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Part III

## Department of Health and Human Services

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Centers for Medicare & Medicaid Services

42 CFR Part 495

Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Modifications to Meaningful Use in 2015 Through 2017; Proposed Rule

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Medicare & Medicaid Services****42 CFR Part 495**

[CMS-3311-P]

RIN 0938-AS58

**Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Modifications to Meaningful Use in 2015 Through 2017****AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would change the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program EHR reporting period in 2015 to a 90-day period aligned with the calendar year, and also would align the EHR reporting period in 2016 with the calendar year. In addition, this proposed rule would modify the patient action measures in the Stage 2 objectives related to patient engagement. Finally, it would streamline the program by removing reporting requirements on measures which have become redundant, duplicative, or topped out through advancements in EHR function and provider performance for Stage 1 and Stage 2 of the Medicare and Medicaid EHR Incentive Programs.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 15, 2015.

**ADDRESSES:** In commenting, please refer to file code CMS-3311-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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-3311-P, P.O. Box 8013, Baltimore, MD 21244-8013.

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-3311-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

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.

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, Medicare EHR Incentive Program and Medicare payment adjustment.

Elisabeth Myers (CMS), (410) 786-4751, Medicare EHR Incentive Program.

Thomas Romano (CMS), (410) 786-0465, Medicaid EHR Incentive Program.

**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.

**Acronyms**

ARRA—American Recovery and Reinvestment Act of 2009  
 AAC—Average Allowable Cost (of certified EHR Technology)  
 ACO—Accountable Care Organization  
 AIU—Adopt, Implement, Upgrade (certified EHR Technology)  
 CAH—Critical Access Hospitals  
 CAHPS—Consumer Assessment of Healthcare Providers and Systems  
 CCN—CMS Certification Number  
 CDC—Centers for Disease Control  
 CEHRT—Certified Electronic Health Record Technology  
 CFR—Code of Federal Regulations  
 CHIP—Children's Health Insurance Program  
 CHIPRA—Children's Health Insurance Program Reauthorization Act of 2009  
 CMS—Centers for Medicare and Medicaid Services  
 CPOE—Computerized Physician Order Entry  
 CQM—Clinical Quality Measure  
 CY—Calendar Year  
 EHR—Electronic Health Record  
 EP—Eligible Professional  
 ePHI—Electronic Protected Health Information  
 EPO—Exclusive Provider Organization  
 FACA—Federal Advisory Committee Act  
 FFP—Federal Financial Participation  
 FFY—Federal Fiscal Year  
 FFS—Fee-for-Service  
 FQHC—Federally Qualified Health Center  
 FTE—Full Time Equivalent  
 FY—Fiscal Year  
 HEDIS—Healthcare Effectiveness Data and Information Set  
 HHS—Department of Health and Human Services  
 HIE—Health Information Exchange  
 HIT—Health Information Technology  
 HITPC—Health Information Technology Policy Committee  
 HIPAA—Health Insurance Portability and Accountability Act of 1996  
 HITECH—Health Information Technology for Economic and Clinical Health Act  
 HMO—Health Maintenance Organization  
 HOS—Health Outcomes Survey  
 HPSA—Health Professional Shortage Area  
 HRSA—Health Resources and Services Administration  
 IAPD—Implementation Advanced Planning Document  
 ICR—Information Collection Requirement  
 IHS—Indian Health Service  
 IPA—Independent Practice Association  
 IPPS—Inpatient Prospective Payment System

IQR—Inpatient Quality Reporting  
 IT—Information Technology  
 MA—Medicare Advantage  
 MAC—Medicare Administrative Contractor  
 MCO—Managed Care Organization  
 MITA—Medicaid Information Technology Architecture  
 MMIS—Medicaid Management Information Systems  
 MSA—Medical Savings Account  
 MU—Meaningful Use  
 NAAC—Net Average Allowable Cost (of certified EHR Technology)  
 NCQA—National Committee for Quality Assurance  
 NCVHS—National Committee on Vital and Health Statistics  
 NPI—National Provider Identifier  
 NQF—National Quality Forum  
 ONC—Office of the National Coordinator for Health Information Technology  
 PAHP—Prepaid Ambulatory Health Plan  
 PAPD—Planning Advanced Planning Document  
 PFFS—Private Fee-for-Service  
 PHO—Physician Hospital Organization  
 PHS—Public Health Service  
 PHSA—Public Health Service Act  
 PIHP—Prepaid Inpatient Health Plan  
 POS—Place of Service  
 PPO—Preferred Provider Organization  
 PQRS—Physician Quality Reporting System  
 PHI—Protected Health Information  
 PSO—Provider Sponsored Organization  
 RHC—Rural Health Clinic  
 RPPO—Regional Preferred Provider Organization  
 SAMHSA—Substance Abuse and Mental Health Services Administration  
 SMHP—State Medicaid Health Information Technology Plan  
 TIN—Tax Identification Number

## I. Executive Summary and Background

### A. Executive Summary

#### 1. Purpose of Regulatory Action

##### a. Need for Regulatory Action

In this proposed rule, we would implement changes to Stage 1 and Stage 2 of the Medicare and Medicaid EHR Incentive Programs. In the March 30, 2015 **Federal Register** (80 FR 16731 through 16804), we published in the proposed rule for Stage 3 of meaningful use which included changes to the objectives and measures of meaningful use for providers beginning in 2017. These changes included removing redundant, duplicative, and topped out measures, and focusing the EHR Incentive Programs on advanced use of EHR technology. In order to reduce reporting burden, eliminate redundant and duplicative reporting, and to better align the objectives and measures of meaningful use for 2015 through 2017 with the proposed Stage 3 requirements which would be optional in 2017 and required beginning in 2018, we are proposing to make similar modifications to Stage 1 and Stage 2 of the EHR Incentive Programs.

In addition, in order to accommodate these changes, we propose additional modifications to the EHR reporting period and timeline of the Medicare and Medicaid EHR Incentive Programs in 2015 and 2016. We believe these changes would better align reporting periods for providers, support a flexible, clear framework to reduce provider burden, and ensure future sustainability of the Medicare and Medicaid EHR Incentive Programs.

##### b. Legal Authority for the Regulatory Action

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, and Critical Access Hospitals (CAHs), and Medicare Advantage (MA) organizations to promote the adoption and meaningful use of Certified Electronic Health Record Technology (CEHRT). 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. (There are no payment adjustments under Medicaid.) (For a more detailed explanation of the statutory basis for the EHR incentive payments, see the July 28, 2010 Stage 1 final rule (75 FR 44316 through 44317).)

#### 2. Summary of Major Provisions

##### a. Aligning Meaningful Use in 2015 Through 2017 With the Stage 3 Proposals for Meaningful Use in 2017 and Subsequent Years

The Stage 1 final rule sets the foundation for the Medicare and Medicaid EHR Incentive Programs by establishing requirements for the electronic capture of clinical data, including providing patients with electronic copies of health information. We outlined Stage 1 meaningful use criteria, and finalized core and menu

objectives for EPs, eligible hospitals, and CAHs. (For a full discussion of the objectives and measures of Stage 1, we refer readers to the Stage 1 final rule at 75 FR 44313 through 44588.) In the Stage 1 rulemaking, we discussed the idea that alignment of stage of meaningful use and payment year should synchronize for all providers in 2015. However, while we stated a goal to align the stages of meaningful use across all providers in 2015 (75 FR 44322), we did not finalize such changes in the Stage 2 final rule. Furthermore, we stated in subsequent rulemaking (see for example the 2014 CERHT Flexibility rule at 79 FR 52923 and 52596) that the requirements for each stage for the program must be informed by analysis of program data related to performance and participation milestones.

In the September 4, 2012 stage 2 final rule, we maintained the same core-menu structure finalized for several Stage 1 core and menu objectives. We finalized that EPs must meet the measure or qualify for an exclusion to 17 core objectives and 3 of 6 menu objectives. We finalized that eligible hospitals and CAHs must meet the measure or qualify for an exclusion to 16 core objectives and 3 of 6 menu objectives. We combined several Stage 1 measures into Stage 2. With the experience providers gained from the Stage 1 final rule, we also increased functional objective measure thresholds in Stage 2 to increase efficiency, effectiveness, and flexibility. Also, beginning in 2014, we finalized a set of clinical quality measures (CQMs) for all providers participating in any Stage of the program to report to CMS. (For a full discussion of the meaningful use objectives and measures, and the CQMs we finalized under Stage 2, we refer readers to the Stage 2 final rule at 77 FR 53968 through 54162.)

In the Stage 3 proposed rule, we built on the groundwork established in the Stage 1 and Stage 2 final rules, including continuing our goal started under Stage 2 to increase interoperability among providers. We also proposed to make changes to the Medicare and Medicaid EHR Incentive Programs that simplify reporting requirements and reduce program complexity. These changes were intended to balance the statutory requirements in the HITECH Act with responsiveness to providers expressing confusion and concerns over increased reporting burden related to the number of program requirements, the multiple stages of program participation, and the timing of EHR reporting periods. Therefore, we proposed for Stage 3 a

single set of 8 objectives and related measures to meet the definition of meaningful use. We proposed that this single set of 8 objectives would be optional for 2017 and mandatory beginning in 2018. Also, the Stage 3 proposed rule would move all providers to an EHR reporting period of one full calendar year, with a limited exception for Medicaid providers demonstrating meaningful use for the first time, to support program alignment and simplify reporting requirements among provider types. The Stage 3 proposed rule and the 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications (hereinafter referenced as the “2015 Edition proposed rule”) published by the Office of the National Coordinator for Health Information Technology (ONC) may be reviewed at 80 FR 16731 through 16804 and 80 FR 16804 through 1692, respectively. The Stage 3 proposed rule would align the stages of meaningful use across all providers beginning in 2018.

In this proposed rule, we are seeking to make changes to the requirements for Stage 1 and Stage 2 of meaningful use for 2015 through 2017 to align with the approach for Stage 3 of meaningful use in 2017 and subsequent years. The analysis conducted during the planning process for Stage 3 also allowed insight into the progress toward program milestones and provider performance on the objectives and measures. This analysis allowed us to identify an approach to be responsive to stakeholder concerns about program complexity and revisit the consideration that the stage of meaningful use and EHR reporting periods should align where possible. Therefore, we are proposing a number of changes to both the EHR reporting period, and to the number of objectives and measures to which a provider must attest to demonstrate meaningful use. Specifically, we are proposing to move all providers to an EHR reporting period based on the calendar year beginning in 2015. Also, we propose to align the objectives and measures used in 2015 through 2017 with those identified in the Stage 3 proposed rule for use in 2017 and subsequent years. This includes a proposal that, beginning with an EHR reporting period in 2015, providers would no longer be required to attest to certain objectives and measures which have been identified through our analysis to have reduced utility because they may now be redundant, duplicative, or “topped

out”. (For further discussion of this selection process for Stage 3, we direct readers to sections I.A.2. and II.A.2. of the Stage 3 proposed rule at (80 FR 16733 through 16735 and 16767 through 16768, respectively). The related selection process for the proposed changes to meaningful use in 2015 through 2017 uses a similar approach to reducing the reporting burden while also seeking to meet our statutory requirement to include more stringent measures of meaningful use. Our approach for applying these principals for meaningful use in 2015 through 2017 is discussed in more detail in section II.B.1.c. of this proposed rule.

#### b. EHR Reporting Period in 2015 and 2016

We are proposing to align the definition of an EHR reporting period with the calendar year for all providers beginning in 2015 and continuing through 2016 onward. Specifically, this proposal would change the EHR reporting period for eligible hospitals and CAHs from a period based on the fiscal year to the calendar year beginning in 2015. This aligns with the provision outlined in the Stage 3 proposed rule to move all providers to an EHR reporting period of 1 full calendar year beginning in 2017 with a limited exception for Medicaid providers demonstrating meaningful use for the first time (80 FR 16734 and 80 FR 16737 through 16739). For 2015 and 2016, we are proposing to allow new participants in the EHR Incentive Program to attest to meaningful use for an EHR reporting period of any continuous 90-day period within the calendar year. In addition, for 2015 only, we are proposing to allow all EPs (regardless of their prior participation in the program) to attest to an EHR reporting period of any continuous 90-day period within the calendar year. For 2015 only, we are proposing to allow eligible hospitals and CAHs (regardless of their prior participation in the program) to attest to an EHR reporting period of any continuous 90-day period within the period beginning October 1, 2014 and the close of the 2015 calendar year. This 90-day EHR reporting period for 2015 would allow providers additional time to address any remaining issues with the implementation of technology certified to the 2014 Edition and to accommodate the changes to the objectives and measures of meaningful use proposed in this rule.

In 2016, we propose EPs, eligible hospitals, and CAHs that are demonstrating meaningful use for the first time may use an EHR reporting

period of any continuous 90-day period between January 1, 2016 and December 31, 2016. However, all returning participants would use an EHR reporting period of a full calendar year from January 1, 2016 through December 31, 2016. In 2017, all providers, both new and existing participants, would use an EHR reporting period of 1 full calendar year as proposed in the Stage 3 proposed rule at (80 FR 16737 through 16739) with a limited exception for Medicaid providers demonstrating meaningful use for the first time.

#### c. Meaningful Use Objectives and Measures for 2015 Through 2017

In the Stage 3 proposed rule, we outlined our method and approach for identifying the objectives and measures retained for Stage 3 of meaningful use in 2017. We also identified those objectives and measures which are now redundant, duplicative, or topped out; and therefore, would no longer be required for the successful demonstration of meaningful use for Stage 3. For further discussion of this approach, we refer readers to (80 FR 16733 through 16735 and 16767 through 16768).

In this proposed rule, we discuss how we have used the same method to identify objectives and measures from Stages 1 and 2 of meaningful use which we believe should no longer be required for a provider to demonstrate meaningful use in 2015 through 2017 as these measures have been identified as redundant, duplicative, or topped out. These changes would remove the menu and core structure of Stages 1 and 2 and reduce the overall number of objectives to which a provider must attest. We discuss this approach in section II.B.1.c. of this proposed rule.

In addition, we are proposing changes to individual objectives and measures for Stage 2 of meaningful use as follows:

- Changing the threshold from the Stage 2 Objective for Patient Electronic Access measure number 2 from “5 percent” to “equal to or greater than 1”.
- Changing the threshold from the Stage 2 Objective Secure Electronic Messaging from being a percentage-based measure, to yes-no measure stating the “functionality fully enabled”.
- Consolidating all public health reporting objectives into one objective with measure options following the structure of the Stage 3 Public Health Reporting Objective (80 FR 16745 through 16767).
- Changing the eligible hospital electronic prescribing objective from a “menu” objective to a mandatory

objective with an exclusion available for certain eligible hospitals and CAHs.

These proposed changes would apply for providers beginning with the EHR reporting period in 2015. We note that these proposals include provisions to maintain the existing definitions for the objectives and measures including numerator and denominator calculation, provisions to maintain measure thresholds for 2015, and provisions to allow exclusions for certain eligible providers in 2015 in order to facilitate the transition for providers already engaged in the workflows, data capture and measure calculation for meaningful use for an EHR reporting period in 2015.

#### d. Certification Requirements

Under this proposed rule, we are not proposing changes to the individual certification requirements for the objectives and measures of meaningful use for an EHR reporting period in 2015 through 2017. Until a transition to EHR technology certified to the 2015 Edition is required (proposed in the Stage 3 proposed rule beginning with an EHR reporting period in 2018 at (80 FR 16767 and 16768), we are proposing that providers would continue to use EHR technology certified to the 2014 Edition for an EHR reporting period in 2015, 2016, and 2017. As outlined in the Stage 3 proposed rule, providers may upgrade early to EHR technology certified to the 2015 Edition for an EHR reporting period prior to 2018. (For further information on this, and to review the applicable definition of CEHRT, we direct readers to the Stage 3 proposed rule at (80 FR 16767 and 16768).

#### e. Medicaid EHR Incentive Program in 2015 through 2017

The proposals included in this proposed rule would also apply for the Medicaid EHR Incentive Program, including the proposed changes to the EHR reporting period in 2015 and 2016, and the objectives and measures required to demonstrate meaningful use in 2015 through 2017. Consistent with the Stage 3 proposed rule, we propose to continue to offer states flexibility under the Medicaid EHR Incentive Program for the public health reporting objective. For meaningful use in 2015 through 2017, we would continue the policy stated in the Stage 2 final rule (77 FR 53979) to allow states to specify the means of transmission of the data or otherwise change the public health measure (as long as it does not require EHR functionality above and beyond that which is included in the certification requirements specified under the 2014 Edition certification criteria). (For more information see the

Stage 3 proposed rule (80 FR 16737 through 16739).)

#### f. Clinical Quality Measurement

We are not proposing changes to the CQM selection or reporting scheme (9 or 16 CQMs across at least 3 domains) from the CQM requirements previously established for all providers seeking to demonstrate meaningful use in the Medicare and Medicaid EHR Incentive Programs defined in earlier rulemaking (see, for example, 77 FR 54049 through 54089). For an EHR reporting period in 2015, and for providers demonstrating meaningful use for the first time in 2016, we are proposing that providers may—

- Attest to any continuous 90-day period of CQM data during the calendar year through the Medicare EHR Incentive Program registration and attestation site; or

- Electronically report CQM data using the established methods for electronic reporting.

For 2016 and subsequent years, providers beyond their first year of meaningful use may attest to one full calendar year of CQM data or they may electronically report their CQM data using the established methods for electronic reporting outlined in section II.C. of this proposed rule.

#### g. Demonstration of Meaningful Use

We are proposing to continue our common method for demonstrating meaningful use in both the Medicare and Medicaid EHR Incentive Programs. The demonstration methods we adopt for Medicare would automatically be available to states for use in their Medicaid programs. We are proposing to continue the use of attestation as the method for demonstrating that an EP, eligible hospital, or CAH has met the objectives and measures of meaningful use. In lieu of individual Medicare EP attestation through the CMS registration and attestation system, we are proposing to continue the existing optional batch file process for attestation. We are additionally proposing changes to the attestation deadlines to accommodate the proposed change to reporting based on the calendar year for eligible hospitals and CAHs beginning with an EHR reporting period in 2015, as well as the proposed change to a 90-day EHR reporting period for all providers in 2015. We are proposing changes to the attestation deadlines for new meaningful EHR users in 2015 and 2016 to avoid the Medicare payment adjustments in 2016 and 2017. Finally, we are proposing an alternate attestation option for certain Medicaid providers to demonstrate meaningful use in 2015

and subsequent years to avoid Medicare payment adjustments.

#### h. Payment Adjustments and Hardship Exceptions

We are proposing changes to the definition of an EHR reporting period for a payment adjustment at \$ 495.4 as well as the attestation deadlines for certain providers to demonstrate meaningful use for an EHR reporting period to avoid the Medicare payment adjustment.

#### i. Summary of Cost Benefit Analysis

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). Accordingly, we have prepared a regulatory impact analysis that to the best of our ability presents the costs and benefits of the proposed rule.

The regulatory impact analysis of this proposed rule for modification to the Medicare and Medicaid EHR Incentive Programs from 2015 through 2017 outlines the reduction in the reporting burden for providers demonstrating meaningful use in 2015 and estimates the total annual cost savings. The low and high estimates for these total savings are \$52,547,132 and \$68,617,864 respectively. In addition to these reductions, we believe there are substantial cost savings accruing to eligible hospitals and EPs related to having additional time to achieve meaningful use.

#### B. Overview of the Regulatory History

The American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5)(ARRA) amended Titles XVIII and XIX of the Act to authorize incentive payments to EPs, eligible hospitals, and CAHs, and MA organizations to promote the adoption and meaningful use of CEHRT. In the July 28, 2010 **Federal Register** (75 FR 44313 through 44588), we published a final rule (“Medicare and Medicaid Programs; Electronic Health Record Incentive Program”, or “Stage 1 final rule”) that specified the Stage 1 criteria EPs, eligible hospitals, and CAHs must meet in order to qualify for an incentive payment, calculation of the incentive payment amounts, and other program participation requirements. (For a full explanation of the amendments made by ARRA, see the Stage 1 final rule at 75 FR 44316.) In that Stage 1 final rule, we also detailed that the Medicare and Medicaid EHR

Incentive Program would consist of three different stages of meaningful use requirements.

In the September 4, 2012 **Federal Register** (77 FR 53967 through 54162), we published a final rule (“Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2; Final Rule” or “Stage 2 final rule”) that specified the Stage 2 criteria that EPs, eligible hospitals, and CAHs would have to meet in order to qualify for incentive payments. In addition, the Stage 2 final rule finalized payment adjustments and other program participation requirements under Medicare for covered professional and hospital services provided by EPs, eligible hospitals, and CAHs failing to demonstrate meaningful use of CEHRT, and finalized the revision of certain Stage 1 criteria, and finalized criteria that applied regardless of stage.

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” (December 7, 2012 IFC). The Department of Health and Human Services (HHS) issued the 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 (MU) 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.

The December 7, 2012 IFC also provided notice of our intention to issue technical corrections to the electronic specifications for CQMs released on October 25, 2012.

In the September 4, 2014 **Federal Register** (79 FR 52910 through 52933) CMS and ONC published a final rule titled “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” (“2014 CEHRT Flexibility final rule”). Due to issues related to EHR technology certified to the 2014 Edition availability delays, the 2014 CEHRT Flexibility final rule included policies allowing EPs, eligible hospitals, and CAHs that could not fully implement EHR technology certified to the 2014 Edition for an EHR reporting period in 2014 to continue to use one of the following options for reporting periods in CY 2014 and FY 2014, respectively—

- EHR technology certified to the 2011 Edition; or
- A combination of EHR technology certified to the 2011 Edition and EHR technology certified to the 2014 Edition for the EHR reporting periods.

These CEHRT options applied only to those providers that could not fully implement EHR technology certified to the 2014 Edition to meet meaningful use for an EHR reporting period in 2014 due to delays in 2014 Edition availability. Although the 2014 CEHRT flexibility final rule did not alter the attestation or hardship exception application deadlines for 2014, it did make changes to the attestation process to support these flexible options for CEHRT. This 2014 CEHRT Flexibility final rule also discussed the provisions of the December 7, 2012 IFC and finalized policies relating to the provisions contained in the December 7, 2012 IFC.

In the November 13, 2014 **Federal Register**, we published an interim final rule with comment period, under the Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015 (79 FR 67976 through 67978) (“November 13, 2014 IFC”). Under this November 13, 2014 IFC, we recognized a hardship exception for EPs and eligible hospitals for 2014 under the established category of extreme and uncontrollable circumstances in accordance with the Secretary’s discretionary authority. To accommodate this hardship exception, we further extended the hardship application deadline for EPs and eligible hospitals to November 30 for 2014 only. We also amended the regulations to allow CMS to specify a later hardship application deadline for certain

hardship categories for EPs, eligible hospitals, and CAHs.

In the March 30, 2015 **Federal Register**, we published a proposed rule entitled “Medicare and Medicaid Programs; Electronic Health Record Incentive Program Stage 3” (80 FR 16731 through 16804). In this March 30, 2015 Stage 3 proposed rule, we specified the proposed meaningful use criteria that EPs, eligible hospitals, and critical access hospitals must meet in order to demonstrate meaningful use of certified EHR technology for Stage 3 of the EHR Incentive Programs. It also specifies the proposed requirements for electronic submission of CQMs and creates a single set of meaningful use requirements for Stage 3 which would be optional for providers in 2017 and required for all providers beginning in 2018. Finally, the Stage 3 proposed rule would also change the EHR reporting period so that all providers would report under a calendar year timeline.

For Stages 1 and 2, CMS and the ONC worked closely to ensure that the definition of meaningful use of CEHRT and the associated standards and certification criteria were coordinated. (Current ONC regulations may be found at 45 CFR part 170.) For the Stage 3 proposed rule and the ONC 2015 Edition proposed rule, CMS and ONC have aligned the proposed rules (80 FR 16731 through 16804 and 80 FR 16804 through 16921) and would again work together to align the final regulations.

(Readers may also visit: [www.cms.hhs.gov/EHRincentiveprograms](http://www.cms.hhs.gov/EHRincentiveprograms) and [www.healthit.gov](http://www.healthit.gov) for more information on the efforts at the Department of Health and Human Services (HHS) to advance HIT initiatives.)

## II. Provisions of the Proposed Regulations

### A. Introduction

When the EHR Incentive Program began in 2011, the requirements for the objectives and measures of meaningful use were designed to begin a process toward health care delivery system transformation aligning with foundational goals defined in the HITECH Act. First, the statute requires the Secretary to seek to improve the use of EHR and health care quality over time by requiring more stringent measures of meaningful use (see section 1848(o)(2)(A)(iii) of the Act). To meet this goal, we established stages of meaningful use to move providers along a progression from adoption to advanced use of certified EHR technology. Second, the statute includes requirements for the use of EHR

technology, which defines both the functions that should be available within the EHR and the purpose to which those functions should be applied. These requirements include functions that are similar to the following (see section 1848(o)(4) of the Act)—

- The capacity to provide clinical decision support;
- To support provider order entry;
- To capture and query information relevant to health care quality; and
- To exchange protected health information with, and integrate such information from other sources.

The statute also defines key foundational principles of meaningful use such as electronic prescribing, the electronic exchange of health information to support the improvement of care and care coordination, and the use of EHR technology to submit information on clinical quality measures and other measures (see section 1848(o)(2)(A) of the Act).

Since the EHR Incentive Programs began in 2011, a number of environmental changes have occurred which prompted us to reevaluate the program requirements in relation to progress toward goals. These changes include a wide range of factors including—

- Expansion of basic certified EHR technology infrastructure;
- Advancements in EHR and related health information technology;
- Widespread adoption of certain standards and functionality;
- Increased use of CEHRT to support quality improvement; and
- Performance on certain measures reaching maximum potential.

The Certified Health IT Product List (ONC CHPL) developed by ONC assists providers in identifying certified EHR technology products that have been certified by an ONC-Authorized Certification Body (ONC-ACB). Certified EHR technology products, certified to the 2014 Edition, are required for use in the Medicare and Medicaid EHR Incentive Programs to meet meaningful use criteria for Stage 1 and 2 for an EHR reporting period in 2015. We reviewed data related to the ONC CHPL as of March 20, 2015 and found 1956 unique products that are currently certified to the 2011 Edition and 2157 unique products that are certified to the 2014 Edition. A unique product is a product that is certified and receives a unique certification ID (product updates and product version changes are included in the unique product count). Data from March 2013 to March 2015 shows an increase of 104

percent in the total number of certified EHR technology products and an increase of 133 percent in total unique certified EHR technology products in the last 2 years alone. We believe the increase in the number of certified EHR technology products available is a positive step for providers seeking to meet meaningful use requirements and advance EHR technology. The data provided and additional information related to the ONC CHPL may be found on the HealthIT.gov Web site at <http://healthit.gov/chpl>.

For a wide range of data and reports on health IT adoption rates, use of certification functions and standards, updates to eCQM specifications and testing, as well as the performance data for providers in relation to the available software, we direct readers to the ONC Web site (<http://www.healthit.gov>), 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)), and the CMS EHR Incentive Programs data and reports Web site (<http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html>).

As the program has increased the overall adoption of EHRs and as EHR technology has automated certain clinical functions and supported standardized data capture, we propose modifications, which would recognize these changes and realign the program with ongoing program goals. Our quality reporting programs regularly reevaluate measures based on factors like clinical relevance, updates to electronic specifications, and measure performance. We consider modifications to the objectives and measures of this program similar to those regularly made in our quality reporting programs.

In addition to these environmental changes, stakeholder associations and provider groups have through correspondence, public forums, and public comment requested that we consider changes to the requirements to demonstrate meaningful use of certified EHR technology in the EHR Incentive Programs which would reduce the overall complexity of the program and the burden on providers. We believe some of these recommended changes may contradict certain statutory requirements for this program. For example, certain provisions such as electronic prescribing or health information exchange cannot be fully “optional” because they are expressly required under the statute (see section 1848(o)(2)(A) of the Act). The statutory directive to require increasingly more stringent measures of meaningful use

(see section 1848(o)(2)(A)(iii) of the Act) prohibits the removal of all measure thresholds. Further examples are also discussed in the Stage 3 proposed rule at (80 FR 16737 through 16742).

However, there are methods that could be employed to modify Stages 1 and 2 of the program to address stakeholder concerns, meet the statutory requirements for the program defined in the HITECH Act, and continue to support progress toward the program’s foundational goals. In addition, these methods would move providers along a continuum from data capture to advanced use of certified EHR technology including electronic prescribing, health information exchange, and quality improvement with increasingly stringent measures as identified in the Act and discussed in section II.B.1.b. of this proposed rule. Therefore, we are proposing modifications to Stages 1 and 2 and are seeking public comment on these proposals, which are intended to be responsive to the changing environment and to stakeholder concern over program complexity and redundant reporting requirements. We propose these modifications to address these concerns and to continue to support the overall goal of the widespread adoption and meaningful use of EHR technology in efforts to transform our health care delivery system and improve health care quality.

#### *B. Meaningful Use Requirements for EHR Reporting Periods in 2015 Through 2017*

##### 1. Definitions Across the Medicare Fee for Service, Medicare Advantage, and Medicaid Programs

###### a. Uniform Definitions

As discussed in prior rules, we finalized several uniform definitions applicable for the Medicare FFS, Medicare Advantage, and Medicaid EHR Incentive Programs. We set forth these uniform definitions in part 495 subpart A of the regulations. (For further discussion of the uniform definitions finalized previously, we refer readers to the Stage 1 and Stage 2 final rules at 75 FR 44317 through 44321 and 77 FR 53972 respectively.) (For discussion of the proposed changes to uniform definitions outlined in the Stage 3 proposed rule, we refer readers to the Stage 3 proposed rule at (80 FR 16736 through 16737).

In this proposed rule, we are proposing to maintain the previously finalized uniform definitions except as stated in this proposed rule.

b. Changes to Definitions for 2015 Through 2017

We are proposing changes to a number of definitions previously finalized for meaningful use in the Stage 1 and Stage 2 rules in order to modify the program in response to the changing health IT environment and related stakeholder concerns. These changes address the following:

- An overall simplification of the program aligned to the overarching goals of sustainability as discussed in the Stage 3 proposed rule (80 FR 16737) and in section II.B.1.b.(1). of this proposed rule and a related change to requirements necessary to accommodate these changes outlined in section II.B.1.b.(2) of this proposed rule.

- Moving all providers to an EHR reporting period aligned with the calendar year as outlined in section II.B.1.b.(3).A. of this proposed rule.
- Providing flexibility for providers in 2015 to accommodate the proposed changes as outlined in section II.B.1.b of this proposed rule.
- Removing requirements for objectives and measures which are redundant or duplicative or which have “topped out” as described at (80 FR 16767) of the Stage 3 proposed rule and outlined in section II.B.1.c.(1). of this proposed rule.
- Restructuring the remaining measures and objectives to streamline requirements for 2015 through 2017 and to accommodate the changes for an EHR reporting period in 2015 as outlined in section II.B.1.c.(2). of this proposed rule.

- Refocusing the existing program on building toward advanced use of EHR technology, aligned with the Stage 3 proposed rule, through maintaining the objectives and measures outlined in section II.B.2. of this proposed rule.

(1) Stages of Meaningful Use

In the phased approach to meaningful use, we finalized the criteria for meaningful use through staggered rulemaking, which covered Stages 1 and 2 of the EHR Incentive Program. (For further explanation of the criteria we finalized in Stages 1 and 2, we refer readers to 75 FR 44314 through 44588, 77 FR 53968 through 54162, and 79 FR 52910 through 52933). The current progression of the stages as finalized in prior rulemaking is outlined in Table 1.

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
2011 .....	1	1	1	1 or 2* .....	2	2	3	3	TBD
2012 .....		1	1	1 or 2* .....	2	2	3	3	TBD
2013 .....			1	1* .....	2	2	3	3	TBD
2014 .....				1* .....	1	2	2	3	3
2015 .....					1	1	2	2	3
2016 .....						1	1	2	2
2017 .....							1	1	2

In the Stage 3 proposed rule, we noted our intent for Stage 3 to be the final stage in meaningful use and that no further stages would be developed. We further proposed that all providers may optionally move to Stage 3 in 2017, and that all providers are required to move to Stage 3 beginning in 2018 regardless of their prior participation or stage of meaningful use. (For further discussion on this proposal, we direct readers to (80 FR 16774).

In this proposed rule to modify Stages 1 and 2 for meaningful use in 2015 through 2017, we propose to further reduce complexity in the program and work toward this overall shift to a single set of objectives and measures in Stage 3 in 2018. We propose to require all providers to attest to a single set of objectives and measures beginning with

an EHR reporting period in 2015. These objectives and measures would leverage existing objectives and measures of meaningful use. Because this change may occur after providers have already begun their work toward meeting meaningful use in 2015, we propose accommodations within individual objectives for providers in different stages of meaningful use. These accommodations include retaining the different specifications between Stage 1 and Stage 2, and allowing special exclusions for certain objectives or measures for eligible providers previously scheduled to participate in Stage 1 for an EHR reporting period in 2015.

In this rule, we propose all providers would be required to attest to certain objectives and measures finalized in the

Stage 2 final rule, which would align with those objectives and measures proposed for Stage 3 of meaningful use. In effect, this would create a new progression using the existing objectives and measures where providers attest to a modified version of Stage 2 with accommodations for Stage 1 providers (equivalent to a reduced version of Stage 3) in 2015; a modified version of Stage 2 in 2016 (equivalent to a reduced version of Stage 3); either a modified version of Stage 2 (equivalent to a reduced version of Stage 3) or the full version of Stage 3 outlined in the Stage 3 proposed rule in 2017; and the full version of Stage 3 outlined in the Stage 3 proposed rule beginning in 2018.

The revised timeline based on this proposal and the Stage 3 proposed rule is outlined in Table 2.

TABLE 2—STAGE OF MEANINGFUL USE CRITERIA BY FIRST YEAR

First year as a meaningful EHR user	Stage of meaningful use			
	2015	2016	2017	2018
2011 .....	Modified Stage 2 .....	Modified Stage 2 .....	Modified Stage 2 Or Stage 3 .....	Stage 3
2012 .....	Modified Stage 2 .....	Modified Stage 2 .....	Modified Stage 2 Or Stage 3 .....	Stage 3
2013 .....	Modified Stage 2 .....	Modified Stage 2 .....	Modified Stage 2 Or Stage 3 .....	Stage 3
2014 .....	Modified Stage 2* .....	Modified Stage 2 .....	Modified Stage 2 Or Stage 3 .....	Stage 3
2015 .....	Modified Stage 2* .....	Modified Stage 2 .....	Modified Stage 2 Or Stage 3 .....	Stage 3



TABLE 2—STAGE OF MEANINGFUL USE CRITERIA BY FIRST YEAR—Continued

First year as a meaningful EHR user	Stage of meaningful use			
	2015	2016	2017	2018
2016 .....	- NA - .....	Modified Stage 2 .....	Modified Stage 2 Or Stage 3 .....	Stage 3

\* The Modifications to Stage 2 proposed in this rule include alternate exclusions and specifications for certain objectives and measures for providers that were scheduled to demonstrate Stage 1 of meaningful use in 2015.

For simplification and reader clarity, we would therefore refer to the “Stage” designation in relation to the EHR Incentive Program rules and to the objectives and measures as follows:

- Meaningful use objectives and measures for 2015 through 2017
- Stage 3 meaningful use objectives and measures for 2017 and subsequent years

This alignment of Stages 1 and 2 to the proposals for Stage 3 essentially creates a new paradigm for providers in 2015 through 2017. This includes a simplified structure and focus on the objectives and measures with sustainable growth potential aligned to the programs foundational goals prior to the full implementation of Stage 3 in 2018. This change could alleviate the

need to include the option in 2017 to allow providers to choose to demonstrate Stage 3 of the program in 2017. To better understand the impact and potential complexity, we seek comment on whether or not we should implement only the modifications proposed in this rule from 2015 through 2017 and begin Stage 3 in 2018 without an option year in 2017, or if we should allow providers the option to demonstrate Stage 3 beginning in 2017 as discussed in the Stage 3 proposed rule (80 FR 16774).

We seek comment on these proposals.

(2) Meaningful EHR User

In the Stage 3 proposed rule (80 FR 16731 through 16804), we proposed to modify the definition of “Meaningful

EHR User” in 42 CFR 495.4 to include the Stage 3 objectives and measures proposed at § 495.7. We further propose to redesignate some of the numbering of the regulation text under Part 495 to more clearly identify which sections of the regulation apply to specific years of the program. This would allow more direct references for the objectives and measures, while also preserving the content that applies for prior program years. We note this numerical redesignation would not affect the content of the regulation text except where noted in this proposed rule, nor would it change the proposed objectives and measures of Stage 3 of meaningful use at (80 FR 16745 through 16767). The redesignated numerical references for the regulation text are as follows:

Current section designation	Proposed section redesignation
§ 495.6—Objectives and Measures .....	§ 495.20—Objectives and Measures Prior to 2015
§ 495.7*—Stage 3 Objectives and Measures .....	§ 495.22—Objectives and Measures Beginning in 2015
§ 495.8—Demonstration of Meaningful Use .....	§ 495.24—Stage 3 Objectives and Measures
§ 495.10—Participation Requirements .....	§ 495.40—Demonstration of Meaningful Use
	§ 495.60—Participation Requirements

\* Indicates a new section that was proposed in the Stage 3 proposed rule.

In this proposed rule, we refer to § 495.20 for the objectives and measures that apply for years prior to 2015, § 495.22 for the objectives and measures proposed in this rule for 2015 through 2017, and § 495.24 for the objectives and measures proposed in the Stage 3 proposed rule for 2017 and subsequent years. Pending public comment and agency review of these proposals, all changes in Part 495 would be reconciled through the final rule.

(3) EHR Reporting Periods in 2015 Through 2017

In 42 CFR 495.4, we define an EHR reporting period for eligible hospitals and CAHs based on the federal fiscal year (October 1 through September 30). However, the fiscal year EHR reporting period has resulted in varying reporting timelines between provider types and a shortened timeline for system developers to meet hospital and CAH technology needs. In the Stage 3 proposed rule, we outline changes to the EHR reporting period beginning with

the EHR reporting period in 2017 in order to move eligible hospitals and CAHs to EHR reporting periods based on a calendar year. (For further discussion of this proposal and the relationship to program alignment with quality reporting programs, we direct readers to 80 FR 16739.)

In this proposed rule, our intent is to modify the program to remove redundant and duplicative measures; reduce reporting burden for measures that have “topped out” while preserving the program’s foundational goals and the requirement for stringent or robust measurement; and better align the existing program with other CMS quality reporting programs. In order to move these efforts forward and to accommodate the proposed changes beginning in 2015 while still allowing providers time to complete an EHR reporting period after the effective date of a final rule, we are proposing changes to the uniform definition of an “EHR reporting period” in § 495.4 beginning in 2015. We are also proposing similar

changes to the definition of an “EHR reporting period for a payment adjustment year” in § 495.4 beginning in 2015 as discussed in section II.E.1. of this proposed rule. We are proposing changes to the attestation deadlines for purposes of the incentive payments and payment adjustments in section I.A.1.i. of this proposed rule.

(a) Calendar Year Reporting Beginning in 2015

Beginning in 2015, we are proposing to change the definition of “EHR reporting period” at § 495.4 for EPs, eligible hospitals, and CAHs such that the EHR reporting period would begin and end in relation to a calendar year. This change would allow eligible hospitals and CAHs the same amount of time as EPs from the release of a new edition by ONC to the required date for full implementation of the EHR technology certified in accordance with those criteria. In addition, this change would allow providers additional time to accommodate the changes proposed

in this rule for demonstrating meaningful use in 2015. Finally, this change would align EHR reporting periods for the EHR Incentive Program with EHR reporting periods in CMS quality reporting programs, which have similar or related requirements.

In this proposal, all providers (EPs, eligible hospitals, and CAHs) would be required to complete an EHR reporting period within January 1 and December 31 of the calendar year in order to demonstrate meaningful use. In order to accommodate eligible hospitals and CAHs that may have planned their EHR reporting period in 2015 during the federal fiscal year and want to continue to use that time period for reporting, we propose for 2015 only these providers may begin an EHR reporting period as early as October 1 of 2014 and end by December 31 of 2015. Beginning with 2016, the EHR reporting period must be completed within January 1 and December 31 of the calendar year.

We seek comment on this proposal.

(b) 90-Day EHR Reporting Period for All Providers in 2015

In the 2014 CEHRT Flexibility rule (79 FR 52919) we noted that many commenters had requested a 90-day EHR reporting period in 2015. In that rule, we discussed the reasons we did not propose or finalize a change to allow for an EHR reporting period of 90 days in 2015. We stated that we did not finalize changes to the EHR reporting period, because we believed such changes were not necessary to mitigate risk associated with the delay in the availability of EHR technology certified to the 2014 Edition (79 FR 52919). In addition, we stated that such changes would put the forward progress of the program at risk, and potentially cause further delay in implementing effective health IT infrastructure and misalignment with the CMS quality reporting programs (79 FR 52919). We maintain the assertion that the delay in 2014 Edition availability does not necessitate changes to the EHR reporting period 2015; and that the proposed change to the EHR reporting period in 2015 in conjunction with the other modifications to the EHR Incentive Program proposed in this rule does represent a potential risk to the continued development of effective health IT infrastructure.

Subsequent to the publication of the 2014 CEHRT Flexibility final rule, we conducted a full analysis of provider performance on Stage 1 and Stage 2 measures and identified areas where measures were topped out or had become redundant or duplicative based on the widespread adoption of EHR

technology certified to the 2014 Edition and successful implementation of the more complex Stage 2 objective functions. We determined that there was significant potential for a positive impact through reducing the reporting burden, simplifying the program, and realigning the program with long term goals for advanced use of EHRs.

However, in order to implement these changes, a shortened EHR reporting period would be necessary in 2015 to allow both providers and CMS time to make necessary changes to systems. We believe the benefits to be gained from the proposals in this rule outweigh the potential risk of misalignment introduced by the shortened reporting period, if the risk is limited to only be allowable for an EHR reporting period in 2015. Therefore, we are proposing to allow a 90-day EHR reporting period in 2015 only to accommodate implementation of the other changes proposed in this rule.

For 2015 only, we are proposing to change the definition of "EHR reporting period" at § 495.4 for EPs, eligible hospitals, and CAHs such that the EHR reporting period in 2015 would be any continuous 90-day period within the calendar year. We intend this change to allow providers adequate time to plan for any necessary changes to their implementation of meaningful use required in order to accommodate the changes outlined in this proposed rule. We further believe this change is responsive to provider and stakeholder feedback received through correspondence, public forums, and public comment, which requested that we allow a 90-day EHR reporting period in 2015 in order to provide flexibility for continuing difficulties providers are experiencing with successful implementation of EHR technology certified to the 2014 Edition.

We propose that for an EHR reporting period in 2015, eligible professionals may select an EHR reporting period of any continuous 90-day period from January 1, 2015 through December 31, 2015; while eligible hospitals and CAHs may select an EHR reporting period of any continuous 90-day period from October 1, 2014 through December 31, 2015. This is intended to accommodate the shift from reporting based on the federal fiscal year to the calendar year for eligible hospitals and CAHs.

In 2016, for eligible professionals, eligible hospitals, and CAHs that have not successfully demonstrated meaningful use in a prior year and are first-time participants in the program, the EHR reporting period would be any continuous 90-day period between January 1, 2016 and December 31, 2016.

However, for all returning participants that have successfully demonstrated meaningful use in a prior year, the EHR reporting period would be a full calendar year from January 1, 2016 through December 31, 2016. In 2017, the EHR reporting period would be 1 full calendar year for all providers, as proposed in the Stage 3 proposed rule (80 FR 16739).

We invite comment on these proposals.

c. Definition of Meaningful Use

(1) Considerations in Defining Meaningful Use

In order to update the definition of meaningful use of certified EHR technology and make modifications to program requirements to reflect a changing health IT environment, we analyzed the existing objectives and measures of meaningful use to consider if they should be modified for the program beginning in 2015. As outlined in the Stage 3 proposed rule, we looked at the set of potential objectives and measures for inclusion in the program for 2017 and subsequent years, and sought to determine if they were redundant, duplicative, or had reached a performance level considered to be "topped out." We stated that redundant measures include those objectives where there is now a viable health IT-based solution which may replace paper-based actions and therefore a provider should no longer be required to also report on the objective where the measure includes paper-based actions, such as the Stage 2 Clinical Summary objective (77 FR 53998 through 54002). We stated that duplicative measures include those objectives where a measure which is also captured in the course of meeting another objective, such as recording vital signs which is also a required part of the Consolidated Clinical Document Architecture (C-CDA) in the Summary of Care objective (77 FR 54014 through 54016). Finally, we stated that "topped out" measures do not provide a meaningful gain in the effort to improve the use of EHR and health care quality over time by requiring more stringent measures of meaningful use. (For further discussion of this approach to identifying the objectives and measures for Stage 3, we direct readers to (80 FR 16740 through 16744).

In this proposed rule, we have taken a similar approach to review the current objectives and measures of meaningful use with a few additional considerations. These included reviewing the functions and standards included the 2014 Edition when

determining if a measure is redundant or duplicative; and adding a review of isolated performance rates for providers in the first year of meaningful use in addition to reviewing quartile performance rates for topped out measures. (For further discussion on “topped out” measures in the Stage 3 proposed rule, we direct readers to (80 FR 16741 and 16742). For further information on the performance rates for

new participants as well as quartile performance rates for individual measures, we direct readers to the CMS EHR Incentive Program Web site data and reports page.<sup>1</sup>

Our analysis of the objectives and measures of meaningful use Stages 1 and 2 identified a number of measures, which meet these criteria as either redundant, duplicative, or topped out with new participants consistently

performing at a statistically comparable rate to returning participants. Table 3 identifies the current objectives and measures which meet these criteria. We are therefore proposing to no longer require providers to attest to these objectives and measures as currently codified in the CFR under § 495.6 in order to demonstrate meaningful use beginning in 2015.

TABLE 3—OBJECTIVES AND MEASURES IDENTIFIED BY PROVIDER TYPE WHICH ARE REDUNDANT, DUPLICATIVE OR TOPPED OUT

Provider type	Objectives and measures	
Eligible Professional .....	Record Demographics ..... Record Vital Signs ..... Record Smoking Status ..... Clinical Summaries ..... Structured Lab Results ..... Patient List ..... Patient Reminders ..... Summary of Care ..... Measure 1—Any Method Measure 3—Test Electronic Notes ..... Imaging Results ..... Family Health History .....	42 CFR § 495.6 (j)(3)(i) and (ii). 42 CFR § 495.6 (j)(4)(i) and (ii). 42 CFR § 495.6 (j)(5)(i) and (ii). 42 CFR § 495.6 (j)(11)(i) and (ii). 42 CFR § 495.6 (j)(7)(i) and (ii). 42 CFR § 495.6 (j)(8)(i) and (ii). 42 CFR § 495.6 (j)(9)(i) and (ii). 42 CFR § 495.6 (j)(14)(i) and (ii). 42 CFR § 495.6 (j)(9)(i) and (ii). 42 CFR § 495.6 (k)(6)(i) and (ii). 42 CFR § 495.6 (k)(2)(i) and (ii).
Eligible Hospital/CAH .....	Record Demographics ..... Record Vital Signs ..... Record Smoking Status ..... Structured Lab Results ..... Patient List ..... Summary of Care ..... Measure 1—Any Method Measure 3—Test eMAR ..... Advanced Directives ..... Electronic Notes ..... Imaging Results ..... Family Health History ..... Structure Labs to Ambulatory Providers .....	42 CFR § 495.6 (l)(2)(i) and (ii). 42 CFR § 495.6 (l)(3)(i) and (ii). 42 CFR § 495.6 (l)(4)(i) and (ii). 42 CFR § 495.6 (l)(6)(i) and (ii). 42 CFR § 495.6 (l)(7)(i) and (ii). 42 CFR § 495.6 (l)(11)(i) and (ii). 42 CFR § 495.6 (l)(16)(i) and (ii). 42 CFR § 495.6 (m)(1)(i) and (ii). 42 CFR § 495.6 (m)(2)(i) and (ii). 42 CFR § 495.6 (m)(2)(i) and (ii). 42 CFR § 495.6 (m)(3)(i) and (ii). 42 CFR § 495.6 (m)(6)(i) and (ii).

We note that many of these objectives and measures include actions that may be valuable to providers and patients, such as providing a clinical summary to a patient after an office visit. We encourage providers to continue to conduct these activities as best suits their practice and the preferences of their patient population. The removal of these measures is in no way intended as a removal of endorsement of these best practices or to discourage providers from conducting and tracking these activities for their own quality improvement goal. Instead, we would no longer require providers to calculate and attest to the results of these measures in order to demonstrate meaningful use beginning in 2015.

We seek comment on this proposal.

(2) Changes to Definition of Meaningful Use for 2015 Through 2017

In order to implement the proposed changes to no longer require providers to attest to their performance on the identified objectives and measures and to accomplish the related goal of restructuring the program to align with long-term goals, there are a number of changes, which must be made to other requirements of meaningful use. These changes fall into the following two major categories:

- Changes to streamline the structure for 2015 through 2017 to align with the proposed structure for Stage 3 of meaningful use in 2017 and subsequent years; and
- Changes to accommodate this shift to allow providers to successfully demonstrate meaningful use for an EHR reporting period in 2015.

In addition, we have heard from stakeholder associations and provider representatives that providers have faced significant challenges in implementing the patient engagement objectives, which require patient action. These are outlined in the Stage 2 final rule at 77 FR 54046 under the Health Outcomes Policy Priority “Engage patients and families in their care”: The Patient Electronic Access objective Stage 2 measure 2 for more than 5 percent of patients to view, download or transmit their health information; and, the EPs secure electronic messaging objective for more than 5 percent of patients to send a secure message using CEHRT. These concerns have included both the barriers to successful implementation of the required health IT or CEHRT functions necessary to support the measures and especially the

<sup>1</sup> CMS EHR Incentive Programs Web site: “Data and Reports” <https://www.cms.gov/Regulations->

[and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html](https://www.cms.gov/Regulations-DataAndReports.html).

secure transmission function; and the challenges to effectively changing patient behavior including patient IT knowledge gaps, lack of widespread access to technologies, and cultural barriers among specific patient populations. We recognize these concerns and are proposing changes to these objectives to allow providers to focus on improvements without jeopardizing their ability to successfully demonstrate meaningful use. These changes are outlined in section II.B.1.c.(2).(c). of this proposed rule.

(a) Structural Requirements of Meaningful Use in 2015 Through 2017

If we remove the requirement to attest to the identified measures and objectives, the distribution requirements between menu and core objectives can no longer be applicable. In addition, stakeholder associations and provider representatives have expressed through correspondence, public forum, and public comment on regulation that the core and menu structure is unnecessarily complex and a source of confusion for providers. Therefore, we propose to eliminate the distinction between core and menu objectives, and further propose that all retained objectives and measures would be required for the program. We note that for Stage 1 providers, this means three current menu objectives would now be required; and for Stage 2 eligible hospitals and CAHs, one current menu objective would now be a required objective. These objectives are as follows:

- Stage 1 Menu: Perform Medication Reconciliation
- Stage 1 Menu: Patient Specific Educational Resources

- Stage 1 Menu: Public Health Reporting Objectives (multiple options)
- Stage 2 Menu Eligible Hospitals and CAHs Only: Electronic Prescribing

We note that the objectives and measures retained in each case for all providers would be the Stage 2 objectives and measures; however, we are proposing to establish alternate exclusions and specifications to mitigate any additional burden on providers for an EHR reporting period in 2015. These related proposals are discussed further in section II.B.3.c.(2).(b). of this proposed rule.

For the public health reporting objectives and measures, we are proposing to consolidate the different Stage 2 core and menu objectives into a single objective with multiple measure options. We proposed this approach for the Stage 3 public health reporting objective as we believe it provides greater flexibility for providers and supports continued efforts to engage providers and public health agencies in the essential data capture and information exchange which supports quality improvement, emergency response, and population health management initiatives. For further discussion of the rationale for the Stage 3 objective, we direct readers to (80 FR 16731 through 16804). We discuss the proposal for the consolidated public health reporting objective for meaningful use in 2015 through 2017 in section II.B.2.j. of this proposed rule. We propose that EPs must select to report on any combination of 2 of the 5 available options outlined in section II.B.2.j. of this proposed rule and eligible hospitals and CAHs must select

to report on any combination of 3 of the 6 available options in section II.B.2.j. of this proposed rule. If a provider is scheduled to attest to Stage 1 of meaningful use in 2015, we propose to allow these EPs in 2015 to select to report on only 1 of the 5 available options outlined in section II.B.2.j. of this proposed rule and these eligible hospitals and CAHs in 2015 to select to report on any combination of 2 of the 6 available options in section II.B.2.j. of this proposed rule.

Therefore, we propose that the structure of meaningful use for 2015 through 2017 would be 9 required objectives for EPs using the Stage 2 objectives for EPs with alternate exclusions and specifications for Stage 1 providers in 2015. We propose that the structure of meaningful use for 2015 through 2017 would be 8 required objectives for eligible hospitals and CAHs using the Stage 2 objectives for eligible hospitals and CAHs with alternate exclusions and specifications for Stage 1 providers and some stage 2 providers in 2015. In addition, EPs would be required to report on a total of 2 measures from the public health reporting objective or meet the criteria for exclusion from up to 5 measures, and eligible hospitals and CAHs would be required to report on a total of 3 measures from the public health reporting objective or meet the criteria for exclusion from up to 6 measures. We reiterate that the alternate exclusions and specifications mentioned are further defined in section II.B.1.c.(2).(b). of this section of this proposed rule, and the objectives and measures are defined in section II.B.2. of this proposed rule.

TABLE 4—CURRENT STAGE STRUCTURE, RETAINED OBJECTIVES, AND PROPOSED STRUCTURE

	Current stage 1 structure	Retained objectives	Proposed structure
EP .....	13 core objectives ..... 5 of 9 menu objectives including 1 public health objective.	6 core objectives ..... 3 menu objectives .....	9 core objectives. 1 public health objective (2 measure options).
EH/CAH .....	11 core objectives ..... 5 of 10 menu objectives including 1 public health objective.	5 core objectives ..... 3 menu objectives .....	8 core objectives. 1 public health objective (3 measure options).
EP .....	17 core objectives including public health objectives. 3 of 6 menu objectives .....	9 core objectives ..... 0 menu objectives .....	9 core objectives. 1 public health objective (2 measure options).
EH/CAH .....	16 core objectives including public health objectives. 3 of 6 menu objectives .....	4 public health objectives ..... 7 core objectives ..... 1 menu objective .....	8 core objectives. 1 public health objective (3 measure options).
		3 public health objectives .....	

(b) Alternate Exclusions and Specifications for Stage 1 Providers for Meaningful Use in 2015

We are proposing several alternate exclusions and specifications for providers scheduled to demonstrate Stage 1 of meaningful use in 2015, which would allow these providers to continue to demonstrate meaningful use despite the proposals to use only the Stage 2 objectives and measures identified for meaningful use in 2015 through 2017. These provisions fall into the following two major categories:

- Maintaining the specifications for objectives and measures which have a lower threshold or other measure difference between Stage 1 and Stage 2.
- Establishing an exclusion for Stage 2 measures which do not have an equivalent Stage 1 measure associated with any Stage 1 objective or where the provider did not plan to attest to the menu objective which would now be otherwise required.

For the first category, we propose that providers who are scheduled to demonstrate Stage 1 of meaningful use for an EHR reporting period in 2015 may attest to meaningful use using the specifications established for the Stage 1 objectives and measures defined at 42 CFR 495.6 for each retained objective or measure where there is a difference in specifications between Stages 1 and 2. For example, in Stage 1 the electronic prescribing objective for EPs requires that “More than 40 percent of all permissible prescriptions written by the EP are transmitted electronically using certified EHR technology” (75 FR 44338). While the Stage 2 electronic prescribing objectives requires that “More than 50 percent of all permissible prescriptions written by the EP are compared to at least one drug formulary and transmitted electronically using Certified EHR Technology” (77 FR 53990). Therefore, we are proposing that for an EHR reporting period in 2015, providers scheduled to demonstrate Stage 1 of meaningful use may attest based on the specifications associated with the Stage 1 measure. We note that for an EHR reporting period beginning in 2016, all providers must attest to the specifications including the measure thresholds associated with the Stage 2 measure. For an EHR reporting period in 2016, all providers, including those who would otherwise be scheduled for Stage 1 in 2016, would be required to meet the Stage 2 specifications with no alternate exclusions.

For the second category, we note that some objectives, such as the Patient Electronic Access objective, have the same requirements for one measure

(more than 50 percent of patients are provided access to view, download, and transmit their health information) for both Stage 1 and Stage 2, but also have an additional measure for Stage 2 (more than 5 percent of patients view, download, or transmit their health information). Other objectives, such as the Summary of Care objective, are designated as a menu objective for Stage 1 but are a core objective for Stage 2 and also may have additional measure requirements in Stage 2 that are not applicable for Stage 1 (77 FR 54013 through 54017). Finally, some objectives consist of requirements from multiple objectives from Stage 1 that were consolidated into a single objective for Stage 2 such as drug-drug and drug-allergy decision support interventions. For these consolidated objectives, all providers would be required to attest to the Stage 2 objective and measures. For objectives where there is a measure that is not equivalent between Stage 1 and Stage 2 or where the objective moves from menu to core between Stage 1 and Stage 2, we propose to include an exclusion for providers who were scheduled to demonstrate Stage 1 of meaningful use for the EHR reporting period in 2015. For example, Stage 1 providers may exclude from the requirement to send an electronic summary of care record for more than 10 percent of transitions of care as required in the Stage 2 Summary of Care objective measure 2 (75 FR 44364).

These alternate exclusions and specifications for certain objectives and measures of meaningful use for an EHR reporting period in 2015 are defined for each objective and measure in the description of each objective and measure included in section II.B.2. of this proposed rule.

We invite public comment on this proposal.

(c) Changes to Patient Engagement Requirements for 2015 Through 2017

Through correspondence, public forums, and public comment on our proposed regulations, stakeholders have expressed concern that certain factors like demographics, low utilization of internet capable technology among their patient population, or other external barriers which are beyond their control are impacting providers' ability to meet certain measures which require providers to track patient action. In addition, providers and system developers have noted through similar means an overall immaturity in the market with health IT equipped with the functions required to support the transmission of health information by a patient or the delivery of a secure

message from a patient to a third party. Providers have indicated that while they support the goal of improved patient engagement, these issues are impacting their ability to meet the measure requirements. We note that data obtained from provider attestations shows performance on these measures is concentrated around the median rate (around 20 percent<sup>2</sup>) which indicates the potential for ongoing performance that exceeds the existing threshold. However, there is a wide variance at the high and low ends, which indicates that there may be external factors impacting performance. Therefore, we are seeking to mitigate these concerns by making changes to the related measures. We believe these changes would allow providers the necessary time to work toward patient education about the availability of these resources as well as allowing the industry as a whole time to develop a stronger infrastructure supporting patient engagement.

There are two objectives for EPs and one objective for eligible hospitals and CAHs, which specifically contain measures requiring a provider to track patient action. We propose to modify these measures as follows:

- Patient Action To View, Download, or Transmit Health Information

++ Remove the 5 percent threshold for Measure 2 from the EP Stage 2 Patient Electronic Access (VDT) objective. Instead require that at least 1 patient seen by the provider during the EHR reporting period views, downloads, or transmits his or her health information to a third party. This would demonstrate the capability is fully enabled and workflows to support the action have been established by the provider.

++ Remove the 5 percent threshold for Measure 2 from the eligible hospital and CAH Stage 2 Patient Electronic Access (VDT) objective. Instead require that at least 1 patient discharged from the hospital during the EHR reporting period views, downloads, or transmits his or her health information to a third party. This would demonstrate the capability is fully enabled and workflows to support the action have been established by the provider.

We seek comment on potential alternate proposals for this proposed change to the threshold for Measure 2 of the Stage 2 Patient Electronic Access objective. For example, we seek

<sup>2</sup> CMS EHR Incentive Programs Web site: “Data and Reports: Performance data through February 2015” [https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/AttestationPerformanceData\\_Feb2015.pdf](https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/AttestationPerformanceData_Feb2015.pdf)

comment on potential alternates such as a percentage threshold less than 5 percent, or a numerator greater than 10 patients, or another similar numerical alternative. We further seek comment on suggestions for other potential alternatives which would accomplish the goals here stated of reducing the burden on providers to account for patient actions while still continuing to encourage IT supported patient engagement.

- Secure Electronic Messaging Using CEHRT

++ Convert the measure for the Stage 2 EP Secure Electronic Messaging objective from the 5 percent threshold to a yes/no attestation to the statement: “The capability for patients to send and receive a secure electronic message was enabled during the EHR reporting period”.

These changes are reflected in the discussion of these objectives in section II.B.2. of this proposed rule. We note that these changes are intended to allow providers to work toward meaningful patient engagement through health IT using the methods best suited to their practice and their patient population. We further note that the Stage 3 proposed rule includes an objective exclusively focused on patient engagement with an expanded set of measures and increased thresholds which providers would be required to meet beginning in 2018 (and optionally in 2017). (For further information on that proposed objective, we direct readers to 80 FR 16755 through 16758.)

We invite public comment on this proposal.

## 2. Meaningful Use Objectives and Measures for 2015, 2016, and 2017

We propose the following objectives and measures for EPs, eligible hospitals, and CAHs to successfully demonstrate meaningful use for an EHR reporting period in 2015 through 2017. We note that there are 9 proposed objectives for EPs plus one consolidated public health reporting objective, and 8 proposed objectives for eligible hospitals and CAHs plus one consolidated public health reporting objective which would be required with alternate exclusions for certain providers in 2015 and which would be mandatory for all providers for an EHR reporting period beginning in 2016.

### a. Protect Electronic Health Information

We are proposing to retain with certain modifications the Stage 2 objective and measure for Protect Electronic Health Information for meaningful use in 2015 through 2017.

(For further information and discussion of the existing Stage 2 Protect Electronic Health Information objective and measure, please refer to 77 FR 54002 and 54003).

*Proposed Objective:* Protect electronic health information created or maintained by the CEHRT through the implementation of appropriate technical capabilities.

In the Stage 2 final rule (77 FR 54002 through 54003), we discussed the benefits of safeguarding electronic protected health information (ePHI), as doing so is essential to all other aspects of meaningful use. Unintended and unlawful disclosures (or both) of ePHI could diminish consumers' confidence in EHRs and health information exchange. Ensuring that ePHI is adequately protected and secured would assist in addressing the unique risks and challenges that may be presented by electronic health records.

*Proposed Measure:* Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of data stored in Certified EHR Technology in accordance with requirements in 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the EP, eligible hospital, or CAHs risk management process.

A review must be conducted for each EHR reporting period and any security updates and deficiencies that are identified should be included in the provider's risk management process and implemented or corrected as dictated by that process. We refer providers to the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of data at rest in accordance with requirements in 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), of the HIPAA Security Rule for compliance. The HHS Office for Civil Rights (OCR) has issued guidance on conducting a security risk analysis in accordance with the HIPAA Security Rule (<http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/rafinalguidancepdf.pdf>). Other free tools and resources available to assist providers include a Security Risk Assessment (SRA) Tool developed by ONC and OCR <http://www.healthit.gov/providers-professionals/security-risk-assessment-tool>.

The scope of the security risk analysis for purposes of this meaningful use measure applies to ePHI created or maintained by CEHRT. However, we note that other ePHI may be subject to the HIPAA Rules and we refer providers

to those rules for additional security requirements.

We invite public comment on this proposal.

### b. Clinical Decision Support

We are proposing to retain the Stage 2 objective and measures for Clinical Decision Support (CDS) for meaningful use in 2015 through 2017. This is a consolidated objective, which incorporates the Stage 1 objective to implement drug-drug and drug-allergy interaction checks. (For further information and discussion of the existing consolidated Stage 2 CDS objective and measures, please refer to 77 FR 53995 through 53998.)

*Proposed Objective:* Use clinical decision support to improve performance on high-priority health conditions.

We propose to retain the Stage 2 clinical decision support (CDS) objective such that CDS would be used to improve performance on high-priority health conditions. It would be left to the provider's clinical discretion to select the most appropriate CDS interventions for his or her patient population. CDS interventions selected should be related to four or more of the clinical quality measures (CQMs) on which providers would be expected to report. The goal of the proposed CDS objective is for providers to implement improvements in clinical performance for high-priority health conditions that would result in improved patient outcomes. We propose to maintain that providers must implement the CDS intervention at a relevant point in patient care when the intervention can influence clinical decision making before an action is taken on behalf of the patient.

*Proposed Measure:* In order for EPs, eligible hospitals, and CAHs to meet the objective they must satisfy both of the following measures:

- Measure 1: Implement five clinical decision support interventions related to four or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. Absent four clinical quality measures related to an EP, eligible hospital or CAH's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions.

- Measure 2: The EP, eligible hospital, or CAH has enabled and implemented the functionality for drug-drug and drug allergy interaction checks for the entire EHR reporting period.

For the first measure, it is suggested that one of the five clinical decision support interventions be related to improving healthcare efficiency.

Exclusion: For the second measure, any EP who writes fewer than 100 medication orders during the EHR reporting period.

#### Alternate Exclusions and Specifications for Stage 1 Providers for Meaningful Use in 2015

We propose that providers who are scheduled to demonstrate Stage 1 of meaningful use for an EHR reporting period in 2015 may attest to meaningful use using the specifications established for the Stage 1 objectives and measures as they are currently defined at 42 CFR 495.6 for each retained objective or measure where there is a difference in specifications between Stages 1 and 2. We note that the Stage 1 Clinical Decision Support objective has a different requirement than the Stage 2 Clinical Decision Support objective measure 1 defined previously. For Stage 1, the objective reads "Implement one clinical decision support rule relevant to specialty or high clinical priority along with the ability to track compliance with that rule" for EPs and "Implement one clinical decision support rule related to a high priority hospital condition along with the ability to track compliance with that rule" for eligible hospitals and CAHs (42 CFR 495.6). Therefore, for an EHR reporting period in 2015 only, we propose that an EP, eligible hospital or CAH who is scheduled to participate in Stage 1 in 2015 may satisfy the following Stage 1 measure instead of the Stage 2 measure 1 stated previously:

- *Alternate Objective and Measure (For Measure 1):* Objective: Implement one clinical decision support rule relevant to specialty or high clinical priority, or high priority hospital condition, along with the ability to track compliance with that rule. Measure: Implement one clinical decision support rule.

We propose that for an EHR reporting period in 2015, an EP, eligible hospital or CAH who is scheduled to participate in Stage 1 in 2015 must also satisfy the Stage 2 measure 2 previously stated because it is the same as an existing Stage 1 measure (77 FR 53998). There are no alternate exclusions for this objective.

We invite public comment on this proposal.

#### c. Computerized Provider Order Entry (CPOE)

We are proposing to retain the Stage 2 objective and measures for Computerized Provider Order Entry (CPOE) for meaningful use in 2015 through 2017, with the modifications proposed here as alternate exclusions

and specifications for Stage 1 providers for an EHR reporting period in 2015. (For further information and discussion of the existing Stage 2 CPOE objective and measures, please refer to 77 FR 53985 through 53987.)

*Proposed Objective:* Use computerized provider order entry for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local, and professional guidelines.

We define CPOE as entailing the provider's use of computer assistance to directly enter medical orders (for example, medications, consultations with other providers, laboratory services, imaging studies, and other auxiliary services) from a computer or mobile device. The order is then documented or captured in a digital, structured, and computable format for use in improving safety and efficiency of the ordering process. CPOE improves quality and safety by allowing clinical decision support at the point of the order and therefore influences the initial order decision. CPOE improves safety and efficiency by automating aspects of the ordering process to reduce the possibility of communication and other errors.

*Proposed Measures:* In Stage 2 of meaningful use, we adopted three measures for this objective:

- *Measure 1:* More than 60 percent of medication orders created by the EP or by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.

- *Measure 2:* More than 30 percent of laboratory orders created by the EP or by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.

- *Measure 3:* More than 30 percent of radiology orders created by the EP or by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry. We propose to retain the three measures of this current Stage 2 objective to calculate a percentage threshold for all three types of orders: Medication, laboratory, and radiology. We propose to retain exclusionary criteria for those providers who so infrequently issue an order type that it is not practical to implement CPOE for that order type. To calculate the

percentage, CMS and ONC have worked together to define the following for this objective:

- *Measure 1:*

Denominator: Number of medication orders created by the EP or authorized providers in the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of orders in the denominator recorded using CPOE.

Threshold: The resulting percentage must be more than 60 percent in order for an EP, eligible hospital or CAH to meet this measure.

Exclusion: Any EP who writes fewer than 100 medication orders during the EHR reporting period.

- *Measure 2:*

Denominator: Number of laboratory orders created by the EP or authorized providers in the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of orders in the denominator recorded using CPOE.

Threshold: The resulting percentage must be more than 30 percent in order for an EP, eligible hospital or CAH to meet this measure.

Exclusion: Any EP who writes fewer than 100 laboratory orders during the EHR reporting period.

- *Measure 3:*

Denominator: Number of radiology orders created by the EP or authorized providers in the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of orders in the denominator recorded using CPOE.

Threshold: The resulting percentage must be more than 30 percent in order for an EP, eligible hospital or CAH to meet this measure.

Exclusion: Any EP who writes fewer than 100 radiology orders during the EHR reporting period.

An EP through a combination of meeting the thresholds and exclusions (or both) must satisfy all three measures for this objective. A hospital must meet the thresholds for all three measures.

#### Alternate Exclusions and Specifications for Stage 1 Providers for Meaningful Use in 2015

We propose that providers who are scheduled to demonstrate Stage 1 of meaningful use for an EHR reporting period in 2015 may attest to meaningful use using the specifications and thresholds established for the Stage 1 objectives and measures as they are currently defined at 42 CFR 495.6 for each retained objective or measure

where there is a difference in specifications between Stages 1 and 2.

In the Stage 1 final rule, the CPOE measure requires that “More than 30 percent of all unique patients with at least one medication in their medication list seen by the EP or admitted to the eligible hospital’s or CAH’s inpatient or emergency department (POS 21 or 23) during the EHR reporting period have at least one medication order entered using CPOE” (75 FR 44334). In addition, in the Stage 2 final rule, we established an optional alternative to this measure for Stage 1 of “More than 30 percent of medication orders created by the EP or authorized providers of the eligible hospital’s or CAH’s inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE.” (77 FR 53988). Therefore, we are proposing that for an EHR reporting period in 2015, providers scheduled to demonstrate Stage 1 of meaningful use may attest to the specification associated with the Stage 1 measure.

We further propose that providers scheduled to demonstrate Stage 1 of meaningful use for an EHR reporting period in 2015 may claim an exclusion for any retained Stage 2 measure where there is not an equivalent Stage 1 measure currently defined at 42 CFR 495.6. The Stage 2 CPOE objective includes measures for laboratory and radiology orders, whereas the Stage 1 CPOE objective does not include these measures. Thus, we propose that for an EHR reporting period in 2015 only, providers scheduled to demonstrate Stage 1 of meaningful use in 2015 may exclude the Stage 2 CPOE measures for laboratory and radiology orders (measures 2 and 3 listed previously). We propose that for an EHR reporting period beginning in 2016, all providers must attest to the Stage 2 objective and measures, and meet the thresholds associated with all three of the Stage 2 measures discussed previously in order to successfully demonstrate meaningful use.

*Alternate Measure 1:* More than 30 percent of all unique patients with at least one medication in their medication list seen by the EP or admitted to the eligible hospital’s or CAH’s inpatient or emergency department (POS 21 or 23) during the EHR reporting period have at least one medication order entered using CPOE; or more than 30 percent of medication orders created by the EP during the EHR reporting period, or created by the authorized providers of the eligible hospital or CAH for patients admitted to their inpatient or emergency departments (POS 21 or 23) during the EHR reporting period, are recorded

using computerized provider order entry.

*Alternate Exclusion for Measure 2:* Provider may claim an exclusion for measure 2 (laboratory orders) of the Stage 2 CPOE objective for an EHR reporting period in 2015.

*Alternate Exclusion for Measure 3:* Provider may claim an exclusion for measure 3 (radiology orders) of the Stage 2 CPOE objective for an EHR reporting period in 2015.

We invite public comment on this proposal.

#### d. Electronic Prescribing

We are proposing to retain the Stage 2 objective and measure for Electronic Prescribing (eRx) for EPs as well as for eligible hospitals and CAHs for meaningful use in 2015 through 2017. We note that the Stage 2 objective for eligible hospitals and CAHs is currently a menu objective, but we propose it would be required for 2015 through 2017, with an exception for Stage 1 eligible hospitals and CAHs for an EHR reporting period in 2015. (For further information and discussion of the existing Stage 2 eRx objectives and measures, please refer to 77 FR 53989 through 53990 for EPs and 77 FR 54035 through 54036 for eligible hospitals and CAHs.)

##### (1) EP Proposed Objective

*Proposed EP Objective:* Generate and transmit permissible prescriptions electronically (eRx).

The use of electronic prescribing has several advantages over having the patient carry the prescription to the pharmacy or directly faxing a handwritten or typewritten prescription to the pharmacy. When the EP generates the prescription electronically, CEHRT can recognize the information and can provide decision support to promote safety and quality in the form of adverse interactions and other treatment possibilities. The CEHRT can also provide decision support that promotes the efficiency of the health care system by alerting the EP to generic alternatives or to alternatives favored by the patient’s insurance plan that are equally effective. Transmitting the prescription electronically promotes efficiency and safety through reduced communication errors. It also allows the pharmacy or a third party to automatically compare the medication order to others they have received for the patient. This comparison allows for many of the same decision support functions enabled at the generation of the prescription, but bases them on potentially greater information.

*Proposed EP Measure:* More than 50 percent of all permissible prescriptions, or all prescriptions, written by the EP are queried for a drug formulary and transmitted electronically using Certified EHR Technology.

We propose to retain the exclusion introduced for Stage 2 that would allow EPs to exclude this objective if no pharmacies within 10 miles of an EP’s practice location at the start of his/her EHR reporting period accept electronic prescriptions. This is 10 miles in any straight line from the practice location independent of the travel route from the practice location to the pharmacy. We stated that EPs practicing at multiple locations would be eligible for the exclusion if any of their practice locations that are equipped with CEHRT meet this criteria. An EP would not be eligible for this exclusion if he or she is part of an organization that owns or operates its own pharmacy within the 10 mile radius regardless of whether that pharmacy can accept electronic prescriptions from EPs outside of the organization.

We also propose to retain the exclusion for EPs who write fewer than 100 permissible prescriptions during the EHR reporting period.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

Denominator: Number of prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances during the EHR reporting period; or Number of prescriptions written for drugs requiring a prescription in order to be dispensed during the EHR reporting period.

Numerator: The number of prescriptions in the denominator generated, queried for a drug formulary and transmitted electronically using CEHRT.

Threshold: The resulting percentage must be more than 50 percent in order for an EP to meet this measure.

Exclusions: Any EP who:

- Writes fewer than 100 permissible prescriptions during the EHR reporting period; or
- Does not have a pharmacy within his or her organization and there are no pharmacies that accept electronic prescriptions within 10 miles of the EP’s practice location at the start of his or her EHR reporting period.

Alternate Exclusions and Specifications for Stage 1 Providers for Meaningful Use in 2015

We propose that providers who are scheduled to demonstrate Stage 1 of meaningful use for an EHR reporting period in 2015 may attest to meaningful



use using the specifications established for the Stage 1 objectives and measures as they are currently defined at 42 CFR 495.6 for each retained objective or measure where there is a difference in specifications between Stages 1 and 2.

In Stage 1, the electronic prescribing measure for EPs requires that “More than 40 percent of all permissible prescriptions written by the EP are transmitted electronically using certified EHR technology” (75 FR 44338).

Therefore, we are proposing that for an EHR reporting period in 2015, EPs scheduled to demonstrate Stage 1 of meaningful use may attest to the specifications and threshold associated with the Stage 1 measure. We note that for an EHR reporting period beginning in 2016, all EPs must meet the specifications and threshold for the retained Stage 2 measure in order to successfully demonstrate meaningful use.

*Alternate EP Measure:* More than 40 percent of all permissible prescriptions written by the EP are transmitted electronically using Certified EHR Technology.

There are no alternate exclusions for this EP objective.

## (2) Eligible Hospital/CAH Proposed Objective

*Proposed Eligible Hospital/CAH Objective:* Generate and transmit permissible discharge prescriptions electronically (eRx).

In the Stage 2 final rule at 77 FR 54035, we describe that the use of electronic prescribing has several advantages over having the patient carry the prescription to the pharmacy or directly faxing a handwritten or typewritten prescription to the pharmacy. When the hospital generates the prescription electronically, CEHRT can provide support for a number of purposes such as promoting safety and quality in the form of decision support around adverse interactions and other treatment possibilities; increasing the efficiency of the health care system by alerting the EP to generic alternatives or to alternatives favored by the patient’s insurance plan that are equally effective; and reducing communication errors by allowing the pharmacy or a third party to automatically compare the medication order to others they have received for the patient. This allows for many of the same decision support functions enabled at the generation of the prescription, but with access to potentially greater information. For this reason, we continue to support the use of electronic prescribing for discharge prescriptions in a hospital setting.

*Proposed Eligible Hospital/CAH Measure:* More than 10 percent of hospital discharge medication orders for permissible prescriptions (for new, changed and refilled prescriptions) are queried for a drug formulary and transmitted electronically using Certified EHR Technology.

We propose to retain the exclusion that would allow a hospital to exclude this objective if there is no internal pharmacy that can accept electronic prescriptions and is not located within 10 miles of any pharmacy that accepts electronic prescriptions at the start of their EHR reporting period.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

*Denominator:* Number of new, changed, or refill prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances for patients discharged during the EHR reporting period.

*Numerator:* The number of prescriptions in the denominator generated, queried for a drug formulary and transmitted electronically.

*Threshold:* The resulting percentage must be more than 10 percent in order for an eligible hospital or CAH to meet this measure.

*Exclusion:* Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions and is not located within 10 miles of any pharmacy that accepts electronic prescriptions at the start of their EHR reporting period.

Alternate Exclusions and Specifications for Stage 1 Providers for Meaningful Use in 2015

We propose that eligible hospitals and CAHs scheduled to report on Stage 1 objectives for an EHR reporting period in 2015 may claim an exclusion for the Stage 2 eRx measure as there is not an equivalent Stage 1 measure defined at 42 CFR 495.6. We further propose that eligible hospitals and CAHs scheduled to report Stage 2 objectives for an EHR reporting period in 2015 who were not intending to attest to the eRx menu objective and measure may also claim an exclusion. We note that for an EHR reporting period beginning in 2016, all providers must attest to the objective and measure and meet the specifications and threshold for the Stage 2 measure in order to successfully demonstrate meaningful use.

*Alternate Eligible Hospital/CAH Exclusion:* Provider may claim an exclusion for the eRx objective and measure if for an EHR reporting period in 2015 they were either scheduled to

demonstrate Stage 1 which does not have an equivalent measure, or if they are scheduled to demonstrate Stage 2 but did not intend to select the Stage 2 eRx menu objective for an EHR reporting period in 2015.

There are no alternate specifications for this eligible hospital and CAH objective.

We invite public comment on this proposal.

## e. Summary of Care

We are proposing to retain only the second measure of the existing Stage 2 objective for Summary of Care for meaningful use in 2015 through 2017 with the modifications discussed in this proposed rule. (For further information and discussion of the existing Stage 2 Summary of Care objective and measures, we refer readers to the discussion in the Stage 2 final rule at 77 FR 54013 through 54021.)

*Proposed Objective:* The EP, eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care provides a summary care record for each transition of care or referral.

In the Stage 2 final rule, we outlined the following benefits of this objective. By assuring lines of communication between providers caring for the same patient, all of the providers of care can operate with better information and more effectively coordinate the care they provide. Electronic health records, especially when linked directly or through health information exchanges, reduce the burden of such communication. The purpose of this objective is to ensure a summary of care record is provided to the receiving provider when a patient is transitioning to a new provider or has been referred to another provider while remaining in the care of the referring provider.

*Proposed Measure:* The EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care that—(1) uses CEHRT to create a summary of care record; and (2) electronically transmits such summary to a receiving provider for more than 10 percent of transitions of care and referrals.

We are proposing to retain an updated version of the second measure of the Stage 2 Summary of Care objective with modifications based on guidance provided through CMS responses to frequently asked questions we have received since the publication of the Stage 2 final rule. We are proposing to retain this measure for electronic transmittal because we believe that the electronic exchange of health

information between providers would encourage the sharing of the patient care summary from one provider to another and the communication of important information that the patient may not have been able to provide, which can significantly improve the quality and safety of referral care and reduce unnecessary and redundant testing. Use of common standards in creating the summary of care record can significantly reduce the cost and complexity of interfaces between different systems and promote widespread exchange and interoperability.

The proposed updates to this measure reflect stakeholder input regarding operational challenges in meeting this measure, and seek to increase flexibility for providers while continuing to drive interoperability across care settings and encouraging further innovation. Currently, the measure specifies the manner in which the summary of care must be electronically transmitted. Providers must either—(1) electronically transmit the summary of care using CEHRT to a recipient; or (2) where the recipient receives the summary of care record via exchange facilitated by an organization that is a NwHIN Exchange participant or in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network. We propose to update this measure to state simply that a provider would be required to create the summary of care record using CEHRT and transmit the summary of care record electronically.

To calculate the percentage of the measure, CMS and ONC have worked together to define the following for this objective:

**Denominator:** Number of transitions of care and referrals during the EHR reporting period for which the EP or eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) was the transferring or referring provider.

**Numerator:** The number of transitions of care and referrals in the denominator where a summary of care record was created using Certified EHR Technology and is exchanged electronically.

**Threshold:** The percentage must be more than 10 percent in order for an EP, eligible hospital or CAH to meet this measure.

**Exclusion:** Any EP who transfers a patient to another setting or refers a patient to another provider less than 100 times during the EHR reporting period.

Alternate Exclusions and Specifications for Stage 1 Providers for Meaningful Use in 2015

We propose that providers scheduled to demonstrate Stage 1 of meaningful use for an EHR reporting period in 2015 may claim an exclusion for Measure 2 of the Stage 2 Summary of Care core objective, as there is not an equivalent Stage 1 measure. The measure related to the electronic transmission of a summary of care record in the Summary of Care core objective requires an electronic summary of care document to be sent for transitions and referrals and is only applicable for Stage 2. There is not an equivalent objective and measure in Stage 1. We note that for an EHR reporting period beginning in 2016, all providers must attest to the complete objective and meet the specifications and threshold for the both Stage 2 measures in order to successfully demonstrate meaningful use.

**Alternate Exclusion:** Provider may claim an exclusion for the measure of the Stage 2 Summary of Care objective which requires the electronic transmission of a summary of care document if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1, which does not have an equivalent measure.

There are no alternate specifications for this objective.

We invite public comment on this proposal.

#### f. Patient Specific Education

We are proposing to retain the Stage 2 objective and measure for Patient Specific Education for meaningful use for 2015 through 2017. (For further information and discussion of the existing Stage 2 Patient Specific Education objective and measure, please refer to 77 FR 54011 and 54012.)

**Proposed Objective:** Use clinically relevant information from Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient.

In the Stage 2 proposed rule, we explained that providing clinically relevant education resources to patients is a priority for the meaningful use of CEHRT. While CEHRT must be used to identify patient-specific education resources, these resources or materials do not have to be stored within or generated by the CEHRT. We are aware that there are many electronic resources available for patient education materials, such as through the National Library of Medicine's MedlinePlus (<http://www.nlm.nih.gov/medlineplus>, that can be queried via CEHRT (that is, specific patient characteristics are

linked to specific consumer health content). The EP or hospital should utilize CEHRT in a manner where the technology suggests patient-specific educational resources based on the information stored in the CEHRT. Certified EHR technology is certified to use the patient's problem list, medication list, or laboratory test results to identify the patient-specific educational resources. The EP or hospital may use these elements or additional elements within CEHRT to identify educational resources specific to patients' needs. The EP or hospital can then provide these educational resources to patients in a useful format for the patient (such as, electronic copy, printed copy, electronic link to source materials, through a patient portal or PHR).

**Proposed EP Measure:** Patient-specific education resources identified by Certified EHR Technology are provided to patients for more than 10 percent of all unique patients with office visits seen by the EP during the EHR reporting period.

We propose to retain the exclusion for EPs who have no office visits in order to accommodate such EPs.

The resources would have to be those identified by CEHRT. If resources are not identified by CEHRT and provided to the patient then it would not count in the numerator. We do not intend through this requirement to limit the education resources provided to patient to only those identified by CEHRT. The education resources would need to be provided prior to the calculation and subsequent attestation to meaningful use.

To calculate the percentage for EPs, CMS and ONC have worked together to define the following for this objective:

**Denominator:** Number of unique patients with office visits seen by the EP during the EHR reporting period.

**Numerator:** Number of patients in the denominator who were provided patient-specific education resources identified by the Certified EHR Technology.

**Threshold:** The resulting percentage must be more than 10 percent in order for an EP to meet this measure.

**Exclusion:** Any EP who has no office visits during the EHR reporting period.

**Proposed Eligible Hospital/CAH Measure:** More than 10 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) are provided patient specific education resources identified by Certified EHR Technology.

To calculate the percentage for hospitals, CMS and ONC have worked

together to define the following for this objective:

**Denominator:** Number of unique patients admitted to the eligible hospital or CAH inpatient or emergency departments (POS 21 or 23) during the EHR reporting period.

**Numerator:** Number of patients in the denominator who are subsequently provided patient-specific education resources identified by CEHRT.

**Threshold:** The resulting percentage must be more than 10 percent in order for an eligible hospital or CAH to meet this measure.

#### Alternate Exclusions and Specifications for Stage 1 Providers for Meaningful Use in 2015

While the Patient Specific Education objective is designated as an optional menu objective in Stage 1 of meaningful use, the same objective is a mandatory core objective in Stage 2 of meaningful use. We expect that not all Stage 1 scheduled providers were planning to choose this menu objective when attesting in an EHR reporting period in 2015. Therefore, we propose that any provider scheduled to demonstrate Stage 1 of meaningful use for an EHR reporting period in 2015 who was not intending to attest to the Stage 1 Patient Specific Education menu objective, may claim an exclusion to the measure. We note that for an EHR reporting period beginning in 2016, all providers must attest to the objective and measure and meet the Stage 2 specifications and threshold in order to successfully demonstrate meaningful use.

**Alternate Exclusion:** Provider may claim an exclusion for the measure of the Stage 2 Patient Specific Education objective if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1 but did not intend to select the Stage 1 Patient Specific Education menu objective.

There are no alternate specifications for this objective.

We invite public comment on this proposal.

#### g. Medication Reconciliation

We are proposing to retain the Stage 2 objective and measure for Medication Reconciliation for meaningful use in 2015 through 2017. (For further information and discussion of the existing Stage 2 Medication Reconciliation objective and measure, please refer to 77 FR 54012 and 54013.)

**Proposed Objective:** The EP, eligible hospital or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.

Medication reconciliation allows providers to confirm that the information they have on the patient's medication is accurate. This not only assists the provider in his or her direct patient care, it also improves the accuracy of information they provide to others through health information exchange.

In the Stage 2 proposed rule, we noted that that when conducting medication reconciliation during a transition of care, the EP, eligible hospital or CAH that receives the patient into their care should conduct the medication reconciliation. We reiterated that the measure of this objective does not dictate what information must be included in medication reconciliation. Information included in the process of medication reconciliation is appropriately determined by the provider and patient. We defined medication reconciliation as the process of identifying the most accurate list of all medications that the patient is taking, including name, dosage, frequency, and route, by comparing the medical record to an external list of medications obtained from a patient, hospital or other provider.

**Proposed Measure:** The EP, eligible hospital or CAH performs medication reconciliation for more than 50 percent of transitions of care in which the patient is transitioned into the care of the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23).

For the purposes of this measure, we propose to maintain the definition of a transition of care as the movement of a patient from one setting of care (for example, a hospital, ambulatory primary care practice, ambulatory specialty care practice, long-term care, home health, rehabilitation facility) to another and referrals are cases where one provider refers a patient to another, but the referring provider maintains his or her care of the patient as well.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

**Denominator:** Number of transitions of care during the EHR reporting period for which the EP or eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) was the receiving party of the transition.

**Numerator:** The number of transitions of care in the denominator where medication reconciliation was performed.

**Threshold:** The resulting percentage must be more than 50 percent in order for an EP, eligible hospital or CAH to meet this measure.

**Exclusion:** Any EP who was not the recipient of any transitions of care during the EHR reporting period.

#### Alternate Exclusions and Specifications for Stage 1 Providers for Meaningful Use in 2015

While the Medication Reconciliation objective is designated as an optional menu objective in Stage 1 of meaningful use, the same objective is a mandatory core objective in Stage 2 of meaningful use. We expect that not all Stage 1 scheduled providers were planning to choose this menu objective when attesting in an EHR reporting period in 2015. Therefore, we propose that any provider scheduled to demonstrate Stage 1 of meaningful use for an EHR reporting period in 2015 who was not intending to attest to the Stage 1 Medication Reconciliation menu objective, may claim an exclusion to the measure. We note that for an EHR reporting period beginning in 2016, all providers must attest to the objective and measure and meet the Stage 2 specifications and threshold in order to successfully demonstrate meaningful use.

**Alternate Exclusion:** Provider may claim an exclusion for the measure of the Stage 2 Medication Reconciliation objective if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1 but did not intend to select the Stage 1 Medication Reconciliation menu objective.

There are no alternate specifications for this objective.

We invite public comment on this proposal.

#### h. Patient Electronic Access (VDT)

We are proposing to retain the Stage 2 objective for Patient Electronic Access for meaningful use in 2015 through 2017. We are proposing to retain the first measure of the Stage 2 objective without modification. We are proposing to retain the second measure for the Stage 2 objective with modification to the measure threshold. (For further information and discussion of the existing Stage 2 Patient Electronic Access objective and measures, please refer to 77 FR 54007 through 54011.)

**Proposed EP Objective:** Provide patients the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP.

**Proposed Eligible Hospital/CAH Objective:** Provide patients the ability to view online, download, and transmit information about a hospital admission.

In the Stage 2 proposed rule, we stated that the goal of this objective was

to allow patients easy access to their health information as soon as possible, so that they can make informed decisions regarding their care or share their most recent clinical information with other health care providers and personal caregivers as they see fit.

The ability to have this information online means it is always retrievable by the patient, while the download function ensures that the patient can take the information with them when secure internet access is not available. The patient must be able to access this information on demand, such as through a patient portal or personal health record (PHR). We note that while a covered entity may be able to fully satisfy a patient's request for information through VDT, the measure does not replace the covered entity's responsibilities to meet the broader requirements under HIPAA to provide an individual, upon request, with access to PHI in a designated record set. Providers should also be aware that while meaningful use is limited to the capabilities of CEHRT to provide online access there may be patients who cannot access their EHRs electronically because of their disability. Additionally, other health information may not be accessible. Finally, we noted that providers who are covered by civil rights laws must provide individuals with disabilities equal access to information and appropriate auxiliary aids and services as provided in the applicable statutes and regulations.

#### Proposed EP Measures

- *EP Measure 1:* More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely (within 4 business days after the information is available to the EP) online access to their health information subject to the EP's discretion to withhold certain information.

- *EP Measure 2:* At least one patient seen by the EP during the EHR reporting period (or their authorized representatives) views, downloads, or transmits his or her health information to a third party.

In order to meet this objective, the following information must be made available to patients electronically within 4 business days of the information being made available to the EP:

- ++ Patient name.
- ++ Provider's name and office contact information.
- ++ Current and past problem list.
- ++ Procedures.
- ++ Laboratory test results.

- ++ Current medication list and medication history.

- ++ Current medication allergy list and medication allergy history.

- ++ Vital signs (height, weight, blood pressure, BMI, growth charts).

- ++ Smoking status.

- ++ Demographic information (preferred language, sex, race, ethnicity, date of birth).

- ++ Care plan field(s), including goals and instructions.

- ++ Any known care team members including the primary care provider (PCP) of record.

As we stated in the Stage 2 proposed rule, this is not intended to limit the information made available by the EP. An EP can make available additional information and still align with the objective. In circumstances where there is no information available to populate one or more of the fields previously listed, either because the EP can be excluded from recording such information (for example, vital signs) or because there is no information to record (for example, no medication allergies or laboratory tests), the EP may have an indication that the information is not available and still meet the objective and its associated measure. Please note that while some of the information made available through this measure is similar to the information made available in the summary of care document that must be provided following transitions of care or referrals, the list of information provided is specific to the view online, download, and transmit objective. Patients and providers have different information needs and contexts, so we have established separate required fields for each of these objectives.

We propose to retain the exclusion that any EP who neither orders nor creates any of the information listed for inclusion as part of this measure may exclude from this measure as well as the exclusion for limited broadband access in an EP's service area.

To calculate the percentage of the first measure for providing patient with timely online access to health information, CMS and ONC have worked together to define the following for this objective:

- *EP Measure 1:* More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely (within 4 business days after the information is available to the EP) online access to their health information subject to the EP's discretion to withhold certain information.

*Denominator:* Number of unique patients seen by the EP during the EHR reporting period.

*Numerator:* The number of patients in the denominator who have timely (within 4 business days after the information is available to the EP) online access to their health information.

*Threshold:* The resulting percentage must be more than 50 percent in order for an EP to meet this measure.

- *EP Measure 2:* At least one patient seen by the EP during the EHR reporting period (or his or her authorized representatives) views, downloads, or transmits his or her health information to a third party.

- *Exclusions:* Any EP who—

- (a) Neither orders nor creates any of the information listed for inclusion as part of the measures; or

- (b) Conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period.

#### Proposed Eligible Hospital/CAH Measures:

- *Eligible Hospital/CAH Measure 1:* More than 50 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH have their information available online within 36 hours of discharge.

- *Eligible Hospital/CAH Measure 2:* At least 1 patient who is discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH (or his or her authorized representative) views, downloads, or transmits to a third party his or her information during the EHR reporting period.

The following information must be available to satisfy the objective and measure:

- ++ Patient name.
- ++ Admit and discharge date and location.
- ++ Reason for hospitalization.
- ++ Care team including the attending of record as well as other providers of care.
- ++ Procedures performed during admission.
- ++ Current and past problem list.
- ++ Vital signs at discharge.
- ++ Laboratory test results (available at time of discharge).
- ++ Summary of care record for transitions of care or referrals to another provider.
- ++ Care plan field(s), including goals and instructions.

- ++ Discharge instructions for patient.
- ++ Demographics maintained by hospital (sex, race, ethnicity, date of birth, preferred language).
- ++ Smoking status.

This is not intended to limit the information made available by the hospital. A hospital can make available additional information and still align with the objective. Please note that while some of the information made available through this measure is similar to the information made available in the summary of care document that must be provided following transitions of care or referrals, this list of information provided is specific to the view online, download, and transmit objective. Patients and providers have different information needs and contexts, so CMS has established separate required fields for each of these objectives.

To calculate the percentage of the first measure for providing patients timely access to discharge information, CMS and ONC have worked together to define the following for this objective:

- *Eligible Hospital/CAH Measure 1:* More than 50 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH have their information available online within 36 hours of discharge.

*Denominator:* Number of unique patients discharged from an eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

*Numerator:* The number of patients in the denominator whose information is available online within 36 hours of discharge.

*Threshold:* The resulting percentage must be more than 50 percent in order for an eligible hospital or CAH to meet this measure.

- *Eligible Hospital/CAH Measure 2:* At least 1 patient who is discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH (or his or her authorized representative) views, downloads, or transmits to a third party his or her information during the EHR reporting period.

- *Exclusion:* Any eligible hospital or CAH that is located in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period.

Alternate Exclusions and Specifications for Stage 1 Providers for Meaningful Use in 2015

The Patient Electronic Access objective has two associated measures, the first (provide access to view, download, and transmit health information) is applicable for both Stage 1 and Stage 2 while the second (patients view, download, or transmit their health information) is only applicable for Stage 2. Therefore, we propose that providers scheduled to demonstrate Stage 1 of meaningful use for an EHR reporting period in 2015 may additionally claim an exclusion for the second measure of the Stage 2 Patient Electronic Access objective as there is not an equivalent Stage 1 measure defined at 42 CFR 495.6. We note that for an EHR reporting period beginning in 2016, all providers must attest to the objective and both measures and meet the specifications and threshold associated with the retained Stage 2 objective and measures in order to successfully demonstrate meaningful use.

- *Alternate Exclusion Measure 2:* Provider may claim an exclusion for the second measure if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1, which does not have an equivalent measure.

There are no alternate specifications for this objective.

We invite public comment on this proposal.

#### i. Secure Electronic Messaging

We are proposing to retain the Stage 2 objective for secure electronic messaging with modifications to the measure for meaningful use in 2015 through 2017. (For further information and discussion of the existing Stage 2 secure electronic messaging objective and measure, please refer to 77 FR 54033.)

*Proposed Objective:* Use secure electronic messaging to communicate with patients on relevant health information.

In the Stage 2 proposed rule, we outlined the following benefits of using secure electronic messaging to communicate with patients: Electronic messaging (for example, email) is one of the most widespread methods of communication for both businesses and individuals. The ability to communicate through forms of electronic messaging is essential to the provider-patient relationship. Electronic messaging is very inexpensive on a transactional basis and allows for communication even when the provider and patient are not available at the same moment in time. However, common email services

may not be secure enough to be appropriate for the exchange of ePHI. Therefore, the exchange of ePHI through electronic messaging requires additional security measures while maintaining its ease of use for communication. While secure email with the necessary safeguards is probably the most widely used method of electronic messaging, for the purposes of meeting this objective, secure electronic messaging could also occur through functionalities of patient portals, PHRs, or other stand-alone secure messaging applications.

For EPs, secure electronic messaging is critically important to two National Quality Strategy (NQS) priorities—

- Ensuring that each person/family is engaged as partners in their care; and
- Promoting effective communication and coordination of care.

Secure electronic messaging could make care more affordable by using more efficient communication vehicles when appropriate. Specifically, research demonstrates that secure messaging has improved patient adherence to treatment plans, which reduces readmission rates. In addition, secure messaging has led to increased patient satisfaction with their care and is one of the top ranked features according to patients. In addition, despite some trepidation, providers have seen a reduction in time responding to inquiries and less time spent on the phone.<sup>3</sup>

*Proposed Measure:* During the EHR reporting period, the capability for patients to send and receive a secure electronic message with the provider was fully enabled.

We propose to retain the exclusion for EPs who have no office visits, and for those EPs who lack the infrastructure required for secure electronic messaging due to being located in areas with limited broadband availability as identified by the FCC.

*Measure:* During the EHR reporting period, the capability for patients to send and receive a secure electronic message with the provider was fully enabled.

*Exclusion:* Any EP who has no office visits during the EHR reporting period,

<sup>3</sup> Rosenberg SN, Shnaiden TL, Wagh AA, Juster IA (2008) "Supporting the patient's role in guideline compliance: a controlled study" American Journal of Managed Care 14(11):737-44; Gustafson DH, Hawkins R, Boberg E, Pingree S, Serlin RE, Graziano F, Chan CL (1999) "Impact of a patient-centered, computer-based health information/support system" American Journal of Preventive Medicine 16(1):1-9. Ralston JD, Carrell D, Reid R, Anderson M, Moran M, Hereford J (2007) "Patient web services integrated with a shared medical record: patient use and satisfaction" Journal of the American Medical Informatics Association 14(6):798-806.

or any EP who conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period.

#### Alternate Exclusions and Specifications for Stage 1 Providers for Meaningful Use in 2015

For the secure electronic messaging objective, there is no Stage 1 objective or measure which relates to the requirements of the Stage 2 objective and measure. We therefore propose that an EP scheduled to demonstrate Stage 1 of meaningful use for an EHR reporting period in 2015 may claim an exclusion for the secure electronic messaging objective measure as there is not an equivalent Stage 1 objective or measure defined at 42 CFR 495.6. We note that for an EHR reporting period beginning in 2016, all providers must attest to the objective and measure of the retained Stage 2 secure electronic messaging objective in order to successfully demonstrate meaningful use.

- *Alternate Exclusion:* An EP may claim an exclusion for the measure if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1, which does not have an equivalent measure.

There are no alternate specifications for this objective and there is no equivalent objective for eligible hospitals and CAHs in the Stage 2 objectives and measures for meaningful use.

We invite public comment on this proposal.

#### j. Public Health and Clinical Data Registry (CDR) Reporting

As mentioned previously, we are proposing to adopt the consolidated Stage 3 version of the public health reporting objectives for all providers to demonstrate meaningful use for an EHR reporting period in 2015 through 2017. We note that this change does not fundamentally change a provider's ability to demonstrate meeting the requirements of meaningful use with any actions they may have already taken or are in the progress of taking to meet the prior requirements of meaningful use defined in the Stage 1 and Stage 2 rules for public health reporting. These requirements are currently defined at (75 FR 44325 through 44326) for EPs and (75 FR 44364 through 44368) for eligible hospitals and CAHs in the Stage 1 final rule. In the Stage two final rule the requirements may be found at (77 FR 54021 through 54026) for EPs and

(77 FR 54029 through 54031) for eligible hospitals and CAHs. We further note that this change does not require the addition of any new technology or standard not already available in CEHRT to demonstrate meaningful use in 2014.

This objective is designed based on the objective proposed in the Stage 3 proposed rule at which builds on the requirements set forth in the Stage 2 final rule (see for example 77 FR 54047 through 54048 under the Health Outcomes Policy Priority "Improve population and public health"). In the Stage 3 proposed rule, we proposed changes to the Stage 1 and Stage 2 public health and specialty registry objectives to consolidate the prior objectives and measures into a single objective in alignment with efforts to streamline the program and support flexibility for providers (80 FR 16739 and 16740).

*Proposed Objective:* The EP, eligible hospital, or CAH is in active engagement with a Public Health Agency (PHA) or clinical data registry (CDR) to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited and in accordance with applicable law and practice.

In the Stage 3 proposed rule, we highlighted our intention to remove the prior ongoing submission requirement and replace it with an "active engagement" requirement. We believe that "active engagement" as defined in the Stage 3 rule at (80 FR 16739 and 16740) and reiterated in this section is more aligned with the process providers undertake to report to a clinical registry or to a PHA.

For purposes of meeting this new objective, EPs, eligible hospitals and CAHs would be required to demonstrate that "active engagement" with a PHA or CDR has occurred. Active engagement means that the provider is in the process of moving towards sending "production data" to a PHA or CDR, or— is sending production data to a PHA or CDR. We note that the term "production data" refers to data generated through clinical processes involving patient care, and it is here used to distinguish between this data and "test data" which may be submitted for the purposes of enrolling in and testing electronic data transfers. We propose that "active engagement" may be demonstrated by any of the following options:

*Active Engagement Option 1— Completed Registration to Submit Data:* The EP, eligible hospital, or CAH registered to submit data with the PHA or, where applicable, the CDR to which the information is being submitted;

registration was completed within 60 days after the start of the EHR reporting period; and the EP, eligible hospital, or CAH is awaiting an invitation from the PHA or CDR to begin testing and validation. This option allows providers to meet the measure when the PHA or the CDR has limited resources to initiate the testing and validation process. Providers that have registered in previous years do not need to submit an additional registration to meet this requirement for each EHR reporting period.

*Active Engagement Option 2— Testing and Validation:* The EP, eligible hospital, or CAH is in the process of testing and validation of the electronic submission of data. Providers must respond to requests from the PHA or, where applicable, the CDR within 30 days; failure to respond twice within an EHR reporting period would result in that provider not meeting the measure.

*Active Engagement Option 3— Production:* The EP, eligible hospital, or CAH has completed testing and validation of the electronic submission and is electronically submitting production data to the PHA or CDR.

We note that the change in definition is intended to better capture the activities a provider may conduct in order to engage with a PHA or CDR, and that any prior action taken to meet the non-consolidated public health reporting objectives of meaningful use Stages 1 and 2 would count toward meeting the active engagement requirement of this objective.

*Proposed Measures:* We are proposing a total of 6 possible measures for this objective. For meaningful use in 2015 through 2017, EPs would be required to choose from Measures 1 through 5, and would be required to successfully attest to any combination of two measures. For meaningful use in 2015 through 2017, eligible hospitals and CAHs would be required to choose from Measures 1 through 6, and would be required to successfully attest to any combination of three measures. In 2015 only for providers scheduled to be in Stage 1, EPs would be required to choose from Measures 1 through 5, but would be permitted to successfully attest to one measure; and eligible hospitals and CAHs would be required to choose from Measures 1 through 6, but would be permitted to successfully attest to any combination of two measures. The measures are as shown in Table 5. As noted, measures 4 and 5 for Public Health Registry Reporting and Clinical Data Registry Reporting may be counted more than once if more than one Public Health Registry or Clinical Data Registry is available.

The measures are as follows:

TABLE 5—MEASURES FOR OBJECTIVE 8—PUBLIC HEALTH AND CLINICAL DATA REGISTRY REPORTING OBJECTIVE

Measure	Maximum times measure can count towards objective for EP	Maximum times measure can count towards objective for eligible hospital or CAH
Measure 1—Immunization Registry Reporting .....	1	1
Measure 2—Syndromic Surveillance Reporting .....	1	1
Measure 3—Case Reporting .....	1	1
Measure 4—Public Health Registry Reporting* .....	3	4
Measure 5—Clinical Data Registry Reporting** .....	3	4
Measure 6—Electronic Reportable Laboratory Results .....	N/A	1

\* EPs, eligible hospitals, and CAHs may choose to report to more than one public health registry (measure 4) to meet the number of measures required to meet the objective.

\*\* EPs, eligible hospitals, and CAHs may choose to report to more than one clinical data registry (measure 5) to meet the number of measures required to meet the objective.

For EPs, we propose that an exclusion for a measure does not count toward the total of two measures. Instead, in order to meet this objective an EP would need to meet two of the total number of measures available to them. If the EP qualifies for multiple exclusions and the remaining number of measures available to the EP is less than two, the EP can meet the objective by meeting the one remaining measure available to them and claiming the applicable exclusions. If no measures remain available, the EP can meet the objective by claiming applicable exclusions for all measures. An EP who is scheduled to be in Stage 1 in 2015 must report at least one measure unless they can exclude from all available measures. Available measures include ones for which the EP does not qualify for an exclusion.

For eligible hospitals and CAHs, we propose that an exclusion for a measure does not count toward the total of three measures. Instead, in order to meet this objective an eligible hospital or CAH would need to meet three of the total number of measures available to them. If the eligible hospital or CAH qualifies for multiple exclusions and the total number of remaining measures available to the eligible hospital or CAH is less than three, the eligible hospital or CAH can meet the objective by meeting all of the remaining measures available to them and claiming the applicable exclusions. If no measures remain available, the eligible hospital or CAH can meet the objective by claiming applicable exclusions for all measures. An eligible hospital or CAH that is scheduled to be in Stage 1 in 2015 must report at least two measures unless they can either—(1) exclude from all but one available measure and report that one measure; or (2) can exclude from all available measures. Available measures include ones for which the eligible

hospital or CAH does not qualify for an exclusion.

We note that we are proposing to allow EPs, eligible hospitals, and CAHs to choose to report to more than one public health registry to meet the number of measures required to meet the objective. We are also proposing to allow EPs, eligible hospitals, and CAHs to choose to report to more than one clinical data registry to meet the number of measures required to meet the objective. We believe that this flexibility allows for EPs, eligible hospitals, and CAHs to choose reporting options that align with their practice and that would aid the provider’s ability to care for their patients.

To calculate the measures:

- *Measure 1—Immunization Registry Reporting:* The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).

We believe the immunization registry reporting measure remains a priority for the EHR Incentive Programs because the exchange of information between certified EHR technology and immunization registries allows a provider to use the most complete immunization history available to inform decisions about the vaccines a patient may need. Public health agencies and providers also use immunization information for emergency preparedness and to estimate population immunization coverage levels of certain vaccines.

We propose that to successfully meet the requirements of this measure, bidirectional data exchange between the provider’s certified EHR technology system and the immunization registry/IIS is required. We understand that

many states and local public health jurisdictions are exchanging immunization data bidirectionally with providers, and that the number of states and localities able to support bidirectional exchange continues to increase. In the 2015 Edition proposed rule (80 FR 16851), the ONC is proposing to adopt a bidirectional exchange standard for reporting to immunization registries/IIS. We believe this functionality is important for patient safety and improved care because it allows for the provider to use the most complete immunization record possible to make decisions on whether a patient needs a vaccine. Immunization registries and health IT systems also are able to provide immunization forecasting functions which can inform discussions between providers and patients on what vaccines they may need in the future and the timeline for the receipt of such immunizations. Therefore, we believe that patients, providers, and the public health community would benefit from technology that can accommodate bidirectional immunization data exchange.

We welcome comment on this proposal.

*Exclusion:* Any EP, eligible hospital, or CAH meeting one or more of the following criteria may be excluded from the immunization registry reporting measure if the EP, eligible hospital, or CAH:

- ++ Does not administer any immunizations to any of the populations for which data is collected by their jurisdiction’s immunization registry or immunization information system during the EHR reporting period;

- ++ Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT

definition at the start of the EHR reporting period; or

++ Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data from the EP, eligible hospital or CAHs at the start of the EHR reporting period.

• *Measure 2—Syndromic Surveillance Reporting:* The EP, eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data from a non-urgent care ambulatory setting for EPs, or an emergency or urgent care department for eligible hospitals and CAHs (POS 23).

This measure remains a policy priority for the EHR Incentive Programs because electronic syndromic surveillance is valuable for early detection of outbreaks, as well as monitoring disease and condition trends.

We are distinguishing between EPs and eligible hospital or CAHs reporting locations because as discussed in the Stage 2 final rule, few PHAs appeared to have the ability to accept non-emergency or non-urgent care ambulatory syndromic surveillance data electronically (77 FR 53979). We continue to observe differences in the infrastructure and current environments for supporting electronic syndromic surveillance data submission to PHAs between eligible hospitals or CAHs and EPs. Because eligible hospitals and CAHs send syndromic surveillance data using different methods as compared to EPs, we are defining slightly different exclusions for each setting as described by the following:

*Exclusion for EPs:* Any EP meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure if the EP—

++ Does not treat or diagnose or directly treat any disease or condition associated with a syndromic surveillance system in his or her jurisdiction;

++ Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data from EPs in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or

++ Operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from EPs at the start of the EHR reporting period.

*Exclusion for eligible hospitals/CAHs:* Any eligible hospital or CAH meeting one or more of the following criteria

may be excluded from the syndromic surveillance reporting measure if the eligible hospital or CAH—

++ Does not have an emergency or urgent care department;

++ Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data from eligible hospitals or CAHs in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or

++ Operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from eligible hospitals or CAHs at the start of the EHR reporting period.

• *Measure 3—Case Reporting:* The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions.

This is a new reporting option that was not part of Stage 2. The collection of electronic case reporting data greatly improves reporting efficiencies between providers and the PHA. Public health agencies collect “reportable conditions” as defined by the state, territorial, and local PHAs to monitor disease trends and support the management of outbreaks. In many circumstances, there has been low reporting compliance because providers do not know when, where, or how to report. In some cases, the time burden to report can also contribute to low reporting compliance. Electronic case reporting, however, presents a core benefit to public health improvement, and a variety of stakeholders have identified electronic case reporting as a high value element of patient and continuity of care. Further, we believe that electronic case reporting reduces burdensome paper-based and labor intensive case reporting. Electronic reporting would support more rapid exchange of case reporting information between PHAs and providers and can include structured questions or data fields to prompt the provider to supply additional required or care-relevant information.

To support case reporting, the ONC has proposed a certification criterion that includes capabilities to enable certified EHR systems to send initial case reporting data and receive a request from the public health agency for supplemental or ad hoc structured data in the 2015 Edition proposed rule (80 FR 16855).

*Exclusion:* Any EP, eligible hospital, or CAH meeting one or more of the following criteria may be excluded from

the case reporting measure if the EP, eligible hospital, or CAH:

++ Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction’s reportable disease system during the EHR reporting period;

++ Operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or

++ Operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data at the start of the EHR reporting period.

• *Measure 4—Public Health Registry Reporting:* The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit data to public health registries.

In the Stage 2 final rule, we were purposefully general in our use of the term “specialized registry” (other than a cancer registry) to encompass both registry reporting to public health agencies and clinical data registries in order to prevent inadvertent exclusion of certain registries through an attempt to be more specific (77 FR 54030). In response to insight gained from the industry through listening sessions, public forums, and responses to a **Federal Register** notice soliciting public comments on the proposed information collections to develop a centralized repository on public health readiness to support meaningful use (79 FR 7461); we propose to carry forward the concept behind this broad category from Stage 2, but also propose to split public health registry reporting from clinical data registry reporting into two separate measures which better define the potential types of registries available for reporting. We propose to define a “public health registry” as a registry that is administered by, or on behalf of, a local, state, territorial, or national PHA and which collects data for public health purposes. While immunization registries are a type of public health registry, we propose to keep immunization registry reporting separate from the public health registry reporting measure to retain continuity from Stage 1 and 2 policy in which immunization registry reporting was a distinct and separate objective (77 FR 54023). We believe it is important to retain the public health registry reporting option for Stage 3 because these registries allow the public health community to monitor health and disease trends, and inform the development of programs and policy for



population and community health improvement.

We reiterate that any EP, eligible hospital, or CAH may report to more than one public health registry to meet the total number of required measures for the objective. For example, if a provider meets this measure through reporting to both the National Hospital Care Survey and the National Healthcare Safety Network registry, the provider could get credit for meeting two measures. ONC would consider the adoption of standards and implementation guides in future rulemaking. Should these subsequently be finalized, they may then be adopted as part of the certified EHR technology definition as it relates to meeting the public health registry reporting measure through future rulemaking for the EHR Incentive Programs.

We further note that ONC adopted standards for ambulatory cancer case reporting in its 2014 Edition final rule (see § 170.314(f)(6)) and CMS provided EPs the option to select the cancer case reporting menu objective in the Stage 2 final rule (77 FR 54029 through 54030). We included cancer registry reporting as a separate objective from specialized registry reporting because it was more mature in its development than other registry types, not because other reporting was intended to be excluded from meaningful use. For the Stage 3 public health agency reporting measure, given the desire to provide more flexible options for providers to report to the registries most applicable for their scope of practice, we propose that EPs would have the option of counting cancer case reporting under the public health registry reporting measure. Under this measure, we note that cancer case reporting is not an option for eligible hospitals and CAHs, because hospitals have traditionally diagnosed and treated cancers (or both) and have the infrastructure needed to report cancer cases.

*Exclusions:* Any EP, eligible hospital, or CAH meeting at least one of the following criteria may be excluded from the public health registry reporting measure if the EP, eligible hospital, or CAH—

++ Does not diagnose or directly treat any disease or condition associated with a public health registry in their jurisdiction during the EHR reporting period;

++ Operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards

required to meet the CEHRT definition at the start of the EHR reporting period; or

++ Operates in a jurisdiction where no public health registry for which the EP, eligible hospital, or CAH is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period.

• *Measure 5—Clinical Data Registry Reporting:* The EP, eligible hospital, or CAH is in active engagement to submit data to a clinical data registry.

As discussed in the Public Health Registry Reporting measure, we propose to split specialized registry reporting into two separate, clearly defined measures: Public health registry reporting and clinical data registry reporting. In Stage 2 for EPs, reporting to specialized registries is a menu objective and this menu objective includes reporting to clinical data registries. For Stage 3, we propose to include clinical data registry reporting as an independent measure. The National Quality Registry Network defines clinical data registries as those that record information about the health status of patients and the health care they receive over varying periods of time<sup>4</sup>. We propose to further differentiate between clinical data registries and public health registries as follows: For the purposes of meaningful use, “public health registries” are those administered by, or on behalf of, a local, state, territorial, or national public health agencies; and, “clinical data registries” are administered by, or on behalf of, other non-public health agency entities. We believe that clinical data registries are important for providing information that can inform patients and their providers on the best course of treatment and for care improvements, and can support specialty reporting by developing reporting for areas not usually covered by PHAs but that are important to a specialist’s provision of care. Clinical data registries can also be used to monitor health care quality and resource use.

As noted previously, we reiterate that any EP, eligible hospital, or CAH may report to more than 1 clinical data registry to meet the total number of required measures for this objective. ONC would consider the adoption of standards and implementation guides in future rulemaking. Should these subsequently be finalized, they may then be adopted as part of the certified EHR technology definition as it relates to meeting the clinical data registry

reporting measure through future rulemaking for the EHR Incentive Programs.

*Exclusion:* Any EP, eligible hospital, or CAH meeting at least one of the following criteria may be excluded from the clinical data registry reporting measure if the EP, eligible hospital, or CAH—

++ Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period;

++ Operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or

++ Operates in a jurisdiction where no clinical data registry for which the EP, eligible hospital, or CAH is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period.

• *Measure 6—Electronic Reportable Laboratory Result Reporting:* The eligible hospital or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results. This measure is available to eligible hospitals and CAHs only. Electronic reportable laboratory result reporting to PHAs is required for eligible hospitals and CAHs in Stage 2 (77 FR 54021). We propose to retain this measure for the EHR Incentive Programs to promote the exchange of laboratory results between eligible hospitals/CAHs and PHAs for improved timeliness, reduction of manual data entry errors, and more complete information.

*Exclusion:* Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the electronic reportable laboratory result reporting measure if the eligible hospital or CAH—

++ Does not perform or order laboratory tests that are reportable in their jurisdiction during the EHR reporting period;

++ Operates in a jurisdiction for which no public health agency is capable of accepting the specific ELR standards required to meet the CEHRT definition at the start of the EHR reporting period; or

++ Operates in a jurisdiction where no public health agency has declared readiness to receive electronic reportable laboratory results from eligible hospitals or CAHs at the start of the EHR reporting period.

<sup>4</sup> <https://download.ama-assn.org/resources/doc/qqi/x-pub/nqm-what-is-clinical-data-registry.pdf>

We seek public comment on this proposal.

TABLE 6—MEANINGFUL USES OBJECTIVES AND MEASURES FOR 2015 THROUGH 2017

Provider type	Proposed objectives for 2015, 2016 and 2017	Proposed measures for providers in 2015, 2016 and 2017	Proposed alternate measures, exclusions and/or specifications for certain providers in 2015 ONLY
Eligible Professional ...	CPOE .....	<ul style="list-style-type: none"> <li>• <i>Measure 1:</i> More than 60 percent of medication orders created by the EP or by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.</li> <li>• <i>Measure 2:</i> More than 30 percent of laboratory orders created by the EP or by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.</li> <li>• <i>Measure 3:</i> More than 30 percent of radiology orders created by the EP or by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.</li> </ul>	<p>If for an EHR reporting period in 2015, the provider is scheduled to demonstrate Stage 1:</p> <ul style="list-style-type: none"> <li>• <i>Alternate Measure 1:</i> More than 30 percent of all unique patients with at least one medication in their medication list seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have at least one medication order entered using CPOE; or more than 30 percent of medication orders created by the EP during the EHR reporting period, or created by the authorized providers of the eligible hospital or CAH for patients admitted to their inpatient or emergency departments (POS 21 or 23) during the EHR reporting period, are recorded using computerized provider order entry.</li> <li>• <i>Alternate Exclusion for Measure 2:</i> Provider may claim an exclusion for measure 2 (laboratory orders) of the Stage 2 CPOE objective for an EHR reporting period in 2015.</li> <li>• <i>Alternate Exclusion for Measure 3:</i> Provider may claim an exclusion for measure 3 (radiology orders) of the Stage 2 CPOE objective for an EHR reporting period in 2015.</li> </ul>
	Electronic Prescribing	<p><i>EP Measure:</i> More than 50 percent of all permissible prescriptions, or all prescriptions, written by the EP are queried for a drug formulary and transmitted electronically using Certified EHR Technology.</p>	<p>If for an EHR reporting period in 2015, the provider is scheduled to demonstrate Stage 1:</p> <p><i>Alternate EP Measure:</i> More than 40 percent of all permissible prescriptions written by the EP are transmitted electronically using Certified EHR Technology.</p>
	Clinical Decision Support.	<ul style="list-style-type: none"> <li>• <i>Measure 1:</i> Implement five clinical decision support interventions related to four or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. Absent four clinical quality measures related to an EP, eligible hospital or CAH's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions. It is suggested that one of the five clinical decision support interventions be related to improving healthcare efficiency.</li> <li>• <i>Measure 2:</i> The EP, eligible hospital, or CAH has enabled and implemented the functionality for drug-drug and drug allergy interaction checks for the entire EHR reporting period. Exclusion: For the second measure, any EP who writes fewer than 100 medication orders during the EHR reporting period.</li> </ul>	<p>If for an EHR reporting period in 2015, the provider is scheduled to demonstrate Stage 1:</p> <p><i>Alternate Objective and Measure 1:</i> Objective: Implement one clinical decision support rule relevant to specialty or high clinical priority, or high priority hospital condition, along with the ability to track compliance with that rule. <i>Measure:</i> Implement one clinical decision support rule.</p>
	Patient Electronic Access (VDT).	<ul style="list-style-type: none"> <li>• <i>EP Measure 1:</i> More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely (within 4 business days after the information is available to the EP) online access to their health information subject to the EP's discretion to withhold certain information.</li> </ul>	<p><i>Alternate Exclusion Measure 2:</i> Provider may claim an exclusion for the second measure if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1, which does not have an equivalent measure.</p>

TABLE 6—MEANINGFUL USES OBJECTIVES AND MEASURES FOR 2015 THROUGH 2017—Continued

Provider type	Proposed objectives for 2015, 2016 and 2017	Proposed measures for providers in 2015, 2016 and 2017	Proposed alternate measures, exclusions and/or specifications for certain providers in 2015 ONLY
	Protect Electronic Health Information.	<ul style="list-style-type: none"> <li>• <i>EP Measure 2:</i> At least one patient seen by the EP during the EHR reporting period (or their authorized representatives) views, downloads, or transmits his or her health information to a third party.</li> </ul> <p><i>Measure:</i> Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI data stored in Certified EHR Technology in accordance with requirements in 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the EP, eligible hospital, or CAHs risk management process.</p>	NONE.
	Patient Specific Education.	<p><i>EP Measure:</i> Patient-specific education resources identified by Certified EHR Technology are provided to patients for more than 10 percent of all unique patients with office visits seen by the EP during the EHR reporting period.</p>	<p><i>Alternate Exclusion:</i> Provider may claim an exclusion for the measure of the Stage 2 Patient Specific Education objective if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1 but did not intend to select the Stage 1 Patient Specific Education menu objective.</p>
	Medication Reconciliation.	<p><i>Measure:</i> The EP, eligible hospital or CAH performs medication reconciliation for more than 50 percent of transitions of care in which the patient is transitioned into the care of the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23).</p>	<p><i>Alternate Exclusion:</i> Provider may claim an exclusion for the measure of the Stage 2 Medication Reconciliation objective if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1 but did not intend to select the Stage 1 Medication Reconciliation menu objective.</p>
	Summary of Care .....	<p><i>Measure:</i> The EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care (1) uses CEHRT to create a summary of care record; and (2) electronically transmits such summary to a receiving provider for more than 10 percent of transitions of care and referrals.</p>	<p><i>Alternate Exclusion:</i> Provider may claim an exclusion for Measure 2 of the Stage 2 Summary of Care objective if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1, which does not have an equivalent measure.</p>
	Secure Messaging .....	<p><i>Measure:</i> During the EHR reporting period, the capability for patients to send and receive a secure electronic message with the provider was fully enabled.</p>	<p><i>Alternate Exclusion:</i> An EP may claim an exclusion for the measure if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1, which does not have an equivalent measure.</p>
	Public Health .....	<ul style="list-style-type: none"> <li>• <i>Measure Option 1—Immunization Registry Reporting:</i> The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).</li> <li>• <i>Measure Option 2—Syndromic Surveillance Reporting:</i> The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit syndromic surveillance data from a non-urgent care ambulatory setting for EPs, or an emergency or urgent care department for eligible hospitals and CAHs (POS 23).</li> <li>• <i>Measure Option 3—Case Reporting:</i> The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions.</li> </ul>	NONE.

TABLE 6—MEANINGFUL USES OBJECTIVES AND MEASURES FOR 2015 THROUGH 2017—Continued

Provider type	Proposed objectives for 2015, 2016 and 2017	Proposed measures for providers in 2015, 2016 and 2017	Proposed alternate measures, exclusions and/or specifications for certain providers in 2015 ONLY
Eligible Hospital/CAH ..	CPOE .....	<ul style="list-style-type: none"> <li>• <i>Measure Option 4—Public Health Registry Reporting:</i> The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit data to public health registries.</li> <li>• <i>Measure Option 5—Clinical Data Registry Reporting:</i> The EP, eligible hospital, or CAH is in active engagement to submit data to a clinical data registry.</li> <li>• <i>Measure 1:</i> More than 60 percent of medication orders created by the EP or by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.</li> <li>• <i>Measure 2:</i> More than 30 percent of laboratory orders created by the EP or by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.</li> <li>• <i>Measure 3:</i> More than 30 percent of radiology orders created by the EP or by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.</li> </ul>	<p>If for an EHR reporting period in 2015, the provider is scheduled to demonstrate Stage 1:</p> <ul style="list-style-type: none"> <li>• <i>Alternate Measure 1:</i> More than 30 percent of all unique patients with at least one medication in their medication list seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have at least one medication order entered using CPOE; or more than 30 percent of medication orders created by the EP or created by the authorized providers of the eligible hospital or CAH for patients admitted to their inpatient or emergency departments (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.</li> <li>• <i>Alternate Exclusion for Measure 2:</i> Provider may claim an exclusion for measure 2 (laboratory orders) of the Stage 2 CPOE objective for an EHR reporting period in 2015.</li> <li>• <i>Alternate Exclusion for Measure 3:</i> Provider may claim an exclusion for measure 3 (radiology orders) of the Stage 2 CPOE objective for an EHR reporting period in 2015.</li> </ul>
	Clinical Decision Support.	<ul style="list-style-type: none"> <li>• <i>Measure 1:</i> Implement five clinical decision support interventions related to four or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. Absent four clinical quality measures related to an EP, eligible hospital or CAH's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions. It is suggested that one of the five clinical decision support interventions be related to improving healthcare efficiency.</li> <li>• <i>Measure 2:</i> The EP, eligible hospital, or CAH has enabled and implemented the functionality for drug-drug and drug allergy interaction checks for the entire EHR reporting period. Exclusion: For the second measure, any EP who writes fewer than 100 medication orders during the EHR reporting period.</li> </ul>	<p>If for an EHR reporting period in 2015, the provider is scheduled to demonstrate Stage 1:</p> <p><i>Alternate Measure 1:</i> Implement one clinical decision support rule. We propose that for an EHR reporting period in 2015, an EP, eligible hospital or CAH who is scheduled to participate in Stage 1 in 2015 must also satisfy the Stage 2 measure 2 previously stated because it is the same as an existing Stage 1 measure (77 FR 53998). There are no alternate exclusions for this objective.</p>

TABLE 6—MEANINGFUL USES OBJECTIVES AND MEASURES FOR 2015 THROUGH 2017—Continued

Provider type	Proposed objectives for 2015, 2016 and 2017	Proposed measures for providers in 2015, 2016 and 2017	Proposed alternate measures, exclusions and/or specifications for certain providers in 2015 ONLY
	Patient Electronic Access (VDT).	<ul style="list-style-type: none"> <li>• <i>Eligible Hospital/CAH Measure 1:</i> More than 50 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH have their information available online within 36 hours of discharge.</li> <li>• <i>Eligible Hospital/CAH Measure 2:</i> At least 1 patient who is discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH (or his or her authorized representative) views, downloads, or transmits to a third party his or her information during the EHR reporting period.</li> </ul>	<i>Alternate Exclusion Measure 2:</i> Provider may claim an exclusion for the second measure if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1, which does not have an equivalent measure.
	Protect Electronic Health Information.	<i>Measure:</i> Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI data stored in Certified EHR Technology in accordance with requirements in 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the EP, eligible hospital, or CAHs risk management process.	NONE.
	Patient Specific Education.	<i>Eligible Hospital/CAH Measure:</i> More than 10 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) are provided patient specific education resources identified by Certified EHR Technology.	<i>Alternate Exclusion:</i> Provider may claim an exclusion for the measure of the Stage 2 Patient Specific Education objective if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1 but did not intend to select the Stage 1 Patient Specific Education menu objective.
	Medication Reconciliation.	<i>Measure:</i> The EP, eligible hospital or CAH performs medication reconciliation for more than 50 percent of transitions of care in which the patient is transitioned into the care of the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23).	<i>Alternate Exclusion:</i> Provider may claim an exclusion for the measure of the Stage 2 Medication Reconciliation objective if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1 but did not intend to select the Stage 1 Medication Reconciliation menu objective.
	Summary of Care .....	<i>Measure:</i> The EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care (1) uses CEHRT to create a summary of care record; and (2) electronically transmits such summary to a receiving provider for more than 10 percent of transitions of care and referrals.	<i>Alternate Exclusion:</i> Provider may claim an exclusion for Measure 2 of the Stage 2 Summary of Care objective if for an EHR reporting period in 2015 they were scheduled to demonstrate Stage 1, which does not have an equivalent measure.
	Electronic Prescribing	<i>Eligible Hospital/CAH Measure:</i> More than 10 percent of hospital discharge medication orders for permissible prescriptions (for new, changed and refilled prescriptions) are queried for a drug formulary and transmitted electronically using Certified EHR Technology.	<i>Alternate EH Exclusion:</i> Measure Exclusion: Provider may claim an exclusion for the eRx objective and measure if for an EHR reporting period in 2015 they were either scheduled to demonstrate Stage 1 which does not have an equivalent measure, or if they are scheduled to demonstrate Stage 2 but did not intend to select the Stage 2 eRx menu objective for an EHR reporting period in 2015.
	Public Health .....	<ul style="list-style-type: none"> <li>• <i>Measure Option 1—Immunization Registry Reporting:</i> The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).</li> </ul>	NONE.

TABLE 6—MEANINGFUL USES OBJECTIVES AND MEASURES FOR 2015 THROUGH 2017—Continued

Provider type	Proposed objectives for 2015, 2016 and 2017	Proposed measures for providers in 2015, 2016 and 2017	Proposed alternate measures, exclusions and/or specifications for certain providers in 2015 ONLY
		<ul style="list-style-type: none"> <li>• <i>Measure Option 2—Syndromic Surveillance Reporting:</i> The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit syndromic surveillance data from a non-urgent care ambulatory setting for EPs, or an emergency or urgent care department for eligible hospitals and CAHs (POS 23).</li> <li>• <i>Measure Option 3—Case Reporting:</i> The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions.</li> <li>• <i>Measure Option 4—Public Health Registry Reporting:</i> The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit data to public health registries</li> <li>• <i>Measure Option 5—Clinical Data Registry Reporting:</i> The EP, eligible hospital, or CAH is in active engagement to submit data to a clinical data registry.</li> <li>• <i>Measure Option 6—Electronic Reportable Laboratory Result Reporting:</i> The eligible hospital or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results.</li> </ul>	

3. Certified EHR Technology

Certified EHR technology is defined for the Medicare and Medicaid EHR Incentive Programs at 42 CFR 495.4, which references ONC’s definition of CEHRT in 45 CFR 170.102. The definition establishes the requirements for EHR technology that must be used by providers to meet the meaningful use objectives and measures. The Stage 2 final rule requires that CEHRT must be used by EPs, eligible hospitals, and CAHs to satisfy their CQM reporting requirements in the Medicare and Medicaid EHR Incentive Programs. In addition, the CQM data reported to CMS must originate from EHR technology that is certified to “capture and export” in accordance with 45 CFR 170.314(c)(1) and “electronic submission” in accordance with 45 CFR 170.314(c)(3) (77 FR 54053).

Rather than establishing a meaningful use specific CEHRT definition for the EHR Incentive Programs in the ONC 2015 Edition proposed rule, we instead proposed to define the term “Certified EHR Technology” in the Stage 3 proposed rule at § 495.4 (80 FR 16767 and 16768). This proposed change is designed to simplify the overall regulatory relationship between ONC and CMS rules for stakeholders and to ensure that relevant CMS policy for the Medicare and Medicaid EHR Incentive

Programs is clearly defined in CMS regulations.

We are proposing no further changes to the definition of CEHRT in this proposed rule. We reiterate that providers must use EHR technology certified to the 2014 Edition for an EHR reporting period in 2015. As proposed in the Stage 3 proposed rule, providers must use EHR technology certified at least to the 2014 Edition in 2016 and 2017. Providers may adopt EHR technology certified to the 2015 Edition prior to the beginning of Stage 3 in 2017 or 2018, and that technology could be used to satisfy the definition of CEHRT under § 495.4 to demonstrate meaningful use (80 FR 16767 through 16768).

4. Medicaid EHR Incentive Program in 2015 Through 2017

The proposals included in this proposed rule would apply for providers participating in the Medicaid EHR Incentive Program in 2015 through 2017.

Consistent with both Stage 1 and 2, we propose to continue to offer states flexibility in the Medicaid EHR Incentive Program for meaningful use in 2015 through 2017. This flexibility would apply to the public health reporting objective and measures where we propose to continue to allow states to specify the means of transmission of

the data or otherwise change the public health reporting objective and measures as long as it does not require EHR functionality above and beyond that which is included in 45 CFR part 170 as stated in the Stage 2 final rule (77 FR 53979).

Finally, we propose to provide an alternate attestation option for Medicaid providers who are seeking to demonstrate meaningful use to avoid the Medicare payment adjustment and who are prohibited from switching between the Medicare and Medicaid EHR incentive programs. For these providers, we propose that they may use the Medicare Registration and Attestation system to attest to meaningful use without switching programs solely for the purposes of avoiding the Medicare payment adjustment. We are proposing this alternate attestation option in response to concerns about providers who participate in the Medicaid EHR Incentive Program; but, due to their patient volume or another similar factor, they are unable to attest to meaningful use through their state Medicaid program for a given year. If such a provider uses the alternate attestation option to demonstrate meaningful use for an EHR reporting period, they may avoid the Medicare payment adjustment associated with that EHR reporting period without switching out of the

Medicaid EHR Incentive Program. This option is discussed in further detail in section II.D. of this proposed rule.

We invite public comment on these proposals.

### C. Clinical Quality Measurement

Under sections 1848(o)(2)(A), 1886(n)(3)(A), and 1814(l)(3)(A) of the Act and 42 CFR 495.4, EPs, eligible hospitals, and CAHs must report on CQMs selected by CMS using certified EHR technology, as part of being a meaningful EHR user under the Medicare and Medicaid EHR Incentive Programs. In the Stage 2 final rule, we outlined the CQMs available for use in the EHR Incentive Programs beginning in 2014 for EPs, eligible hospitals, and CAHs at (77 FR 54057 through 54068 for EPs and 77 FR 54081 through 54087 for eligible hospitals/CAHs) as well as the form and method for submission at (77 FR 54076 through 54080 for EPs and 77 FR 54087 through 54089 for eligible hospitals/CAHs). Following the publication of the Stage 2 final rule, we also established requirements for reporting on CQMs under the EHR Incentive Program in the PFS and IPPS rules (see for example 79 FR 50319 through 50321 and 79 FR 67779). In sections II.B.1.a. and b. of the preamble of the Stage 3 proposed rule, we outlined the requirements for CQM reporting for all providers for the EHR Incentive Programs in 2017 and subsequent years (80 FR 16768 and 16769) as well as the intent to continue program alignment with other CMS quality reporting programs in the IPPS and PFS rules.

In this proposed rule for meaningful use in 2015 through 2017, we are proposing to maintain the existing requirements established in earlier rulemaking for the reporting of CQMs. The options for CQM submission for providers in the Medicare EHR Incentive Program are as follows:

- EP Options for Medicare EHR Incentive Program Participation (*single program participation*)

- ++ Option 1: Attest to CQMs through the EHR Registration & Attestation System.

- ++ Option 2: Electronically report CQMs through Physician Quality Reporting System (PQRS) Portal.

- EP Options for Electronic Reporting for Multiple Programs (*for example: EHR Incentive Program plus PQRS participation*)

- ++ Option 1: Report individual eligible professionals' CQMs through PQRS Portal.

- ++ Option 2: Report group's CQMs through PQRS Portal.

We note that under option 2, this may include an EP reporting using the group reporting option, either electronically using QRDA, or via the GPRO Web Interface through Pioneer ACO participation.

- Eligible hospital and CAH Options for Medicare EHR Incentive Program Participation (*single program participation*)

- ++ Option 1: Attest to CQMs through the EHR Registration & Attestation System.

- ++ Option 2: Electronically report CQMs through QualityNet Portal.

- Eligible hospital and CAH Options for Electronic Reporting for Multiple Programs (*for example: EHR Incentive Program plus IQR participation*)

- ++ Electronically report through QualityNet Portal.

For the Medicaid EHR Incentive Program, states would continue to be responsible for determining whether and how electronic reporting of CQMs would occur, or if they wish to allow reporting through attestation. Any changes that states make to their CQM reporting methods must be submitted through the State Medicaid Health IT Plan (SMHP) process for our review and approval prior to being implemented.

We are also proposing to maintain the existing CQM reporting requirements of nine CQMs covering at least three NQS domains for EPs and 16 CQMs covering at least three NQS domains for eligible hospitals and CAHs (77 FR 54058 for EPs and 77 FR 54056 for eligible hospitals and CAHs).

As discussed in section II.B.2(a) of this proposed rule, beginning in 2015, we are proposing to change the definition of "EHR reporting period" in § 495.4 for eligible hospitals and CAHs such that the EHR reporting period would begin and end in relation to a calendar year. In connection with this proposal, we also propose that in 2015 and for all methods of reporting, eligible hospitals and CAHs would be required to complete a reporting period for clinical quality measures aligned with the calendar year in order to demonstrate meaningful use. In order to accommodate eligible hospitals and CAHs that may have planned their clinical quality measure reporting in 2015 based on the federal fiscal year, we propose for 2015 only that eligible hospitals and CAHs that are submitting CQMs via attestation, may begin a reporting period as early as October 1 of 2014 and end by December 31 of 2015. Eligible hospitals and CAHs submitting CQMs via electronic reporting must meet the requirements established in the FY 2015 final rule (79 FR 50319 through 50321).

As discussed in section II.B.1.b.(3). of this proposed rule, for 2015 only, we are proposing to change the EHR reporting period for all EPs, eligible hospitals, and CAHs to any continuous 90-day period within the calendar year. In connection with this proposal, we also propose a 90-day reporting period for clinical quality measures for all EPs, eligible hospitals, and CAHs that report clinical quality measures by attestation. We are proposing eligible professionals may select any continuous 90-day period from January 1, 2015 through December 31, 2015, while eligible hospitals and CAHs may select any continuous 90-day period from October 1, 2014 through December 31, 2015, to report CQMs via attestation using the EHR Incentive Program registration and attestation system. In accordance with our existing policy, it is acceptable for a provider to use a continuous 90-day reporting period for CQMs even if it is different from their continuous 90-day EHR reporting period for the meaningful use objectives and measures if that provider is reporting via attestation. We also propose that a provider may choose to attest to a CQM reporting period of greater than 90-days up to and including 1 full calendar year of data.

We further propose to continue our existing policy that providers in any year of participation for the EHR Incentive Programs for 2015 through 2017 may instead electronically report CQM data using the options previously outlined for electronic reporting either for single program participation in the Medicare EHR Incentive Programs, or for participation in multiple programs if the requirements of the aligned quality program are met.

We note that EPs seeking to participate in multiple programs with a single electronic submission would be required to submit a full calendar year of CQM data using the 2014 electronic specifications for the CQMs (which are also known as eCQMs) for a reporting period in 2015. These specifications include the annual updates released in June of 2014 and are available at the CMS eCQMs Library ([http://cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM\\_Library.html](http://cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html))

Eligible hospitals and CAHs seeking to participate in multiple programs with a single electronic submission for a reporting period in 2015 would be required to submit 1 calendar quarter of data for 2015 from either Q1 (January 1, 2015–March 31, 2015), Q2 (April 1, 2015–June 30, 2015), or Q3 (July 1, 2015–September 30, 2015) and would require of the use of the April 2014 release of the eCQMs available at 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)). For further information, we direct readers to the FY 2015 IPPS final rule at 79 FR 50319 through 50321.

We note that an EHR certified for CQMs under the 2014 Edition certification criteria does not need to be recertified each time it is updated to a more recent version of the eCQMs. (For further information on CQM reporting, we direct readers to the EHR Incentive Program Web site where guides and tip sheets are available for each reporting option ([www.CMS.gov/ehrincentiveprograms](http://www.CMS.gov/ehrincentiveprograms))).

We invite public comment on this proposal.

#### *D. Demonstration of Meaningful Use for 2015 Through 2017*

##### 1. Common Methods of Demonstration in Medicare and Medicaid

We are proposing to continue our common method for demonstrating meaningful use in both the Medicare and Medicaid EHR Incentive Programs. The demonstration methods we adopt for Medicare would automatically be available to the states for use in their Medicaid programs.

##### 2. Methods for Demonstration of the Criteria for Meaningful Use in 2015 Through 2017

As mentioned previously in section II.B.2. of this proposed rule, we are redesignating the numbering of certain sections of the regulation text under 42 CFR part 495. In prior rules, we defined the criteria for the demonstration of meaningful use at 42 CFR 495.8, which would be redesignated as § 495.40. In this proposed rule, we define the criteria for the demonstration of meaningful use at § 495.40 including references to the objectives and measures of meaningful use as well as the requirement to report CQMs. In order to demonstrate meaningful use in 2015 through 2017, we are proposing that the requirements at § 495.40 include a reference to the objectives and measures of meaningful use for 2015 through 2017 outlined at § 495.22 which the provider must satisfy.

We are proposing to continue the use of attestation as the method for demonstrating that an EP, eligible hospital, or CAH has met the objectives and measures of meaningful use. Instead of individual Medicare EP attestation through the CMS Registration and Attestation System, we are also proposing to continue the existing optional batch file process for attestation. Further, we are proposing

changes to the deadlines for EPs, eligible hospitals, and CAHs to demonstrate meaningful use in 2015 and 2016; as well as specific changes to the deadlines for providers to demonstrate meaningful use for the first time in order to avoid a payment adjustment in 2015 and 2016.

##### a. Attestation Deadlines for Meaningful Use in 2015 and 2016

In order to accommodate the proposed changes to the EHR reporting period, we are proposing changes to the attestation deadlines for eligible hospitals and CAHs for 2015 and 2016. Currently, in order to demonstrate meaningful use, eligible hospitals and CAHs are required to complete an EHR reporting period within a federal fiscal year. These providers must then attest to that EHR reporting period by the end of the open attestation period 2 months after the close of the federal fiscal year. For 2015, this means that eligible hospitals and CAHs must complete an EHR reporting period between October 1, 2014 and September 30, 2015 and must attest by November 30, 2015. However, we are proposing in section II.B.3.a. of this proposed rule that eligible hospitals and CAHs would instead be required to complete an EHR reporting period for 2015 between October 1, 2014 and the end of the calendar year on December 31, 2015, and to complete an EHR reporting period for 2016 between January 1, 2016 and December 31, 2016.

Therefore, we are proposing a change to the attestation deadlines as follows:

- For an EHR reporting period in 2015, an eligible hospital or CAH must attest by February 29, 2016.
- For an EHR reporting period in 2016, an eligible hospital or CAH must attest by February 28, 2017.

In addition, despite the proposed change to a 90-day EHR reporting period in 2015 discussed previously in this proposed rule, providers would not be able to attest to meaningful use for an EHR reporting period in 2015 prior to January 1, 2016. This would allow us adequate time to make the system changes necessary to accept attestations reflecting the proposals in this proposed rule. This would mean that even if providers successfully complete a continuous 90-day EHR reporting period in the first quarter of FY or CY 2015, they would attest after the close of the fourth quarter of CY 2015. This change would not delay incentive payments for Medicare EPs, because 2015 cannot be an EP's first payment year under section 1848(o)(1)(B)(v) of the Act. Thus, all EPs who qualify for an incentive payment for 2015 would be returning participants

in the program and would have had the full CY 2015 (as their EHR reporting period under our current policy). We understand that this may delay incentive payments for eligible hospitals and CAHs. However, most eligible hospitals and CAHs in the program are beyond their first year of demonstrating meaningful use; thus, would not have been attesting until after September 30, 2015 under our current policy.

Therefore, for most eligible hospitals and CAHs, this change would shift the incentive payment by 1 quarter within the same federal fiscal year. Thus, we believe the potential negative impact of this change would be minimal and outweighed by the opportunity to capitalize on efficiencies created by aligning the EHR reporting periods across EPs, eligible hospitals, and CAHs.

We invite public comment on this proposal.

##### b. New Participant Attestation Deadlines for Meaningful Use in 2015 and 2016 To Avoid a Payment Adjustment

In § 495.4 the definition of an EHR reporting period for a payment adjustment year establishes special deadlines for attestation for EPs and eligible hospitals that are demonstrating meaningful use for the first time in the year immediately preceding a payment adjustment year. Generally stated, a provider must complete an EHR reporting period in the first 3 quarters of the preceding year, and the deadlines for attestation are October 1 for EPs and July 1 for eligible hospitals of the preceding year. For CAHs, the EHR reporting period is within the federal fiscal year that is the payment adjustment year and the deadline for attestation for CAHs is the same for purposes of the incentive payment and the payment adjustment (November 30, 2015). After the October 1 or July 1 deadlines, EPs and eligible hospitals may still attest for an EHR reporting period in the fourth quarter of the CY or FY, respectively. However, if they attest after the respective deadlines, then they would not avoid the Medicare payment adjustment in the subsequent payment adjustment year.

In the Stage 2 proposed rule (77 FR 13769 for EPs and 77 FR 13773 through 13774 for eligible hospitals/CAHs), we explained the rationale for these special deadlines for attestation. We explained that these EHR reporting periods provide adequate time both for the systems changes that will be required for us to apply any applicable payment adjustments and for providers to be informed in advance of the payment year whether a payment adjustment



would apply. Those deadlines also provide appropriate flexibility by allowing more recent adopters of EHR technology a reasonable opportunity to establish their meaningful use of the technology and to avoid application of the payment adjustments. However, we are proposing a later deadline for attestation only for 2015 to allow enough time for all providers to complete a 90-day EHR reporting period after the anticipated effective date of the final rule. As a result of this later deadline, in 2016, providers that are new participants in the EHR Incentive Program may be subject to a payment adjustment on claims submitted prior to attestation to meaningful use for an EHR reporting period in 2015. After successful attestation, the payment adjustment would be removed and any adjustments previously applied to claims in 2016 would be reprocessed and reconciled for the provider. However, as our policies seek to minimize the claims reprocessing burden, we note these are exceptional circumstances caused by the need for a later attestation deadline to accommodate a 90-day EHR reporting period in 2015 after the effective date of the final rule, and this is not an acceptable long-term solution. For the reasons previously stated in the Stage 2 proposed rule, the special deadlines for first-time meaningful EHR users (October 1 for EPs and July 1 for eligible hospitals) are necessary in 2016 and subsequent years where no extenuating circumstances exist. For these reasons, we propose changes to the attestation deadlines for purposes of the payment adjustment years in section II.E.2.(a) through (c) of this proposed rule.

We invite public comment on these proposals.

### 3. Alternate Method of Demonstration for Certain Medicaid Providers Beginning in 2015

At 42 CFR 495.10, redesignated as § 495.60, we defined the requirements for EPs switching between the Medicare and Medicaid EHR Incentive Programs. An EP who qualifies as both a Medicaid EP and a Medicare EP must notify us as to whether he or she elects to participate in the Medicare or the Medicaid EHR Incentive Program, and after receiving at least one incentive payment, may switch between the two EHR incentive programs only one time, and only for a payment year before 2015. For further discussion of this policy we direct readers to (75 FR 44324 through 44325). We are not proposing any changes to the switching requirements under § 495.60.

However, we note that an EP who qualifies as both a Medicaid EP and a

Medicare EP would be subject to the Medicare payment adjustment if the EP fails to demonstrate meaningful use for the applicable EHR reporting period for a payment adjustment year. We recognize it is possible that an EP who receives an incentive payment under the Medicaid EHR Incentive Program for a given year may fail in a subsequent year to meet the eligibility criteria for the Medicaid EHR Incentive Program. For example, the EP would be unable to qualify for a Medicaid EHR incentive payment for 2015, if he or she receives a Medicaid EHR incentive payment for meaningful use for the 2013 payment year, but does not meet the 30 percent Medicaid patient volume requirement for purposes of the 2015 payment year. Under § 495.60(e), in this example in order to avoid the Medicare payment adjustment, the EP would be unable to switch to the Medicare EHR Incentive Program for the 2015 payment year; thus, the EP would not have a way to demonstrate meaningful use for an applicable EHR reporting period for the payment adjustment year. Therefore, for purposes of avoiding the Medicare payment adjustment, we are proposing to establish an additional attestation option to allow EPs who have received at least one incentive payment under the Medicaid EHR Incentive Program (for either AIU or meaningful use) to demonstrate meaningful use by attestation using the EHR Incentive Program Registration and Attestation system. We note that this attestation would not constitute a switch from the Medicaid EHR Incentive Program to the Medicare EHR Incentive Program, and EPs who attest under this option would not earn an incentive payment in either program for the year. We are proposing this attestation option for the purposes of demonstrating meaningful use to avoid the Medicare payment adjustment only. In the prior example, the EP whose Medicaid patient volume was less than the required threshold would be able to attest to meaningful use for an EHR reporting period in 2015 to avoid the 2017 payment adjustment. This EP would continue to be designated a Medicaid EHR Incentive Program participant. In 2016 in order to earn an incentive payment and avoid a Medicare payment adjustment, if the EP meets the Medicaid patient volume threshold with regard to the 2016 payment year, then the EP would be required to demonstrate meaningful use in the Medicaid program for an EHR reporting period.

As stated above, we are proposing that EPs who have previously received an incentive payment under Medicaid for

adopting, implementing, or upgrading to certified EHR technology may also use this alternate attestation option even if it is their first year of demonstrating meaningful use. However, these EPs would be required to demonstrate meaningful use for the EHR reporting periods established for the Medicare EHR Incentive Program for EPs who have never successfully demonstrated meaningful use in a prior year. In the Stage 3 proposed rule (80 FR 16739), we propose that beginning in 2017, EPs who demonstrate meaningful use for the first time under the Medicare EHR Incentive Program must use an EHR reporting period of one full calendar year. Accordingly, under our proposal in this rule, Medicaid providers using this alternate attestation option in 2017 or subsequent years would also be required to use an EHR reporting period of 1 full calendar year even if they are demonstrating meaningful use for the first time.

We invite public comment on this proposal.

### 4. Data Collection for Online Posting, Program Coordination, and Accurate Payments

We propose no changes to the data collection requirements or to the registration requirements under § 495.10, redesignated as § 495.60. As noted in section II.C.2 of the Stage 3 proposed rule, we note that we intend to continue to post meaningful use participation data both at an individual and aggregate level for the purposes of data transparency, program integrity, and for use with aligned CMS quality reporting programs.

### 5. Hospital-Based Eligible Professionals

Section 1848(o)(1)(C)(i) of the Act, as added by section 4101(a) of the HITECH Act, states that hospital-based EPs are not eligible for Medicare incentive payments. Similarly, the majority of hospital-based EPs will not be eligible for Medicaid incentive payments under section 1903(t)(2)(A) of the Act (the only exception to this rule is for those practicing predominantly in an FQHC or RHC). Sections 4101(a) and 4201(a) of the HITECH Act originally defined the term “hospital-based eligible professional” to mean an EP, such as a pathologist, anesthesiologist, or emergency physician, who furnishes substantially all of his or her Medicare covered professional services during the relevant EHR reporting period in a hospital setting (whether inpatient or outpatient) through the use of the facilities and equipment of the hospital, including the hospital’s qualified EHRs. Following publication of the Stage 1

proposed rule (75 FR 1844 through 2011), Congress modified the definition of hospital-based EPs. Specifically, on April 15, 2010, President Obama signed into law the Continuing Extension Act of 2010 (Pub. L. 111–157). Section 5 of the Continuing Extension Act of 2010 (Pub. L. 111–157) made the following changes to the Act as it applies to both the Medicare and Medicare EHR incentives for EPs:

- Qualifications for Clinic-based Physicians

++ Medicare—Section 1848(o)(1)(C)(ii) of the Act (42 U.S.C. 1395w–4(o)(1)(C)(ii)) is amended by striking “setting (whether inpatient or outpatient)” and inserting “inpatient or emergency room setting”.

++ Medicaid—Section 1903(t)(3)(D) of the Act (42 U.S.C. 1396b(t)(3)(D)) is amended by striking “setting (whether inpatient or outpatient)” and inserting “inpatient or emergency room setting”.

These amendments were effective as if included in the enactment of the HITECH Act. The previous sections indicate that the determination of whether an EP is a hospital-based EP shall be made on the basis of the site of service, as defined by the Secretary, and without regard to any employment or billing arrangement between the EP and any other provider. For example, the hospital-based determination for an EP would not be affected by whether the EP is an employee of the hospital, under a contractual relationship with the hospital, or with respect to whether he or she has made a reassignment to the hospital for Part B billing purposes. In addition, section 1848(a)(7)(D) of the Act, as added by section 4101(b) of the HITECH Act, exempts hospital-based EPs from the downward payment adjustment applied under section 1848(a)(7)(A)(i) of the Act to covered professional services provided during a payment year by EPs who are not meaningful EHR users for the relevant payment year beginning in 2015.

Based on section 4101(a) of the HITECH Act (and prior to the amendments in the Continuing Extension Act of 2010), we proposed in the Stage 1 proposed rule (75 FR 1904 through 1907) that an EP would be considered a hospital-based EP; therefore, ineligible to receive a Medicare or Medicaid EHR incentive payment if more than 90 percent of their services are provided in the following place of service (POS) codes for HIPAA standard transactions—

- 21—Inpatient Hospital;
- 22—Outpatient Hospital;
- 23—Emergency Room.

In the Stage 1 final rule (75 FR 44439 through 44442), we incorporated the changes to the hospital-based definition, that were included in the Continuing Extension Act of 2010, into our definition of “hospital-based EP” under § 495.4. We defined an EP as hospital-based if he or she furnishes 90 percent or more of his or her covered professional services in sites of service identified as an inpatient hospital (POS 21) or emergency room (POS 23) setting in the year preceding the payment year. We did not include POS 22 for outpatient hospital settings in our final definition.

As noted previously, section 1848(a)(7)(D) of the Act exempts hospital-based EPs who are not meaningful EHR users from the downward payment adjustments under Medicare. In the Stage 2 final rule (77 FR 54102), for purposes of the Medicare payment adjustments, we amended the definition of hospital-based EP under § 495.4 to define a hospital-based EP as an EP who furnishes 90 percent or more of his or her covered professional services in sites of service identified as an inpatient hospital (POS 21) or emergency room (POS 23) setting in either of the 2 years before the year preceding a payment adjustment year.

However, recently several hospital associations, individual providers, and other stakeholders have raised concerns with our current definition of a hospital-based EP. Specifically, these stakeholders asserted that the limitation of hospital-based to POS codes 21 and 23, covering inpatient and emergency room settings only, does not adequately capture all settings where services might be furnished by a hospital-based EP. They stated that POS 22, which covers an outpatient hospital place of service, is also billed by hospital-based EPs, especially in relation to certain CPT codes. These stakeholders expressed the belief that our current definition of hospital-based EP in the regulations is too narrow and will unfairly subject many EPs who are not hospital-based under our definition, but who stakeholders would consider to be hospital-based, to the downward payment adjustment under Medicare in 2015. Accordingly, these stakeholders recommended that we consider adding additional place of service codes or settings to the regulatory definition of hospital-based EP.

We appreciate this feedback from stakeholders and are requesting public comment on our current definition of a hospital-based EP under § 495.4 for the EHR Incentive Programs.

We are seeking public comment on whether additional place of service

codes or settings should be included in our definition of a hospital-based EP. As stated previously, stakeholders specifically identified POS 22 for outpatient hospital settings as an area of concern; therefore, we are especially interested in comments on POS 22 for outpatient hospital settings. In addition, we seek comments on whether and how the inclusion of additional POS codes or settings in our definition of hospital-based EP might affect the eligibility of EPs for the EHR incentive payments under Medicare or Medicaid.

We welcome public comment.

#### *E. Payment Adjustments and Hardship Exceptions*

Sections 4101(b) and 4102(b) of the HITECH Act, amending sections 1848, 1853, and 1886 of the Act, require reductions in payments to EPs, eligible hospitals, and CAHs that are not meaningful users of certified EHR technology, beginning in CY 2015 for EPs, FY 2015 for eligible hospitals, and in cost reporting periods beginning in FY 2015 for CAHs.

##### 1. Statutory Basis for Payment Adjustment and Hardship Exceptions

Section 1848(a)(7) of the Act provides for payment adjustments, effective for CY 2015 and subsequent years, for EPs as defined in § 495.100, who are not meaningful EHR users during the relevant EHR reporting period for the year. Section 1848(a)(7) of the Act provides that in general, beginning in 2015, if an EP is not a meaningful EHR user for the EHR reporting period for the year, then the Medicare physician fee schedule (PFS) amount for covered professional services furnished by the EP during the year (including the fee schedule amount for purposes of determining a payment based on the fee schedule amount) is adjusted to equal the “applicable percent” of the fee schedule amount that would otherwise apply. The term “applicable percent” is defined in section 1848(a)(7)(A)(ii) of the Act as: (I) For 2015, 99 percent (or, in the case of an EP who was subject to the application of the payment adjustment [if the EP was not a successful electronic prescriber] under section 1848(a)(5) of the Act for 2014, 98 percent); (II) for 2016, 98 percent; and (III) for 2017 and each subsequent year, 97 percent.

In addition, section 1848(a)(7)(A)(iii) of the Act provides that if, for CY 2018 and subsequent years, the Secretary finds the proportion of EPs who are meaningful EHR users is less than 75 percent, the applicable percent shall be decreased by 1 percentage point for EPs who are not meaningful EHR users from

the applicable percent in the preceding year, but that in no case shall the applicable percent be less than 95 percent.

Section 1848(a)(7)(B) of the Act provides that the Secretary may, on a case-by-case basis, exempt an EP who is not a meaningful EHR user for the reporting period for the year from the application of the payment adjustment if the Secretary determines that compliance with the requirements for being a meaningful EHR user would result in a significant hardship, such as in the case of an EP who practices in a rural area without sufficient internet access. The exception is subject to annual renewal, but in no case may an EP be granted an exception for more than 5 years.

We established regulations implementing these statutory provisions under 42 CFR 495.102. We refer readers to the Stages 1 and 2 final rules (75 FR 44442 through 44448, 77 FR 54093 through 54102) for more information.

Section 1886(b)(3)(B)(ix)(I) of the Act, as amended by section 4102(b)(1) of the HITECH Act, provides for an adjustment to the applicable percentage increase to the IPPS payment rate for those eligible hospitals that are not meaningful EHR users for the associated EHR reporting period for a payment adjustment year, beginning in FY 2015. Specifically, section 1886(b)(3)(B)(ix)(I) of the Act provides that, for FY 2015 and each subsequent fiscal year, an eligible hospital that is not a meaningful EHR user for an EHR reporting period will receive a reduced update to the IPPS standardized amount. This reduction applies to “three-quarters of the percentage increase otherwise applicable” prior to the application of statutory adjustments under sections 1886(b)(3)(B)(viii), 1886(b)(3)(B)(xi), and 1886(b)(3)(B)(xii) of the Act, or three-quarters of the applicable market basket update. The reduction to three-quarters of the applicable update for an eligible hospital that is not a meaningful EHR user would be “33 1/3 percent for FY 2015, 66 2/3 percent for FY 2016, and 100 percent for FY 2017 and each subsequent FY.” In other words, for eligible hospitals that are not meaningful EHR users, the Secretary must reduce the applicable percentage increase (prior to the application of other statutory adjustments) by—

- 25 percent (33 1/3 of 75 percent) in FY 2015;
- 50 percent (66 2/3 percent of 75 percent) in FY 2016; and
- 75 percent (100 percent of 75 percent) in FY 2017 and subsequent years.

Section 4102(b)(1)(B) of the HITECH Act also provides that the reduction “shall apply only with respect to the FY involved and the Secretary shall not take into account such reduction in computing the applicable percentage increase for a subsequent FY.”

Section 412.64(d) of our regulations sets forth the adjustment to the percentage increase in the market basket index for those eligible hospitals that are not meaningful EHR users for the EHR reporting period for a payment year, beginning in FY 2015.

Section 1886(b)(3)(B)(ix)(II) of the Act, as amended by section 4102(b)(1) of the HITECH Act, provides that the Secretary may, on a case-by-case basis, exempt a hospital from the application of the applicable percentage increase adjustment for a fiscal year if the Secretary determines that requiring such hospital to be a meaningful EHR user would result in a significant hardship, such as in the case of a hospital in a rural area without sufficient internet access. This section of the Act also provides that such determinations are subject to annual renewal, and that in no case may a hospital be granted an exception for more than 5 years.

Section 4102(b)(2) of the HITECH Act amended section 1814(l) of the Act to include an adjustment to a CAH’s Medicare reimbursement for inpatient services if the CAH is not a meaningful EHR user for an EHR reporting period. The adjustment would be made for cost reporting periods that begin in FY 2015, FY 2016, FY 2017, and each subsequent FY thereafter. Specifically, sections 1814(l)(4)(A) and (B) of the Act provide that, if a CAH does not demonstrate meaningful use of CEHRT for an applicable EHR reporting period, then for a cost reporting period beginning in FY 2015, the CAH’s reimbursement shall be reduced from 101 percent of its reasonable costs to 100.66 percent of reasonable costs. For a cost reporting period beginning in FY 2016, its reimbursement would be reduced to 100.33 percent of its reasonable costs. For a cost reporting period beginning in FY 2017 and each subsequent fiscal year, its reimbursement would be reduced to 100 percent of reasonable costs.

However, as provided for eligible hospitals, a CAH, may, on a case by case basis, be granted an exception from this adjustment if CMS or its Medicare contractor determines, on an annual basis, that a significant hardship exists, such as in the cases of a CAH in a rural area without sufficient internet access. However, in no case may a CAH be granted this exception for more than 5 years.

In the Stage 1 final rule (75 FR 44564 and 44574), we finalized the regulations regarding the CAH adjustment at § 495.106(e) and § 413.70(a)(6).

## 2. EHR Reporting Period for a Payment Adjustment Year

Section 1848(a)(7)(E)(ii) of the Act provides the Secretary with broad authority to choose the EHR reporting period that would apply for purposes of determining the payment adjustments for EPs for CY 2015 and subsequent years. In the Stage 2 final rule (77 FR 54095 through 54097), we adopted a policy that the EHR reporting periods for the payment adjustments will begin and end prior to the year of the payment adjustment. We stated that this is based on our desire to avoid creating a situation in which it might be necessary either to recoup overpayments or make additional payments after a determination is made about whether the payment adjustment should apply, and the resulting implications for beneficiary coinsurance. Specifically, we finalized under § 495.4 of our regulations that for EPs, the EHR reporting period for a payment adjustment year is the full calendar year that is 2 years before the payment adjustment year. For example, the full calendar year of 2015 would be the EHR reporting period for the CY 2017 payment adjustment year. We also finalized an exception to this rule for EPs who have never successfully attested to meaningful use. Generally stated, under this exception, for an EP who is demonstrating meaningful use for the first time, the EHR reporting period for a payment adjustment year is any continuous 90-day period. For a full description of this exception, including limitations on when the continuous 90-day period must occur in relation to the payment adjustment year and the deadlines for registration and attestation, we refer readers to the definition of “EHR reporting period for a payment adjustment year” under § 495.4 of our regulations and the discussion in the Stage 2 final rule (77 FR 54095 through 54096). We established that these policies apply for the CY 2015 payment adjustment year and subsequent payment adjustment years.

Similarly, section 1886(b)(3)(B)(ix)(IV) of the Act makes clear that the Secretary has discretion to specify as the EHR reporting period any period (or periods) that will apply with respect to a fiscal year. In the Stage 2 final rule at 77 FR 54104 through 54105, we finalized the applicable EHR reporting period for purposes of determining whether an eligible hospital is subject to the

payment adjustment. As with EPs, we finalized that the EHR reporting period for the payment adjustment year for eligible hospitals will begin and end prior to the year of the payment adjustment. We finalized under § 495.4 of our regulations that for eligible hospitals, the EHR reporting period for a payment adjustment year is the full federal fiscal year that is 2 years before the payment adjustment year. We established this policy beginning with the FY 2015 payment adjustment year and continuing in subsequent years. For example, the full federal fiscal year of 2015 would be the EHR reporting period for the FY 2017 payment adjustment year. We finalized an exception to the general rule of a full federal fiscal year EHR reporting period for eligible hospitals that have never successfully attested to meaningful use. Generally stated, under this exception, for an eligible hospital that is demonstrating meaningful use for the first time, the EHR reporting period for a payment adjustment year is any continuous 90-day period. For a full description of this exception, including limitations on when the continuous 90-day period must occur in relation to the payment adjustment year and the deadlines for registration and attestation, we refer readers to the definition of “EHR reporting period for a payment adjustment year” under § 495.4 of the regulations and the discussion in the Stage 2 final rule (77 FR 54104 through 54105).

In Stage 2, we amended the definition of the EHR reporting period that would apply for purposes of the payment adjustment for CAHs under § 495.4 (77 FR 54109 and 54110). For CAHs, this is the full federal fiscal year that is the same as the payment adjustment year (unless a CAH is in its first year of demonstrating meaningful use, in which case a continuous 90-day EHR reporting period within the payment adjustment year would apply). The adjustment applies based upon the cost reporting period that begins in the payment adjustment year (that is, FY 2015 and thereafter). Thus, if a CAH is not a meaningful EHR user for FY 2015, and thereafter, then the payment adjustment is applied to the CAH’s reasonable costs incurred in a cost reporting period that begins in the affected FY as described in § 413.70(a)(6)(i). We further finalized that CAHs submit their attestations on meaningful use by November 30th of the following FY. For example, if a CAH is attesting that it was a meaningful EHR user for FY 2015, the attestation must be submitted no later than November 30, 2015. Such an attestation or lack

thereof, would then affect interim payments to the CAH made after December 1st of the applicable FY. If the cost reporting period ends prior to December 1st of the applicable FY, then any applicable payment adjustment would be made through the cost report settlement process.

In the Stage 3 proposed rule (80 FR 16774 through 16779), we proposed to eliminate the exception discussed previously for a 90-day EHR reporting period for new meaningful EHR users in the Medicare EHR Incentive Program beginning with the EHR reporting period in 2017, with a limited exception for new meaningful EHR users under the Medicaid EHR Incentive Program. We also proposed for eligible hospitals and CAHs to shift the EHR reporting period for a payment adjustment year from a fiscal year basis to a calendar year basis. We proposed that for EPs and eligible hospitals demonstrating meaningful use under the Medicare EHR Incentive Program, including those who have successfully demonstrated meaningful use in a prior year as well as those who have not, the EHR reporting period for a payment adjustment year would be the full calendar year that is 2 years before the payment adjustment year. For further information on these proposals, we direct readers to the Stage 3 proposed rule (80 FR 16739 and 16740).

In the Stage 3 proposed rule, we also proposed a change to the EHR reporting period that would apply for the payment adjustments for CAHs, beginning with the FY 2017 payment adjustment year. Similar to what we proposed for eligible hospitals, we proposed that the EHR reporting period for a payment adjustment year for CAHs would be a full calendar year, rather than a full federal fiscal year. We proposed the EHR reporting period for a payment adjustment year would be the calendar year that overlaps the last 3 quarters of the federal fiscal year that is the payment adjustment year. For example, in order for a CAH to avoid application of the adjustment to its reasonable costs incurred in a cost reporting period that begins in FY 2017, the CAH must demonstrate it is a meaningful EHR user for an EHR reporting period of the full 2017 calendar year. For further information on these proposals, we direct readers to the Stage 3 proposed rule (80 FR 16777 through 16779).

In the Stage 3 proposed rule, we proposed amendments to the definition of “EHR reporting period for a payment adjustment year” under § 495.4 to reflect these proposals for EPs, eligible hospitals, and CAHs.

In this proposed rule, we are proposing several changes to the definition of the EHR reporting period for a payment adjustment year for EPs, eligible hospitals, and CAHs at § 495.4, in connection with other proposals made in this rule. Specifically, as stated in section I.A.2.b. of this proposed rule, we propose to change the EHR reporting period in 2015 to 90 days for all providers. This 90-day EHR reporting period in 2015 would allow adequate time to accommodate the changes to the objectives and measures of meaningful use proposed in this rule. We are also proposing to move all providers to an EHR reporting period based on the calendar year beginning in 2015 to support program alignment and simplify reporting requirements among provider types (section I.A.2.a. of this proposed rule).

**a. Changes to the EHR Reporting Period for a Payment Adjustment Year for EPs**

We propose a change to our current policy for 2015 only. We propose that for all EPs, including those who have demonstrated meaningful use in a prior year and those who have not, the EHR reporting period for a payment adjustment year would be any continuous 90-day period in CY 2015 and would apply for purposes of the payment adjustments in CY 2016 for EPs demonstrating meaningful use for the first time in 2015 and for purposes of the payment adjustments in CY 2017 for both returning and new participant EPs who demonstrate meaningful use in 2015. We propose the deadline for attestation would be February 29, 2016.

We would maintain our current policy for 2016. Under that policy, if an EP is demonstrating meaningful use for the first time in 2016, the EHR reporting period for a payment adjustment year is any continuous 90-day period in CY 2016 and applies for purposes of the payment adjustments in CYs 2017 and 2018. To avoid the payment adjustment in CY 2017, the 90-day period must occur within the first three quarters of CY 2016 and the EP must attest by October 1, 2016. If an EP has previously demonstrated meaningful use, the EHR reporting period for a payment adjustment year is the full CY 2016 and applies for purposes of the payment adjustment in CY 2018.

We invite comment on this proposal.

**b. Changes to the EHR Reporting Period for a Payment Adjustment Year for Eligible Hospitals**

We propose a change to our current policy for 2015. We propose that for all eligible hospitals, including those that have demonstrated meaningful use in a

prior year and those that have not, the EHR reporting period for a payment adjustment year would be any continuous 90-day period beginning October 1, 2014 and ending December 31, 2015. This EHR reporting period would apply for purposes of the payment adjustments in FY 2016 for eligible hospitals demonstrating meaningful use for the first time in 2015 and for purposes of the payment adjustments in FY 2017 for both returning and new participant eligible hospitals that demonstrate meaningful use in 2015. We propose the deadline for attestation would be February 29, 2016.

We also propose to change our current policy for 2016. We propose that if an eligible hospital is demonstrating meaningful use for the first time in 2016, the EHR reporting period for a payment adjustment year would be any continuous 90-day period in CY 2016 and apply for purposes of the payment adjustments in FYs 2017 and 2018. To avoid the payment adjustment in FY 2017, the 90-day period must occur within the first three quarters of CY 2016, and the eligible hospital must attest by October 1, 2016. If an eligible hospital has previously demonstrated meaningful use, the EHR reporting period for a payment adjustment year would be the full CY 2016, the attestation deadline would be February 28, 2017, and this EHR reporting period would apply for purposes of the payment adjustment in FY 2018.

### c. Changes to the EHR Reporting Period for a Payment Adjustment Year for CAHs

For CAHs, we are proposing to shift the EHR reporting period for a payment adjustment year from the federal fiscal year that is the payment adjustment year to the calendar year that begins on the first day of the second quarter of the federal fiscal year that is the payment adjustment year. In the Stage 3 proposed rule, we outline how CAHs are different from EPs and eligible hospitals in that the EHR reporting period is aligned with the payment adjustment year, rather than in advance of the payment adjustment year. In the Stage 3 proposed rule, we propose a similar change to this definition for an EHR reporting period for a payment adjustment year beginning in 2017 and explain how this change to the calendar year would work for CAHs. For further discussion of this proposal, we direct readers to the Stage 3 proposed rule (80 FR 16739 through 16740).

In this proposed rule, we propose a change to our current policy for 2015. We propose that for all CAHs, including

those that have demonstrated meaningful use in a prior year and those that have not, the EHR reporting period for a payment adjustment year would be any continuous 90-day period beginning October 1, 2014 and ending December 31, 2015. This EHR reporting period would apply for purposes of the payment adjustments for the cost reporting period that begins in federal FY 2015. We propose the deadline for attestation would be February 29, 2016.

Any CAH that does not demonstrate meaningful use for an EHR reporting period in 2015 would receive a downward adjustment to payments for its reasonable costs incurred in the cost reporting period that begins in federal FY 2015. If a CAH fails to demonstrate meaningful use in 2015 and has a fiscal year that ends between October 1, 2015 and March 1, 2016, then the payment adjustment would be applied through the cost report reconciliation process.

We also propose to change our current policy for 2016. We propose that if a CAH is demonstrating meaningful use for the first time in 2016, the EHR reporting period for a payment adjustment year would be any continuous 90-day period in CY 2016 and apply for purposes of the payment adjustments for the cost reporting period that begins in federal FY 2016. The deadline for attestation would be February 28, 2017. If a CAH has previously demonstrated meaningful use, the EHR reporting period for a payment adjustment year would be the full CY 2016, the attestation deadline would be February 28, 2017, and this EHR reporting period would apply for purposes of the payment adjustments for the cost reporting period that begins in federal FY 2016.

Any CAH that does not demonstrate meaningful use for an EHR reporting period in 2016 would receive a downward adjustment to payments for its reasonable costs incurred in the cost reporting period that begins in federal FY 2016. If a CAH fails to demonstrate meaningful use in 2016 and has a fiscal year that ends between October 1, 2016 and March 1, 2017, then the payment adjustment would be applied through the cost report reconciliation process.

### 3. Hardship Exceptions

As stated previously, sections 1848(a)(7)(B) and 1886(b)(3)(B)(ix)(II) of the Act provide the Secretary with discretionary authority to exempt, on a case by case basis, a provider from the application of the Medicare payment adjustment if the Secretary determines that compliance with the requirements for being a meaningful EHR user would result in a significant hardship. We have

established various types of hardship exceptions for which providers may apply as well as deadlines for application. For more information, we refer readers to the Stage 2 final rule at 77 FR 54093 through 54113.

In this proposed rule, we propose no changes to the existing hardship exceptions under our regulations.

### III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to evaluate fairly whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The following is a discussion of the requirements contained in this proposed regulation that we believe are subject to PRA and information collection requirements (ICRs). The projected numbers of EPs, eligible hospitals, and CAHs, MA organizations, MA EPs and MA-affiliated hospitals are based on the numbers used in the impact analysis assumptions as well as estimated federal costs and savings in the section IV.C.3.a. and b. of this proposed rule. The actual burden would remain constant for per year as EPs, eligible hospitals, and CAHs would need to attest that they have successfully demonstrated meaningful use under the proposed definition in 2015 through 2017. For the purposes of this analysis, we are focusing only on 2015, the first year in which a provider may use the proposed definition of meaningful use. We do not believe the burden for EPs, eligible hospitals, and CAHs participating in Stages 1 and 2 prior to 2015 would be different from the Agency Information Collection Activities (75 FR 65354) based on this proposed rule. Beginning in 2012, Medicare EPs, eligible hospitals, and CAHs had the option to electronically report their clinical quality measures through the respective aligned quality reporting programs;

however, for the purposes of defining the burden for 2015 through 2017, we maintain the estimates for attestation to CQM data.

In this proposed rule, the definition of meaningful use with associated reporting requirements would replace all prior definitions and requirements beginning in 2015. At that point, all eligible providers would be required to report meaningful use requirements on an annual basis. For 2017, providers may simply repeat this proposed definition of meaningful use or move on to Stage 3. The same reporting burden would apply to all providers. Consequently, the proposed ICRs reflect the provider burden associated with complying with and reporting of the proposed requirements beginning in 2015 and each subsequent year. We note that the proposals in this rule result in a reduction of the reporting burden on providers attesting to meaningful use as compared to the existing program requirements finalized in the Stage 2 final rule (77 FR 54132).

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

*A. ICR Regarding Demonstration of Meaningful Use Criteria (§ 495.20 Through § 495.60)*

In § 495.40 we propose that to successfully demonstrate meaningful use of certified EHR technology for meaningful use in 2015 through 2017, an EP, eligible hospital, or CAH (collectively referred to as “provider” in this section) must attest, through a secure mechanism in a specified manner, to the following during the EHR reporting period: (1) The provider used certified EHR technology and specified the technology was used; and (2) the provider satisfied each of the applicable objectives and associated

measures in § 495.22. In § 495.40, we stipulate that providers must also successfully report the clinical quality measures selected by CMS to CMS or the states, as applicable. We estimate that the certified EHR technology adopted by the provider captures many of the objectives and associated measures and generate automated numerator and denominator information where required, or generate automated summary reports. We also expect that the provider would enable the functionality required to complete the objectives and associated measures for which they are required to attest.

We propose that EPs would be required to report on a total of 10 objectives and associated measures and eligible hospitals and CAHs would report on a total of 9 objectives and associated measures. In this proposed rule, there are 6 objectives that would require an EP to enter numerators and denominators during attestation. Eligible hospitals and CAHs would have to attest that they have met 6 objectives that require numerators and denominators. For objectives and associated measures requiring a numerator and denominator, we limit our estimates to actions taken in the presence of certified EHR technology. We do not anticipate a provider would maintain 2 recordkeeping systems when certified EHR technology is present. Therefore, we assume that all patient records that would be counted in the denominator would be kept using certified EHR technology. We expect it would take an individual provider or designee approximately 10 minutes to attest to each meaningful use objective and associated measure that requires a numerator and denominator to be generated, as well as approximately 1 hour 30 minutes to attest to CQM requirements.

Additionally, providers would be required to report they have completed

objectives and associated measures that require a “yes” or “no” response during attestation. For EPs, there are 3 objectives that would require a “yes” or “no” response during attestation. For eligible hospitals and CAHs, there are 2 objectives and that would require a “yes” or “no” response during attestation. We expect that it would take a provider or their designee 1 minute to attest to each objective that requires a “yes” or “no” response.

Providers would also be required to attest that they are protecting ePHI. We estimate completion of the analysis required to meet successfully the associated measure for this objective would take approximately 6 hours, which is identical to our estimate for the Stage 1 and Stage 2 requirements. This burden estimate assumes that covered entities are already conducting and reviewing these risk analyses under current HIPAA regulations. Therefore, we have not accounted for the additional burden associated with the conduct or review of such analyses.

Table 7 lists those objectives and associated measures for EPs and eligible hospitals and CAHs. We estimate the objectives and associated measures would take an EP 6 hours 49 minutes to complete, and would take an eligible hospital or CAH 6 hours 48 minutes to complete.

In this proposed rule EPs, eligible hospitals, and CAHs have nearly identical reporting burdens. Eligible hospitals and CAHs are required to report to one additional registry than EPs are required to report; however, EPs have an additional objective, Secure Electronic Messaging, which requires a “yes” or “no” response. Consequently, we have not prepared lowest and highest burdens. Rather, we have computed a burden for EPs and a burden for eligible hospitals and CAHs.

TABLE 7—BURDEN ESTIMATES

Eligible professionals	Eligible hospitals and CAHs	Measures	Burden estimate per respondent (EPs)	Burden estimate per respondent (hospitals)
<b>Objectives and Measures</b>				
Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines.	Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines.	More than 60% of medication, 30% of laboratory, and 30% of radiology orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE.	10 minutes .....	10 minutes.

TABLE 7—BURDEN ESTIMATES—Continued

Eligible professionals	Eligible hospitals and CAHs	Measures	Burden estimate per respondent (EPs)	Burden estimate per respondent (hospitals)
Generate and transmit permissible prescriptions electronically (eRx).	Generate and transmit permissible discharge prescriptions electronically (eRx).	More than 50% of all permissible prescriptions, or all prescriptions written by the EP and queried for a drug formulary and transmitted electronically using CEHRT.	10 minutes.	10 minutes.
Use clinical decision support to improve performance on high-priority health conditions.	Use clinical decision support to improve performance on high-priority health conditions.	More than 10% of hospital discharge medication orders for permissible prescriptions (for new, changed, and refilled prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.	1 minute .....	1 minute.
Provide patients the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP.	Provide patients the ability to view online, download, and transmit information about a hospital admission.	<ol style="list-style-type: none"> <li>1. Implement five clinical decision support interventions related to four or more clinical quality measures at a relevant point in care for the entire EHR reporting period. Absent four clinical quality measures related to an EP, eligible hospital or CAH's scope of practice or patient population, the clinical decision support interventions must be related to improving healthcare efficiency.</li> <li>2. The EP, eligible hospital or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.</li> </ol>	10 minutes.	10 minutes.
Use CEHRT to identify patient-specific education resources and provide those resources to the patient.	Use CEHRT to identify patient-specific education resources and provide those resources to the patient.	<ol style="list-style-type: none"> <li>1. More than 50% of all unique patients seen by the EP during the EHR reporting period are provided timely (within 4 business days after the information is available to the EP) online access to their health information subject to the EP's discretion to withhold certain information.</li> <li>2. At least 1 patient seen by the EP during the EHR reporting period (or their authorized representatives) views, downloads, or transmits to a third party their health information.</li> </ol>	10 minutes .....	10 minutes.
Use secure electronic messaging to communicate with patients on relevant health information.		<ol style="list-style-type: none"> <li>1. More than 50% of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH have their information available online within 36 hours of discharge.</li> <li>2. At least 1 patient (or their authorized representatives) who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH views, downloads or transmits to a third party their information during the reporting period.</li> </ol> <p>Patient-specific education resources identified by CEHRT are provided to patients for more than 10% of all unique patients with office visits seen by the EP during the EHR reporting period.</p> <p>More than 10% of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) are provided patient-specific education resources identified by CEHRT.</p> <p>The secure electronic messaging function was fully enabled for the EHR reporting period.</p>	10 minutes.	

TABLE 7—BURDEN ESTIMATES—Continued

Eligible professionals	Eligible hospitals and CAHs	Measures	Burden estimate per respondent (EPs)	Burden estimate per respondent (hospitals)
The EP who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.	The eligible hospital or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.	The EP, eligible hospital or CAH performs medication reconciliation for more than 50% of transitions of care in which the patient is transitioned into the care of the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23).	10 minutes .....	10 minutes.
The EP who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care provides a summary care record for each transition of care or referral.	The eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care provides a summary care record for each transition of care or referral.	1. The EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 10% of such transitions and referrals either (a) electronically transmitted using CEHRT to a recipient or (b) where the recipient receives the summary of care record via exchange facilitated by an organization that is a NwHIN Exchange participant or in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network.	10 minutes .....	10 minutes.
Active engagement with a public health agency to report public health data.	Active engagement with a public health agency to report public health data.	EPs must attest to at least 2 options out of 5.	1 minute .....	1 minute.
Protect electronic protected health information created or maintained by the CEHRT through the implementation of appropriate technical capabilities.	Protect electronic protected health information created or maintained by the CEHRT through the implementation of appropriate technical capabilities.	Eligible Hospitals and CAHs must attest to at least 3 options out of 6. Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of data stored in CEHRT in accordance with requirements under 45 CFR 164.312 (a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the provider's risk management process.	6 hours.	
Time to Attest to Objectives and Measures .....			6 hours 49 minutes.	6 hours 48 minutes.
Time to Attest and Report Clinical Quality Measures .....			1 hour 30 minutes.	1 hour 30 minutes.
Total—Objectives + CQM Reporting .....			8 hours 19 minutes.	8 hours 18 minutes.

In this proposed rule, we estimate that it would take no longer than 6 hours 49 minutes for an EP to attest to each of the applicable objectives and associated measures. The total burden hours for an EP to attest to the meaningful use objectives and measures and to report CQMs would be 8 hours 19 minutes. We estimate that there could be approximately 595,100 nonhospital-based Medicare EPs in 2014. Based on the historical data, we anticipate approximately 60 percent (357,060) of these EPs may attest to the objectives and measures of meaningful use. In addition, we believe approximately 30,000 Medicaid only EPs, or approximately 51 percent of the Medicaid-only EPs, will successfully

demonstrate meaningful use in 2015. The total estimated annual cost burden for all EPs to attest to meaningful use would be \$297,076,291 (387,060 × 8 hours 19 minutes × \$92.25 (mean hourly rate for physicians based on May 2013 BLS data)). Similarly, eligible hospitals and CAHs would attest that they have met the meaningful use objectives and associated measures, and would submit the clinical quality measures. We estimate that it would take no longer than 6 hours 48 minutes to attest to each of the applicable objectives and associated measures. Therefore, the total burden hours for an eligible hospital or CAH to attest to the meaningful use objectives and measures and to report CQMs, would be 8 hours 18 minutes.

We estimate that there are about 4,900 eligible hospitals and CAHs that may attest to the aforementioned criteria in FY 2015 of which 95 percent are expected to successfully demonstrate meaningful use. The total estimated annual cost burden for all eligible hospitals and CAHs to attest to meaningful use would be \$2,451,872 (4,655 eligible hospitals and CAHs × \$63.46 (8 hours 18 minutes × \$63.46 (mean hourly rate for lawyers based on May 2013 BLS) data)).

We provide the estimate of the burden for the approximately 13,635 MA EPs in the MA organization burden section. The total annual burden estimates for meaningful use under this proposed rule are shown in Table 10.



For the purpose of this proposed collection of information, we assumed that all eligible providers would comply with the requirements of Meaningful Use as previously defined if the policies proposed in this rule were not finalized. Therefore, in this proposed rule, we estimate that the policies contained

herein, once finalized, would result in an overall reduction in the reporting burden for providers of 1.45 hours to 1.9 hours for EPs and 2.62 hours for eligible hospitals and CAHs per respondent. While batch reporting for objectives and measures, and group reporting for CQMs, are available for EPs in the

current program; the program is based upon successful individual provider demonstration of meaningful use and so individual totals are used to identify the estimated reduction in provider reporting burden. This reduction of burden is outlined in Table 8.

TABLE 8—REDUCTION IN REPORTING BURDEN HOURS

Burden under current program and proposed modifications	Estimated burden per respondent EPs	Estimated burden per respondent eligible hospitals and CAHs
Total Under Current Stage 2 Requirements at 42 CFR 495.6	9 hours 46 minutes	NA.
Core Set (including CQMs) + Least Burdensome Menu Set Criteria	10 hours 13 minutes	10 hours 55 minutes.
Total Under Current Stage 2 Requirements at 42 CFR 495.6	10 hours 13 minutes	10 hours 55 minutes.
Core Set (including CQMs) + Most Burdensome Menu Set Criteria	8 hours 19 minutes	8 hours 18 minutes.
Total Under Proposed Modifications at 495.22	8 hours 19 minutes	8 hours 18 minutes.
All Objectives and Measures + CQMs	1 hour 27 minutes	NA.
Reduction from Least Burdensome Estimate	1 hour 54 minutes	2 hour 37 minutes.
Reduction from Most Burdensome Estimate	1 hour 54 minutes	2 hour 37 minutes.

Using the hourly costs associated with the reporting burden as mentioned previously, this reduction of 1.45 hours to 1.9 hours for EPs and 2.62 hours for eligible hospitals and CAHs represents a

per response savings of \$133.76 to \$175.28 for EPs and \$166.27 for eligible hospitals and CAHs. The total cost reduction in cost for providers demonstrating meaningful use is

estimated at \$48,534,332 at the lowest and \$63,359,464 at the highest. These estimates are further outlined in Table 9.

TABLE 9—REDUCTION IN BURDEN COST SAVINGS

Number of responses	Burden reduction hours	Hourly cost	Reduction per respondent	Total cost reduction
387,060	1.45	\$92.25	\$133.76	\$51,773,146
387,060	1.9	92.25	175.28	67,843,877
4,655	2.62	63.46	166.27	773,987
Total Least				52,547,132
Total Most				68,617,864

*B. ICRs Regarding Qualifying MA Organizations (§ 495.210)*

In this proposed rule, we estimate that the burden would be significantly less for qualifying MA organizations attesting to the meaningful use of their MA EPs, because qualifying MA EPs use the EHR technology in place at a given location or system, so if certified EHR technology is in place and the qualifying MA organization requires its qualifying MA EPs to use the technology, qualifying MA organizations would be able to determine at a faster rate than individual FFS EPs, that its qualifying MA EPs meaningfully used certified EHR technology. In other words, qualifying MA organizations can make the determination in masse if the certified EHR technology is required to be used at its facilities, whereas under FFS, each EP likely must make the determination on an individual basis. We further note, that these differences also mean the total reduction in burden

for MA organizations resulting from the proposals in this rule would be negligible. We estimate that, on average, it would take an individual 45 minutes to collect information necessary to determine if a given qualifying MA EP has met the meaningful use objectives and measures, and 15 minutes for an individual to make the attestation for each MA EP. Furthermore, the individuals performing the assessment and attesting would not likely be the eligible professional, but non-clinical staff. We believe that the individual gathering the information could be equivalent to a GS 11, step 1 (2015 unadjusted for locality rate), with an hourly rate of approximately \$25.00/hour, and the person attesting (and who may bind the qualifying MA organization based on the attestation) could be equivalent to a GS 15, step 1 (2015 unadjusted for locality rate), or approximately \$50.00/hour. Therefore, for the estimated 13,635 potentially qualifying MA EPs with assumed 100

percent successfully demonstrating meaningful use, we believe it would cost the participating qualifying MA organizations approximately \$426,050 annually to collect the required information and make the attestations  $([10,226 \text{ hours} \times \$25.00] + [3,408 \text{ hours} \times \$50.00])$ .

*C. ICRs Regarding State Medicaid Agency and Medicaid EP and Hospital Activities (§ 495.332 Through § 495.344)*

In this proposed rule, we are proposing no changes to State Medicaid Agency reporting which affect the time and effort associated with completing the single provider election repository and each state's process for the administration of the Medicaid incentive payments, including tracking of attestations and oversight; the submission of the state Medicaid HIT Plan and the additional planning and implementation documents; or the enrollment or reenrollment of providers, or for the collection and submission of the data for providers to demonstrate

that they have adopted, implemented, or upgraded certified EHR technology. We believe the burden associated with these requirements has already been accounted for in our discussion in the

Stage 1 and Stage 2 final rules at (75 FR 44516 through 44544 and 77 FR 54125 through 54135). For the collection and submission of the data for providers to demonstrate that they are meaningful

users of such technology, we believe the burden associated with these requirements has already been accounted for in our discussion of the burden for § 495.20 through § 495.60.

TABLE 10—ESTIMATED ANNUAL REPORTING BURDEN FOR MEANINGFUL USE

Regulation section	OMB Control No.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting (\$)	Total cost (\$)
§ 495.22—Objectives/Measures/CQMs (EPs) .....	0938-1158	387,060	387,060	8.32	3,220,339	\$92.25	\$297,076,291
§ 495.22—Objectives/Measures/CQMs (hospitals/CAHs) .....	0938-1158	4,655	4,655	8.3	38,637	63.46	2,451,872
§ 495.210—Gather Attestation Information (MA EPs and EHs) .....	0938-1158	13,635	13,635	0.75	10,226	25.00	255,656
§ 495.210—Attest (MA EPs and EHs) .....	0938-1158	13,635	13,635	0.25	3,409	50.00	170,438
Total .....		418,985	418,985		3,272,611		299,954,257

\* To avoid double counting, this number of respondents is only included once in the total.  
 \*\* There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 10.

If you would like to comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or
2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, *Attention: CMS Desk Officer*, [CMS-3311-P] *Fax: (202) 395-6974; or Email: OIRA\_submission@omb.eop.gov.*

**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 proposed rule, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

**V. Regulatory Impact Analysis**

*A. Statement of Need*

This proposed rule would implement the provisions of the ARRA that provide incentive payments to EPs, eligible hospitals, and CAHs participating in Medicare and Medicaid programs that adopt and meaningfully use certified EHR technology. The proposed rule specifies applicable criteria for demonstrating meaningful use for an EHR reporting period in 2015 through 2017.

*B. Overall Impact*

We have examined the impacts 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). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year).

In relation to the existing program requirements outlined in the Stage 2 final rule (77 FR 53967 through 54162), we do not expect this rule to result in more incentives paid or in more providers failing meaningful use and being assessed a payment adjustment. This is due to the nature of the modifications being proposed in this rule, which, while they reduce the reporting burden on providers, do not affect the clinical processes and IT functions required to successfully meet the objectives and measures of meaningful use. The proposals in this rule do not fundamentally change the technology required to support participation in the meaningful use program. Under the current program, the requirement to report data on the measures and objectives which have

been identified as now redundant to other more advanced measures being retained, or are duplicative of other measures using the same certified EHR technology function, is essentially requiring providers to report on the same action or process twice. Therefore, it is not the occurrence of the action or process which is reduced by the proposals in this rule, but the burden associated with the duplicative and redundant reporting. In addition, the objectives and measures which are considered topped out have reached high performance and the statistical evidence demonstrates that the expected result of any provider attesting to meaningful use would be a score near the maximum. However, the analysis of these measures and their identification as topped out also takes into account the statistical likelihood that the functions of measures and the processes behind them would continue even without a requirement to report the results. Therefore, while the proposals result in a reduction in reporting requirements, this does not correlate to a change in the overall achievement of the measures and objective as compared to the current program. Finally, when compared against historical data, the shortened reporting period in 2015, which has been proposed to accommodate the implementation of the policies of this rule, is expected to have a minimal impact on successful demonstration of meaningful use. This expectation of minimal impact is based on a number of factors:

- The shortened period is for 2015 only and not for 2016 or 2017.
- Historical data on attestations shows no strong correlation between a shorter reporting period and the ability of providers to attest to a second year of

meaningful use, no correlation for providers returning to attest to a third or fourth year of meaningful use, and providers who would otherwise be in their first year of meaningful use would already have a 90-day reporting period.<sup>5</sup>

- Performance data shows statistically negligible disparity among providers attesting for a 90-day reporting period and those attesting for a full year reporting period on the measures which have been identified as redundant, duplicative, and topped out.<sup>6</sup>

For these reasons, we do not believe the proposals in this rule would impact the overall estimates for incentive payments, payment adjustments, and the net transfer costs associated with the program. However, these proposals do affect the costs associated with the reporting burden on providers. The impacts directly attributable with the proposals in this rule relate to both an hourly reduction per response an overall reduction in the cost associated with reporting for providers demonstrating meaningful use. The burden analysis in this proposed rule, as compared to the Stage 2 estimates, reduces the reporting burden for attestation for providers by approximately 1.45 hours to 1.9 hours for EPs and 2.62 hours for eligible hospitals and CAHs per respondent. This burden estimate and analysis of the impact of the policies result in a total cost reduction estimated at \$48,534,332 at the lowest and \$63,359,464 at the highest. However, we believe this proposed rule will have additional impacts—most notably, cost savings for hospitals and providers that would have additional time to achieve meaningful use—which cannot be adequately estimated because of the wide variation among provider types, and therefore a designation as an economically significant rule under the Executive Order and a major rule under the Congressional Review Act is still applicable. The burden estimate and analysis of the impact of the policies proposed in this proposed rule are outlined further in section III. of this proposed rule.

<sup>5</sup> CMS Data and Reports: Quarterly Public Use Files for participation, Monthly Reports for performance rates: <http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html>.

<sup>6</sup> CMS Data and Reports: Quarterly Public Use Files for participation, Monthly Reports for performance rates: <http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html>.

## 1. Overall Effects

### a. Regulatory Flexibility Analysis and Small Entities

The Regulatory Flexibility Act (RFA) requires agencies to prepare an Initial Regulatory Flexibility Analysis to describe and analyze the impact of the proposed rule on small entities unless the Secretary can certify that the rule will not have a significant impact on a substantial number of small entities. In the healthcare sector, Small Business Administration (SBA) size standards define a small entity as one with between \$7 million and \$34 million in annual revenues. For the purposes of the RFA, essentially all non-profit organizations are considered small entities, regardless of size. Individuals and states are not included in the definition of a small entity. Since the vast majority of Medicare providers (well over 90 percent) are small entities within the RFA's definitions, it is the normal practice of HHS simply to assume that all affected providers are "small" under the RFA. In this case, most EPs, eligible hospitals, and CAHs are either nonprofit or meet the SBA's size standard for small business. We also believe that the effects of the incentives program on many and probably most of these affected entities will be economically significant. Accordingly, this RIA section, in conjunction with the remainder of the preamble, constitutes the required Initial Regulatory Flexibility Analysis (RFA).

Data available suggests that more providers have adopted EHR technology since the publication of the Stage 1 final rule. An ONC data brief (No. 16, May 2014) noted that hospital adoption of EHR systems has increased 5 fold since 2008. Nine in ten acute care hospitals possessed CEHRT in 2013, increasing 29 percent since 2011. As of January 1, 2015, more than 95 percent of eligible hospitals had successfully demonstrated meaningful use. In January 2014, a Centers for Disease Control and Prevention (CDC) data brief entitled, "Use and Characteristics of Electronic Health Record Systems Among Office-based Physician Practices: United States, 2001 through 2013 found that 78 percent of office-based used any type of EHR systems, up from 18 percent in 2001. The majority of EPs have already purchased certified EHR technology, implemented this new technology, and trained their staff on its use with over 60 percent earning an incentive payment for participation in the program prior to 2015.

The cost reductions provided by the proposals in this rule offer a benefit to

these providers. Furthermore, we believe that the combination of payment incentives and long-term overall gains in efficiency may compensate for some of the initial expenditures.

### (1) Small Entities

We estimate that EPs would spend approximately \$54,000 to purchase and implement a certified EHR and \$10,000 annually for ongoing maintenance according to the Congressional Budget Office (CBO) (75 FR 44546).

In the paper, Evidence on the Costs and Benefits of Health Information Technology, May 2008, in attempting to estimate the total cost of implementing health IT systems in office-based medical practices, recognized the complicating factors of EHR types, available features and differences in characteristics of the practices that are adopting them. The CBO estimated a cost range of \$25,000 to \$45,000 per physician. Annual operating and maintenance amount was estimated at 12 to 20 percent of initial costs (that is, \$3,000 to \$9,000) per physician. For all eligible hospitals, the range is from \$1 million to \$100 million. Though reports vary widely, we anticipate that the average will be \$5 million for eligible hospitals to achieve meaningful use. We estimate \$1 million for maintenance, upgrades, and training each year per eligible hospital. However, as stated earlier many providers have already purchased systems with expenditures focused on maintenance and upgrades. We believe that future retrospective studies on the costs to implement and EHR and the return on investment (ROI) would demonstrate the actual costs incurred by providers participating in the EHR Incentive Programs. The potential costs savings in this proposed rule would benefit these providers as a reduction in the overall cost of program participation.

### (2) Conclusion

As discussed later in this analysis, we believe that there are many positive effects of adopting EHR on health care providers. Furthermore, we believe that the proposals in this rule will result in an overall reduction in the reporting burden for providers of all types. Accordingly, we believe that the object of the RFA to minimize burden on small entities is met by this proposed rule.

### b. Small Rural Hospitals

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis (RIA) if a rule will 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 and has fewer than 100 beds. There is no identifiable disparity among this group and the overall success rates for eligible hospitals and CAHs in demonstrating meaningful use; furthermore, 95 percent of eligible hospitals and CAHs have successfully demonstrated meaningful use as of January 1, 2015. Finally, on the whole we anticipate an estimated reduction in the reporting burden on eligible hospitals as a group to be less than \$1 million. Therefore, we do not believe that this proposed rule would have a significant impact on a substantial number of small entities.

c. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates will require spending in any 1 year \$100 million in 1995 dollars, updated annually for inflation. In 2015, that threshold is approximately \$144 million. UMRA does not address the total cost of a rule. Rather, it focuses on certain categories of cost, mainly those “federal mandate” costs resulting from—(1) imposing enforceable duties on state, local, or tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, state, local, or tribal governments under entitlement programs.

This proposed rule imposes no substantial mandates on states. This program is voluntary for states and states offer the incentives at their option. The state role in the incentive program is essentially to administer the Medicaid incentive program. While this entails certain procedural responsibilities, these do not involve substantial state expense. In general, each state Medicaid Agency that participates in the incentive program would be required to invest in systems and technology to comply. States would have to identify and educate providers, evaluate their attestations and pay the incentive. However, the federal government would fund 90 percent of

the state’s related administrative costs, providing controls on the total state outlay. In addition, the changes being made by this proposed rule have very little impact on any state functions.

d. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This proposed rule would not have a substantial direct effect on state or local governments, preempt state law, or otherwise have a Federalism implication.

2. Effects on EPs, Eligible Hospitals, and CAHs

a. Background and Assumptions

There are no new costs associated with this proposed rule. Furthermore, the estimates for the provisions affecting Medicare and Medicaid EPs, eligible hospitals, and CAHs are somewhat uncertain for the following reasons:

- The program is voluntary although payment adjustments will be imposed on Medicare providers if they are unable to demonstrate meaningful use for the applicable reporting period.
- The potential reduction in burden for EPs rely on relate to assumptions of what options for meaningful use they would otherwise attest to should the policies in this proposed rule not be adopted.
- The net costs and savings for any individual provider may not directly correlate to the total for the organization as larger organizations may employ economies of scale in meaningful use attestations.

However, based on the actual count of providers eligible for the program as of December 31, 2014 which were identified through the process of implementing payment adjustments for 2015, we estimated the numbers of EPs and eligible hospitals, including CAHs under Medicare, Medicaid, and MA for 2015 through 2017 and used the updated estimates throughout the analysis. These total potential eligible providers are as follows:

- About 660,000 Medicare FFS EPs (some of whom will also be Medicaid EPs). About 595,100 non-hospital based Medicare EPs.

- About 58,300 non-Medicare eligible EPs (such as dentists, pediatricians, and eligible non-physicians such as certified nurse-midwives, nurse practitioners, and physicians assistants).

- 4,900 eligible hospitals comprising the following:

- ++ 3,397 acute care hospitals.
- ++ 1,395 CAHs.
- ++ 97 children’s hospitals (Medicaid only).
- ++ 11 cancer hospitals (Medicaid only).
- 16 MA organizations and 13,635 MA EPs

b. Industry Costs and Adoption Rates

In this proposed rule, we are proposing no new policies which would require changes to the development, certification, and implementation of certified EHR technology as compared to the policies in the existing program outlined in the Stage 2 final rule (77 FR 54136 through 54146).

3. Medicare Incentive Program Costs

As noted at the beginning of this analysis, it is difficult to predict the actual impacts of the policies in this proposed rule with certainty. We believe the assumptions and methods described herein are reasonable for estimating the financial impact of the provisions on providers participating in the Medicare and Medicaid programs, but acknowledge the wide range of possible outcomes.

a. Medicare Eligible Professionals (EPs)

In brief, the estimates of Medicare EP burden reduction are based on current participation as of January 1, 2015. We estimate that significant cost reductions for Medicare EPs participating in the EHR Incentive Program will result from the policies in this proposed rule when compared to the requirements of the current program. Our estimates of the reduction in burden cost savings are presented in Table 12. They reflect our assumptions about the proportion of EPs who will demonstrate meaningful use of certified EHR technology outlined in Table 11 based on historical data.

TABLE 11—MEDICARE EPs DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY

	Calendar year		
	2015	2016	2017
Medicare EPs who have claims with Medicare (in thousands) .....	660.0	667.8	675.5
Nonhospital-based Medicare EPs (in thousands) .....	595.1	602.1	609.1
Percent of EPs who are Meaningful Users .....	60	65	70

TABLE 11—MEDICARE EPS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY—Continued

	Calendar year		
	2015	2016	2017
Meaningful Users (in thousands) .....	357.1	391.4	426.4

TABLE 12—ESTIMATED COST REDUCTION FOR MEDICARE EPS

	Calendar year		
	2015	2016	2017
Meaningful Users (in thousands) .....	357.1	391.4	426.4
Lowest Estimated Cost Savings .....	\$47,760,345.60	\$52,353,664.00	\$57,035,264.00
Highest Estimated Cost Savings .....	\$62,585,476.80	\$68,604,592.00	\$74,739,392.00

b. Medicare Eligible Hospitals and CAHs

In brief, the estimates of hospital burden reduction are based on current participation as of January 1, 2015. We estimate that significant cost reductions

for Medicare eligible hospitals and CAHs participating in the EHR Incentive Program would result from the policies in this proposed rule when compared to the requirements of the current program. Our estimates of the reduction in burden cost savings are presented in

Table 12. They reflect our assumptions about the proportion of eligible hospitals and CAHs that will demonstrate meaningful use of certified EHR technology outlined in Table 13 based on historical data.

TABLE 13—MEDICARE ELIGIBLE HOSPITALS AND CAHs DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY

	Calendar year		
	2015	2016	2017
Eligible Hospitals .....	3,397	3,397	3,397
CAHs .....	1,395	1,395	1,395
Percent Demonstrating Meaningful Use .....	95	97	99
Meaningful Users .....	4,552	4,648	4,744

TABLE 14—ESTIMATED COST REDUCTION FOR MEDICARE ELIGIBLE HOSPITALS AND CAHs

	Calendar year		
	2015	2016	2017
Meaningful Users .....	4,552	4,648	4,744
Estimated Cost Savings .....	\$756,861.04	\$772,822.96	\$788,784.88

4. Medicaid Only EPs

We estimate that significant cost reductions for Medicaid only EPs participating in the EHR Incentive

Program will result from the policies in this proposed rule when compared to the requirements of the current program. Our estimates of the reduction in burden cost savings are presented in

Table 16. They reflect our assumptions about the proportion of Medicaid only EPs who will demonstrate meaningful use of certified EHR technology outlined in Table 15 based on historical data.

TABLE 15—MEDICAID ONLY EPs DEMONSTRATING MEANINGFUL USE

	Calendar year		
	2015	2016	2017
Medicaid only EPs .....	58.3	59.4	60.6
Percent of EPs who are Meaningful Users .....	51	53	55
Meaningful Users (in thousands) .....	30	31.48	33.33

TABLE 16—ESTIMATED COST REDUCTION FOR MEDICAID ONLY EPS

	Calendar year		
	2015	2016	2017
Meaningful Users (in thousands) .....	30,000	31,480	33,330
Lowest Estimated Cost Savings .....	\$4,012,800.00	\$4,210,764.80	\$4,458,220.80
Highest Estimated Cost Savings .....	\$5,258,400.00	\$5,517,814.40	\$5,842,082.40

It should be noted that since the Medicaid EHR Incentive Program provides that a Medicaid EP can receive an incentive payment in their first year because he or she has demonstrated a meaningful use or because he or she has adopted, implemented, or upgraded certified EHR technology, these participation rates include only those Medicaid providers who are expected to demonstrate meaningful use. Providers who are dual-eligible have been included in the Medicare EP program

estimates based on the total current volume of Medicare EPs who have demonstrated meaningful use in either Medicare or Medicaid as of January 1, 2015.

b. Medicaid Only Hospitals

The burden reduction for Medicaid only eligible hospitals assumes a similar participation rate for the demonstration of meaningful use as is applicable for Medicare eligible hospitals. We estimate that significant cost reductions for

Medicaid only eligible hospitals participating in the EHR Incentive Program will result from the policies in this proposed rule when compared to the requirements of the current program. Our estimates of the reduction in burden cost savings are presented in Table 18. They reflect our assumptions about the proportion of Medicaid only eligible hospitals that will demonstrate meaningful use of certified EHR technology outlined in Table 17 based on historical data.

TABLE 17—MEDICAID ONLY ELIGIBLE HOSPITALS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY

	Calendar year		
	2015	2016	2017
Eligible Hospitals .....	108	108	108
Percent Demonstrating Meaningful Use .....	95	97	99
Meaningful Users .....	103	105	107

TABLE 18—ESTIMATED COST REDUCTION FOR MEDICARE ELIGIBLE HOSPITALS AND CAHS

	Calendar year		
	2015	2016	2017
Meaningful Users .....	4,552	4,648	4,744
Estimated Cost Savings .....	\$17,125.81	\$17,458.35	\$17,790.89

5. Benefits for all EPs and all Eligible Hospitals

In this proposed rule, we have not quantified the overall benefits to the industry, nor to eligible hospitals or EPs in the Medicare, Medicaid, or MA programs. Although information on the costs and benefits of adopting systems that specifically meet the requirements for the EHR Incentive Programs (for example, certified EHR technology) has not yet been collected, and although some studies question the benefits of health information technology, a 2011 study completed by ONC (Buntin et al, 2011 “The Benefits of Health Information Technology: A Review of the Recent Literature Shows Predominantly Positive Results” *Health Affairs*) found that 92 percent of articles published from July 2007 up to February 2010 reached conclusions that showed the overall positive effects of health information technology on key

aspects of care, including quality and efficiency of health care. Among the positive results highlighted in these articles were decreases in patient mortality, reductions in staffing needs, correlation of clinical decision support to reduced transfusion and costs, reduction in complications for patients in hospitals with more advanced health IT, and a reduction in costs for hospitals with less advanced health IT. A subsequent 2013 study completed by the RAND Corporation for ONC (Shekelle et al. 2013 “Health Information Technology: An Updated Systemic Review with a Focus on Meaningful Use Functionalities) found 77 percent of articles published between January 2010 to August 2013 that evaluated the effects of health IT on healthcare quality, safety, and efficiency reported findings that were at least partially positive. The Centers for Disease Control and Prevention publication in January 2014, (Hsiao et

al, “Use and Characteristics of Electronic Health Record Systems Among Office-based Physician Practices: United States, 2001–2013) concluded that the adoption of basic EHR systems by office-based physicians increased 21 percent between 2012 and 2013, varying widely across the states ranging from 21 percent in New Jersey to 83 percent in North Dakota. Another study, at one hospital emergency room in Delaware, showed the ability to download and create a file with a patient’s medical history saved the ER \$545 per use, mostly in reduced waiting times. A pilot study of ambulatory practices found a positive ROI within 16 months and annual savings thereafter (Greiger et al. 2007, A Pilot Study to Document the Return on Investment for Implementing an Ambulatory Electronic Health Record at an Academic Medical Center <http://www.journalacs.org/article/S1072-7515%2807%2900390-0/abstract—article-footnote-1>.) Another

study compared the productivity of 75 providers within a large urban primary care practice over a 4-year period showed increases in productivity of 1.7 percent per month per provider after EHR adoption (DeLeon et al. 2010, “The business end of health information technology”). Some vendors have estimated that EHRs could result in cost savings of between \$100 and \$200 per patient per year. The proposals in this rule focus on a long term goal of moving providers along a continuum from data capture to advanced use of certified EHR technology. The reduction of reporting burden recognizes progress toward key milestones and is intended to allow providers to refocus on leveraging health IT to support health information exchange, patient engagement, and quality improvement. As participation and adoption increases, there will be more opportunities to capture and report on cost savings and benefits.

6. Benefits to Society

According to the CBO study “Evidence on the Costs and Benefits of Health Information Technology” (<http://www.cbo.gov/ftpdocs/91xx/doc9168/05-20-HealthIT.pdf>) when used effectively, EHRs can enable providers to deliver health care more efficiently. For example, the study states that EHRs can reduce the duplication of diagnostic tests, prompt providers to prescribe cost-effective generic medications, remind patients about preventive care, reduce unnecessary office visits, and assist in managing complex care. This is consistent with the findings in the ONC study cited previously. Further, the CBO report claims that there is a potential to gain both internal and external savings from widespread adoption of health IT, noting that internal savings will likely be in the reductions in the cost of providing care, and that external savings could accrue to the health insurance plan or even the patient, such as the ability to exchange information more efficiently. However, it is important to

note that the CBO identifies the highest gains accruing to large provider systems and groups and claims that office-based physicians may not realize similar benefits from purchasing health IT products. At this time, there is limited data regarding the efficacy of health IT for smaller practices and groups, and the CBO report notes that this is a potential area of research and analysis that remains unexamined. The benefits resulting specifically from this proposed regulation are even harder to quantify because they represent, in many cases, the reduction in the time spent per each individual respondent to attest to the meaningful use objectives and measures. While this time may represent a reduced burden and the opportunity to reallocate resources, there is no viable way to estimate that benefit over a wide range of provider types, practice sizes and other potential variables. For example, the reduction of about 2 hours per respondent for a small practice might be insignificant; however, for a practice of 1,000 providers it may represent as many as 2,000 man hours which could be reallocated to making other improvements in clinical processes and patient outcomes. Conversely, a large practice may instead leverage the batch reporting option and only see an overall reduction of 20 man hours as an organization while a small practice may find an even greater reduction than the estimate which may amount to a significantly increased benefit and more time for the provider to spend in patient care.

In the Stage 2 final rule, we discussed research documenting the association of EHRs with improved outcomes among diabetics (Hunt, JS et al. (2009) “The impact of a physician-directed health information technology system on diabetes outcomes in primary care: A pre- and post-implementation study” *Informatics in Primary Care* 17(3):165–74; Pollard, C et al. (2009) “Electronic patient registries improve diabetes care and clinical outcomes in rural community health centers” *Journal of*

Rural Health 25(1):77–84) and trauma patients (Deckelbaum, D. et al. (2009) “Electronic medical records and mortality in trauma patients” *The Journal of Trauma: Injury, Infection, and Critical Care* 67(3): 634–636), enhanced efficiencies in ambulatory care settings (Chen, C et al. (2009) “The Kaiser Permanente Electronic Health Record: Transforming and Streamlining Modalities Of Care.” *Health Affairs* 28(2):323–333), and improved outcomes and lower costs in hospitals (Amarasingham, R. et al. (2009) “Clinical information technologies and inpatient outcomes: A multiple hospital study” *Archives of Internal Medicine* 169(2):108–14). The 2013 ONC report cited previously reported findings from their literature review on health IT and safety of care, health IT and quality of care, and health IT and efficiency of care in ambulatory and non-ambulatory care settings. The report indicated that a majority of studies that evaluated the effects of health IT on healthcare quality, safety, and efficiency reported findings that were at least partially positive. The report concluded that their findings “suggested that health IT, particularly those functionalities included in the Meaningful Use . . . , can improve healthcare quality and safety.”

C. Accounting Statement

Whenever a rule is considered a significant rule under Executive Order 12866, we are required to develop an accounting statement indicating the classification of the expenditures associated with the provisions of this proposed rule. This rule is considered economically significant as mentioned previously because the impacts directly attributable with the proposals in this rule would result in an overall reduction in the reporting burden and associated costs for providers demonstrating meaningful use. Monetary annualized benefits and nonbudgetary costs are presented as discounted flows using 3 percent and 7 percent factors.

TABLE 19—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COST REDUCTIONS AND BENEFITS CYs 2015 THROUGH 2017  
[In millions]

Category	Benefits			
		Low estimate	High estimate	
Annualized Monetized Cost Reductions to Private Industry Associated with Reporting Requirements.	2015	52.8	68.9	7%
		52.8	68.9	3%

CY 2015

TABLE 19—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COST REDUCTIONS AND BENEFITS CYs 2015 THROUGH 2017—Continued

[In millions]

Category	Benefits			
		Low estimate	High estimate	
Qualitative—Other private industry and societal benefits associated with the reduction in provider reporting burden and with having additional time to achieve meaningful use.				

In this proposed rule, there is no estimated increase in costs associated with incentive payments or payment adjustments for the Medicare and Medicaid EHR Programs attributable to the proposed policies.

*D. Conclusion*

The previous analysis, together with the remainder of this preamble, provides an RIA. We invite public comments on the analysis and request any additional data that will help us determine more accurately the impact on the EPs and eligible hospitals affected by the proposed rule and on Medicare and Medicaid payments to these entities.

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

**List of Subjects in 42 CFR Part 495**

Administrative practice and procedure, Electronic health records, Health facilities, Health professions, Health maintenance organizations (HMO), Medicaid, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to further amend 42 CFR part 495, as previously proposed to be amended on March 30, 2015 (80 FR 16732), as follows:

**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 495.4 is amended as follows:

■ A. Amend the definition of “EHR reporting period” by:

■ i. In paragraph (1)(i) introductory text removing the phrase “before CY 2017” and adding in its place the phrase “before CY 2015”.

■ ii. Redesignating paragraph (1)(ii) as paragraph (1)(iii).  
 ■ iii. Adding a new paragraph (1)(ii).  
 ■ iv. In paragraph (2)(i) introductory text removing the phrase “before CY 2017” and adding in its place the phrase “before CY 2015”.

■ v. Redesignating paragraph (2)(ii) as paragraph (2)(iii).

■ vi. Adding a new paragraph (2)(ii).

■ B. Amend the definition of “EHR reporting period for a payment adjustment year” by:

■ i. In paragraph (1)(i) introductory text removing the phrase “before CY 2017” and adding in its place the phrase “before 2015”.

■ ii. Redesignating paragraph (1)(ii) as paragraph (1)(iii).

■ iii. Adding a new paragraph (1)(ii).

■ iv. In paragraph (2)(i) introductory text removing the phrase “before CY 2017” and adding in its place the phrase “before CY 2015”.

■ v. Redesignating paragraph (2)(ii) as paragraph (2)(iii).

■ vi. Adding a new paragraph (2)(ii).

■ vii. In paragraph (3)(i) introductory text removing the phrase “before CY 2017” and adding in its place the phrase “before CY 2015”.

■ viii. Redesignating paragraph (3)(ii) as paragraph (3)(iii).

■ ix. Adding a new paragraph (3)(ii).

■ C. Amend the definition of “Meaningful EHR user” by:

■ i. In paragraph (1), by removing the reference “§ 495.8” and adding in its place the reference “§§ 495.40”.

■ ii. In paragraph (1), by removing the reference “§ 495.6 or 495.7” and adding in its place the reference “§§ 495.20, 495.22, and 495.24”.

The additions read as follows:

**§ 495.4 Definitions.**

\* \* \* \* \*

*EHR reporting period.* \* \* \*

(1) \* \* \*

(ii) The following are applicable for 2015 and 2016:

(A) For the CY 2015 payment year, any continuous 90-day period within CY 2015.

(B) For the CY 2016 payment year:

(1) For the EP first demonstrating he or she is a meaningful EHR user, any continuous 90-day period within CY 2016.

(2) For the EP who has successfully demonstrated he or she is a meaningful EHR user in any prior year, the CY 2016.

\* \* \* \* \*

(2) \* \* \*

(ii) The following are applicable for 2015 and 2016:

(A) For the FY 2015 payment year, any continuous 90-day period within the period beginning October 1, 2014 and ending December 31, 2015.

(B) For the FY 2016 payment year for the eligible hospital or CAH—

(1) First demonstrating it is a meaningful EHR user, any continuous 90-day period within CY 2016; or

(2) That has successfully demonstrated it is a meaningful EHR user in any prior year, the CY 2016.

\* \* \* \* \*

*EHR reporting period for a payment adjustment year* \* \* \*

(1) \* \* \*

(ii) The following are applicable for 2015 and 2016:

(A) For an EHR reporting period in 2015:

(1) Except as specified under paragraph (1)(ii)(A)(2) of this definition, any continuous 90-day period within the calendar year that is 2 years before the payment adjustment year.

(2) If in the calendar year that is 2 years before the payment adjustment year and in all prior calendar years, the EP has not successfully demonstrated he or she is a meaningful EHR user, then any continuous 90-day period within the calendar year that is 1 year before the payment adjustment year. The EP must successfully register for and attest to meaningful use by February 29, 2016.

(B) For an EHR reporting period in 2016:

(1) Except as specified in paragraphs (1)(ii)(B)(2) and (3) of this definition, the calendar year that is 2 years before the payment adjustment year.

(2) If an EP is demonstrating he or she is a meaningful EHR user for the first time in the calendar year that is 2 years



before the payment adjustment year, then any continuous 90-day period within such (2 years prior) calendar year.

(3) If in the calendar year that is 2 years before the payment adjustment year and in all prior calendar years, the EP has not successfully demonstrated he or she is a meaningful EHR user, then any continuous 90-day period that both begins in the calendar year 1 year before the payment adjustment year and ends at least 3 months before the end of such prior year. The EP must successfully register for and attest to meaningful use by October 1, 2016.

\* \* \* \* \*

(2) \* \* \*

(ii) The following are applicable for 2015 and 2016:

(A) For an EHR reporting period in 2015:

(1) Except as specified in paragraph (2)(ii)(A)(2) of this definition, any continuous 90-day period within the period beginning on October 1, 2014 and ending on the last day of the calendar year that is 2 years before the payment adjustment year.

(2) If in the calendar year that is 2 years before the payment adjustment year and in all prior years, the eligible hospital has not successfully demonstrated it is a meaningful EHR user, then any continuous 90-day period within the period beginning on October 1, 2014 and ending on the last day of the calendar year that is 1 year prior to the payment adjustment year. The eligible hospital must successfully register for and attest to meaningful use by February 29, 2016.

(B) For an EHR reporting period in 2016:

(1) Except as specified in paragraphs (2)(ii)(B)(2) and (3) of this definition, the calendar year that is 2 years before the payment adjustment year.

(2) If an eligible hospital is demonstrating that it is a meaningful EHR user for the first time in the calendar year that is 2 years before the payment adjustment year, then any continuous 90-day period within such (2 years prior) calendar year.

(3) If in the calendar year that is 2 years before the payment adjustment year and in all prior years, the eligible hospital has not successfully demonstrated it is a meaningful EHR user, then any continuous 90-day period that both begins in the calendar year that is 1 year before the payment adjustment year and ends at least 3 months before the end of such prior calendar year. The eligible hospital must successfully register for and attest to meaningful use by October 1, 2016.

\* \* \* \* \*

(3) \* \* \*

(ii) The following are applicable for 2015 and 2016:

(A) The EHR reporting period for the FY 2015 payment adjustment year is any continuous 90-day period within the period beginning on October 1, 2014 and ending on December 31, 2015. The CAH must successfully register for and attest to meaningful use by February 29, 2016.

(B) For an EHR reporting period in 2016:

(1) Except as provided in paragraph (3)(ii)(B)(2) of this definition, the CY 2016 is the EHR reporting period for the FY 2016 payment adjustment year.

(2) If the CAH is demonstrating it is a meaningful EHR user for the first time, the EHR reporting period for the FY 2016 payment adjustment year is any continuous 90-day period within CY 2016.

\* \* \* \* \*

#### § 495.6 [Redesignated as § 495.20]

■ 3. Redesignate § 495.6 as § 495.20.

■ 4. Newly redesignated § 495.20 is amended by revising the section heading and adding new introductory text to read as follows.

#### § 495.20 Meaningful use objectives and measures for EPs, eligible hospitals, and CAHs before 2015.

The following criteria are applicable before 2015:

\* \* \* \* \*

■ 5. Add § 495.22 to read as follows:

#### § 495.22 Meaningful use objectives and measures for EPs, eligible hospitals, and CAHs for 2015 through 2017.

(a) *General rules.* (1) The criteria specified in this section are applicable for all EPs, eligible hospitals, and CAHs for 2015 through 2017.

(2) For 2017 only, EPs, eligible hospitals, and CAHs have the option to use the criteria specified for 2018 (as outlined at § 495.24) instead of the criteria specified in this section.

(b) *Criteria for EPs for 2015 through 2017—(1) General rule regarding criteria for meaningful use for 2015 through 2017 for EPs.* Except as specified in paragraph (b)(2) of this section, EPs must meet all objectives and associated measures of the meaningful use criteria specified under paragraph (e) of this section to meet the definition of a meaningful EHR user.

(2) *Exclusion for nonapplicable objectives.* (i) An EP may exclude a particular objective contained in paragraph (e) of this section, if the EP meets all of the following requirements:

(A) Must ensure that the objective in paragraph (e) of this section includes an

option for the EP to attest that the objective is not applicable.

(B) Meets the criteria in the applicable objective that would permit the attestation.

(C) Attests.

(ii) An exclusion will reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply in paragraph (e) of this section.

(c) *Criteria for eligible hospitals and CAHs for 2015 through 2017—(1) General rule regarding criteria for meaningful use for 2015 through 2017 for eligible hospitals and CAHs.* Except as specified in paragraph (c)(2) of this section, eligible hospitals and CAHs must meet all objectives and associated measures of the meaningful use criteria specified under paragraph (e) of this section to meet the definition of a meaningful EHR user.

(2) *Exclusion for nonapplicable objectives.* (i) An eligible hospital or CAH may exclude a particular objective contained in paragraph (e) of this section, if the eligible hospital or CAH meets all of the following requirements:

(A) Must ensure that the objective in paragraph (e) of this section includes an option for the eligible hospital or CAH to attest that the objective is not applicable.

(B) Meets the criteria in the applicable objective that would permit the attestation.

(C) Attests.

(ii) An exclusion will reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply in paragraph (e) of this section.

(d) *Many of the objectives and associated measures in paragraph (e) of this section rely on measures that count unique patients or actions.* (1) If a measure (or associated objective) in paragraph (e) of this section references paragraph (d) of this section, then the measure may be calculated by reviewing only the actions for patients whose records are maintained using certified EHR technology. A patient's record is maintained using certified EHR technology if sufficient data was entered in the certified EHR technology to allow the record to be saved, and not rejected due to incomplete data.

(2) If the objective and associated measure does not reference this paragraph (d) of this section, then the measure must be calculated by reviewing all patient records, not just those maintained using certified EHR technology.

(e) *Meaningful use objectives and measures for 2015 through 2017—(1) Protect patient health information—(i)*

*Objective.* Protect electronic protected health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

(ii) *Measures—(A) EP measure.* Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI created or maintained in Certified EHR Technology in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the EP's risk management process.

(B) *Eligible hospital or CAH measure.* Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI created or maintained in Certified EHR Technology in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the eligible hospital's or CAH's risk management process.

(2) *Clinical decision support—(i) Objective.* Use clinical decision support to improve performance on high-priority health conditions.

(ii) *EP measures—(A) Measure.* In order for EPs to meet the objective they must satisfy both of the following measures:

(1) Implement five clinical decision support interventions related to four or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. Absent four clinical quality measures related to an EP's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions.

(2) Enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

(B) *Exclusion in accordance with paragraph (b)(2) of this section.* An EP who writes fewer than 100 medication orders during the EHR reporting period may be excluded from the measure under paragraph (e)(2)(i)(A)(2) of this section.

(C) *Alternate exclusions and specifications for an EHR reporting period in 2015—(1) Alternate exclusion.* An EP previously scheduled to be in Stage 1 in 2015 may meet an alternate measure specified in paragraph

(e)(2)(ii)(C)(2) in place of the measure outlined under paragraph (e)(2)(ii)(A)(1) of this section.

(2) *Alternate objective and measure—(i) Alternate objective.* Implement one clinical decision support rule relevant to specialty or high clinical priority along with the ability to track compliance with that rule.

(ii) *Alternate measure.* Implement one clinical decision support rule.

(iii) *Eligible hospital and CAH measures—(A) Measure.* In order for eligible hospitals and CAHs to meet the objective they must satisfy both of the following measures:

(1) Implement five clinical decision support interventions related to four or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. Absent four clinical quality measures related to an eligible hospital or CAH's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions.

(2) Enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

(B) *Alternate specifications for an EHR reporting period in 2015—(1) Alternate objective and measure.* An eligible hospital or CAH previously scheduled to be in Stage 1 in 2015 may meet an alternate measure described in paragraph (e)(2)(iii)(B)(2) of this section in place of the measure described in paragraph (e)(2)(iii)(A)(1) of this section.

(i) *Objective.* Implement one clinical decision support rule related to a high priority hospital condition along with the ability to track compliance with that rule.

(ii) *Measure.* Implement one clinical decision support rule.

(3) *Computerized provider order entry—(i) Objective.* Use computerized provider order entry for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per State, local, and professional guidelines.

(ii) *EP measures—(A) Measures.* An EP must meet the following 3 measures, subject to paragraph (d) of this section:

(1) More than 60 percent of medication orders created by the EP during the EHR reporting period are recorded using computerized provider order entry.

(2) More than 30 percent of laboratory orders created by the EP during the EHR reporting period are recorded using computerized provider order entry.

(3) More than 30 percent of radiology orders created by the EP during the EHR

reporting period are recorded using computerized provider order entry.

(B) *Exclusion in accordance with paragraph (b)(2) of this section.* (1) For the measure specified in paragraph (e)(3)(ii)(A)(1) of this section, any EP who writes fewer than 100 medication orders during the EHR reporting period.

(2) For the measure specified in paragraph (e)(3)(ii)(A)(2) of this section, any EP who writes fewer than 100 laboratory orders during the EHR reporting period.

(3) For the measure specified in paragraph (e)(3)(ii)(A)(3) of this section, any EP who writes fewer than 100 radiology orders during the EHR reporting period.

(C) *Alternate exclusions and specifications for an EHR reporting period in 2015—(1)* An EP previously scheduled to be in Stage 1 in 2015 may meet an alternate measure (e)(3)(ii)(C)(2) in place of the measure outlined under paragraph (e)(3)(ii)(A)(1) of this section, and may exclude the measures outlined under paragraphs (e)(3)(ii)(A)(2) and (3) of this section.

(2) Subject to paragraph (d) of this section—

(i) More than 30 percent of all unique patients with at least one medication in their medication list seen by the EP during the EHR reporting period have at least one medication order entered using CPOE; or

(ii) More than 30 percent of medication orders created by the EP during the EHR reporting period are recorded using computerized provider order entry.

(3) *Alternate exclusions.* An EP previously scheduled to be in Stage 1 in 2015 may exclude the measure—

(i) Specified in paragraph (e)(3)(ii)(A)(2) of this section for an EHR reporting period in 2015.

(ii) Specified in paragraph (e)(3)(ii)(A)(3) of this section for an EHR reporting period in 2015.

(iii) *Eligible hospital and CAH measures—(A)* An eligible hospital or CAH must meet the following 3 measures, subject to paragraph (d) of this section:

(1) More than 60 percent of medication orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.

(2) More than 30 percent of laboratory orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.

(3) More than 30 percent of radiology orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.

(B) *Alternate exclusions and specifications for an EHR reporting period in 2015.* (1) An eligible hospital or CAH previously scheduled to be in Stage 1 in 2015 may—

(i) Meet an alternate measure specified in paragraph (e)(3)(iii)(B)(2) of this section in place of the measure outlined under paragraph (e)(3)(iii)(A)(1) of this section; and

(ii) May exclude the measures outlined under paragraphs (e)(3)(iii)(A)(2) and (e)(3)(iii)(A)(3) of this section.

(2) *Alternate measure 1.* Subject to paragraph (d) of this section,

(i) More than 30 percent of all unique patients with at least one medication in their medication list admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one medication order entered using CPOE; or

(ii) More than 30 percent of medication orders created by the authorized providers of the eligible hospital or CAH for patients admitted to their inpatient or emergency departments (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.

(3) *Alternate exclusions.* An eligible hospital or CAH previously scheduled to be in Stage 1 in 2015 may exclude the measure specified—

(i) In paragraph (e)(3)(iii)(A)(2) of this section for an EHR reporting period in 2015; or

(ii) In paragraph (e)(3)(iii)(A)(3) of this section for an EHR reporting period in 2015.

(4) *Electronic prescribing—(i) Objective.* For EPs, generate and transmit permissible prescriptions electronically (eRx); and, for eligible hospitals and CAHs, generate and transmit permissible discharge prescriptions electronically (eRx).

(ii) *EP measure—(A) Measure.* Subject to paragraph (d) of this section, more than 50 percent of all permissible prescriptions, or all prescriptions, written by the EP are queried for a drug formulary and transmitted electronically using Certified EHR Technology.

(B) *Exclusion in accordance with paragraph (b)(2) of this section.* Any EP who—

(1) Writes fewer than 100 permissible prescriptions during the EHR reporting period; or

(2) Does not have a pharmacy within his or her organization and there are no pharmacies that accept electronic prescriptions within 10 miles of the EP's practice location at the start of his or her EHR reporting period.

(C) *Alternate exclusions and specifications for an EHR reporting period in 2015.* An EP previously scheduled to be in Stage 1 in 2015 may meet an alternate measure under paragraph (e)(4)(ii)(C)(2) of this section in place of the measure outlined under paragraph (e)(4)(ii)(A) of this section.

(1) *Alternate measure.* Subject to paragraph (d) of this section, more than 40 percent of all permissible prescriptions written by the EP are transmitted electronically using Certified EHR Technology.

(2) *Alternate exclusion.* There are no alternate exclusions for this measure

(iii) *Eligible hospital and CAH measure—(A) Measure.* Subject to paragraph (d) of this section, more than 10 percent of hospital discharge medication orders for permissible prescriptions (for new, changed, and refilled prescriptions) are queried for a drug formulary and transmitted electronically using Certified EHR Technology.

(B) *Exclusion in accordance with paragraph (c)(2) of this section.* Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions and is not located within 10 miles of any pharmacy that accepts electronic prescriptions at the start of their EHR reporting period.

(C) *Alternate exclusions and specifications for an EHR reporting period in 2015.* An eligible hospital or CAH previously scheduled to be in—

(1) Stage 1 in 2015 may exclude the measure specified in paragraph (e)(4)(iii)(A) of this section for an EHR reporting period in 2015; or

(2) Stage 2 in 2015 may exclude the measure specified in paragraph (e)(4)(iii)(A) of this section for an EHR reporting period in 2015 if they did not previously intend to select the Stage 2 Electronic Prescribing Menu Objective for an EHR reporting period in 2015.

(5) *Summary of care—(i) Objective.* The EP, eligible hospital or CAH who transitions a patient to another setting of care or provider of care or refers a patient to another provider of care provides a summary care record for each transition of care or referral.

(ii) *EP measure—(A) Measure.* Subject to paragraph (d) of this section, the EP who transitions or refers his or her patient to another setting of care or provider of care must do the following:

(1) Use CEHRT to create a summary of care record.

(2) Electronically transmit such summary to a receiving provider for more than 10 percent of transitions of care and referrals.

(B) *Exclusion in accordance with paragraph (b)(2) of this section.* Any EP who transfers a patient to another setting or refers a patient to another provider less than 100 times during the EHR reporting period.

(C) *Alternate exclusions and specifications for an EHR reporting period in 2015.* An EP previously scheduled to be in Stage 1 in 2015 may exclude the measure specified in paragraph (e)(5)(ii)(A) of this section for an EHR reporting period in 2015.

(iii) *Eligible hospital and CAH measure—(A) Measure.* Subject to paragraph (d) of this section, the eligible hospital or CAH that transitions or refers its patient to another setting of care or provider of care must do the following:

(1) Use CEHRT to create a summary of care record.

(2) Electronically transmit such summary to a receiving provider for more than 10 percent of transitions of care and referrals.

(B) *Alternate exclusions and specifications for an EHR reporting period in 2015.* An eligible hospital or CAH previously scheduled to be in Stage 1 in 2015 may exclude the measure specified in paragraph (e)(5)(iii)(A) of this section for an EHR reporting period in 2015.

(6) *Patient specific education—(i) Objective.* Use clinically relevant information from Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient.

(ii) *EP measure—(A) Measure.* Patient-specific education resources identified by Certified EHR Technology are provided to patients for more than 10 percent of all unique patients with office visits seen by the EP during the EHR reporting period.

(B) *Exclusion in accordance with paragraph (b)(2) of this section.* Any EP who has no office visits during the EHR reporting period.

(C) *Alternate exclusions and specifications for an EHR reporting period in 2015.* An EP previously scheduled to be in Stage 1 in 2015 may exclude the measure specified in paragraph (e)(6)(ii)(A) of this section for an EHR reporting period in 2015 if the EP did not previously intend to select the Stage 1 Patient-Specific Education Resources Menu Objective for an EHR reporting period in 2015.

(iii) *Eligible hospital and CAH measure*—(A) *Measure*. More than 10 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) are provided patient-specific education resources identified by Certified EHR Technology.

(B) *Alternate exclusions and specifications for an EHR reporting period in 2015*. An eligible hospital or CAH previously scheduled to be in Stage 1 in 2015 may exclude the measure specified in paragraph (e)(6)(iii)(A) of this section for an EHR reporting period in 2015 if they did not previously intend to select the Stage 1 Patient-Specific Education Resources Menu Objective for an EHR reporting period in 2015.

(7) *Medication reconciliation*—(i) *Objective*. The EP, eligible hospital or CAH that receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.

(ii) *EP measure*—(A) *Measure*. Subject to paragraph (d) of this section, the EP performs medication reconciliation for more than 50 percent of transitions of care in which the patient is transitioned into the care of the EP.

(B) *Exclusion in accordance with paragraph (b)(2) of this section*. Any EP who was not the recipient of any transitions of care during the EHR reporting period.

(C) *Alternate exclusions and specifications for an EHR reporting period in 2015*. An EP previously scheduled to be in Stage 1 in 2015 may exclude the measure specified in paragraph (e)(7)(ii)(A) of this section for an EHR reporting period in 2015 if they did not previously intend to select the Stage 1 Medication Reconciliation Menu Objective for an EHR reporting period in 2015.

(iii) *Eligible hospital or CAH measure*. An eligible hospital or CAH must meet the following measure, subject to paragraph (d) of this section:

(A) *Measure*. Subject to paragraph (d) of this section, the eligible hospital or CAH performs medication reconciliation for more than 50 percent of transitions of care in which the patient is admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23).

(B) *Alternate exclusions and specifications for an EHR reporting period in 2015*. An eligible hospital or CAH previously scheduled to be in Stage 1 in 2015 may exclude the measure specified in paragraph (e)(7)(iii)(A) of this section for an EHR reporting period in 2015 if they did not

previously intend to select the Stage 1 Medication Reconciliation Menu Objective for an EHR reporting period in 2015.

(8) *Patient electronic access*—(i) *EP objective*. Provide patients the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP.

(A) *EP measures*. An EP must meet the following 2 measures:

(1) More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely (within 4 business days after the information is available to the EP) online access to their health information subject to the EP's discretion to withhold certain information.

(2) At least 1 patient seen by the EP during the EHR reporting period (or their authorized representatives) views, downloads, or transmits his or her health information to a third party.

(B) *Exclusion in accordance with paragraph (b)(2) of this section*. (1) Any EP who neither orders nor creates any of the information listed for inclusion as part of the measure in paragraph (e)(8)(ii)(A)(1) or (2) of this section, except for "Patient name" and "Provider's name and office contact information," is excluded from both paragraphs (e)(8)(ii)(A)(1) and (2) of this section.

(2) Any EP who conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the Federal Communications Commission on the first day of the EHR reporting period is excluded from paragraph (e)(8)(ii)(A)(2) of this section.

(C) *Alternate exclusions and specifications for an EHR reporting period in 2015*. An EP previously scheduled to be in Stage 1 in 2015 may exclude the measure specified in paragraph (e)(8)(ii)(A)(2) of this section for an EHR reporting period in 2015.

(ii) *Eligible hospital and CAH objective*. Provide patients the ability to view online, download, and transmit information within 36 hours of hospital discharge.

(A) *Eligible hospital and CAH measures*. An eligible hospital or CAH must meet the following 2 measures:

(1) More than 50 percent of all unique patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH have their information available online within 36 hours of discharge.

(2) At least 1 patient (or the patient's authorized representative) who is discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH views, downloads or transmits to a third party his or her information during the EHR reporting period.

(B) *Exclusion applicable under (c)(2) of this section*. Any eligible hospital or CAH that is located in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period is excluded from paragraph (e)(8)(iii)(A)(2) of this section.

(C) *Alternate exclusions and specifications for an EHR reporting period in 2015*. An eligible hospital or CAH previously scheduled to be in Stage 1 in 2015 may exclude the measure specified in paragraph (e)(8)(iii)(A)(2) of this section for an EHR reporting period in 2015.

(9) *Secure messaging*—(i) *EP objective*. Use secure electronic messaging to communicate with patients on relevant health information.

(ii) *EP measure*—(A) *Measure*. The capability for patients to send and receive a secure electronic message with the EP was fully enabled during the EHR reporting period.

(B) *Exclusion in accordance with paragraph (b)(2) of this section*. An EP may exclude from the measure if he or she—

(1) Has no office visits during the EHR reporting period; or

(2) Conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the Federal Communications Commission on the first day of the EP's EHR reporting period.

(C) *Alternate exclusions and specifications for an EHR reporting period in 2015*. An EP previously scheduled to be in Stage 1 in 2015 may exclude the measure specified in paragraph (e)(9)(ii)(A) of this section for an EHR reporting period in 2015.

(10) *Public Health and Clinical Data Registry reporting*—(i) *EP Public Health and Clinical Data Registry reporting*—(A) *Objective*. The EP is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.

(B) *Measures*. In order to meet the objective under paragraph (e)(10)(i)(A) of this section, an EP must choose from measures 1 through 5 (as specified in paragraphs (e)(10)(i)(B)(1) through (e)(10)(i)(B)(5) of this section) and must successfully attest to any combination of two measures. These measures may be met by any combination, including meeting measures specified in paragraph (e)(10)(i)(B)(4) or (5) of this section multiple times in accordance with applicable law and practice.

(1) *Immunization registry reporting*. The EP is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).

(2) *Syndromic surveillance reporting*. The EP is in active engagement with a public health agency to submit syndromic surveillance data from a non-urgent care ambulatory setting.

(3) *Case reporting*. The EP is in active engagement with a public health agency to submit case reporting of reportable conditions.

(4) *Public health registry reporting*. The EP is in active engagement with a public health agency to submit data to public health registries.

(5) *Clinical data registry reporting*. The EP is in active engagement to submit data to a clinical data registry.

(C) *Exclusions in accordance with paragraph (b)(2) of this section*. (1) Any EP meeting one or more of the following criteria may be excluded from the immunization registry reporting measure in paragraph (e)(10)(i)(B)(1) of this section if the EP:

(i) Does not administer any immunizations to any of the populations for which data is collected by his or her jurisdiction's immunization registry or immunization information system during the EHR reporting period.

(ii) Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of his or her EHR reporting period.

(iii) Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data from the EP at the start of the EHR reporting period.

(2) Any EP meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure described in paragraph (e)(10)(i)(B)(2) of the section if the EP:

(i) Does not treat or diagnose or directly treat any disease or condition associated with a syndromic surveillance system in his or her jurisdiction.

(ii) Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data from EPs in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from EPs at the start of the EHR reporting period.

(3) An EP meeting one or more of the following criteria may be excluded from the case reporting measure at (e)(10)(i)(B)(3) if the EP:

(i) Does not treat or diagnose any reportable diseases for which data is collected by his or her jurisdiction's reportable disease system during the EHR reporting period.

(ii) Operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of his or her EHR reporting period.

(iii) Operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data at the start of the EHR reporting period.

(4) Any EP meeting at least one of the following criteria may be excluded from the public health registry reporting measure specified in paragraph (e)(10)(i)(B)(4) of this section if the EP:

(i) Does not diagnose or directly treat any disease or condition associated with a public health registry in his or her jurisdiction during the EHR reporting period.

(ii) Operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no public health registry for which the EP is eligible has declared readiness to receive electronic registry transactions at the start of the EHR reporting period.

(5) Any EP meeting at least one of the following criteria may be excluded from the clinical data registry reporting measure specified in paragraph (e)(10)(i)(B)(5) of this section if the EP:

(i) Does not diagnose or directly treat any disease or condition associated with a clinical data registry in his or her jurisdiction during the EHR reporting period.

(ii) Operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no clinical data registry for which the EP is eligible has declared readiness to receive electronic registry transactions at the start of the EHR reporting period.

(D) *Alternate exclusions and specifications for an EHR reporting period in 2015*. An EP previously scheduled to be in Stage 1 in 2015 may choose from measures 1 through 5 (as specified in paragraphs (e)(10)(i)(B)(1) through (e)(10)(i)(B)(5) of this section) and must successfully attest to any one measure in accordance with applicable law and practice for an EHR reporting period in 2015.

(i) *Eligible hospital and CAH Public Health and Clinical Data Registry reporting objective—(A) Objective*. The eligible hospital or CAH is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.

(B) *Measures*. In order to meet the objective under paragraph (e)(10)(ii)(A) of this section, an eligible hospital or CAH must choose from measures 1 through 6 (as described in paragraphs (e)(10)(ii)(B)(1) through (e)(10)(ii)(B)(6) of this section) and must successfully attest to any combination of three measures. These measures may be met by any combination, including meeting the measures specified in paragraph (e)(10)(ii)(B)(4) or (5) of this section multiple times, in accordance with applicable law and practice:

(1) *Immunization registry reporting*. The eligible hospital or CAH is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).

(2) *Syndromic surveillance reporting*. The eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data from an emergency or urgent care department (POS 23).

(3) *Case reporting*. The eligible hospital or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions.

(4) *Public health registry reporting*. The eligible hospital or CAH is in active engagement with a public health agency

to submit data to public health registries.

(5) *Clinical data registry reporting.* The eligible hospital or CAH is in active engagement to submit data to a clinical data registry.

(6) *Electronic reportable laboratory result reporting.* The eligible hospital or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results.

(C) *Exclusions in accordance with paragraph (c)(2) of this section.* (1) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the immunization registry reporting measure specified in paragraph (e)(10)(ii)(B)(1) of this section if the eligible hospital or CAH:

(i) Does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the EHR reporting period.

(ii) Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data from the eligible hospital or CAH at the start of the EHR reporting period.

(2) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure specified in paragraph (e)(10)(ii)(B)(2) of this section if the eligible hospital or CAH:

(i) Does not have an emergency or urgent care department.

(ii) Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data from eligible hospitals or CAHs in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from eligible hospitals or CAHs at the start of the EHR reporting period.

(3) An eligible hospital or CAH meeting one or more of the following criteria may be excluded from the case reporting measure specified in paragraph (e)(10)(ii)(B)(3) of this section if the eligible hospital or CAH:

(i) Does not treat or diagnose any reportable diseases for which data is collected by its jurisdiction's reportable disease system during the EHR reporting period.

(ii) Operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data at the start of the EHR reporting period.

(4) Any eligible hospital or CAH meeting at least one of the following criteria may be excluded from the public health registry reporting measure specified in paragraph (e)(10)(ii)(B)(4) of this section if the eligible hospital or CAH:

(i) Does not diagnose or directly treat any disease or condition associated with a public health registry in their jurisdiction during the EHR reporting period.

(ii) Operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no public health registry for which the eligible hospital or CAH is eligible has declared readiness to receive electronic registry transactions at the start of the EHR reporting period.

(5) Any eligible hospital or CAH meeting at least one of the following criteria may be excluded from the clinical data registry reporting measure specified in paragraph (e)(10)(ii)(B)(5) of this section if the eligible hospital or CAH:

(i) Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period.

(ii) Operates in a jurisdiction where no clinical data registry for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no clinical data registry for which the eligible hospital or CAH is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period.

(6) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the electronic reportable laboratory result

reporting measure specified in paragraph (d)(10)(ii)(B)(6) of this section if the eligible hospital or CAH:

(i) Does not perform or order laboratory tests that are reportable in the eligible hospital's or CAH's jurisdiction during the EHR reporting period.

(ii) Operates in a jurisdiction for which no public health agency that is capable of accepting the specific ELR standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no public health agency has declared readiness to receive electronic reportable laboratory results from eligible hospitals or CAHs at the start of the EHR reporting period.

(D) *Alternate exclusions and specifications for an EHR reporting period in 2015.* An eligible hospital or CAH previously scheduled to be in Stage 1 in 2015 may choose from measures 1 through 6 (as specified in paragraphs (e)(10)(ii)(B)(1) through (e)(10)(ii)(B)(6) of this section) and must successfully attest to any 2 measures. These measures may be met by any combination, including meeting the measures specified in paragraph (e)(10)(ii)(B)(4) or (5) of this section multiple times, in accordance with applicable law and practice.

#### § 495.7 [Redesignated as § 495.24]

■ 6. Redesignate § 495.7 as § 495.24.

#### § 495.8 [Redesignated as § 495.40]

■ 7. Redesignate § 495.8 as § 495.40.

■ 8. Newly redesignated § 495.40 is amended by:

■ A. In paragraph (a) introductory text by removing the cross-reference "under § 495.6 or § 495.7" and adding in its place the cross-reference "under § 495.20 or § 495.24".

■ B. In paragraph (a)(1)(i)(B) by removing the cross-reference "under § 495.6 or § 495.7" and adding in its place the cross-reference "under § 495.20 or § 495.24".

■ C. In paragraph (a)(1)(iii) by removing the cross-reference "in § 495.6 or § 495.7 and § 495.8" and adding in its place the cross-reference "in § 495.20 or § 495.24 and § 495.40".

■ D. Revising paragraph (a)(2)(i)(B).

■ E. In paragraph (a)(2)(i)(D) by removing the cross-reference "under § 495.6(a)(4) or (h)(3)" and adding in its place the cross-reference "in § 495.20(a)(4) or (h)(3)".

■ F. Redesignating paragraph (a)(2)(i)(E) as paragraph (a)(2)(i)(F).

■ G. Adding a new paragraph (a)(2)(i)(E).

■ H. Revising newly redesignated paragraph (a)(2)(i)(F).

- I. Adding paragraph (a)(2)(i)(G).
  - J. In paragraph (a)(2)(iv) by removing the cross-reference “in § 495.6 or § 495.7 and § 495.8” and adding in its place the cross-reference “in § 495.20 or § 495.24 and § 495.40”.
  - K. In paragraph (b)(1)(i)(B) by removing the cross-reference “under § 495.6 or § 495.7” and adding in its place the cross-reference “under § 495.20 or § 495.24”.
  - L. In paragraph (b)(1)(iii) by removing the cross-reference “in § 495.6 or § 495.7 and § 495.8” and adding in its place the cross-reference “in § 495.20 or § 495.24 and § 495.40”.
  - M. Revising paragraph (b)(2)(i)(B).
  - N. In paragraph (b)(2)(i)(D) by removing the cross-reference “under § 495.6(b)(4) or (i)(3)” and adding in its place the cross-reference “in § 495.20(b)(4) or (h)(3)”.
  - O. Redesignating paragraph (b)(2)(i)(E) as paragraph (b)(2)(i)(F).
  - P. Adding a new paragraph (b)(2)(i)(E).
  - Q. Revising newly redesignated paragraph (b)(2)(i)(F).
  - R. Adding paragraph (b)(2)(i)(G).
- The revisions and additions read as follows:

**§ 495.40 Demonstration of meaningful use criteria.**

(a) \* \* \*

- (2) \* \* \*
- (i) \* \* \*
- (B) For calendar years before 2015, satisfied the required objectives and associated measures under § 495.20 for the EP’s stage of meaningful use.
- \* \* \* \* \*
- (E) For CYs 2015 through 2017, satisfied the required objectives and associated measures under § 495.22(e) for meaningful use.
- (F) For CY 2017 only, an EP may satisfy either of the following objectives and measures for meaningful use:
  - (1) Objectives and measures specified in § 495.22(e).
  - (2) Objectives and measures specified in § 495.24(d).
- (G) For CY 2018 and subsequent years, satisfied the required objectives and associated measures under § 495.24(d) for meaningful use.
- \* \* \* \* \*
- (b) \* \* \*
- (2) \* \* \*
- (i) \* \* \*
- (B) For fiscal years before 2015, satisfied the required objectives and associated measures under § 495.20 for the eligible hospital or CAH’s stage of meaningful use.
- \* \* \* \* \*

(E) For CYs 2015 through 2017, satisfied the required objectives and

associated measures under § 495.22(e) for meaningful use.

(F) For CY 2017 only, an eligible hospital or CAH may satisfy either of the following objectives and measures for meaningful use:

(1) Objectives and measures specified at § 495.22(e); or

(2) Objectives and measures specified at § 495.24(d).

(G) For CY 2018 and subsequent years, satisfied the required objectives and associated measures under § 495.24(h) for meaningful use.

\* \* \* \* \*

**§ 495.10 [Redesignated as § 495.60]**

- 9. Redesignate § 495.10 as § 495.60.

Dated: April 2, 2015.

**Andrew M. Slavitt,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

Approved: April 8, 2015.

**Sylvia M. Burwell,**

*Secretary, Department of Health and Human Services.*

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