



This document is scheduled to be published in the Federal Register on 05/23/2014 and available online at <http://federalregister.gov/a/2014-11944>, and on [FDsys.gov](http://FDsys.gov)

CMS-0052-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Part 495**

**CMS-0052-P**

**RIN 0938-AS30**

**Office of the Secretary**

**45 CFR Part 170**

**RIN 0991-AB97**

**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**

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

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would change the meaningful use stage timeline and the definition of certified electronic health record technology (CEHRT). It would also change the requirements for the reporting of clinical quality measures for 2014.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [OFR insert date 60 days after the date of filing for public inspection at OFR.]

**ADDRESSES:** In commenting, please refer to file code CMS-0052-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to **<http://www.regulations.gov>**. Follow the "Submit a comment" instructions.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Attention: CMS-0052-P,  
P.O. Box 8013,  
Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Attention: CMS-0052-P,  
Mail Stop C4-26-05,  
7500 Security Boulevard,  
Baltimore, MD 21244-1850.

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4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Room 445-G, Hubert H. Humphrey Building,  
200 Independence Avenue, SW.,  
Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
7500 Security Boulevard,  
Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.

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Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

**FOR FURTHER INFORMATION CONTACT:**

Elizabeth Holland, (410) 786-1309.

Elisabeth Myers, (410) 786-4751.

Steven Posnack, (202) 690-7151.

**SUPPLEMENTARY INFORMATION:**

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

## **I. Background**

### A. Statutory Basis for the 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 eligible professionals (EPs), eligible hospitals, critical access 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 certified EHR technology (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.

### B. Considerations in Defining Meaningful Use and CEHRT

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 that Medicaid providers adopt, implement, upgrade, or meaningfully use CEHRT if they are to receive incentives under Title XIX of

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the Act. CEHRT used in a meaningful way is one piece of the broader health information technology (HIT) 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
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 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.

**II. Provisions of the Proposed Regulations**

**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 and listening sessions, survey data, and information related to the

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certification and testing process, that the amount of time available after the publication of the Stage 2 final rule in which to make the required coding changes to enable their EHR products to be certified to the 2014 Edition of EHR certification criteria was much too short. We understand, based on information gained from EHR technology developers and ONC-Authorized Certification Bodies on timing, backlogs, and the certification case load, many EHR products were certified later than anticipated, which has impacted the corresponding time available to providers—especially hospitals—to effectively deploy 2014 Edition CEHRT and to make the necessary patient safety, staff training, and workflow investments 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 had received an EHR incentive payment for adopting, implementing, or upgrading, or for successfully demonstrating meaningful use using 2011 Edition CEHRT. All providers need 2014 Edition CEHRT to adopt, implement, or upgrade, or to successfully demonstrate meaningful use for Stage 1 or Stage 2 in 2014. Through letters to CMS, public forums, listening sessions, and public comment at CMS meetings, many provider associations have expressed concern that, although 2014 Edition CEHRT may be available for adoption, there is a backlog of many months for the updated version to be installed and implemented so that providers can successfully attest for 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, (1) a hospital may have different systems in multiple settings, which all require an update and

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integration or (2) a provider may have certain 2014 Edition CEHRT functionality that, once implemented in a live setting, requires software patches or workflow changes.

In an effort to grant more flexibility to providers who have experienced 2014 Edition CEHRT product availability issues that impact the ability to fully implement 2014 Edition CEHRT to attest to meaningful use using 2014 Edition CEHRT, we are proposing the following changes for the Medicare and Medicaid EHR Incentive Programs for 2014 for providers that are not able to fully implement 2014 Edition CEHRT for a full EHR reporting period in 2014. We are proposing to allow these EPs, eligible hospitals, and CAHs that could not fully implement 2014 Edition CEHRT for the 2014 reporting year 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 for providers that could not fully implement 2014 Edition CEHRT to meet meaningful use for the duration of an EHR reporting period in 2014 due to delays in 2014 Edition CEHRT availability.

We are proposing this change for 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.

We strongly recommend eligible professionals, eligible hospitals, and CAHs that have not yet purchased EHR technology to obtain 2014 Edition CEHRT as these

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providers will still need to use 2014 Edition CEHRT for their EHR reporting period in 2015 as stated earlier.

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 are proposing 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 are proposing to revise the definition of "Adopt, Implement or Upgrade" under 42 CFR 495.302 to reflect this proposal.

The edition of certified EHR technology which is available to a provider dictates the stage and version of the meaningful use objectives and measures to which the provider will be able to attest. 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 clinical quality measures a provider can calculate and report because the calculations are part of the software programming within the CEHRT system.

The three 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

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We are proposing 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 were applicable 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, and some of those changes were applicable beginning with 2013 while other changes were applicable beginning with 2014. For ease of reference, we will refer to the Stage 1 objectives and associated measures under 42 CFR 495.6 that were applicable for 2013 as the "2013 Stage 1 objectives and measures," and we will refer to the Stage 1 objectives and associated measures under 42 CFR 495.6 that are 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 are proposing 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

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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 that are necessary to meet the Stage 2 objectives and measures in time to complete their EHR reporting period in 2014.

Therefore, under our proposal, providers who are scheduled to begin Stage 2 for the 2014 EHR reporting period but are unable to fully implement all the functions of their 2014 Edition CEHRT required for Stage 2 objectives and measures due to delays in 2014 Edition CEHRT availability would have the option of using 2014 Edition CEHRT to attest to the 2014 Stage 1 objectives and measures for the 2014 EHR reporting period.

Providers who are 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 are not proposing any changes. Under the current timeline shown in Table 1, providers that first

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demonstrated meaningful use Stage 1 in 2011 or 2012 are required to begin Stage 2 in 2014. We are proposing that the flexibility regarding use of the various editions of CEHRT as outlined earlier would apply only to the EHR reporting periods in 2014 for the EHR Incentive Program. Providers that were scheduled to begin Stage 2 in 2014 that instead meet the Stage 1 criteria in 2014 will be required to begin Stage 2 in 2015 as noted in Table 3. In 2015, all providers, except those in their first year of demonstrating meaningful use, are required to have a full year EHR reporting period. In addition, in 2015, all providers are required to have 2014 Edition CEHRT in order to successfully demonstrate meaningful use.

**Table 2: Proposed CEHRT Systems Available for Use in 2014**

<b>If you were scheduled to demonstrate:</b>	<b>You would be able to attest for Meaningful Use:</b>		
	<b>Using 2011 Edition CEHRT to do:</b>	<b>Using 2011 &amp; 2014 Edition CEHRT to do:</b>	<b>Using 2014 Edition CEHRT to do:</b>
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 reporting period in 2014 due to delays in 2014 Edition CEHRT availability.

The following are example scenarios under our proposal.

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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 delays in 2014 Edition CEHRT availability.
- 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 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 below in section B of this proposal.

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

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required to use 2014 Edition CEHRT and demonstrate Stage 1 of meaningful use in 2014.

Under our proposal, this EP would have one 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 proposed rule.

## 2. Extension of Stage 2

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 are proposing a 1-year extension of Stage 2 for those providers as is reflected in Table 3. We are proposing that Stage 3 would begin in CY 2017 for EPs and FY 2017 for eligible hospitals and CAHs that first became

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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 utilize 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	1 or 2*	2	2	3	3	TBD	TBD	TBD
2013			1	1*	2	2	3	3	TBD	TBD	TBD
2014				1*	1	2	2	3	3	TBD	TBD
2015					1	1	2	2	3	3	TBD
2016						1	1	2	2	3	3
2017							1	1	2	2	3

\*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.

We invite public comment on our proposals.

B. Clinical Quality Measure Submission in 2014

In 2014, as part of the definition of "meaningful EHR user" under 42 CFR 495.4, all providers are required to select and report on clinical quality measures (CQMs) from

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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](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 are proposing 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 clinical quality measures for the selected 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 its EHR reporting period in 2014. If a provider elects to use only 2011 Edition CEHRT for its 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

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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 their EHR reporting periods in 2014. Because of the differences in how CQMs are calculated and tested between the 2011 and the 2014 Editions of CEHRT, we are further proposing 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

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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 are also proposing 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).

We invite public comment on our proposal.

#### C. Revision to the CEHRT Definition for Additional Flexibility in 2014

To support the CMS proposals to provide additional flexibility in the Medicare and Medicaid EHR Incentive Programs during 2014, ONC is proposing to make a minor, but necessary, corresponding revision to the CEHRT definition at 45 CFR 170.102.

ONC is proposing to revise 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.

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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 FY2013/CY 2013. However, paragraph (2) establishes policy that, starting with FY2014/CY 2014, only the use of 2014 Edition certified Complete EHRs and EHR Modules could be used to meet the CEHRT definition.

The following specific proposed revisions to the CEHRT definition are necessary to support the added flexibility we proposed for 2014. The effect of these proposed revisions would be to allow EPs, eligible hospitals, and CAHs to use either 2011 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 Stage 1 for 2014.

Specifically, ONC is proposing to modify 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 eligible professionals) the new required start date for exclusive use of 2014 Edition certified Complete EHRs and EHR Modules to meet the CEHRT definition.

We invite public comment on our proposals.

### **III. 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.

### **IV. Response to Comments**

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

### **V. 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)).

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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). 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 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 proposed rule would not have a significant economic impact on a substantial number of small entities.

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 603 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

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proposed 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 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. Since this rule does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

CMS is proposing, 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 CMS proposals to provide added flexibility in the Medicare and Medicaid EHR Incentive Programs during 2014, ONC is proposing to make 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).

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With respect to our proposal to 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 proposal 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 are making this proposal 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, the ONC proposal to revise the CEHRT definition merely provides additional flexibility in support of the CMS proposals 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.

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## **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 proposed rule, the Centers for Medicare & Medicaid Services is proposing to amend 42 CFR Part 495 and the Department is proposing to amend 45 CFR 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 495.302 is amended by adding paragraph (4) to the definition of "Adopt, implement or upgrade" to read as follows:

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**§ 495.302 Definitions.**

\* \* \* \* \*

Adopt, implement or upgrade means--

\* \* \* \* \*

(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).

\* \* \* \* \*

**Title 45—Public Health**

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

3. 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]**

4. 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 ";".

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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), by removing the phrase "FY and CY 2014" and adding in its place the phrase "FY and CY 2015".

Dated: May 12, 2014

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**Marilyn Tavenner,**

Administrator,

Centers for Medicare & Medicaid Services.

Approved: May 13, 2014

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**Kathleen Sebelius,**

Secretary,

Department of Health and Human Services.

**BILLING CODE 4120-01-P**

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**[FR Doc. 2014-11944 Filed 05/20/2014 at 4:15 pm; Publication Date: 05/23/2014]**