiscal year (for hospitals) or the calendar year (for EPs).).

Therefore, we are clarifying that providers may attest to any 3-month quarter EHR reporting period in 2014 from the date of completion of that reporting period, through the end of the open attestation period for the year. For EPs, this means any point after the close of their chosen reporting period through to 2 months after the end of the calendar year (February 28, 2015). For eligible hospitals and CAHs this means any point after the close of their chosen reporting period through to 2 months after the end of the fiscal year (November 30, 2014).

Comment: Several commenters requested clarification regarding the attestation process. Commenters rrequested that CMS clarify what documentation that would be required to show an inability to fully implement 2014 Edition CEHRT. A commenter recommended that CMS provide an attestation statement for providers to certify they could not fully implement the 2014 Edition CEHRT due to delays in availability. Another commenter suggested that CMS specify when the attestation system will be updated with the new requirements promulgated in the final rule.

Response: For providers attesting for the EHR reporting period in 2014, the system determines the CEHRT edition entered by the provider when the EHR certification number is entered. Providers utilizing the options proposed would be required to attest that they were unable to fully implement 2014 Edition CEHRT for a full EHR reporting period in 2014 due to delays in 2014 Edition CEHRT availability. We did not propose requiring additional documentation from providers at the time of attestation beyond the data required to be entered into the Registration and Attestation System. We present further clarification of the full attestation process in section IV of this final rule.

Comment: Several commenters questioned how the audit process would work given the flexible options for using certified EHR technology. These commenters sought clarification on what types of documentation would be required in cases of an audit. Some commenters request that CMS not require any documentation, in order to alleviate provider burden. However, other commenters, mainly those responsible for attestation, wanted us to require some level of documentation, in order to provide protection in cases of an audit. Commenters were generally concerned with auditors retroactively applying different standards than what is outlined in this rule.

A few commenters wanted the provider's decision to use flexible attestation outside the auditor's purview completely. Other commenters were concerned with the auditor's focus given these flexible requirements. These commenters explained with such a small pool of Stage 2 attesters likely, auditors may not focus their efforts evenly across both Stages, thereby unfairly punishing the smaller Stage 2 attester group, who succeeded in implementing and reporting using the 2014 Edition CEHRT. These commenters suggested ensuring that audits were fairly conducted across both Stages, given the likelihood for a higher number of Stage 1 attesters.

Response: We appreciate the commenters' feedback and would like to clarify some aspects of the audit process in response to the comments. Audits under the EHR Incentive Program do not occur based solely upon provider type, location, stage of meaningful use, or year of participation. Rather, we follow standard guidelines for programs conducting audits including auditing providers based on a random selection process, as well as selection based on key identifiers such as prior audit failure or known incidence of fraud.

Therefore, although we acknowledge that the flexible options for CEHRT we proposed may modify a provider's timeline for implementation of meaningful use, we stress that a provider attesting to Stage 2 using the 2014 Edition CEHRT is no more likely to be subject to an audit than any other provider attesting in 2014.

We also acknowledge providers' concerns about required documentation in cases of an audit. To alleviate those concerns, we wish to clarify that we will provide guidance to auditors relating to this final rule and the attestation process. This instruction should include requiring auditors to work closely with providers on the supporting documentation needed applicable to the

provider's individual case. We further stress that audit determinations are finalized on a case by case basis, which allows us to give individual consideration to each provider. We believe that such case-by-case review will allow us to adequately account for the varied circumstances that may result in a provider selecting a different CEHRT option.

Comment: Some commenters suggested that these changes would lead to many Medicaid EPs not submitting their 2014 attestations until after January 1, 2015; and if they are also Medicare providers they may be subject to the Medicare penalty if they did not submit a hardship exemption by the deadline. Many commenters are concerned that if states extend the attestation period in order to accommodate these changes, it will only result in slowing 2015 work flows. They believe that providers who are already struggling with navigating the requirements must add another layer of decisions in the process.

Response: We do anticipate that if states require additional time to implement system changes to allow providers to attest to meaningful use under these proposed options, a contingent of Medicaid EPs may not be able to submit 2014 attestations until after January 1, 2015. However, if a provider meets meaningful use for an EHR reporting period for 2014 in the Medicaid program, they will not be subject to a Medicare payment adjustment in 2016 even if they attest after January 1, 2015.

It is true that Medicaid providers who do not meet meaningful use for an EHR reporting period in 2014, who are also Medicare providers, may be subject to the Medicare penalty if they did not submit a hardship exception application by the deadline. However, we note that the application deadline for providers who do not demonstrate meaningful use in 2014 is April 1, 2015 for eligible hospitals and July 1, 2015 for EPs. Therefore, there is time for these EPs to apply for an exception if they find they are unable to meet meaningful use in the Medicaid program. Further clarification of hardship exceptions may be found in later in this section of this final rule. Regarding the deadline for attestations, states that have extended this deadline (and in many cases, on an annual basis) in the past, have had a significant number of EPs and eligible hospitals attest during that period. These states have not reported work flow delays as a result. It is important for states, with CMS support, to educate the provider community with the latest information related to meeting the requirements of meaningful use and to raise awareness on CEHRT requirements so providers can make informed decisions and successfully participate in the program.

Comment: Some commenters expressed a variety of concerns around hardship exceptions for the Medicare payment adjustments. Some wanted clarification on the requirements for a hardship exception application for providers who were unable to implement 2014 Edition CEHRT due to delays in 2014 Edition CEHRT availability. A few commenters requested clarification that this final rule did not affect the ability for a provider to receive an incentive payment. Another commenter expressed frustration with losing his incentive payment should he choose to file a hardship exception application. Other commenters stated that their vendors refused to provide letters on their behalf to include with their hardship exception application. A commenter specifically questioned whether the 2014 Edition CEHRT hardship would remain in effect for payment year 2015. Several commenters suggested that we should allow hardship exceptions for those providers near retiring, as the cost to implement and upgrade EHR systems are far too costly for those with one or few more years of practice. Many commenters stated that the deadline to file a hardship application should be extended given the timing of this rule. Other commenters wanted us to consider a blanket hardship exemption allowing all EPs to skip attestations in 2014 without penalty. These commenters noted establishing this alternative would push back penalties to 2016, allowing Medicare EPs to skip 2014 without affecting their Medicare reimbursement rates.

Response: We thank the commenters for their input and we recognize that further clarification is required around the subject of hardship exceptions related to the 2014 Edition CEHRT availability delays. To clarify the basic deadlines, a provider who is unable to demonstrate meaningful use in 2014 may apply to qualify for a hardship exception for the 2016 payment adjustment at any point before April 1, 2015 for eligible hospitals and CAHS, and July 1, 2015 for EPs.

The only providers for whom the hardship exception application deadline has already passed are providers seeking an exception from the 2015 payment adjustment because they did not successfully demonstrate meaningful use in 2013. This may include providers that are participating in the program for the first time in 2014 and seek to demonstrate meaningful use by the deadline established for new participants to avoid the 2015 payment adjustment. A new participant who applied for a hardship by the July 1 deadline, and then later is able to meet meaningful use, may attest to their meaningful use data for 2014 without needing to withdraw the hardship application and without any other penalty.

The proposals allow providers flexible options to meet meaningful use in order to qualify for an incentive payment for 2014, and to meet meaningful use to avoid the 2016 payment adjustment. These options are based on a provider's inability to fully implement 2014 Edition CEHRT caused by a delay in 2014 Edition CEHRT availability.

Again, it is not necessary to extend the hardship exception application deadline for providers who are unable to meet meaningful use in 2014 and therefore wish to apply for an exception to the 2016 payment adjustment. We reiterate that the deadline for eligible hospitals to apply for a hardship exception for the 2016 payment adjustment is April 1, 2015. The deadline for EPs to apply for a hardship exception for the 2016 payment adjustment is July 1, 2015. Comments requesting that we consider other types of hardship exceptions fall outside the scope of this rule and will not be addressed.

Comment: Many commenters questioned whether the proposed changes would affect the payment incentives and payment adjustments for 2014 and subsequent years. Some commenters requested clarification on the progression through the Stage of meaningful use and on the participation schedule if providers use one of the CEHRT options to meet meaningful use for an EHR reporting period in 2014. These comments included suggestions such as extending incentive payments indefinitely and suggestions to provide additional payment incentives for providers who meet meaningful use using 2014 Edition CEHRT in 2014 as scheduled. On payment adjustments, commenters requested that we delay all payments adjustments for multiple years or eliminate payment adjustments entirely.

Response: First, 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. One of the reasons we proposed this rule was because we recognized that 2014 is the last year to begin earning incentive payments under the Medicare EHR Incentive Program. This rule will allow providers to meet meaningful use and earn and incentive payment using the flexible CEHRT options for an EHR reporting period in 2014 if they were unable to fully implement 2014 Edition CEHRT due to 2014 Edition CEHRT availability delays. If a provider meets meaningful use in 2014, that provider may go on to earn incentive payments for successful participation in 2015 and 2016 in the Medicare EHR Incentive Program.

However, both the incentive payment amounts and timing, and the payment adjustment amounts and timing, are set by the HITECH Act. The dollar amounts and timing of the incentive payments under Medicare and Medicaid are established by statute (see, for example, section 1848(o)(1)(B) of the Act), and CMS does not have authority to extend or provide additional incentive payments. Similarly, the statute requires downward adjustments to Medicare payments beginning in 2015 (see, for example, section 1848(a)(7)(A) of the Act) if a provider is not a meaningful EHR user for an EHR reporting period for the payment adjustment year, and we do not have authority to delay or eliminate these adjustments.

Comment: Several commenters suggested that we consider whether the regulation text under 42 CFR Part 495 should be further revised to reflect the proposed options for using CEHRT in 2014 and the corresponding objectives and measures of Stages 1 and 2 of meaningful use to which a provider would attest. In particular, the commenters noted that the regulation text for the Stage 1 criteria of meaningful use for EPs, eligible hospitals, and CAHs under § 495.6 includes references to changes in the criteria applicable beginning in 2014.

Response: We thank the commenters for their suggestions and agree that further changes to the regulation text will help to offer clarity for providers seeking to demonstrate meaningful use for 2014 under these options. Accordingly, we revised § 495.6 to specify the flexible options for using CEHRT in 2014 and the objectives and associated measures of meaningful use to which providers using these options would attest. Specifically, these revisions indicate that for an EHR reporting period in 2014, if a provider could not fully implement 2014 Edition CEHRT due to delays in 2014 Edition CEHRT availability, the following apply. An EP, eligible hospital, or CAH that uses only 2011 Edition CEHRT must satisfy the objectives and measures for Stage 1 applicable for an EHR reporting period in 2013. An EP, eligible hospital, or CAH that uses a combination of 2011 Edition CEHRT and 2014 Edition CEHRT may choose to satisfy the objectives and measures for Stage 1 that were applicable for 2013 or the objectives and measures for Stage 1 that are applicable beginning with 2014, or if they are scheduled to begin Stage 2 in 2014, they may choose to satisfy the objectives and measures for Stage 2. An EP, eligible hospital, or CAH that is scheduled to begin Stage 2 in 2014, but is unable to fully implement all the functions of their 2014 Edition CEHRT required for the Stage 2 objectives and measures due to delays in 2014 Edition CEHRT availability, may choose to satisfy the objectives and measures for Stage 1 that are applicable beginning with 2014 using 2014 Edition CEHRT.

As noted earlier, we proposed that EPs, eligible hospitals, and CAHs that use these options must attest that they are unable to fully implement 2014 Edition CEHRT because of issues related to 2014 Edition CEHRT availability delays when they attest to the meaningful use objectives and measures. In this final rule, we revised § 495.8 to reflect this attestation requirement for providers that use the options for CEHRT in 2014 described in the preceding paragraph.

After reviewing the public comments, and for the reasons stated previously, we are finalizing the proposals discussed in section III.A.1. of this final rule without modification as well as the revisions to the regulation text under §§ 495.6, 495.8, and 495.302.

2. Extension of Stage 2

In the proposed rule, we noted that under the current timeline shown in Table 1, an EP, eligible hospital or CAH that first became a meaningful user in 2011 or 2012 would be required to begin Stage 3 on January 1, 2016 (the first day of CY 2016 for EPs) or October 1, 2015 (the first day of FY 2016 for eligible hospitals or CAHs), respectively. However, because we intend to analyze the meaningful use Stage 2 data to inform our development of the criteria for Stage 3 of meaningful use, we proposed a 1-year extension of Stage 2 for those providers as is reflected in Table 3. We proposed that Stage 3 would begin in CY 2017 for EPs and FY 2017 for eligible hospitals and CAHs that first became meaningful users in 2011 or 2012. The goal of this proposed change is two-fold: first, to allow CMS and ONC to focus efforts on the successful implementation of the enhanced patient engagement, interoperability, and health information exchange requirements in Stage 2; and second, to use data from Stage 2 participation to inform policy decisions for Stage 3.

This proposed change would allow EPs, eligible hospitals, and CAHs that first became meaningful users in 2011 or 2012 to begin Stage 3 on January 1, 2017 (EPs) and October 1, 2016 (eligible hospitals and CAHs). We will maintain the existing timeline for providers that first became meaningful users in 2013 and for those that begin in 2014 and subsequent years or until new certification requirements are adopted in subsequent rulemaking, as shown in Table 3.

TABLE 3—PROPOSED 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	1or 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

TABLE 3—PROPOSED STAGE OF MEANINGFUL USE CRITERIA BY FIRST PAYMENT YEAR—Continued

First payment year	Stage of meaningful use										
	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
2017	.....	.....	.....		.....	.....	1	1	2	2	3

*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.

Comment: Many commenters supported what they considered to be a delay of Stage 2. Some commenters requested that we delay the start of Stage 2 into 2015 for private practices given the significant changes to the EHR systems, which challenge small independent private practices to become knowledgeable about new features and allow enough time to train staff.

Response: As confirmed by the overwhelming number of comments received in support of these proposals, we believe the changes proposed give providers the flexibility and time needed to adequately upgrade and implement 2014 Edition CEHRT. However, we do wish to clarify that the proposals do not delay the start of Stage 2, as characterized by several commenters. Rather, the proposals do two things: provide options to those providers who could not fully implement 2014 Edition CEHRT for an EHR reporting period in 2014 due to delays in the availability of 2014 Edition CEHRT, and extend Stage 2 through 2016 so that providers who would have started Stage 3 in that year will not do so until 2017. Moreover, although we welcome comments and suggestion on the EHR Incentive Program, we did not propose to delay the start of Stage 2 to 2015. The proposed rule was not intended to delay the forward progress from Stage 1 to Stage 2, but to provide relief for providers in any stage of meaningful use who were unable to fully implement 2014 Edition CEHRT as required for any stage or year of participation in the program. We believe the requirements of Stage 2 build on the foundation of Stage 1, and are essential to moving toward advanced use of EHRs, enhanced interoperability and health information exchange, and ultimately will support efforts to improve patient care. For these reasons, we did not propose to change the schedule to begin Stage 2, the reporting requirements, or the objectives and measures of Stage 2 of meaningful use.

Comment: Commenters generally agree with extending Stage 2 through 2016 for providers who would have begun Stage 3; however, many commenters further suggested delaying Stage 3 indefinitely or at least for one or more additional years. Some commenters believe that starting Stage 3 in 2017 is premature. Some commenters requested that Stage 3 remain optional or not even start until at least 2018. Other commenters requested that CMS not finalize Stage 3 yet or at all and continue with Stages 1 and 2 until we change the requirement in future rulemaking. Another commenter suggested we stay on Stage 1 for the next few years and then implement Stages 2 and 3 as optional pilot programs.

Response: Although we always welcome suggestions on ways to improve the EHR Incentive Program, other changes to Stage 3 of meaningful use are not under consideration in this rule. We urge readers to wait until the release of the Stage 3 proposed rule to provide comments on this particular area including potential timing for implementation.

Comment: Commenters generally supported delaying Stage 3 to allow time to evaluate prior performance so that we can incorporate lessons learned from Stage 2 into Stage 3, although some questioned whether the timing for Stage 3 would allow adequate reflection on performance in Stage 2. Some commenters stated that merely delaying Stage 3, as proposed, is not enough. A commenter specifically requested detail on how the data we obtain in Stage 2 would be analyzed and used in Stage 3. Another requested that we conduct surveys of providers as part of Stage 3, to increase the quality of our educational guidance.

Response: We appreciate the commenters' input and reiterate that we intend to use the data received on performance at Stages 1 and 2 of meaningful use to inform policy decisions in consideration for Stage 3. We also are engaged with our partners at ONC in conducting ongoing analysis into meaningful use participation among providers including both readiness for advanced use of EHRs and provider reflections on the functions of CEHRT including the objectives and measures which represent the greatest potential benefit for providers and patients. We will use this information to inform decision making for the provisions included in Stage 3 of meaningful use.

After consideration of the public comments received, and for the reasons stated previously, we are finalizing the proposal to extend Stage 2 through CY 2016 for EPs and FY 2016 for eligible hospitals and CAHs that first became meaningful EHR users in CY/FY 2011 or 2012. These providers will begin Stage 3 in CY or FY 2017, respectively. Stage 3 objectives and measures and reporting criteria will be defined in future rulemaking.

B. Clinical Quality Measure Submission in 2014

In the proposed rule, we described how beginning in 2014, as part of the definition of ''meaningful EHR user'' under 42 CFR 495.4, all eligible providers are required to select and report on CQMs from the relevant sets adopted in the Stage 2 final rule (77 FR 54069 through 54075, and 77 FR 54081 through 54089) and further specified as noted in the December 7, 2012 interim final rule with comment period (77 FR 72985) and published on the CMS eCQM Library [*http://cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html*], regardless of their stage of meaningful use or year of participation in the EHR Incentive Program. We proposed the following changes for reporting on clinical quality measures in 2014 for EPs, eligible hospitals, and CAHs for the Medicare and Medicaid EHR Incentive Programs. The method of CQM submission under this proposal would depend on the edition of CEHRT a provider uses to record, calculate, and report its CQMs for the EHR reporting period in 2014.

Due to limitations in the Registration and Attestation System for the EHR Incentive Program and other CMS data systems, the reporting options and methods for CQMs for 2014 would depend upon the edition of CEHRT that a provider uses for the EHR reporting period in 2014. If a provider elects to use only 2011 Edition CEHRT for the EHR reporting period in 2014, the provider would be required to report CQMs by attestation as follows:

• EPs would report from the set of 44 measures and according to the reporting criteria finalized in the Stage 1 final rule (75 FR 44386 through 44411)—

++ Three core/alternate core;

++ Three additional measures; and

++ The reporting period would be any continuous 90 days within CY 2014 for EPs that are demonstrating meaningful use for the first time or a 3-month CY quarter for EPs that have previously demonstrated meaningful use.

• Eligible hospitals and CAHs would report all 15 measures finalized in the Stage 1 final rule (75 FR 44411 through 44422).

• The reporting period would be any continuous 90 days within FY 2014 for hospitals that are demonstrating meaningful use for the first time or a 3-month FY quarter for hospitals that have previously demonstrated meaningful use.

If a provider elects to use a combination of 2011 Edition and 2014 Edition CEHRT and chooses to attest to the 2013 Stage 1 objectives and measures for its EHR reporting period in 2014, the provider would be required to report CQMs by attestation using the same measure sets and reporting criteria outlined earlier for providers who elect to use only 2011 Edition CEHRT for the EHR reporting period in 2014. Because of the differences in how CQMs are calculated and tested between the 2011 and the 2014 Editions of CEHRT, we further proposed that a provider may attest to data for the CQMs derived exclusively from the 2011 Edition CEHRT for the portion of the reporting period in which 2011 Edition CEHRT was in place.

If a provider elects to use a combination of 2011 Edition and 2014 Edition CEHRT and chooses to attest to the 2014 Stage 1 objectives and measures or the Stage 2 objectives and measures, the provider would be required to submit CQMs in accordance with the requirements and policies established for clinical quality measure reporting for 2014 in the Stage 2 final rule and subsequent rulemakings. For further explanation, we refer readers to the following: For EPs—77 FR 54049 through 54089, 77 FR 72985 through 72991, 78 FR 74753 through 74757; and for eligible hospitals and CAHs—77 FR 54049 through 54089, 77 FR 72985 through 72991, 78 FR 50903 through 50906. We also proposed that a provider must submit CQMs in accordance with the requirements and policies established for 2014 in those rulemakings if the provider elects to use only 2014 Edition CEHRT for the entire duration of its EHR reporting period in 2014, regardless of the stage of meaningful use that the provider chooses to meet. For the Medicaid EHR Incentive Program, the method of reporting CQMs for EPs and eligible hospitals will continue to be at the state's discretion subject to our prior approval, as established in the Stage 2 final rule (77 FR 54075 through 54078, and 54087 through 54089).

Comment: We received a number of comments on a variety of issues relating to the CQMs under the EHR Incentive Program. These comments included multiple suggestions falling outside the scope of the proposals outlined in the proposed rule. These suggestions included changing or excluding one or more measures from the program, general objections to the measures or measure calculations, or suggestions for new measures for inclusion in the program. Other commenters suggested hospitals were simply not ready to report quality measures through electronic health data rather than chart abstraction. These commenters requested that we allow hospitals more time to move into the electronic world. Other commenters expressed concern over the difficulty specialists may encounter in reporting on the current CQMs as some CQMs are not relevant to their practice specialty or their patient population.

Those comments falling within the scope of the proposed rule mainly sought clarification on CQM reporting given the flexible options proposed for the use of CEHRT. Some commenters questioned if a provider, using 2014 Edition CEHRT, could choose to attest to either Stage 1 or Stage 2 objectives and measures, and whether the provider would need to submit CQMs in accordance with the requirements established for clinical quality measure reporting for 2014 in prior final rules.

Other commenters sought clarification on the proper CQM version to use for attestation. Specifically, commenters sought confirmation that a provider must report on the versions of the CQMs in use before 2014 if they attest to the 2013 Stage 1 objectives and measures; and that a provider must report on the 2014 CQMs if they attest to the 2014 Stage 1 objectives and measures or Stage 2 objectives and measures. A few commenters added that under these types of situations, making vendors support older versions of CQMs represents an obstacle and burden to participating using an alternate CEHRT option. A commenter added that most vendors who upgraded to 2014 will not be able to support requirements for the prior version of CQMs.

Other commenters requested clarification regarding quality measure reporting and alignment across programs such as how the proposals affect requirements for the EHR Incentive Program and PQRS. Some commenters encouraged CMS to allow physician participation in PQRS in 2014 to satisfy the quality measure portion of the EHR Incentive Program for 2014. These commenters pointed out that the use of an older edition may not support electronic quality measure reporting, thereby resulting in duplicative reporting in PQRS and the EHR Incentive Programs. The commenters believe such duplicative reporting will be confusing and burdensome to many providers, and requested that CMS consider reporting in PQRS sufficient to cover both programs.

Response: As detailed in previous parts of this final rule, we proposed a limited number of changes for the EHR Incentive Programs in 2014. These changes did not include alterations or exclusions to the CQMs themselves.

We appreciate commenter's concern regarding the limited number of measures applicable to certain specialties and wish to provide some clarification in this area. For these providers, we encourage them to evaluate the entire list of CQMs and choose those CQMs most applicable to their practice, including the more broadly applicable preventive care CQMs. We understand cases may exist where an EP may not find a full set of CQMs where they have data for both the numerator and denominator. We remind providers that they may submit a zero as the denominator for a CQM if that is the resulting calculation displayed by their EHR, and as long as their EHR is certified to report the CQM for providers who are using 2014 Edition CEHRT.

Next, we wish to address those comments raised in relation to CQM reporting for the purposes of meeting meaningful use for an EHR reporting period in 2014. We remind providers that for any of the options for the use of CEHRT, a provider may report CQMs on a 3 month quarter, or any 90 days if demonstrating meaningful use for the first time. A provider may also report a full year of CQM data if they so choose.

We confirm that a provider who chooses to attest to the 2013 Stage 1 objectives and measures must also report the CQMs that were applicable for 2013 through the registration and attestation system in the manner that was required for 2013 for the purposes of meeting meaningful use. Although we acknowledge that this requirement may cause some difficulty with maintaining older measure versions that cannot be

electronically reported, we believe for many providers it outweighs the risk of failing to meet meaningful use due to the inability to fully implement 2014 Edition CEHRT for an EHR reporting period in 2014.

We further clarify that a provider who chooses to attest to the 2014 Stage 1 objectives and measures or the Stage 2 objectives and measures must also report the 2014 CQMs in the manner that was required for 2014 for the purposes of meeting meaningful use. This includes attestation or electronic reporting of CQM data through the established reporting methods.

Finally, while we understand and share the commenter's commitment to quality measurement alignment, we cannot accept submission of CQMs unless they are submitted using the previously established reporting methods for the EHR Incentive Program in 2014 using 2014 Edition CEHRT. In addition, we cannot accept CQM submissions for providers using only 2011 Edition CEHRT unless they are submitted through the attestation process. We seek to align quality reporting programs where appropriate and reduce provider burden wherever possible, as shown by our previous efforts to align some of the reporting and submission requirements for the CQM portion of meaningful use with the EHR reporting option for PQRS. Moving forward, we will continue to evaluate ways to align these programs to reduce provider burden.

Comment: Some commenters wanted clarification of the CQM submission in 2014 and alignment of the GPRO Web interface program with Meaningful Use in 2014 as a GPRO submitter. These commenters questioned if the option to submit quality measures via the GPRO web interface to report the 2014 CQMs and meet the meaningful use requirement for CQM reporting would still be available in 2014 if they are attesting to the 2014 edition of CEHRT for Meaningful Use for either stage 1 or 2.

Response: We appreciate the commenter for these questions and provide confirmation that this understanding is correct. Group practices that successfully complete the PQRS GPRO Web Interface in 2014 will also satisfy the CQM component of meaningful use for the Medicare EHR Incentive Program as long as they use an EHR technology product certified to the 2014 edition certification criteria. However, we note that EPs within the group will still be required to separately attest to their meaningful use objectives through the Medicare EHR Incentive Programs Registration and Attestation System.

Comment: Several commenters wanted the option of mixing and matching between 2013 and 2014 Stage 1 objectives and measures and the related CQMs. These commenters wanted the ability to pick some 2013 stage 1 functional objectives and measures and then some 2014 stage 1 functional objectives and measures and different versions of the CQMs in order to demonstrate meaningful use. Other commenters, along similar lines, wanted to mix and match between the 2013 Stage 1 functional objectives and the 2014 CQMs, or vice versa. Several commenters believe providers should have more flexibility in the CQMs they choose to report, regardless of the specific stage of meaningful use they meet.

Response: We appreciate the commenters' suggestions. However, we did not propose the ability to mix and match between the meaningful use objectives and measures and the CQMs for different years for a number of reasons. First, the flexibility proposed leverages the existing definitions of meaningful use which are tied to the use of specific editions of CEHRT. These CEHRT Editions are required to support specific meaningful use objectives and measures as well as the clinical quality measures required for the program. Second, the complexity of the systems required to support attestation and CQM submission would mean we would be unable to operationalize that flexibility in time to allow providers to attest for an EHR reporting period in 2014 if we allowed for additional flexibility in this manner. Therefore, providers must attest to the required set of objectives and measures applicable for the CEHRT option they choose, as well as the CQMs that relate to that option. If a provider chooses the 2013 Stage 1 objectives and measures they must attest to the CQMs using the reporting requirements specified for 2013. Providers selecting this option for the use of CEHRT have the ability to electronically report the 2014 CQMs to quality programs such as PQRS and IQR separately for participation in those programs should they so choose.

Comment: Some commenters expressed concern about the potential difficulty with reporting CQMs for the EHR reporting period in 2014 under the options outlined in the proposed rule. These concerns included issues around the backward compatibility of 2014 Edition CEHRT to 2011 CQMs, as well as the overall changes to the CQMs available for providers to report in 2014 which may not include CQMs they reported on in previous years. In addition, some commenters mentioned that their EHR modules for reporting CQMs might be entirely separate from the rest of their CEHRT and therefore updated at a different point in time. Providers also mentioned that this could impact the integrity of the data for CQMs which are derived from 2011 Edition CEHRT or a combination of CEHRT editions. A commenter questioned whether an EP using 2011 Edition CEHRT for 60 days of a 90-day reporting period (and 2014 Edition CEHRT for 30 days of the EHR reporting period), would only have to report on CQMs for that 60-day period if they chose to attest to the 2013 Stage 1 meaningful use objectives and measures.

Response: We appreciate the commenters for their insight on how CQM reporting may be a challenge under the proposed options, especially given the nuances of how the CQMs are collected within the CEHRT. As discussed previously, we are not considering an option to decouple the CQMs applicable for use in 2013 from the 2013 Stage 1 objectives and measures, nor are we considering separating the 2014 CQMs from the 2014 Stage 1 objectives and measures or the Stage 2 objectives and measures.

However, providers are already permitted under the EHR Incentive Programs to use a different reporting period for the CQMs for 2014 than for the objectives and measures of meaningful use under § 495.6. We believe this existing provision will help to mitigate the potential of a provider having a different timeline for implementation of a 2014 Edition CEHRT module for CQMs than for the rest of their 2014 Edition CEHRT. This means that providers could use an earlier quarter of data derived from their 2011 Edition CEHRT to report CQMs if they use the option allowing for attestation to the 2013 Stage 1 objectives and measures using 2011 Edition CEHRT or a combination of 2011 and 2014 Edition CEHRT. In addition, we confirm the commenter's query that if a provider chooses to use a combination of 2011 Edition and 2014 Edition CEHRT and attests to the 2013 Stage 1 meaningful use objectives and measures, that provider may use the 2011 Edition CEHRT for 60 days of a 90-day reporting period (and 2014 Edition CEHRT for 30 days of the reporting period), and only report on CQMs for that 60-day period. We proposed allowing providers to use a subset of data for the CQMs in use for 2013 for any period of time in which the 2011 Edition CEHRT was in place if they are

attesting to the 2013 Stage 1 objectives and measures using a combination of 2011 Edition and 2014 Edition CEHRT. We believe this will help mitigate problems for providers that are seeking to use a combination of 2011 Edition and 2014 Edition CEHRT that may no longer have the same CQMs available in their 2014 Edition CEHRT. Finally, we will be clearly categorizing the data received from each reporting option in order to preserve the ability to effectively analyze the data received for the purposes of meaningful use.

After reviewing the public comments, and for the reasons stated previously, we are finalizing the proposals discussed in this section (III.B) without modification.

C. Revision to the CEHRT Definition for Flexibility in 2014

In the May 23, 2014 proposed rule, ONC proposed making a minor, but necessary, corresponding revision to the CEHRT definition at 45 CFR 170.102 to support the CMS proposals to provide additional flexibility in the use of CEHRT for the Medicare and Medicaid EHR Incentive Programs during 2014. This proposal was intended to remove the cutoff date for the use of 2011 Edition CEHRT in order to allow for its continued use by providers to meet meaningful use for an EHR reporting period in 2014.

ONC proposed revising the CEHRT definition to change certain Federal fiscal year (FY)/calendar year (CY) cutoffs in paragraphs (1) and (2) of the CEHRT definition under 45 CFR 170.102. These FY/CY cutoffs were finalized in ONC's 2014 Edition final rule (77 FR 54257 through 54260). The policy in paragraph (1) of the definition applies to any fiscal year/calendar year up to and including 2013. The policy in paragraph (2) of the definition applies to FY 2014/CY 2014 and all subsequent years.

Paragraph 1 sets forth policy that permitted the use of 2011 Edition certified Complete EHRs and EHR Modules, a combination of 2011 and 2014 Edition certified Complete EHRs and EHR Modules, and 2014 Edition certified Complete EHRs and EHR Modules to be used to meet the CEHRT definition through the end of FY 2013/CY 2013. In addition, paragraph 2 establishes that, starting with FY 2014/CY 2014, only the use of 2014 Edition certified Complete EHRs and EHR Modules could be used to meet the CEHRT definition.

Therefore, we proposed the following specific revisions to the CEHRT definition, which are necessary to support the added flexibility in the use of CEHRT for providers to meet meaningful use for an EHR reporting period in 2014. The effect of these revisions would be to allow EPs, eligible hospitals, and CAHs to use either 2011 Edition or a combination of 2011 Edition and 2014 Edition CEHRT, including certified Complete EHRs and EHR Modules, to meet the CEHRT definition required to meet meaningful use for an EHR reporting period in 2014.

Specifically, ONC proposed modifying the CEHRT definition at 45 CFR 170.102 to replace the following:

- ''2013'' with ''2014'' in the first sentence of paragraph (1).
- ''FY and CY 2014'' with ''FY and CY 2015'' in paragraph (1)(i) and (1)(iii).
- ''2014'' with ''2015'' in the first sentence of paragraph (2).

Overall, this proposed revision would make the first day of FY 2015 (for eligible hospitals and CAHs) and CY 2015 (for EPs) the new required start date for exclusive use of 2014 Edition certified Complete EHRs and EHR Modules to meet the CEHRT definition.

As discussed in sections III.A. and III.B. of this final rule, we received numerous comments about the options available for the use of CEHRT; however we received no comments specific to this proposal to change the definition of CEHRT at 45 CFR 170.102. We note that this change does not limit the ability of providers to use 2014 Edition CEHRT for an EHR reporting period in 2014 as scheduled. For the reasons stated previously, we are finalizing this provision as proposed with no further revisions.

IV. Attestation and the Options in This Final Rule

We offer several points of clarification around attestation and the options finalized in this rule, as follows:

- The options outlined in this final rule may be used only by providers who are unable to fully implement 2014 Edition CEHRT for an EHR reporting period in 2014 due to delays in the availability of 2014 Edition CEHRT.
- Providers will be required to attest to their inability to fully implement 2014 Edition CEHRT as part of the attestation process should they select one of the options outlined in this final rule.
- Providers may attest based on an EHR reporting period of any 3-month quarter (or any continuous 90 days for new participants) in 2014 (CY for EPs; FY for eligible hospitals and CAHs) up until the close of the 2014 attestation period 2 months following the end of the fiscal or calendar year.
- Providers must attest to the objectives and measures supported by their CEHRT for the 2013 Stage 1 objectives and measures, the 2014 Stage 1 objectives and measures, or the Stage 2 objectives and measures, as well as the related CQMs specified, for each of the options. There are no options to attest to a mixed set of objectives or split the CQM reporting from the option selected.
- For providers attesting to 2014 Stage 1 objectives and measures or Stage 2 objectives and measures, the CQM reporting methods for the 2014 CQMs are available including attestation and electronic reporting options as outlined in section III.B of this regulation.

Upon the effective date of this final rule, we generally expect the attestation process for the EHR reporting periods in 2014 to be as follows, although we recognize that operational or systems issues may require procedural changes:

- A provider will first select from the ONC's Certified Health IT Product List (CHPL) the certified Complete EHR(s) or certified EHR Module(s) they used for the EHR reporting period in 2014. Upon selecting the certified products used during the EHR reporting period, the provider will need to generate a ''CMS EHR Certification ID'' number for their attestation.
- If the provider selects from the CHPL only EHR technology certified to 2011 Edition certification criteria (to meet the CEHRT definition), the CHPL will create a ''CMS EHR Certification ID'' number that reflects only 2011 Edition EHR technology was selected. When this number is entered in the EHR Registration and Attestation System, it will interpret the number to mean that—

++ The provider is attesting to 2013 Stage 1 performance for 2014;

++ Reporting on the 2013 Stage 1 Objectives and Measures; and

++ Attesting to the CQMs that were applicable for 2013 (2011 Edition).

- If the provider selects from the CHPL only EHR technology certified to 2014 Edition certification criteria (to meet the CEHRT definition), the CHPL will create a ''CMS EHR Certification ID'' number that reflects only 2014 Edition EHR technology was selected. When this number is entered in the EHR Registration and Attestation System, it will interpret the number and will then trigger the system to determine the provider's scheduled Stage of meaningful use participation.

If the provider is scheduled to be in Stage 1 for 2014 the system identifies that—

++ The provider remains in Stage 1 for 2014 and is attesting to 2014 Stage 1 performance;

++ Reporting on the 2014 Stage 1 Objectives and Measures; and

++ Reporting on the 2014 CQMs via attestation or electronic reporting.

• If the provider is scheduled to be in Stage 2 for 2014 the system will offer them a choice to select Stage 1 or Stage 2.

If the provider selects Stage 1, the system then records that—

++ The provider is attesting to 2014 Stage 1 performance instead of their previously required Stage 2 performance level for 2014;

++ Reporting on the 2014 Stage 1 Objectives and Measures; and

++ Reporting on the 2014 CQMs via attestation or electronic reporting;

or

If the provider selects Stage 2, the system then records that—

++ The provider is attesting to Stage 2 performance as scheduled for 2014;

++ Reporting on the Stage 2 Objectives and Measures; and

++ Reporting on the 2014 CQMs via attestation or electronic reporting

• If the provider selects from the CHPL a combination of EHR technology certified to the 2011 Edition and 2014 Edition certification criteria (to meet the CEHRT definition), the CHPL will create a specific ''CMS EHR Certification ID'' number that reflects the combination of 2011 Edition and 2014 Edition EHR technology was selected. When this number is entered in the EHR Registration and Attestation System, it will interpret the number and then ask the provider to select whether they intend to attest to the 2013 Stage 1 objectives and measures or whether they intend to attest to the 2014 Stage 1 objectives and measures or the Stage 2 objectives and measures.

++ If the provider selects 2013 objectives and measures, the provider remains in Stage 1 for 2014 and reports on the 2013 Stage 1 objectives and measures and attests to the clinical quality measures as outline previously for 2011 Edition CEHRT.

++ If the provider selects 2014 objectives and measures, the system determines the provider's scheduled Stage of meaningful use and then provides the options as outlined previously for 2014 Edition CEHRT.

Providers who use a 2011 Edition CEHRT number, or who make any selection which differs from their scheduled participation timeline, will be required to attest that they are unable to fully implement 2014 Edition CEHRT for the EHR reporting period in 2014 because of issues related to 2014 Edition CEHRT availability delays.

Providers must retain all relevant supporting documentation (in either paper or electronic format) used in the completion of the EHR Registration and Attestation System responses. Documentation to support attestation data for meaningful use objectives and CQMs must be retained for 6 years post-attestation. Documentation to support payment calculations (such as cost report data) should continue to follow the current documentation retention processes.

In the attestation disclaimer, providers agree to keep such records as necessary to demonstrate meeting Medicare EHR Incentive Program requirements and to furnish those records to the Medicaid state agency, Department of Health and Human Services, or contractor acting on their behalf.

V. Collection of Information Requirements

This document does not impose any new information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements, as defined under the Paperwork Reduction Act of 1995 (5 CFR 1320). However, it does make reference to the currently approved information collection request associated with the Electronic Health Record Incentive Program. The information collection requirements for the program are currently approved under OMB control number 0938–1158 with an expiration date of April 30, 2015.

VII. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) (Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule does not include provisions which incur significant additional cost beyond the expenditures previously estimated for incentive payments and operations costs for the EHR Incentive Programs in 2014. Therefore, this rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.0 million to $35.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this final rule would not have a significant economic impact on a substantial number of small entities. The reporting burden for small entities does not significantly change as a result of this rule therefore the impact on small entities would be negligible.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this final rule would not have a significant impact

on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2014, that threshold is approximately $141 million. This final rule will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Because the programs allow that states may receive federal assistance for administrative costs incurred to support the Medicaid EHR Incentive Programs, this rule does not impose substantial costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

We proposed, for 2014 only, that EPs, eligible hospitals, and CAHs would be able to use either 2011 Edition, 2014 Edition or a combination of 2011 and 2014 Edition certified Complete EHRs and EHR Modules to meet the CEHRT definition and to demonstrate meaningful use during 2014.

To support the policy to provide added flexibility in the Medicare and Medicaid EHR Incentive Programs during 2014, ONC made a minor, but necessary, corresponding revision to the CEHRT definition specified at 45 CFR 170.102, to change certain FY/CY cutoffs in paragraphs (1) and (2) of the CEHRT definition. These FY/CY cutoffs were finalized in ONC's 2014 Edition final rule (77 FR 54257 through 54260).

This final rule will allow the flexibility to use 2011 Edition Certified EHR Technology, a combination of 2011 Edition and 2014 Edition Certified EHR Technology, or solely 2014 Edition Certified EHR Technology in 2014, we do not believe that this will have a significant impact as it merely gives providers the flexibility to choose to retain and use their 2011 Edition CEHRT, a combination of 2011 and 2014 Edition CEHRT, or 2014 Edition CEHRT in 2014. We finalized this policy in response to concerns that the availability of 2014 Edition CEHRT is quite limited. We refer readers to the impact analyses included in the final rule titled ''Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2'' (77 FR 53698 through 54162). Similarly, ONC finalized the revised CEHRT definition to provide additional flexibility in support of our proposal and ONC does not believe that it will have a significant impact (see ''Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology'' (77 FR 54163 through 54292)).

In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 495

Administrative practice and procedure, Health facilities, Health maintenance, organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

45 CFR Part 170

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Health care, Health information technology, Health insurance, Health records, Hospitals, Incorporation by reference, Laboratories, Medicaid, Medicare, Privacy, Reporting and recordkeeping requirements, Public health, Security.

For the reasons stated in the preamble of this final rule, the Centers for Medicare & Medicaid Services and the Department of Health and Human Services confirms as final without changes the interim rule published on December 7, 2012 at 77 FR 72985 and further amend 42 CFR Part 495 and 45 CFR subtitle A, subchapter D, part 170 as set forth below:

Title 42—Public Health

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 1. The authority citation for part 495 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Section 495.6 is amended by adding paragraphs (a)(4), (b)(4), (h)(3), and (i)(3) to read as follows:

§ 495.6 Meaningful use objectives and measures for EPs, eligible hospitals, and CAHs.

(a) * * *

(4) *Flexible options for using certified EHR technology in 2014.* For an EHR reporting period in 2014, if an EP could not fully implement 2014 Edition certified EHR technology due to delays in availability and uses—

(i) Only 2011 Edition certified EHR technology, the EP must satisfy the objectives and associated measures of the Stage 1 criteria that were applicable for 2013; or

(ii) A combination of 2011 Edition certified EHR technology and 2014 Edition certified EHR technology, the EP may choose to satisfy one of the following sets of objectives and associated measures:

(A) The Stage 1 criteria that were applicable for 2013.

(B) The Stage 1 criteria that are applicable beginning 2014.

(C) If the EP is scheduled to begin Stage 2 in 2014, the Stage 2 criteria.

(b) * * *

(4) *Flexible options for using certified EHR technology in 2014.* For an EHR reporting period in 2014, if an eligible hospital or CAH could not fully implement 2014 Edition certified EHR technology due to delays in availability and uses—

(i) Only 2011 Edition certified EHR technology, the eligible hospital or CAH must satisfy the objectives and associated measures of the Stage 1 criteria that were applicable for 2013;

(ii) A combination of 2011 Edition certified EHR technology and 2014 Edition certified EHR technology, the eligible hospital or CAH may choose to satisfy one of the following sets of objectives and associated measures:

(A) The Stage 1 criteria that were applicable for 2013.

(B) The Stage 1 criteria that are applicable beginning 2014.

(C) If the eligible hospital or CAH is scheduled to begin Stage 2 in 2014, the Stage 2 criteria.

* * * * *

(h) * * *

(3) *Flexible options for using certified EHR technology in 2014.* For an EHR reporting period in 2014, if an EP is scheduled to begin Stage 2 in 2014, but is unable to fully implement all the functions of 2014 Edition certified EHR technology required for the objectives and associated measures of the Stage 2 criteria due to delays in availability, the EP may choose to satisfy the objectives and associated measures of the Stage 1 criteria that are applicable beginning 2014 using 2014 Edition certified EHR technology.

(i) * * *

(3) *Flexible options for using certified EHR technology in 2014.* For an EHR reporting period in 2014, if an eligible hospital or CAH is scheduled to begin

Stage 2 in 2014, but is unable to fully implement all the functions of 2014 Edition certified EHR technology required for the objectives and associated measures of the Stage 2 criteria due to delays in availability, the eligible hospital or CAH may choose to satisfy the objectives and associated measures of the Stage 1 criteria that are applicable beginning 2014 using 2014 Edition certified EHR technology.

* * * * *

■ 3. Section 495.8 is amended by adding paragraphs (a)(2)(i)(D) and (b)(2)(i)(D).

§ 495.8 Demonstration of meaningful use criteria.

(a) * * *

(2) * * *

(i) * * *

(D) For 2014 only, if the EP uses one of the options specified under § 495.6(a)(4) or (h)(3), the EP must attest that he or she is unable to fully implement 2014 Edition certified EHR technology for an EHR reporting period in 2014 due to delays in 2014 Edition certified EHR technology availability.

* * * * *

(b) * * *

(2) * * *

(i) * * *

(D) For 2014 only, if the eligible hospital or CAH uses one of the options specified under § 495.6(b)(4) or (i)(3), it must attest that it is unable to fully implement 2014 Edition certified EHR technology for an EHR reporting period in 2014 due to delays in 2014 Edition certified EHR technology availability.

* * * * *

■ 4. Section 495.302 is amended by adding paragraph (4) to the definition of ''Adopt, implement or upgrade'' to read as follows:

§ 495.302 Definitions.

* * * * *

Adopt, implement or upgrade * * *

(4) For payment year 2014, the references to ''certified EHR technology'' in paragraphs (1) through (3) of this definition are deemed to be references to paragraph (2) of the definition of ''Certified EHR Technology'' under 45 CFR 170.102 (that is, the definition of ''Certified EHR Technology'' for FY and CY 2015 and subsequent years).

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Title 45—Public Welfare

PART 170—HEALTH INFORMATION TECHNOLOGY STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA AND CERTIFICATION PROGRAMS FOR HEALTH INFORMATION TECHNOLOGY

■ 5. The authority citation for part 170 continues to read as follows:

Authority: 42 U.S.C. 300jj–11; 42 U.S.C. 300jj–14; 5 U.S.C. 552.

§ 170.102 [Amended]

■ 6. In § 170.102, the definition of ''Certified EHR Technology'' is amended as follows:

■ A. In paragraph (1) introductory text, by removing the year ''2013'' and adding in its place the year ''2014''.

■ B. In paragraph (1)(i), by removing ''; or'' and adding in its place '';''.

■ C. In paragraph (1)(iii), by removing the phrase ''FY and CY 2014'' and adding in its place the phrase ''FY and CY 2015'' and by removing the cross-reference ''paragraph (2);'' and adding in its place the cross-reference ''paragraph (2) of this definition''.

■ D. In paragraph (2) introductory text, by removing the phrase ''FY and CY 2014'' and adding in its place the phrase ''FY and CY 2015''.

Dated: August 19, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Approved: August 27, 2014.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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