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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412 and 495

[CMS-3310-FC and CMS-3311-FC]

RINs 0938-AS26 and 0938-AS58

Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 through 2017

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rules with comment period.

SUMMARY: This final rule with comment period specifies the requirements that eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) must meet in order to qualify for Medicare and Medicaid electronic health record (EHR) incentive payments and avoid downward payment adjustments under the Medicare EHR Incentive Program. In addition, it changes the Medicare and Medicaid EHR Incentive Programs reporting period in 2015 to a 90-day period aligned with the calendar year. This final rule with comment period also removes reporting requirements on measures that have become redundant, duplicative, or topped out from the Medicare and Medicaid EHR Incentive Programs. In addition, this final rule with comment period establishes the requirements for Stage 3 of the program as optional in 2017 and required for all participants beginning in 2018. The final rule with comment period continues to encourage the electronic submission of clinical quality measure (CQM) data, establishes

requirements to transition the program to a single stage, and aligns reporting for providers in the Medicare and Medicaid EHR Incentive Programs.

DATES: Effective Date: These regulations are effective on [insert date 60 days after the date of publication in the **Federal Register**].

Comment Date: To be assured consideration, comments on sections II.B.1.b.(3).(iii), II.B.1.b.(4).(a), II.B.2.b, II.D.1.e, and II.G.2 of preamble to this final rule with comment period ; paragraphs (1)(ii)(C)(3), (1)(iii), (2)(ii)(C)(3) and 2(iii) of the definition of an EHR reporting period at §495.4; and paragraphs (2)(ii)(C)(2) and (2)(iii) of the definition of an EHR reporting period for a payment adjustment year at §495.4 must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on [insert date 60 days after the date of publication in the **Federal Register**].

ADDRESSES: In commenting, please refer to file code CMS-3310 & 3311-FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. Electronically. You may (and we encourage you to) submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the “submit a comment” tab.

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-3310 &3311-FC,

P.O. Box 8013,
Baltimore, MD 21244-1850.

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

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

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-3310 &3311-FC,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

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, S.W.,
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, please call the telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments 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, we refer readers to the beginning of the "**SUPPLEMENTARY INFORMATION**" section.

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SUPPLEMENTARY INFORMATION:**Electronic Access**

Inspection of Public Comments: All public 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 public 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.

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Acronyms

API	Application Programming Interface
ARRA	American Recovery and Reinvestment Act of 2009
ACO	Accountable Care Organization
AIU	Adopt, Implement, Upgrade (certified EHR Technology)
CAH	Critical Access Hospital
CCD	Continuity of Care Document
CCDA	C-CDA, Consolidated Clinical Document Architecture
CCDS	Common Clinical Data Set
CCN	CMS Certification Number
CDC	Centers for Disease Control& Prevention

CDR	Clinical Data Registry
CDS	Clinical Decision Support
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 & Medicaid Services
CPCI	Comprehensive Primary Care Initiative
CPOE	Computerized Physician Order Entry
CQM	Clinical Quality Measure
CY	Calendar Year
DEC	Data Element Catalog
eCQM	Electronic Clinical Quality Measure
EHR	Electronic Health Record
ELR	Electronic Reportable Lab
EP	Eligible Professional
ePHI	Electronic Protected Health Information
eRx	Electronic Prescribing
FACA	Federal Advisory Committee Act
FAQ	Frequently asked question
FCC	Federal Communications Commission
FFP	Federal Financial Participation

FFS	Fee-for-Service
FQHC	Federally Qualified Health Center
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
HIPAA	Health Insurance Portability and Accountability Act of 1996
HITECH	Health Information Technology for Economic and Clinical Health Act
HMO	Health Maintenance Organization
ICR	Information Collection Requirement
IFC	Interim Final Rule with Comment Period
IPPS	Inpatient Prospective Payment System
IQR	Inpatient Quality Reporting
IT	Information Technology
MA	Medicare Advantage
MACRA	Medicare Access and CHIP Reauthorization Act of 2015
MIPS	Merit-Based Incentive Payment System
MITA	Medicaid Information Technology Architecture
NPI	National Provider Identifier
NPES	National Plan and Provider Enumeration System
NwHIN	Nationwide Health Information Network

NQF	National Quality Forum
ONC	Office of the National Coordinator for Health Information Technology
OTC	Over the counter
PFS	Physician Fee Schedule
PHA	Public Health Agency
PHSA	Public Health Service Act
POS	Place of Service
PQRS	Physician Quality Reporting System
PHI	Protected Health Information
QA	Quality Assurance
QRDA	Quality Reporting Data Architecture
SMHP	State Medicaid Health Information Technology Plan
SRA	Security Risk Assessment
ToC	Transitions of Care
VDT	View, Download, and Transmit

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I. Executive Summary and Background

A. Executive Summary

1. Purpose of Regulatory Action

a. Need for Regulatory Action

This final rule with comment period addresses the proposals made in two separate CMS notices of proposed rulemaking (NPRM); the March 30, 2015 "Medicare and Medicaid Programs; Electronic Health Record Incentive Program Stage 3" NPRM (80 FR 16731 through 16804) (hereafter referred to as the "Stage 3 proposed rule") and the April 9, 2015 "Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Modifications to Meaningful Use in 2015 through 2017" NPRM (80 FR 20346 through 20399) (hereafter referred to as the "EHR Incentive Programs in 2015 through 2017 proposed rule"). However, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10) was enacted on April 16, 2015, after publication of the proposed EHR rule. Section 101(b)(1)(A) of MACRA amended section 1848(a)(7)(A) of the Act to sunset the meaningful use payment adjustment for EPs at the end of CY 2018. Section 101(c) of MACRA added section 1848(q) of the Act requiring the establishment of a Merit-Based Incentive Payment System (MIPS), which would incorporate meaningful use. In light of the passage of MACRA, this final rule with comment period also allows for a 60-day public comment period on certain provisions noted in the "Supplementary Information" section above in part to support the transition to MIPS. The comments received during the comment period may be considered as we prepare for future rulemaking to implement MIPS, which in general is expected to be more broadly focused on quality and care delivery.

The enactment of MACRA has altered the EHR Incentive Programs such that the existing Medicare payment adjustment for EPs under 1848(a)(7)(A) of the Act will end in CY 2018 and be incorporated under MIPS beginning in CY 2019. It is our intent to issue a notice of proposed rulemaking for MIPS by mid-2016. This final rule with comment period synchronizes reporting under the EHR Incentive Programs to end the separate stages of meaningful use, which we believe will prepare Medicare EPs for the transition to MIPS.

In the Stage 3 and the EHR Incentive Program in 2015 through 2017 proposed rules, and in this final rule with comment period, we have responded to public input and comments by providing for flexibility that may assist EPs in preparing for the transition to MIPS. This final rule with comment period establishes a number of key final policies in response to these concerns: a simplification of program requirements, an introduction of flexibility within certain objectives, an option to participate in Stage 3 in 2017 but not required until 2018, and an overall focus on interoperability. We have focused on leveraging health IT to support providers and reduce burdensome requirements within an evolving environment. In light of public interest and in recognition that this is an ongoing and continuous process, we are providing a 60-day public comment period on the final policies for the Stage 3 objectives and measures and the EHR reporting period for Stage 3 in 2017 and subsequent years. Public comments received may be considered as we plan for the incorporation of meaningful use into MIPS, and any policies developed would be addressed in future rulemaking.

The Stage 3 proposed rule (80 FR 16733 through 16735) described the final stage of the program, which would incorporate portions of the prior stages into Stage 3 requirements, while altering other requirements in response to CMS's progress toward policy goals, the widespread

adoption of technology and clinical standards among providers, and high performance on certain objectives among providers. These proposed changes included simplifying and reducing the number of measures, and focusing the Medicare and Medicaid EHR Incentive Programs on the advanced use of EHR technology. In addition, the proposals set a path for providers to move toward aligned reporting on a single set of requirements, with the goal of moving all participants in the Medicare and Medicaid EHR Incentive Programs to a single set of requirements in 2018. The incorporation of the requirements into one stage for all providers is intended to respond to stakeholder concerns by creating simplicity in the program by focusing on the success of certain measures that are part of the meaningful use program to date, and setting a long-term, sustainable foundation based on key advanced use objectives for the Medicare and Medicaid EHR Incentive Programs.

In the EHR Incentive Programs for 2015 through 2017 proposed rule (80 FR 20346 through 20399), we proposed to make similar modifications to Stage 1 and Stage 2 of the Medicare and Medicaid EHR Incentive Programs in order to reduce reporting burden, to eliminate redundant and duplicative reporting, and to better align the objectives and measures of meaningful use with the proposed Stage 3 requirements, which would be optional in 2017 and required beginning in 2018.

In this final rule with comment period, we are finalizing the requirements for the EHR Incentive Programs for 2015 through 2017 and for 2018 and subsequent years. We note that our intent in finalizing the Stage 3 proposed rule along with the changes for 2015 through 2017 while continuing to solicit comments on certain provisions is multifold; we are creating consistency in the policies for the current program in 2015 through 2017 and for 2018 and subsequent years;

and we have established a clear vision of how current participation will assist in meeting our long-term delivery system reform goals. We believe this sustained consistency in policy will support the planning and development for MIPS and the future use of EHR across a multitude of healthcare providers.

We are also finalizing changes to the EHR reporting period, timelines, and structure of the Medicare and Medicaid EHR Incentive Programs for 2015 through 2017 to better align EHR reporting periods for providers; support a flexible, clear framework to reduce provider burden; and support future sustainability of the Medicare and Medicaid EHR Incentive Programs. Overall, the requirements of the program finalized in this rule for 2015 through 2017 seek to support near-term goals for delivery system reform and lay a foundation for our broader efforts to pursue interoperability and quality initiatives focused on improving patient outcomes.

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 EPs, eligible hospitals, CAHs, and Medicare Advantage (MA) organizations to promote the adoption and meaningful use of 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 (FY) 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 titled, "Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule" (75 FR 44316 through 44317).)

2. Summary of Major Provisions

a. Considerations in Defining Meaningful Use

The Stage 1 final rule established 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 their 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 Stage 1 of meaningful use, we refer readers to the Stage 1 final rule (75 FR 44313 through 44588).)

In the September 4, 2012 Stage 2 final rule (77 FR 53967 through 54162), we focused on the next goal: the exchange of essential health data among health care providers and patients to improve care coordination. We also finalized a set of clinical quality measures (CQMs) that all providers participating in any stage of the program are required to report to CMS beginning in 2014. (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 53967 through 54162.)

In the March 30, 2015 **Federal Register**, we published a proposed rule titled "Medicare and Medicaid Programs; Electronic Health Record Incentive Program Stage 3" (80 FR 16731 through 16804) hereafter referred to as the "Stage 3 proposed rule". In the April 15, 2015

Federal Register, we published a proposed rule titled "Medicare and Medicaid Programs; Electronic Health Record Incentive Program--Modifications to Meaningful Use in 2015 through 2017" (80 FR 20346 through 20399) hereafter referred to as the "EHR Incentive Programs in 2015 through 2017 proposed rule". In this final rule, we are finalizing both the Stage 3 proposed rule and the EHR Incentive Programs in 2015 through 2017 proposed rule to build on the groundwork established in Stage 1 and Stage 2 and continue our Stage 2 goal of increasing interoperable health data sharing among providers. In addition, this final rule also focuses on the advanced use of EHR technology to promote improved patient outcomes and health information exchange. We are also finalizing proposals to continue improving program efficiency, effectiveness, and flexibility by making changes to the Medicare and Medicaid EHR Incentive Programs that simplify reporting requirements and reduce program complexity.

One significant change we proposed in the Stage 3 proposed rule (80 FR 16734) included establishing a single set of objectives and measures (tailored to EPs or eligible hospitals/CAHs) to meet the definition of meaningful use for Stage 3 in 2017 and subsequent years. In the EHR Incentive Program in 2015 through 2017 proposed rule (80 FR 20351), we additionally proposed a transitional period in 2015 through 2017 that would help move providers along a participation continuum toward the long term goals proposed under the Stage 3 proposed rule. In this final rule, we are adopting this transition toward a new, streamlined set of requirements, including an optional year for any provider who chooses to attest to the objectives and measures for Stage 3 for an EHR reporting period in 2017. We are additionally finalizing the objectives and measures that will be required for all eligible providers — regardless of prior participation in the Medicare and Medicaid EHR Incentive Programs— for an EHR reporting period in 2018 and subsequent

years.

In the Stage 3 proposed rule (80 FR 16741), we outlined our proposed approach and method for measure selection that removed topped out, redundant, and duplicative measures from reporting requirements and focused on only those measures that represent the most advanced use of the functions and standards supported by CEHRT. In the EHR Incentive Program in 2015 through 2017 proposed rule (80 FR 20352), we proposed adopting this approach as applicable to the current objectives and measures in use for Stage 1 and Stage 2 of the program and aligning the current objectives and measures with those identified for long-term use in the Stage 3 proposed rule. In this final rule, we adopt the approach for the Stage 3 objectives and measures, as well as the similar approach for the objectives and measures of the EHR Incentive Program in 2015 through 2017.

b. Meaningful Use Requirements, Objectives, and Measures for 2015 through 2017

(1) EHR Reporting Period

In this final rule, we adopt changes to the EHR reporting period for the Medicare and Medicaid EHR Incentive Programs in 2015, 2016, and 2017 and finalize the changes that align reporting periods to the calendar year. We also finalize the proposal to adopt a 90-day reporting period for all providers in 2015 and new participants in 2016, and based on public comment we are finalizing a 90-day reporting period for new participants in 2017.

(2) Objectives and Measures

In the Stage 3 proposed rule (80 FR 16741), we outlined our method and approach for identifying the objectives and measures retained for Stage 3 of meaningful use beginning in 2017. We also identified those objectives and measures that are now redundant, duplicative, or

topped out, and therefore will no longer be required for the successful demonstration of meaningful use for Stage 3. For further discussion of this approach, we refer readers to section II.B.1.b.(4).(a) of this final rule with comment period.

In this final rule, we are adopting the proposed approach from the EHR Incentive Program in 2015 through 2017 proposed rule to use a similar method to identify the objectives and measures from Stages 1 and 2 of meaningful use that we believe should no longer be required for a provider to demonstrate meaningful use in 2015 through 2017 because these measures have been identified as redundant, duplicative, or topped out. We are also finalizing changes to remove the menu and core structure of Stage 1 and Stage 2 and reduce the overall number of objectives to which a provider must attest. In addition, we are finalizing changes to individual objectives and measures for Stage 2 of meaningful use as follows:

- Changing the threshold for two measures requiring patient action (the second measure for the Stage 2 Objective for Patient Electronic Access and the measure for the Stage 2 Objective for Secure Electronic Messaging).
- Consolidating all public health reporting objectives into one objective with measure options similar to the structure of the Stage 3 Public Health Reporting Objective (80 FR 16762 through 16767).
- Changing the eligible hospital electronic prescribing objective from a menu objective to a required objective with an exclusion available for eligible hospitals and CAHs in 2015 and 2016.

We are additionally finalizing the proposal to maintain the existing definitions for the objectives and measures, including the numerator and denominator calculations, the proposal to

maintain certain measure specifications for 2015, and the proposal to allow exclusions for certain measures in 2015 and 2016 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 and 2016. For further discussion of this approach, we refer readers to section II.B.1.b.(4).(b).of this final rule.

c. Meaningful Use Requirements, Objectives, and Measures for Stage 3 in 2017 and Subsequent Years

(1) EHR Reporting Period

In this final rule, we are adopting changes to the EHR reporting period for 2017, 2018, and subsequent years based on the Stage 3 proposed rule (80 FR 16739) and public comments received. We are finalizing the proposal for full calendar year reporting for providers beginning in 2018 with a limited exception for Medicaid providers in their first year of demonstrating meaningful use. We are also finalizing an optional 90-day reporting period for providers demonstrating the Stage 3 requirements for an EHR reporting period in 2017. For further discussion, we refer readers to section II.B.1.b.(3)of this final rule.

(2) Objectives and Measures

The methodology outlined in the Stage 3 proposed rule at 80 FR 16741 for the selection of objectives and measures for the Medicare and Medicaid EHR Incentive Programs for Stage 3 in 2017 and subsequent years included the following:

- Review attestation data for Stages 1 and 2 of meaningful use;
- Conduct listening sessions and interviews with providers, EHR system developers, regional extension centers, and health care provider associations; and

- Review recommendations from government agencies and advisory committees focused on health care improvement, such as the Health Information Technology (HIT) Policy Committee, the National Quality Forum (NQF), and the Centers for Disease Control and Prevention(CDC).

The information we gathered from these sources focused on analyzing measure performance, implementing discrete EHR functionalities and standards, and examining objectives and measures presenting the best opportunity to improve patient outcomes and enhance provider support.

Based on this analysis and consideration of public comment received, we are finalizing a set of 8 objectives with associated measures designed to meet the following policy goals:

- Align with national health care quality improvement efforts;
- Promote interoperability and health information exchange; and
- Focus on the 3-part aim of reducing cost, improving access, and improving quality.

We intend for Stage 3 to be the final stage of the meaningful use framework, which leverages the structure identified in the Stage 1 and Stage 2 final rules, while simultaneously establishing a single set of objectives and measures designed to promote best practices and continued improvement in health outcomes in a sustainable manner. Measures in the Stage 1 and Stage 2 final rules that included paper-based workflows, chart abstraction, or other manual actions have been removed or transitioned to an electronic format utilizing EHR functionality for Stage 3. In addition, we are finalizing the removal of topped out measures, or measures that are no longer useful in gauging performance, because these less advanced measures are now achieving widespread adoption.

d. Certified EHR Technology Requirements for the EHR Incentive Programs

In the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20374), we proposed no changes to the individual certification requirements for the objectives and measures of meaningful use for an EHR reporting period in 2015 through 2017 using EHR technology certified to the 2014 Edition certification criteria. In the Stage 3 proposed rule (80 FR 16767), we proposed that providers use EHR technology certified to the 2015 Edition certification criteria for an EHR reporting period in 2018. In this rule, we are finalizing that providers may continue to use technology certified to the 2014 Edition until EHR technology certified to the 2015 Edition is required with an EHR reporting period beginning in 2018. In the Stage 3 proposed rule, we also noted our intent to allow providers to upgrade to technology certified to the 2015 Edition as soon as such technology is available if they determine that the EHR technology certified to the 2015 Edition would support and meet the requirements of the EHR Incentive Programs in 2015 through 2017. We are finalizing that providers may use EHR technology certified to the 2014 Edition for an EHR reporting period in 2015; EHR technology certified to either the 2014 Edition, the 2015 Edition, or a combination of the two in 2016 and 2017; and EHR technology certified to the 2015 Edition for an EHR reporting period in 2018 and subsequent years.

We are also finalizing a definition of CEHRT within 42 CFR 495.4 that includes the functions and standards outlined for the certification of health information technology to the 2014 and 2015 Edition certification criteria for use in the Medicare and Medicaid EHR Incentive Programs. For further discussion of the definition and use of CEHRT, we direct readers to section II.B.3 of this final rule.

e. Clinical Quality Measurement

EPs, eligible hospitals, and CAHs must report CQMs in order to meet the requirements of the Medicare and Medicaid EHR Incentive Programs. We are committed to continuing to promote the electronic capture, calculation, and reporting of key clinical data through the use of CEHRT. We are also focused on improving alignment of reporting requirements for CMS programs that leverage EHR technology for clinical quality reporting and quality measurement to streamline reporting mechanisms for providers and increase quality data integrity.

This final rule addresses quality reporting alignment on several fronts. Our long-term vision seeks to have hospitals, clinicians, and other health care providers report through a single, aligned mechanism for multiple CMS programs. In order to facilitate continuous quality improvement, we noted in the Stage 3 proposed rule our intent to implement changes to quality reporting requirements in conjunction with the quality reporting programs through the annual Medicare payment rules, such as the Physician Fee Schedule (PFS) and the Inpatient Prospective Payment Systems (IPPS) rules. In the Stage 3 proposed rule, we proposed to continue encouraging CQM data submission through electronic submission for Medicare participants in 2017 and to require electronic submission of CQMs where feasible beginning in 2018 for Medicare providers demonstrating meaningful use. (We further discuss Medicaid CQM submission in section II.F.3 of this final rule.)

We did not propose 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 77 FR 54049 through 54089). In the EHR Incentive Programs

in 2015 through 2017 proposed rule, for an EHR reporting period in 2015, and for providers demonstrating meaningful use for the first time in 2016 or 2017, we proposed 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.

We are finalizing these reporting periods for CQM reporting for 2015 and 2016. We are finalizing that for 2017, 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 final rule. In addition, we are finalizing that for an EHR reporting period in 2018, all providers are required to submit CQM data for the Medicare EHR Incentive Program using these established methods for electronic reporting. We refer readers to section II.C. of this final rule for further information on clinical quality measurement.

f. Demonstration of Meaningful Use

We are finalizing our proposal to continue our common method for meaningful use in both the Medicare and Medicaid EHR Incentive Programs of attestation as the method for demonstrating that an EP, eligible hospital, or CAH has met the requirements of the Medicare and Medicaid EHR Incentive Programs. We are additionally finalizing changes to the attestation deadlines to accommodate the 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 also finalizing

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 adopting the alternate attestation method proposed in the EHR Incentive Program in 2015 through 2017 proposed rule for certain Medicaid providers to demonstrate meaningful use in 2015 and subsequent years to avoid Medicare payment adjustments. For further discussion, we refer readers to section II.D of this final rule.

g. Payment Adjustments and Hardship Exceptions

The HITECH statute requires Medicare payment adjustments beginning in 2015. In this final rule, we are maintaining the payment adjustment policies for EPs, eligible hospitals, and CAHs as finalized in the Stage 2 final rule (77 FR 54093 through 54113 and 54115 through 54119), except for a change to the relationship between the EHR reporting period year, the payment adjustment year, and the attestation deadlines to avoid the payment adjustment. For the discussion of payment adjustments and hardship exceptions, we refer readers to section II.E of this final rule with comment period.

h. Modifications to the Medicaid EHR Incentive Program

Sections 1903(a)(3)(F) and 1903(t) of the Act provide the statutory basis for the Medicaid EHR Incentive Program. In this final rule with comment period, we finalize the proposed changes to EHR reporting periods that would begin in 2017; Medicaid EPs and eligible hospitals demonstrating meaningful use for the first time in the Medicaid EHR Incentive Program would be required to attest for an EHR reporting period of any continuous 90-day period in the calendar year for purposes of receiving an incentive, as well as avoiding the payment adjustment under the Medicare Program (80 FR 16779).

We will continue to allow states to set up a CQM submission process that Medicaid EPs and eligible hospitals may use to report on CQMs for 2017 and subsequent years. We are also finalizing amendments to state reporting on providers who are participating in the Medicaid EHR Incentive Program, as well as state reporting on implementation and oversight activities.

The provisions included in this final rule with comment period will apply for the Medicaid EHR Incentive Program, including the changes to the EHR reporting period in 2015 and 2016, and the objectives and measures required to demonstrate meaningful use in 2015 through 2017. We will continue to allow states flexibility under the Medicaid EHR Incentive Program for the public health reporting objective. Specifically, for meaningful use in 2015 through 2017 and for Stage 3, we will 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). We refer readers to section II.G of this final rule with comment period for further information on the Medicaid EHR Incentive Programs.

3. Summary of Costs and Benefits

Upon finalization, the provisions in this final rule with comment period are anticipated to have an annual effect on the economy of \$100 million or more, making it an economically significant rule under the Executive Order and a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the final rule with comment period.

Based on prior rulemaking, we expect spending under the EHR Incentive Programs for

transfer payments to Medicare and Medicaid providers between 2015 and 2017 to be \$14.2 billion; however, the policies in this final rule with comment period do not change estimates over the current period.

Our analysis of impacts for the policies in this final rule with comment period relate to the reduction in cost associated with provider reporting burden estimates for 2015 through 2017 as affected by the adopted changes to the current program. The estimates also relate to the transfer payments for incentives for Medicaid providers and reductions in payments for Medicare providers through payment adjustments for 2018 and subsequent years. For 2015 through 2017, we estimate the reduction in the reporting burden for providers demonstrating meaningful use in a calendar year as 1.45 to 1.9 hours per EP respondent and 2.62 hours per eligible hospital or CAH respondent. We estimate the total annual cost savings related to this reduction at \$52,547,132 for a low estimate and \$68,617,864 for a high estimate. We expect spending under the EHR Incentive Programs for transfer payments to Medicare and Medicaid providers between 2017 and 2020 to be \$3.7 billion (this estimate includes net payment adjustments in the amount of \$0.8 billion for Medicare providers who do not achieve meaningful use).

In this final rule with comment period, we do not estimate total costs and benefits to the provider industry, but rather provide a possible per EP and per eligible hospital outlay for implementation and maintenance. Nonetheless, we believe there are substantial benefits that can be obtained by society (perhaps accruing to eligible hospitals and EPs), including cost reductions related to improvements in patient safety and patient outcomes and cost savings benefits through maximizing efficiencies in clinical and business processes facilitated by certified HIT.

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 final rule with comment period.

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, 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 the Stage 1 final rule, we also detailed that

the Medicare and Medicaid EHR Incentive Programs 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, 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 the Office of the National Coordinator for Health Information Technology(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 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 availability delays for EHR technology certified to the 2014 Edition, 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.

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 titled "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; Final Rule" (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 titled "Medicare and Medicaid Programs; Electronic Health Record Incentive Program Stage 3" (80 FR 16731 through 16804). In the 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 CEHRT for Stage 3 of the Medicare and Medicaid EHR Incentive Programs. The proposed rule also specified the proposed requirements for electronic submission of CQMs and created a single set of meaningful use requirements for Stage 3 that 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.

In the April 15, 2015 **Federal Register**, we published a proposed rule titled "Medicare and Medicaid Programs; Electronic Health Record Incentive Program--Modifications to Meaningful Use in 2015 through 2017" (80 FR 20346 through 20399). In the proposed rule, we proposed to change the EHR reporting period in 2015 to a 90-day period aligned with the calendar year and to align the EHR reporting period in 2016 with the calendar year. In addition, in the proposed rule, we proposed to modify the patient action measures in the Stage 2 objectives related to patient engagement. Finally, we proposed to streamline the program by removing reporting requirements on measures that 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.

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

Readers may also visit: <http://www.cms.hhs.gov/EHRincentiveprograms> and <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 and Analysis of and Responses to Public Comments

A. Introduction

When the Medicare and Medicaid EHR Incentive Programs began in 2011, the requirements for the objectives and measures of meaningful use were designed to begin a process of health care delivery system transformation aligning with foundational goals defined in the Health Information Technology for Economic and Clinical Health Act (HITECH) Act. The HITECH Act 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); requiring 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(see section 1848(o)(4) of the Act); and defining key foundational principles of meaningful use 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).

In 2015, we published two notices of proposed rulemaking in 2015 relating to the EHR Incentive programs to address near term goals in 2015 through 2017 and long-term goals for Stage 3 in 2017 and subsequent years.

In the March 30, 2015 Stage 3 proposed rule (80 FR 16734), we proposed the requirements for the Medicare and Medicaid EHR Incentive Programs for 2017 and subsequent years to build a long-term sustainable program focused on the advanced use

of CEHRT to support clinical effectiveness, health information exchange, and quality improvement. We proposed a total of eight objectives that focus on supporting advanced clinical processes, promoting interoperability and health information exchange, continuing progress in electronic public health reporting, and expanding the scope and methods for provider and patient engagement.

In the April 15, 2015 EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20347), we proposed modifications to Stage 1 and Stage 2 to reflect this long-term vision and to be responsive to the changing environment and stakeholder concern over program complexity and redundant reporting requirements. The proposed rule included a reduced set of objectives and measures based on the Stage 2 objectives and measures that align with the policies for Stage 3. The proposed rule also proposed removing measures that had become topped out, redundant or duplicative, and easing requirements around measures requiring providers to be accountable for patient action. We proposed the modifications to address stakeholder concerns and to continue to support the overall goal of the widespread adoption and meaningful use of CEHRT in efforts to transform our health care delivery system and improve health care quality.

Comment: Many commenters supported the policies proposed in the EHR Incentive Programs in 2015 through 2017 proposed rule. A few commenters stated that the proposed rule was a more accurate reflection of what caregivers are able to provide to patients and the tools they have available to do so. Additionally, they stated that the proposals reflected what patients are willing to provide to the caregivers.

A few commenters indicated that CMS should update the measures and

requirements to ensure they are appropriately aligned and would improve a provider's ability to successfully demonstrate meaningful use. A commenter stated that we should first receive provider input before adding or suggesting any changes to the requirements.

Response: We appreciate the supportive comments and reiterate that our goals include reducing the reporting burden, eliminating redundant and duplicative reporting, and better aligning the objectives and measures of meaningful use for 2015 through 2017 with the Stage 3 requirements.

We proposed revisions to the requirements according to provider and stakeholder feedback received through correspondence, public forums, and listening sessions. Additionally, we proposed these changes through a notice of proposed rulemaking and accepted comments from the public during the comment periods for both proposed rules. We believe that providers helped to shape the requirements for meaningful use in part through those processes.

Comment: A few commenters stated that the proposal for the EHR Incentive Programs in 2015 through 2017 proposed rule imposes unreasonable financial constraints and reporting burdens. Other commenters stated the EHR Incentive Program in 2015 through 2017 proposed rule moves the program backward instead of forward. Another commenter stated that there are administrative burdens that providers face daily that distract from patient care or force implementation of alternative workflows or processes that do not relate to real-world care or improved quality and that the EHR Incentive Programs add to that burden.

Response: We understand cost and burden are factors for health care providers.

As previously noted in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20386), the regulatory impact analysis outlines the reduction in the reporting burden for providers demonstrating meaningful use in 2015 and estimates the total annual cost savings. We believe the modifications to Stage 1 and Stage 2 in the EHR Incentive Programs in 2015 through 2017 proposed rule represent forward progress for the program by better aligning reporting periods for providers; supporting a flexible, clear framework to reduce provider burden; and ensuring future sustainability of the Medicare and Medicaid EHR Incentive Programs. We understand the competing demands on a provider's time. However, as we have stated previously in the Stage 3 proposed rule (80 FR 16735), we believe the efficiencies to be gained by the HIT user will provide a long-term benefit for providers and outweigh the short-term concern over revisions to workflows, staff training, and other administrative needs.

Comment: A commenter on the EHR Incentive Programs in 2015 through 2017 proposed rule stated that new measures should not be added and changes should either eliminate measures or reduce the measurement thresholds.

Response: We did not propose to add new measures to the EHR Incentive Programs in 2015 through 2017. We proposed to require that all providers attest to a reduced set of objectives and measures beginning in 2015. The reduced set of objectives and measures are based on the existing Stage 1 and Stage 2 objectives and measures already required for the EHR Incentive Programs.

Additionally, we proposed to remove measures that we believe are redundant, duplicative, or topped out based on provider performance.

Comment: Many commenters on the Stage 3 proposed rule supported the proposals in the Stage 3 proposed rule to establish a single set of objectives and measures, align the Medicare and Medicaid EHR Incentive Programs timeline and requirements for clinical quality measure reporting with other CMS quality reporting programs that use CEHRT, and have optional Stage 3 participation in 2017.

Response: We appreciate the supportive comments and reiterate that our priority is to improve the efficiency, effectiveness, and flexibility of the EHR Incentive Programs by simplifying the reporting requirements and reducing the complexity of the program.

Comment: Several commenters on the Stage 3 proposed rule believed that the proposals made in the Stage 3 proposed rule would be burdensome, more time-consuming, and do little to improve patient care. Some commenters attributed the increased burden to increased measure thresholds.

Response: We recognize clinical workflows and maintaining documentation may require modifications upon implementation of the requirements for Stage 3. However, the changes were proposed in response to stakeholder concerns and designed to reduce burdens associated with the number of program requirements, the multiple stages of program participation, and the timing of EHR reporting periods.

Patient-focused care is very important to us, and we have proposed to maintain measures specific to patient engagement and that support a patient's access to their health information. The measures promote increased communication between providers and their patients, while placing focus on a patient's involvement in their care.

As noted in the Stage 3 proposed rule, (80 FR 16734), Stage 3 is intended to align

the timeline and requirements for clinical quality measure reporting in the Medicare and Medicaid EHR Incentive Programs with other CMS quality reporting programs that use CEHRT. This alignment is meant to reduce provider burden associated with reporting on multiple CMS programs and enhance CMS operational efficiency.

In addition, we understand that the increase in thresholds proposed in the Stage 3 rule may increase the work required to achieve an individual measure. However, we noted that part of our decision making process in the overall reduction of the number of objectives in the program was to reduce the burden on providers for those measures by allowing them to focus on advanced use objectives that support clinical effectiveness, patient safety, patient engagement, and care coordination. We believe providers should prioritize their efforts to strive to achieve high performance on these important measures. In addition, as noted in the proposed rule (80 FR 16740), the statute specifically requires the Secretary to seek to improve the use of EHRs and health care quality over time by requiring more stringent measures of meaningful use (see, for example, section 1848(o)(2)(A)(iii) of the Act). Therefore, for these reasons, we intend to continue to use measure thresholds that may increase over time and to incorporate advanced use functions of CEHRT into meaningful use objectives and measures.

Comment: A commenter on the EHR Incentive Programs in 2015 through 2017 proposed rule suggested that with Stage 3 in place, the Physician Quality Reporting System (PQRS) program and the Hospital Inpatient Quality Reporting (IQR) Program should be eliminated in 2018.

Response: We cannot eliminate the PQRS and Hospital IQR Programs because

they are required by statute (see sections 1848(a)(8) and 1886(b)(3)(B)(viii) of the Act, respectively). Furthermore, although PQRS payment adjustments sunset after 2018 in accordance with section 101(b)(2)(A) of MACRA, certain provisions and processes under PQRS will continue to apply for purposes of MIPS. MIPS is also required by statute (see section 1848(q) of the Act, as added by section 101(c) of MACRA). One of the focal points for Stage 3, however, is alignment with other quality programs such as the Hospital IQR Program and PQRS, not replacement of them.

Comment: A few commenters relayed concerns regarding financial issues related to costs associated with Stage 3 implementation, upgrading, installing, testing, and maintenance of EHRs that are outside of normal operating practices. A commenter stated maintenance of EHRs requires many expenses that surpass what is considered reasonable.

Response: We understand cost is a factor for health care providers. Our goal with Stage 3 is to simplify reporting requirements, reduce program complexity, and focus on the advanced use of EHR technology to promote improved patient outcomes and health information exchange to minimize burdens placed on providers.

The Stage 3 objectives and measures were designed to focus on the three-part aim of better health, better care, and lower costs. We believe that the costs associated with EHR adoption and continued maintenance are outweighed by the long-term benefits a provider may experience from meaningfully using CEHRT, including practice efficiencies and improvements in medical outcomes. For example, EHR supported processes such as drug-drug and drug-allergy interaction and clinical decision support, as well as electronic prescribing and computerized provider order entry for medication

orders, can all work in tandem to support a provider's efforts to effectively and safely prescribe and administer medications and reduce costs and risks associated with adverse events. In addition, while there may be a cost associated with HIT supported patient engagement as compared to not engaging with patients, the use of HIT allows providers to leverage economies of scale and engage with a large number and wide range of patients in ways not otherwise possible. Patient education and patient engagement in many forms support improved care and reduced cost of care as patients who are engaged with their health care have better outcomes and cost savings for their care¹. The use of CEHRT, while representing a capital investment in procurement and maintenance, can result in improved care and long term cost reduction and we believe these investments provide a strong return on investment for both providers and patients in our healthcare system.

Comment: A commenter on the Stage 3 proposed rule recommended that CMS eliminate measures that focus on data entry in favor of measures that focus on interoperability. Some commenters stated the Medicare and Medicaid EHR Incentive Programs do little to establish or promote interoperability among providers, between providers and consumers, or among participants in the health information ecosystem. Some commenters stated that many of the Stage 3 requirements depend on interoperability of EHR systems, which has not yet been realized except within health systems sharing the same software. These limited networks contribute to a decrease in

¹Recent research cites an 8 percent cost of care reduction in the first year and 20 percent in subsequent years attributable to patient engagement.

Hibbard, Judith H and Jessica Greene. "What The Evidence Shows About Patient Activation: Better Health Outcomes And Care Experiences; Fewer Data On Costs" *Health Affairs*: February 2013 32:207-214

patient access to care, choice, and timely availability of specialists, thus thwarting many of the overall objectives intended by the Medicare and Medicaid EHR Incentive Programs and creating a challenge for providers. Some commenters stated interoperability must expand in order for Stage 3 of the EHR Incentive Programs to generate the significant quality, safety, efficiency, coordination, and public health outcomes needed. Those commenters suggested that one approach to this challenge would be for CMS and ONC to establish an interoperability benchmark first, and then measure its progress.

Response: We disagree that the Medicare and Medicaid EHR Incentive Programs do little to establish or promote interoperability. As stated in the Stage 3 proposed rule(80 FR 16734), the Stage 3 measures and objectives are designed to promote interoperability with a focus on the advanced use of EHR technology, the use of electronic standards, and the interoperable exchange of health information between systems. The program leverages the ONC HIT Certification Program and the associated editions of certification criteria to ensure that eligible providers possess health IT that conforms with standards and the requirements for the capture and exchange of certain data in a structured format. This improves interoperability by ensuring that data within one system can be received and used by the recipient system. Various objectives within the Stage 3 proposed rule aim to increase interoperability through--

- Provider to provider exchange through the transmission of an electronic summary of care document;
- Provider to patient exchange through the provision of electronic access to view,

download, or transmit health information; and

- Provider to public health agency exchange through the public health reporting objectives.

Research supports our belief that the policies established in the EHR Incentive Programs, the ONC HIT Certification Program, and the related effort to support provider participation at a state and national level have had a significant impact on the development of health information exchange infrastructure in the United States. For EHR reporting periods in 2014, more than 3,700 eligible hospitals and CAHs and more than 232,000 EPs received incentive payments under the EHR Incentive Programs for meaningful use of CEHRT, which included exchanging health information electronically with other providers and with their patients. In addition, research shows a significant shift since the program began in 2011. Hospital electronic health information exchange (HIE) with other hospitals or ambulatory care providers outside their organization increased by 85 percent from 2008 to 2014 and increased by 23 percent since 2013².

The Stage 3 proposed rule focuses less on data capture and entry and more on interoperable health data sharing by including additional functions and requirements for the transmission and consumption of standardized health data through electronic exchange. The proposed Stage 3 objectives can essentially be broken into 2 categories:

- Category 1 objectives that support clinical effectiveness and patient safety, and
- Category 2 objectives that support health information exchange.

For Category 2, four of the eight proposed objectives are clearly focused on the electronic

² http://www.healthit.gov/sites/default/files/data-brief/ONC_DataBrief24_HIE_Final.pdf

exchange of health information through interoperable systems: Patient Electronic Access, Coordination of Care through Patient Engagement, Health Information Exchange, and Public Health and Clinical Data Registry Reporting. Each of these objectives involves the capture of structured data using a standard and the transmission of that data in a standardized format that can be sent, received, and incorporated electronically. These objectives build on the transmission standards established in prior rules by incorporating receipt standards and consumption requirements for HIE. We also proposed to expand the technology functions that may be used for transmission including a wider range of options, such as application-program interface (API) functionality.

In addition, two of the three objectives that fall into the first category (for example, computerized provider order entry and electronic prescribing) may also be categorized as objectives that support the interoperable exchange of health information through the process of creating and transmitting prescriptions, medication orders, laboratory order, and diagnostic imaging orders using standards established by CEHRT for that purpose.

We believe this continued emphasis on requiring standards in the technology and the use of these standards in clinical settings will continue to support and promote interoperability. Furthermore, we believe the expansion of the requirements around data transmission will continue to drive use and the ongoing development and strengthening of an interoperable HIE infrastructure.

We also received numerous comments on the EHR Incentive Programs in 2015 through 2017 and Stage 3 proposed rules during the public comment periods that were

either unrelated to the Medicare and Medicaid EHR Incentive Programs or outside the scope of the proposed rules. These comments included considerations for future rulemaking activities, requests for new incentives for various provider types that are not currently eligible to participate, requests to create a sliding scale for payment adjustments, and support or recommendations for ONC's 2015 Edition proposals. We thank all the commenters for their suggestions and feedback on the Medicare and Medicaid EHR Incentive Programs. However, comments unrelated to the proposals fall outside the scope of the proposed rule and are not addressed in this final rule with comment period.

B. Meaningful Use Requirements, Objectives, and Measures

1. Definitions across the Medicare Fee-for-Service, Medicare Advantage, and Medicaid Programs

a. Uniform Definitions

We proposed changes to the uniform definitions in part 495 subpart A of the regulations, in both the Stage 3 proposed rule (80 FR 16736 through 16737) and the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20351 through 20352). We proposed to maintain these definitions, unless specifically stated otherwise in the proposed rule. We proposed moving to a single set of criteria for meaningful use, which we herein call Stage 3, in order to eliminate the varying stages of the Medicare and Medicaid EHR Incentive Programs. We proposed that a modified version of Stage 1 and Stage 2 would be applicable for 2015 through 2017. We proposed that the Stage 3 definition of meaningful use would be optional for providers in 2017 and mandatory for

all providers beginning in 2018. To support these changes, we proposed revising the uniform definitions under 42 CFR 495.4 for "EHR reporting period" and "EHR reporting period for a payment adjustment year," as discussed in sections II.B.1.b.(3) and section II.E.2.2 of this final rule with comment period.

b. Definitions for 2015 through 2017, and 2017 and Subsequent Years

In the Stage 3 proposed rule (80 FR 16737), we sought to streamline the criteria for meaningful use. We intended to do this by--

- Creating a single stage of meaningful use objectives and measures (herein called Stage 3) that would be optional for all providers in 2017 and mandatory for all providers in 2018;

- Allowing providers flexible options for 2017;

- Changing the EHR reporting period to a full calendar year for all providers;

and

- Aligning with other CMS quality reporting programs using CEHRT, such as PQRS and Hospital IQR, for clinical quality measurement.

In the EHR Incentive Program in 2015 through 2017 proposed rule (80 FR 20352), we proposed changes to a number of definitions previously finalized for the EHR Incentive Programs in the Stage 1 and Stage 2 final rules in order to modify the program in response to the changing HIT 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) and (4) of this final rule with comment period, and a related change to requirements necessary to accommodate these changes, outlined in sections II.B.1.b.(2). and (3). of this final rule with comment period.

- 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 final rule with comment period.

- Allowing flexibility for providers in 2015 to accommodate the proposed changes, as outlined in section II.B.1.b. of this final rule with comment period.

- Removing requirements for objectives and measures that are redundant or duplicative or that have "topped out," as described in the Stage 3 proposed rule (80 FR 16741 through 16742) and outlined in section II.B.1.b.(4).(a). of this final rule with comment period.

- 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.b.(2). and (3). and II.B.1.b.(4).(b). of this final rule with comment period.

- Refocusing the existing program so that it is building toward advanced use of EHR technology, aligned with the Stage 3 proposed rule (80 FR 16741) through maintaining the objectives and measures outlined in section II.B.2 of this final rule with comment period.

(1) Stages of Meaningful Use

In the phased approach to meaningful use, we finalized the criteria for meaningful use through incremental rulemaking that covered Stage 1 and Stage 2 of the Medicare

and Medicaid EHR Incentive Programs. (For further explanation of the criteria we finalized in Stage 1 and Stage 2, we refer readers to 75 FR 44314 through 44588, 77 FR 53968 through 54162, and 79 FR 52910 through 52933).

In the Stage 3 proposed rule (80 FR 16737 through 16739), we proposed to set a new foundation for this evolving program by proposing a number of changes to the Medicare and Medicaid EHR Incentive Programs. First, we proposed a definition of meaningful use that would apply beginning in 2017. This definition, although herein referred to as Stage 3, would be the only definition for the Medicare and Medicaid EHR Incentive Programs and would incorporate certain requirements and aspects of Stage 1 and Stage 2. Beginning with 2018, we proposed to require all EPs, eligible hospitals, and CAHs, regardless of their prior participation in the Medicare and Medicaid EHR Incentive Programs, to satisfy the requirements, objectives, and measures of Stage 3. However, for 2017, we proposed that Stage 3 would be optional for providers. This proposed option would allow a provider to meet to Stage 3 in 2017 or to remain at Stage 2 or Stage 1, depending on their prior participation.

Furthermore, we proposed that Stage 3 would adopt a simplified reporting structure on a focused set of objectives and associated measures to replace all criteria under Stage 1 and Stage 2. Specifically, we proposed criteria for meaningful use for EPs, eligible hospitals, and CAHs (optional in 2017 and mandatory beginning in 2018), regardless of a provider's prior participation in the Medicare and Medicaid EHR Incentive Programs.

In the EHR Incentive Program in 2015 through 2017 proposed rule

(80 FR 20352), we proposed to further reduce complexity in the program and to realign the current program to work toward this overall shift to a single set of objectives and measures in Stage 3 in 2018. We proposed to require that all providers attest to a single set of objectives and measures beginning with an EHR reporting period in 2015 instead of waiting until Stage 3 in 2018. Because this change may occur after providers have already begun their work toward meeting meaningful use in 2015, we proposed accommodations within individual objectives for providers in different stages of participation. These accommodations include retaining the different specifications between Stage 1 and Stage 2 and allowing special exclusions for certain objectives or measures for EPs previously scheduled to participate in Stage 1 for an EHR reporting period in 2015.

We proposed all providers would be required to attest to certain objectives and measures finalized in the Stage 2 final rule that 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 (80 FR 16738).

We sought comment on whether or not we should implement only the

modifications proposed in the rule from 2015 through 2017 (80 FR 20351 through 20353) 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 16738).

Comment: Several commenters supported the option of moving to Stage 3 or remaining in Modified Stage 2 in 2017 in the EHR Incentive Program in 2015 through 2017 proposed rule. Many commenters believed that having the option to attest to Stage 3 in 2017 would allow vendor development and upgrades to be spread over a longer period of time. Other providers supported the option for providers to attest to either Stage 1, Stage 2, or Stage 3 in calendar year 2017.

Numerous commenters on the EHR Incentive Program in 2015 through 2017 proposed rule supported the proposal to move all providers to Stage 3 in 2018. They stated it is very complicated to keep track of all providers and their various programs, stages, and years, and that the proposed approach would ease the burden associated with reporting different stages of meaningful use. Numerous commenters on the Stage 3 proposed rule supported the proposal to move all providers to Stage 3 in 2018.

Response: We appreciate the number of commenters who supported the proposal for optional Stage 3 participation in 2017. We believe the option to attest to Stage 3 in 2017 offers flexibility for those providers ready to move forward to Stage 3 requirements, while allowing additional time for providers who may need to update, implement, and optimize the technology certified to the 2015 Edition. We believe vendors, developers, and providers will have an appropriate amount of time between the publication date of

the final rule with comment period and 2018 to transition to Stage 3.

We thank commenters for their support of the proposal to move all providers to Stage 3 in 2018. As noted in the EHR Incentive Programs in 2015 through 2017 proposed rule, the proposal was based in part on comments received in earlier rulemaking that relayed confusion and concerns regarding increased reporting burden related to the number of program requirements, the multiple stages of program participation, and the timing of EHR reporting periods.

Comment: We received multiple comments on the Stage 3 proposed rule opposing the proposal to move all providers to Stage 3 in 2018. Commenters indicated this proposal changes CMS' prior plan to permit providers who had not spent 2 years in either Stage 1 or Stage 2 to remain in that stage for a second year before transitioning to Stage 3. A commenter suggested that CMS consider extending Stage 1 and Stage 2 requirements for 2015 through 2017 to also include 2018. A few commenters stated providers should remain in each stage of meaningful use for 3 years to allow sufficient time to update, implement, and optimize the new technology. Some commenters requested that CMS delay Stage 3 to 2019 or later based on a lack of data related to experience for Stage 2.

Response: We appreciate the feedback from commenters. We recognize that our proposals would modify our earlier approach of allowing providers to remain in Stage 1 and Stage 2 for 2 years prior to transitioning to Stage 3. In the EHR Incentive Program in 2015 through 2017 proposed rule (80 FR 20352), we proposed to reduce the complexity of the program by proposing to require providers to attest to a single set of objectives and

measures starting in 2015. We proposed alternate exclusions and specifications for 2015 to accommodate Stage 1 providers working toward demonstration of meaningful use in 2015. Therefore, the combination of Stage 1 and Stage 2 objectives and measures into a single stage (Modified Stage 2) beginning in 2015 effectively removes the "Stage" designation. Under our proposal, providers would have the option to meet the single set of objectives and measures for Modified Stage 2 for up to 3 years (2015 through 2017) prior to moving to Stage 3. We are therefore removing the requirement that providers remain in each Stage for a set number of years because we believe our proposal to streamline the objectives and measures reduces the complexity of the program.

We proposed to align the objectives and measures of meaningful use for 2015 through 2017 with the Stage 3 objectives and measures in part because we believe this will provide a smoother transition for providers to Stage 3. Additionally, we believe that interoperability and EHR functionalities will continue to advance prior to 2018, when Stage 3 would be required of all eligible providers, which should increase providers' success in meeting the program requirements. Multiple providers have expressed their support for the option to attest to Stage 3 in 2017, indicating confidence in the transition. Therefore, we are maintaining the timeframe for implementation of Stage 3.

Comment: Some commenters believed that Stage 3, like its predecessors, takes a "one size fits all" approach with requirements that may not be applicable to all eligible participants.

Response: We disagree that Stage 3 is a "one size fits all" approach. We believe our proposal for Stage 3 allows flexibility within the objectives to allow providers to

focus on implementations that support their practice. For example, we proposed to incorporate flexibility for the Stage 3 objectives of Coordination of Care through Patient Engagement, Health Information Exchange, and Public Health Reporting so that providers can choose the measures most relevant to their unique practice setting.

Comment: A few commenters on the EHR Incentive Program in 2015 through 2017 proposed rule expressed concern that providers entering the program in 2015 or 2016 and those experiencing financial constraints would have difficulty moving to Stage 3 in 2018.

Response: As previously noted, we proposed to align the objectives and measures of meaningful use for 2015 through 2017 with the Stage 3 objectives and measures. We believe that the modified Stage 2 we proposed for 2015 through 2017 will provide a smoother transition for providers to Stage 3, including new participants in the program. For example, new participants who would otherwise have been in Stage 1 will be able to take advantage of the alternate exclusions and specifications of these Modified Stage 2 requirements. We understand cost is a factor for health care providers. However, as noted in prior rules, we believe the benefits of EHR adoption outweigh the potential costs (for more information, see the Stage 2 final rule at 77 FR 53971).

Comment: A commenter on the Stage 3 proposed rule requested clarity on the expectations for the 90-day "gap" hospitals will have from October 1 through December 31, 2016, and whether hospitals need to demonstrate meaningful use during that timeframe.

Response: In the Stage 3 proposed rule (80 FR 16739 through 16740), we noted a

possible reporting gap from October 1 through December 31, 2016 as a result of our proposal to align the EHR reporting period for eligible hospitals and CAHs with the calendar year beginning in 2017. After the Stage 3 proposed rule was published, we published the EHR Incentive Program in 2015 through 2017 proposed rule, in which we proposed this alignment with the calendar year would begin earlier, in 2015, eliminating the potential for a gap in the fourth quarter of CY 2016.

Comment: Some commenters on the EHR Incentive Program in 2015 through 2017 proposed rule opposed having an option to attest to Stage 3 in 2017, stating that keeping providers at the same stage allows performance to remain at the same level, thereby making it easier to track and measure. Additional commenters stated the option does not support CMS efforts to streamline the EHR Incentive Programs.

A few commenters were concerned that many providers will have difficulty attesting to Stage 3 in 2017 if other collaborating partners are not operating with the same CEHRT.

A few commenters indicated that a provider electing to attest to a later stage was a rarity in previous years when given an option.

Response: We thank commenters for their feedback. First, we note that providers have not been given an option to move forward in their Stage progression in the past, and that CMS has in fact received multiple requests to allow providers to do so in past years. Second, we understand the challenges faced by providers who are not ready or able to move to Stage 3 in 2017. However, as other comments have shown, several stakeholders are supportive of the option for 2017 and, because it is an option and not a requirement

for 2017, providers would not be required to meet Stage 3 requirements in 2017 if they were not ready to do so. Finally, the meaningful use objectives and measures proposed for 2015 through 2017 align with the objectives and measures proposed for Stage 3. Therefore, we believe many providers may seek to work toward meeting Stage 3 in 2017. If they find they are unable to meet the Stage 3 requirements, they would be able to successfully attest to Modified Stage 2 in 2017. Additionally, there is no requirement nor any technological limitation on providers to only collaborate with other providers with EHR technology certified to the same Edition of certification criteria. In fact, many of the certification criteria are similar between the 2014 Edition and the 2015 Edition. Therefore, we believe the transition to Stage 3 will be less complex and the program will be more streamlined moving forward. We believe offering the option of a transitional year in 2017 would enable providers to weigh the risks and benefits of moving to Stage 3 and decide for themselves what is most appropriate based on their individual circumstances.

Comment: Regarding the EHR Incentive Program in 2015 through 2017 proposed rule, other commenters stated that the timeline in the proposed rule represents an aggressive deadline for health IT vendors and developers supporting customers who might choose to begin Stage 3 in 2017. A few commenters stated removal of the option to participate in Stage 3 in 2017 would give EHR vendors and developers an additional 12 months to deploy EHR Technology certified to the 2015 Edition.

Response: We recognize stakeholder concerns and the potential burden that these changes may have on vendor upgrades in relation to timing for system changes. We

believe that some vendors, developers, and providers will be able to make the necessary system changes in time to implement Stage 3 in 2017. We encourage discussion between vendors, developers, and providers on the feasibility to upgrade to EHR technology certified to the 2015 Edition and attest to Stage 3 in 2017. However, we remind commenters that this upgrade is optional in 2017 and for those providers who choose to attest to Modified Stage 2 and not to Stage 3, EHR technology certified to the 2015 Edition would not be required until 2018. In addition, providers may also choose to upgrade some modules as early as 2016 if the CEHRT is available.

Comment: The majority of commenters on the Stage 3 proposed rule supported the option of participating in Stage 3 in 2017 and of using technology certified to either the 2014 or 2015 Edition in 2017 and believed this would provide relief to the industry. Some commented they would support this flexibility in all future years where changes to CEHRT will be required and noted transitioning to technology certified to a new Edition can be complex and can require more resources and time than anticipated. Other commenters suggested that providing an optional year to transition to technology certified to a new Edition allows the time necessary to help ensure a safe transition for patients and a smoother transition for providers. Other commenters were also appreciative of CMS' response to their concerns as reflected in the Stage 3 proposed rule.

Some commenters on the EHR Incentive Program in 2015 through 2017 proposed rule indicated that in the case of unanticipated challenges or delays with the adoption and implementation of the technology certified to the 2015 Edition, CMS should preemptively detail alternative scenarios to avoid future rule changes.

However, other commenters stated that 2017 is not a realistic start date for Stage 3 due to the expected timing of the final rule; necessary upgrades to technology; transitional processes after deployment such as training, workflow, and validation of reporting; and full year reporting requirements. A commenter suggested there would be only 12-15 months from the publication date of the final rule (assuming publication in late 2015) until technology certified to the 2015 Edition would need to be available from vendors and developers and implemented by organizations with necessary staff training completed for new workflows. Some commenters indicated EHR vendors and developers need on average 18 months to develop, test, market, and implement new functionality, while providers need lead time to re-work their processes and systems to new or revised requirements. Other commenters indicated concern about the timeline of transitioning to Stage 3 in 2017 and 2018, stating that 18 months is the minimum length of time needed between the final rules and the start of any stage of the EHR Incentive Program. Furthermore, as the change requires a technology upgrade, and given the likely timing for the publication of the final rules, the proposed Stage 3 timetable will not allow for a full 18-month timeline before the beginning of Stage 3 as an option in 2017.

Some commenters on the EHR Incentive Program in 2015 through 2017 proposed rule indicated that in case of unanticipated challenges or delays with the adoption and implementation of the technology certified to the 2015 Edition, CMS should proactively detail alternative scenarios to avoid future rule changes.

Response: We appreciate the commenters' feedback and seek to explain a few points related to the proposed option for providers to participate in Stage 3 in 2017. First

we note that providers may upgrade to EHR technology certified to the 2015 Edition when it becomes available. We note that CMS will allow a provider to successfully attest in 2015, 2016, or 2017 with technology certified to either the 2014 Edition, the 2015 Edition, or a combination of the two as long, as the technology possessed can support the objectives and measures to which they plan to attest. Therefore, providers may adopt technology certified to the 2015 Edition prior to 2017, either in a modular approach or in total, and may still choose to attest to Modified Stage 2 and wait to begin Stage 3 until 2018.

Providers who are seeking to demonstrate Stage 3 in 2017 cannot do so without the support of certain functions that are only available for certification as part of the 2015 Edition certification criteria. This means that for 2017 a provider must have at least a combination of EHR technology certified to the 2014 Edition and the 2015 Edition in order to support participation in Stage 3. However, as Stage 3 is optional, providers are not required to upgrade to technology certified to the 2015 Edition until 2018.

As discussed further in section II.B.3 of this final rule with comment period, this means providers have flexibility to use EHR technology certified to either the 2014 or 2015 Edition (or a combination of CEHRT modules certified to different Editions). We proposed the flexibility to allow providers to move forward with upgrading their EHR technology at their own speed and to optionally attest to Stage 3 in 2017 if they are able to do so.

In total, these proposals allow for a staggered upgrade timeline for developers and providers of more than 24 months between the date of the publication of this final rule

with comment period and 2018, when providers must begin using EHR technology certified to the 2015 Edition.

Because of this more than 24 month lead time for development, we do not anticipate significant challenges or delays in the adoption and implementation of the 2015 Edition CEHRT. We will continue to monitor and assess providers' progress towards adoption and implementation as EHR technology certified to the 2015 Edition becomes available.

Comment: Some commenters on the Stage 3 proposed rule noted the previous transitional difficulties for Stage 2 and recommended removing the option to demonstrate Stage 3 in 2017 and only require the Modified Stage 2 in 2017. These commenters suggested keeping the required start of Stage 3 at 2018, but allowing a 90-day or calendar year quarter EHR reporting period for the first year of Stage 3 in 2018.

Response: We disagree with the recommendation to remove the option of demonstrating Stage 3 in 2017. Although recognizing that not all providers will have the necessary technology to move to Stage 3 in 2017, many commenters supported allowing this option for those providers who are able to do so and we wish to maintain this proposed flexibility for providers. We address the suggestion for a 90-day EHR reporting period for Stage 3 in further detail in section II.B.1.b.(3).(iii) of this final rule with comment period.

After consideration of the public comments received, we are finalizing our approach to the timing of the stages of meaningful use as proposed in the EHR Incentive Program in 2015 through 2017 proposed rule and the Stage 3 proposed rule. We are

finalizing that all EPs, eligible hospitals, and CAHs must attest to the Modified version of Stage 2 beginning with an EHR reporting period in 2015, with alternate exclusions and specifications for certain providers, as discussed further in section II.B.1.b.(4).(b).(iii). of this final rule with comment period. We finalize as proposed the option for all EPs, eligible hospitals, and CAHs to attest to Stage 3 for an EHR reporting period in 2017 and the requirement for all providers to attest to Stage 3 beginning with an EHR reporting period in 2018.

TABLE 1: STAGE OF MEANINGFUL USE CRITERIA BY FIRST YEAR

First Year Demonstrating Meaningful Use	Stage of Meaningful Use				
	2015	2016	2017	2018	2019 and future years
2011	Modified Stage 2	Modified Stage 2	Modified Stage 2 or Stage 3	Stage 3	Stage 3
2012	Modified Stage 2	Modified Stage 2	Modified Stage 2 or Stage 3	Stage 3	Stage 3
2013	Modified Stage 2	Modified Stage 2	Modified Stage 2 or Stage 3	Stage 3	Stage 3
2014	Modified Stage 2	Modified Stage 2	Modified Stage 2 or Stage 3	Stage 3	Stage 3
2015	Modified Stage 2	Modified Stage 2	Modified Stage 2 or Stage 3	Stage 3	Stage 3
2016	- NA -	Modified Stage 2	Modified Stage 2 or Stage 3	Stage 3	Stage 3

First Year Demonstrating Meaningful Use	Stage of Meaningful Use				
	2015	2016	2017	2018	2019 and future years
2017	-NA -	- NA -	Modified Stage 2 or Stage 3	Stage 3	Stage 3
2018	-NA -	- NA -	- NA -	Stage 3	Stage 3
2019 and future years	- NA -	- NA -	- NA -	- NA -	Stage 3

We are adopting these provisions under the definition of a "Meaningful EHR user" at § 495.4 as noted in section II.B.1.b.(2) of this final rule with comment period and as noted in further detail in section II.B.2.a. and II.B.2.b of this final rule with comment period.

(2) Meaningful EHR User

In the Stage 3 proposed rule (80 FR 16737), we proposed to modify the definition of "Meaningful EHR user" under 42 CFR 495.4 to include the Stage 3 objectives and measures defined at § 495.7.

In the EHR Incentive Program in 2015 through 2017 proposed rule (80 FR 20353), we additionally proposed 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. 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 § 495.22 – Objectives and Measures Beginning in 2015
§ 495.7* – Stage 3 Objectives and Measures	§ 495.24 – Stage 3 Objectives and Measures
§ 495. 8 – Demonstration of Meaningful Use	§ 495.40 – Demonstration of Meaningful Use
§ 495.10 – Participation Requirements	§ 495.60 – Participation Requirements

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

We indicated that all proposed changes in part 495 would be reconciled through this final rule with comment period.

We received no comments specific to these proposals, and therefore, are finalizing them without modification.

(3) EHR Reporting Period

In both the EHR Incentive Program in 2015 through 2017 and Stage 3 proposed rules (80 FR 16739 and 80 FR 20353), we proposed changes to the EHR reporting period in order to accomplish the following:

- Simplify reporting for providers, especially groups and diverse systems.
- Support further alignment with CMS quality reporting programs using certified health IT such as Hospital IQR and PQRS.

- Simplify HHS system requirements for data capture.
- Provide for greater flexibility in developing, implementing, stress testing, and conducting Quality Assurance (QA) of systems before deployment.

In the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20353), we proposed changes to the uniform definition of an "EHR reporting period" in § 495.4 beginning in 2015. We proposed 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.2 of this final rule with comment period. We proposed changes to the attestation deadlines for purposes of the incentive payments and payment adjustments as discussed in section II.D of this final rule with comment period.

(i) Calendar Year Reporting

In the EHR Incentive Program 2015 through 2017 proposed rule (80 FR 20354), beginning in 2015, we proposed 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. We proposed 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 fulfill the requirements of the EHR Incentive Programs. We proposed that for 2015 only, eligible hospitals and CAHs may begin an EHR reporting period as early as October 1, 2014 and must end by December 31, 2015. Beginning with 2016, the EHR reporting period must be completed within January 1 and December 31 of a calendar year.

For the payment adjustments under Medicare, we proposed changes to the EHR

reporting periods applicable for payment adjustment years in the EHR Incentive Program 2015 through 2017 proposed rule at 80 FR 20379.

Comment: The majority of commenters for the EHR Incentive Program in 2015 through 2017 proposed rule supported the move to calendar year reporting for all providers and believed this would simplify the reporting, monitoring, and attestation for hospitals. Other commenters stated aligning the reporting period would ease provider reporting burden for larger organizations that will not have to track their providers through different stages. Another commenter stated that this not only allows those health IT vendors and developers who service both outpatient and inpatient clients to be better aligned in their deployment and support, but also permits them to better harmonize technology implementation and program reporting. Other commenters stated that calendar year reporting, combined with the new "Active Engagement" options for public health and clinical data registry reporting (see section II.B.2.a.x of this final rule with comment period), will permit them to onboard, test, and deploy participants in a timely manner based upon the ability to meet their own internal resource constraints, while ensuring all participants can meet their meaningful use objectives.

Response: We thank the commenters for support of this proposal. As we stated in the EHR Incentive Program in 2015 through 2017 proposed rule (80 FR 20353), the movement of all providers to calendar year reporting supports program alignment and simplifies reporting requirements among provider types.

Comment: A commenter stated the move to reporting on the calendar year would eliminate the 3-month gap that currently exists between the end of the hospital EHR

reporting period and the end of the EPEHR reporting period. This could cause issues, especially among organizations that share resources to support build, testing, and report validation for eligible hospitals, CAHs, and EPs. Other commenters stated aligning all providers to a calendar year would diminish their time to troubleshoot unexpected issues with final reports and validate the accuracy of data or lead to an increased risk in data entry errors in order to meet the February deadline for attestation for both EPs, eligible hospitals, and CAHs.

Response: We understand the concerns stated by stakeholders over the changes proposed for the EHR reporting periods. Because this final rule with comment period maintains the existing definitions for the objectives and measures, including the numerator and denominator calculations and measure thresholds for 2015, we believe vendors, developers, and providers will have minimal issues in the upgrades and testing for 2015. Likewise, the requirements for 2015 through 2017 use the existing measure specifications and EHR technology requirements with minimal changes. Finally, the hospital attestation period is currently October 1 through the end of November of a given year, while the new attestation period was proposed as January 1 through the end of February. The attestation window would still be the same amount of time, and with the single period providers (especially those organizations that support both EPs and hospitals) can plan for testing and data validation for all settings in advance of the required deadline for attestation.

Comment: A few commenters on the EHR Incentive Program in 2015 through 2017 proposed rule stated that hospitals should be able to choose whether to report on a

fiscal or calendar year basis in 2015 and 2016. Some commenters indicated that the proposed change to calendar year reporting would delay incentive payments for at least 3 months and cause financial and budgeting challenges. Additionally, some of the commenters stated hospitals have already made reporting plans and fiscal projections for these years.

Response: We disagree with the commenters' recommendation to allow hospitals to choose a fiscal or calendar year EHR reporting period in 2015 and 2016. Allowing hospitals this option would be inconsistent with the goal of program simplification and alignment. We agree that for most eligible hospitals and CAHs, this change would shift the incentive payment by one quarter within the same federal fiscal year. However, these are incentive payments and not reimbursements and, as noted in the EHR Incentive Program in 2015 through 2017 proposed rule (80 FR 20376), 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.

Comment: A commenter stated this alignment would further stress the CMS reporting system because the systems currently struggle to handle the surge of activity that occurs with the staggered reporting periods. The commenter suggested we improve the capacity of the attestation systems to ease the burden of the reporting process.

Response: We understand the commenter's concerns. However, historical evidence has shown that the vast majority of the more than 200,000 EPs have attested during the open attestation window from the beginning of January through the end of

February and have done so successfully each year. In addition, consistent with past experience, the expectation and planning for the CMS systems in 2015 was that the majority of providers would be attesting during this time, as most would have been required to attest for a full year EHR reporting period. The addition of fewer than 5,000 attestations by eligible hospitals and CAHs during this time will not significantly impact the load on the system. We do recommend that providers try to attest in January and not wait until the end of February to allow adequate time to address any issues that may arise, such as issues related to the accuracy of their attestation or their contact and banking information. CMS will also monitor readiness and attestation progress throughout the period and work to mitigate any risk that should arise.

After consideration of the public comments received, we are finalizing the proposal in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20348) to align the EHR reporting period for eligible hospitals and CAHs with the calendar year beginning in 2015. For 2015 only, eligible hospitals and CAHs may begin an EHR reporting period as early as October 1, 2014 and must end by December 31, 2015. Beginning with 2016, the EHR reporting period must be completed within January 1 and December 31 of the calendar year. We made corresponding revisions to the definition of an "EHR Reporting Period" at § 495.4. For the payment adjustments under Medicare, we discuss the duration and timing of the EHR reporting period in relation to the payment adjustment year in section II.E.2 of this final rule with comment period.

(ii) EHR Reporting Period in 2015 through 2017

In the EHR Incentive Program in 2015 through 2017 proposed rule (80 FR 20354), we proposed to allow a 90-day EHR reporting period in 2015 for all providers to accommodate implementation of the other changes proposed in that rule. For 2015 only, we proposed 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 proposed that for an EHR reporting period in 2015, EPs may select an EHR reporting period of any continuous 90-day period from January 1, 2015 through December 31, 2015; eligible hospitals and CAHs may select an EHR reporting period of any continuous 90-day period from October 1, 2014 through December 31, 2015.

We proposed that in 2016, for EPs, eligible hospitals, and CAHs that have not successfully demonstrated meaningful use in a prior year, 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.

For the payment adjustments under Medicare, we proposed changes to the EHR reporting periods applicable for payment adjustment years in the EHR Incentive Programs in 2015 through 2017 proposed rule at (80 FR 20379).

Comment: All comments received on the EHR Incentive Program in 2015 through 2017 proposed rule overwhelmingly supported the 90-day EHR reporting period in 2015. Many commenters stated the 90-day EHR reporting period would be beneficial

for small and rural providers and provide the time needed to implement the required changes for the next stage of meaningful use. Other commenters stated that this is essential due to vendors and developers struggling to keep their systems up-to-date with all the changes and new requirements.

We also received numerous comments on the Stage 3 proposed rule strongly supporting the proposal for a 90-day EHR reporting period for all providers in 2015. Some commenters noted that the reduction to a 90-day EHR reporting period would assist providers transitioning from Stage 1 to Stage 2 without compromising patient care. Another commenter stated changing to any continuous 90 days (as opposed to calendar quarters) allows for needed flexibility in the event of unforeseen circumstances that could otherwise impede reporting within the originally planned timeframe.

Response: As stated in the EHR Incentive Program in 2015 through 2017 proposed rule (80 FR 20348), this 90-day EHR reporting period in 2015 would allow providers additional time to address any remaining issues with the implementation of EHR technology certified to the 2014 Edition and to accommodate the proposed changes to the objectives and measures of meaningful use for 2015. We also proposed an EHR reporting period of any continuous 90 days not tied to a specific calendar quarter in 2015.

Comment: A commenter on the EHR Incentive Program in 2015 through 2017 proposed rule suggested that the 90-day EHR reporting period was too short. Another commenter stated that he or she believes the modification to the EHR reporting period would present a real and material risk to patients and that patients should have the benefit of a full year EHR reporting period. However, some commenters stated that if a provider

can demonstrate meaningful use for 90 days, that provider must have the technology and workflows in place for meaningful use and therefore should not be required to submit a full year of data to confirm they are in compliance.

Response: We agree that a full year EHR reporting period is the most effective way to ensure that all actions related to patient safety that leverage CEHRT are fully enabled for the duration of the year. This is one of the primary considerations of our continued push for full year reporting whenever feasible, in addition to promoting greater alignment with other CMS quality reporting programs. However, we stated in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20348) that a 90-day EHR reporting period would allow providers additional time to address any remaining issues related to implementation of technology certified to the 2014 Edition. A 90-day EHR reporting period is necessary in order to accommodate the proposed changes to the program that reduce the overall burden on providers to allow greater focus on the objectives and measures that promote patient safety, support clinical effectiveness, and drive toward advanced use of health IT. Despite the allowance for a 90-day EHR reporting period, we believe it is essential to maintain the processes and the workflows supporting and promoting patient safety enabled and fully implemented throughout the year. The EHR reporting period alone should not dictate a provider's commitment to patient safety.

In response to commenters who suggest that, in the future, demonstrating meaningful use for a 90-day period should serve as confirmation of a full year of compliance with program requirements, we note that if a provider does have the

necessary workflows and processes in place for a full year there is no valid reason that provider should not demonstrate meaningful use for a full year. If extreme circumstances outside of the provider's control prohibit a full year of meaningful use, the provider may file for a hardship exception from the Medicare payment adjustments.

Comment: A commenter in the EHR Incentive Programs in 2015 through 2017 proposed rule requested quarterly reporting, stating that it is far more efficient and that eligible hospitals and EPs are now familiar with reporting quarters and can plan accordingly. Another commenter requested the option to choose either a 90-day consecutive reporting period or a calendar quarter. Another commenter suggested a 60-day reporting period for 2015.

Response: We understand that some commenters may favor quarterly reporting due to the ease of planning based on a calendar quarter and to the prior requirement finalized in the Stage 2 final rule for EHR reporting periods in 2014 (77 FR 53974). However, an EHR reporting period of any continuous 90 days would still allow for providers to select and report on a quarter in the calendar year if they so choose. We disagree with the appropriateness of a 60-day EHR reporting period, and further note that a shorter EHR reporting period is not easier to meet than a longer period if the provider is fully engaged in the workflows and has the functions fully enabled. Statistically, a larger number of patient encounters allow providers a wider margin to meet the overall threshold. As the majority of providers would already have been meaningfully using their CEHRT and then attesting based on a full year EHR reporting period, or for a minimum of a 90-day EHR reporting period, these workflows should be implemented

and functioning for at least that length of time. Therefore, the necessity for a shorter EHR reporting period as dictated by the need to accommodate the changes in this final rule with comment period is limited in scope to 90 days.

Comment: A commenter stated that their group practice has already gathered data for some EPs for quarters 1 and 2 and have new EPs for whom they would like to be able to report for quarter 4. The commenter requested organizations be allowed to use a different EHR reporting period for each EP.

Response: Each EP is required to individually meet the requirements of meaningful use regardless of their affiliation with a group practice. Therefore, each EP may use a separate EHR reporting period to demonstrate meaningful use and in 2015, that EHR reporting period may be any continuous 90-day period in the calendar year selected by each individual EP.

Comment: A few commenters from the EHR Incentive Programs in 2015 through 2017 proposed rule stated CMS previously requiring a full year of reporting and then subsequently removing that requirement dilutes the message to providers and sets an expectation that goals do not need to be met.

Response: We note that this perception is of concern and is not reflective of our policy goals for the program. As we stated in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20348), the 90-day EHR reporting period is intended only to accommodate the changes to the EHR Incentive Programs in 2015 through 2017, which are in turn intended to drive toward the long-term goals outlined in the Stage 3 proposed rule.

Comment: A commenter requested CMS acknowledge the challenges associated with reporting on a full calendar year for EPs newly employed by a health system during the course of a program year, switching EHRs, system downtime, cyber-attacks, and office relocation.

A few commenters strongly recommended in the EHR Incentive Program in 2015 through 2017 proposed rule that CMS retain the 90-day attestation option for providers who change employers during the year. Furthermore, the commenters further stated they do not believe an organization can sufficiently rely upon the actions of a previous employer to complete the necessary validation, analysis, and implementation of an EHR that would satisfy CMS audit requirements. If a previous employer's data is found to be faulty, the current organization is put at risk for the data reported.

Response: We understand the commenters' concerns and note that EPs may consider applying for a hardship exception from the reduction to Medicare PFS payments based on extreme and uncontrollable circumstances. Specifically, in the case of issues related to CEHRT, situations involving technology upgrades, switching products during the year, or the decertification of a product may be reason for a provider to apply for a hardship.

EPs who are switching employment or practicing in multiple locations during an EHR reporting period may apply for a hardship exception that would be reviewed on a case-by-case basis. However, we disagree that CMS should take into account the business practices of individual EPs in establishing the requirements for the entirety of the program. It is incumbent on the individual EP to establish their own contractual or

business arrangements for the purposes of attesting for the Medicare and Medicaid EHR Incentive Programs.

Comment: A commenter suggested the EHR reporting period should be at least 90 days or 3 calendar months. The commenter suggested this would allow a provider to create a monthly report within their EHR system using their dashboard, regardless of the number of days in any given month, as long as they capture at least 90 days or 3 calendar months. As an example, the commenter suggested that an EP or administrator can run a report for October through December that would provide 92 days of data, or February through April that would provide 89 days of data.

Response: We thank the commenter for their suggestion and respectfully disagree. The EHR reporting period must be at least 90 continuous days in order to ensure that all providers are meeting at least the same minimum requirement. While a provider may choose a period longer than 90 days, they may not choose a period that is less, so the use of the designated months is not adequate. Furthermore, a 90-day period need not be tied to the beginning or end of a month. Therefore, the use of 90 days is the most appropriate for this policy as it allows flexibility for providers to choose any continuous 90-day period, or any 3-month period of at least 90 days, or any calendar year quarter of at least 90 days, without adding additional complexity. As proposed in the EHR Incentive Programs in 2015 through 2017 proposed rule(80 FR 20348), the EHR reporting period would be any continuous 90 days for all providers in 2015. This change allows for greater flexibility in the reporting requirements.

Comment: A few commenters stated they believed the statute does not obligate

CMS to require a year for reporting and believed the full year reporting requirement will discourage EPs from participation and increases risk of non-success.

Response: We agree that the statute allows discretion to specify the EHR reporting period and does not require a full year. As mentioned in our Stage 2 final rule (77 FR 53974), the more robust data set provided by a full year EHR reporting period offers more opportunity for alignment of programs, such as PQRS, than the data set provided by a shorter EHR reporting period, especially when compared across several years. We believe the full reporting year will yield data necessary to sustain and further progress the program. Furthermore, we believe, as previously noted, that the actions and workflows that support the requirements of the EHR Incentive Programs are intended to be in effect continuously, not enabled and implemented for only 90 days. Finally, we believe in the importance of alignment with and support of quality measurement and quality improvement initiatives like Accountable Care Organizations (ACOs) and the Comprehensive Primary Care Initiative (CPCI) as well as the value based purchasing programs that require full year reporting for the efficacy of data on clinical processes and patient outcomes. Thus, our policy has been to allow a 90-day reporting period only in circumstances where a shorter reporting period is warranted to allow providers to implement program changes or to begin participation in the program.

Comment: Several commenters recommended the reporting period should be 90 days for 2016 and subsequent years, as this would greatly reduce the reporting burden. A few commenters stated that a full year of reporting in 2016 is unreasonable. Multiple commenters stated that a full year reporting period for all participants in 2016 does not

adequately account for a number of real life scenarios that could cause issues with meeting the requirements, such as environmental setbacks, infrastructure problems, vendor-related difficulties, and human resource issues. Some commenters strongly recommended CMS retain the 90-day EHR reporting period for first-time attestors in the program in future years.

Response: We decline to extend the 90-day EHR reporting period to 2016 for all returning participants because we disagree that full year reporting is unreasonable. In 2012 and 2013, thousands of returning providers successfully attested to program requirements for an EHR reporting period of one full year. In addition, as noted previously, hardship exceptions may be available for providers experiencing extreme and uncontrollable circumstances. However, as proposed in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20348), all providers demonstrating meaningful use for the first time may use an EHR reporting period of any continuous 90 days in 2016, which has been the policy in past years, to support these providers beginning implementation of the program.

After consideration of the public comments received, we are finalizing a 90-day EHR reporting period in 2015 for all providers as proposed. Eligible professionals may select an EHR reporting period of any continuous 90-day period from January 1, 2015 through December 31, 2015; eligible hospitals and CAHs may select an EHR reporting period of any continuous 90-day period from October 1, 2014 through December 31, 2015. We are finalizing a 90-day EHR reporting period in CY 2016 for EPs, eligible hospitals, and CAHs that have not successfully demonstrated meaningful

use in a prior year. For all providers who have successfully demonstrated meaningful use in a prior year, we are finalizing an EHR reporting period of the full CY 2016. We have made corresponding revisions to the definition of "EHR reporting period" under § 495.4. For the payment adjustments under Medicare, we discuss the duration and timing of the EHR reporting period in relation to the payment adjustment year in section II.E.2 of this final rule with comment period.

(iii) EHR Reporting Period in 2017 and Subsequent Years

In the Stage 3 proposed rule (80 FR 16739), we proposed that beginning in 2017, and for all EPs, eligible hospitals, and CAHs, the EHR reporting period would be one full calendar year. We proposed to eliminate the 90-day EHR reporting period for new meaningful EHR users beginning in 2017, with a limited exception for Medicaid EPs and eligible hospitals demonstrating meaningful use for the first time. For that exception, we proposed to maintain the 90-day EHR reporting period for a provider's first payment year based on meaningful use for EPs and eligible hospitals participating in the Medicaid EHR Incentive Program. We noted that the EHR incentive payments under Medicare fee-for-service (FFS) and MA (sections 1848(o), 1886(n), 1814(l)(3), 1853(l) and (m) of the Act) will end before 2017. We stated that under these proposals, EPs and eligible hospitals that seek to qualify for an incentive payment under Medicaid would have a full calendar year EHR reporting period if they are not demonstrating meaningful use for the first time.

These proposals would allow for a single EHR reporting period of a full calendar year for all providers across all settings. We proposed corresponding revisions to the

definition of "EHR reporting period" under § 495.4. For the payment adjustments under Medicare, we proposed changes to the EHR reporting periods applicable for payment adjustment years in the Stage 3 proposed rule (80 FR 16774 through 16777).

Comment: Several commenters supported the proposal to eliminate the 90-day EHR reporting period for new meaningful EHR users beginning in 2017, with a limited exception for Medicaid EPs and eligible hospitals demonstrating meaningful use for the first time. A commenter appreciated the effort to standardize reporting timelines to other CMS quality programs. Other commenters stated that longer reporting periods would facilitate public health reporting, as Public Health Agencies (PHAs) have more time to work with providers and their EHR vendors and developers to submit data to meet their public health measures. A few commenters indicated annual reporting has the benefit of yielding valuable data that may not necessarily be captured with a short 90-day reporting period.

Response: We appreciate the support of these comments. We believe full year reporting will allow for the collection of more comparable data and increase alignment across quality reporting programs, where measure data is typically collected over a calendar year period. The more robust data set provided by a full year EHR reporting period offers more opportunity for alignment than the data set provided by a shorter EHR reporting period, especially when compared across several years.

Comment: We received many comments opposing the full year reporting period, indicating that it is very challenging and may add administrative burdens. Commenters also indicated the following areas of concerns that could impact the ability to demonstrate

a full year of meaningful use:

- EPs change in place of service (POS)
- EPs joining a practice in the middle of the year.
- Ongoing software updates (for example, ICD-10).
- Difficulty in getting data from previous places of employment.
- Not enough time for the vendors and developers to make software updates.
- Timing of the data submission.

Other commenters stated full year reporting does not allow sufficient time for these practices to identify shortcomings in their adherence to meaningful use and implement corrective actions before the next reporting period.

Response: First, we understand the commenters' concerns and note that providers may consider applying for a hardship exception from the Medicare payment adjustments based on extreme circumstances outside the provider's control that contribute to their inability to meet the requirements of the EHR Incentive Programs. Second, we note that the thresholds of the measures themselves are designed to provide leeway for providers to adjust workflows and implementation as necessary during the EHR reporting period. With the exception of maintaining drug interaction and drug allergy clinical decision supports for the duration of the EHR reporting period, no measure has a threshold of 100 percent. We believe that system downtime could be expected in some cases for software or system maintenance, but providers may still meet meaningful use if they meet the threshold for each measure and are using the required CEHRT Edition for the EHR reporting period. Third, as noted previously, if a provider is fully implementing the

requirements of the program, the workflows and implementation of the technology would not be limited to only 90 days, and thus a longer EHR reporting period should be feasible.

Comment: A commenter recommended shortening the reporting period from 12 months to 3 months and that CMS should consider an “incentive” for providers who report on a 6-month period or even a 12-month period. Another commenter similarly suggested reopening incentive payments for the program including providing additional monies for new participants successfully demonstrating meaningful use for a full year under the Stage 3 requirements.

Response: While we appreciate the commenter's suggestion of additional incentives for providers, we do not have discretion to alter the timing and duration of the incentive payments under Medicare and Medicaid that are established by statute.

Comment: Some commenters also stated that the yearly reporting period also introduces problems for quality reporting and that vendors and developers have insufficient time to update and test the products, especially for new quality measures that will not be finalized under the Medicare PFS until November 1 of the previous year. Other commenters stated that vendors and developers are unlikely to be able to implement the changes made in the Medicare PFS final rule in time to deliver updated products prior to the January 1, 2018 Stage 3 deadline, and these conflicting deadlines will continue to be a problem that will impact future program years.

Response: We note that CMS quality reporting programs for EPs (for example, PQRS and Value-Based Payment Modifier) have a full year reporting or performance period and that the CQMs used for those programs require a full year of data. CMS

quality reporting programs are working in partnership with the EHR developer and vendor community to streamline the annual update process to ensure the integrity of data and the effectiveness of eCQM specifications. (For further information, we refer readers to section II.C of this final rule with comment period.)

Comment: A number of commenters requested a 90-day reporting period for providers in the first year of Stage 3 especially for any providers seeking to demonstrate the Stage 3 objectives and measures in the optional year in 2017. Some of these commenters indicated that they agree with the need for full year reporting, but believe that it is appropriate to allow a 90-day EHR reporting period when providers move to a new stage in order to mitigate issues with workflows, ensure the effective implementation of new technologies, and integrate new processes into clinical operations.

Response: We disagree that a 90-day EHR reporting period is appropriate for all providers moving to Stage 3, as we believe the lead time required for participation in 2018 is sufficient. In addition, the optional year in 2017 allows providers to work toward the Stage 3 measures and test workflows prior to their required implementation in 2018. However, we agree that the allowance of a 90-day EHR reporting period may be appropriate for providers attesting to the objectives and measures of Stage 3 in 2017. A 90-day EHR reporting period in this case would recognize the shorter time period from development of the technology to implementation for use in 2017 and a shorter time period for the necessary testing and implementation of workflows and new technologies. A 90-day EHR reporting period in 2017 would allow for further flexibility in the installation and implementation of the overall upgrade to technology certified to the 2015

Edition by spreading out the demand over a greater period of time. In addition, a 90-day EHR reporting period in 2017 for Stage 3 providers would provide a benefit by easing the transition for those providers who choose to move to Stage 3 early and will potentially make that choice more accessible for a greater number of providers. Therefore, we agree that allowing a 90-day EHR reporting period for Stage 3 providers in 2017 would support the transition to a new technology, the adoption of technology and clinical workflows, and the overall progress toward program goals.

After consideration of the public comments received, we are finalizing our proposal to require a full CY EHR reporting period for all providers (with a limited exception for new meaningful EHR users under Medicaid) beginning in CY 2017, with a modification for providers attesting to Stage 3 of meaningful use in 2017. For EPs, eligible hospitals, and CAHs that choose to meet Stage 3 in 2017, the EHR reporting period is any continuous 90-day period within CY 2017. For all other providers, the EHR reporting period is the full CY 2017. Beginning in CY 2018, for all EPs, eligible hospitals, and CAHs (including those attesting to Stage 3 for the first time), the EHR reporting period is the full CY.

We finalize our proposal to maintain the 90-day EHR reporting period for a provider's first payment year based on meaningful use for EPs and eligible hospitals participating in the Medicaid EHR Incentive Program for 2017 and subsequent years.

We revised the definition of "EHR reporting period" under § 495.4 to reflect these final policies. As we noted previously and in the Stage 3 proposed rule (80 FR 16739), the incentive payments under FFS and MA (sections 1848(o), 1886(n), 1814(l)(3),

1853(l)and(m) of the Act) will end before 2017. Thus the final policies for the EHR reporting period we adopt here would apply only for EPs and eligible hospitals that seek to qualify for an incentive payment under Medicaid. For the payment adjustments under Medicare, we discuss the duration and timing of the EHR reporting period for a payment adjustment year in section II.E.2 of this final rule with comment period.

(4) Considerations in Defining Meaningful Use

(a) Considerations in Review and Analysis of the Objectives and Measures for Meaningful Use

In the Stage 3 proposed rule (80 FR 16740), we noted that for the Stage 1 and Stage 2 final rules, the requirements of the EHR Incentive Programs included the concept of a core and a menu set of objectives that a provider needed to meet as part of demonstrating meaningful use of CEHRT. In Stage 2, we also combined some of the objectives of Stage 1 and incorporated them into objectives for Stage 2. In the Stage 2 final rule (77 FR 53973), we signaled that the Stage 2 core and menu objectives would all be included in the Stage 3 proposal.

However, since the Stage 2 final rule publication, we have reviewed program performance from both a qualitative and quantitative perspective including analyzing performance rates; reviewing the adoption and use of CEHRT; and considering information gained by engaging with providers through listening sessions, correspondence, and open forums like the HIT Policy Committee. The data supported the following key points for consideration:

- Providers are performing higher than the thresholds for some of the meaningful

use measures using some EHR functionalities that—prior to the Stage 1 and Stage 2 final rules—were not common place (such as the maintenance of problem lists).

- Providers in different specialties and settings implemented CEHRT and met objectives in different ways.
- Providers express support for reducing the reporting burden on measures that have "topped out."
- Providers expressed support for advanced functionality that would offer value to providers and patients.
- Providers expressed support for flexibility regarding how objectives are implemented in their practice settings.
- Providers in health systems and large group practices expressed frustration about the reporting burden of having to compile multiple reports spanning multiple stages and objectives.

Since the beginning of the Medicare and Medicaid EHR Incentive Programs in 2011, stakeholder associations and providers have requested that we consider changes to the number of objectives and measures required to meet the program requirements, including the recommendation to allow a provider to fail any two objectives, thus making all objectives "menu" objectives. We noted in the Stage 3 proposed rule (80 FR 16740) that we decline to follow these recommendations for several reasons. First, the statute specifically 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, for example, section 1848(o)(2)(A)(iii) of the Act). Second, there are certain objectives and

measures that capture policies specifically required by the statute as core goals of meaningful use of CEHRT, such as electronic prescribing for EPs, HIE, and clinical quality measurement (see sections 1848(o)(2)(A) and 1886(n)(3)(A) of the Act).

Furthermore, the statute requires that the CEHRT providers must be a "qualified EHR" as defined in section 3000(13) of the Public Health Service Act as an electronic record of health-related information on an individual that includes patient demographic and clinical health information, such as medical history and problem lists; and has the capacity to --

- Provide clinical decision support;
- Support physician order entry;
- Capture and query information relevant to health care quality; and
- Exchange electronic health information with, and integrate such information

from, other sources (see section 1848(o)(4) of the Act).

We analyzed the objectives and measures in Stage 1 and Stage 2 of the program to determine where measures are redundant, duplicative, or have topped out. "Topped out" is the term used to describe measures that have achieved widespread adoption at a high rate of performance and no longer represent a basis upon which provider performance may be differentiated. We considered redundant objectives and measures to include those where a viable health IT-based solution may replace paper-based actions, such as the Stage 2 Clinical Summary objective (77 FR 54001 through 54002). We considered duplicative objectives and measures to include those where some aspect is also captured in the course of meeting another objective or measure, such as recording vital signs.

We proposed (as discussed in sections II.B.1.b.(3) and II.C of this final rule with comment period) to reduce provider burden and simplify the program by aligning EHR reporting periods and CQM reporting. Our proposals for Stage 3 would continue the precedent of focusing on the advanced use of CEHRT and reduce the reporting burden; eliminate measures that are now redundant, duplicative, and topped out; create a single set of objectives for all providers with limited variation between EPs, eligible hospitals, and CAHs as necessary; and provide flexibility within the objectives to allow providers to focus on implementations that support their practice.

(i) Topped out Measures and Objectives

In the Stage 3 proposed rule (80 FR 16741 through 16742), we proposed to adopt an approach to evaluate whether objectives and measures have become topped out and, if so, whether a particular objective or measure should be considered for removal from reporting requirements. We proposed to apply the following two criteria, which are similar to the criteria used in the Hospital Inpatient Quality Reporting(IQR) and Hospital Value Based Purchasing(HVBP) Programs (79 FR 50203): (1) statistically indistinguishable performance at the 75th and 99th percentile, and (2) performance distribution curves at the 25th, 50th, and 75th percentiles as compared to the required measure threshold.

Comment: A large number of commenters on the Stage 3 proposed rule are in support of the removal of reporting requirements for measures that have achieved high rates of compliance. Some commenters wrote that this would greatly reduce the reporting burden for EPs and eligible hospitals.

Response: We thank the commenters for their support of this proposal. As we stated in the Stage 3 proposed rule (80 FR 16741), the removal of topped out measures is intended in part to focus on reduction of the reporting burden on providers for measures already achieving widespread adoption.

Comment: A few commenters stated they do not believe that performance rates alone provide a valid reason to consider a measure topped out. High performance rates on some measures among reporting EPs may be partly attributable to intensified improvement efforts motivated by the reporting opportunities. Furthermore, classifying any given measure as having a high performance rate when the Stage 2 reporting rate is less than 10 percent of all EPs is premature.

Response: Performance rates are only one factor considered in the decision to discontinue use of a measure in the Medicare and Medicare EHR Incentive Programs. Similarly, measure performance among hospitals (whether a measure is "topped out") is one of several criteria considered when determining whether to remove Hospital IQR Program measures (79 FR 50203). Multiple factors beyond performance are included in the determination of whether a measure should be considered for removal from reporting requirements.

For the 2014 EHR reporting period, more than 1,800 eligible hospitals and CAHs and 60,000 EPs attested for their performance on the Stage 2 objectives and measures. However, we did not limit our analysis to only Stage 2 providers. Instead, we looked at performance rates across the longevity of the program for providers in all levels of participation. Most of the measures identified are at exceptionally high performance

among first time participants in Stage 1 as well, with little or no variation as compared to providers in 3 or more years of participation. For the Medicare and Medicaid EHR Incentive Programs, we additionally looked at measures that represent static data capture measures and measures for which the action is now automated by the EHR technology, as opposed to active measures that use the structure data to inform a clinical decision, provide patient specific education, or are used in care coordination. Once the performance on a static measure exceeds the point at which reasonable differentiation can be made among providers using CEHRT, we believe that the active use of the data elements is more beneficial for both provider and patient than the continued requirement to measure the capture of these elements.

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 website data and reports page.

Comment: A commenter cautioned against removing measures that may appear to be topped out but are clinically significant or focused on patient safety. Another commenter suggested that CMS consider both the pediatric population, as well as the adult population before they determine that a measure is topped out.

Response: As we stated in the Stage 3 proposed rule (80 FR 16741) and in the previous responses to comments, we believe it is appropriate to remove some measures which have reached widespread adoption. However, we agree that the analysis of these measures and their identification as topped out should take into account other factors such as clinical significance and patient safety. In the proposed rule we specifically

discussed reviewing the provider performance on measures identified as redundant and duplicative measures, as this impacts the statistical likelihood that the functions of measures and the processes behind them would continue even without a requirement to report the results (80 FR 16742). For example, electronic prescribing for EPs may be considered topped out if only the performance percentiles are considered. However, we proposed to maintain this measure because it relates to clinical effectiveness and patient safety and is foundational to the program (80 FR 16747).

For the commenter mentioning pediatric versus adult populations, the EHR Incentive Programs do not include a separate set of meaningful use objectives and measures for adult populations versus pediatric populations. Nor does CMS collect individual patient data through the EHR Incentive Programs. While certain measures may include specifications related to age, CMS only collects summary-level data in the form of numerators and denominators. Therefore we are not able to compare performance on these measures for different patient populations. However, we would note that the measures we proposed to remove had significantly high performance, with providers in all specialties performing well above the required thresholds.

Comment: Another commenter is concerned that by suddenly eliminating measures, CMS may be creating uncertainty and inadvertently sending the message that sustained performance is no longer necessary. The commenter believes it is important that EPs be given proper notice of the agency's plans for eliminating measures.

Some commenters stated removing the measures may lead to EHR vendors and developers not providing metrics on the measures in reports that are used for

benchmarking and internal quality improvement work. These commenters recommended that providers should continue to be required to report on all topped out measures without a threshold, where the measure would be to attest that the provider is recording the information.

Response: We notified the public of our intent to remove measures from the program through notice of proposed rulemaking and requested public comment on these changes in both the Stage 3 proposed rule and the EHR Incentive Programs in 2015 through 2017 proposed rule. In addition, as noted in the Stage 3 proposed rule (80 FR 16741), evaluation of measures and performance is common practice for CMS programs to ensure ongoing program effectiveness.

We disagree that threshold measures should be replaced with "check box" measures for each of the topped out measures as this would provide no value for measurement and is counter to the effort to reduce the reporting burden on providers. Providers who wish to independently measure the capture of a particular data element should work with their EHR developer and vendor to ensure they are receiving the most appropriate analytics for their practice and patient population – just as they would with any data element they wished to track that was not already required by the Medicare and Medicaid EHR Incentive Programs.

Comment: A few commenters stated the impact of reducing the reporting burden for meaningful use is minimal and that the burden of meeting the requirements of the EHR Incentive Programs lies in bridging clinical workflow and best practices, patient safety, technology, and program understanding.

Response: While we agree that the objectives and measures required in the program are directly correlated with clinical workflows, technology, program understanding, and patient safety, we are responding to concerns stated by a wide range and significant number of stakeholders, including the burden of reporting requirements and complexity within the program.

After consideration of the public comments received, we are finalizing as proposed our approach for evaluating whether objectives and measures are "topped out," and if so, whether a particular objective or measure should be considered for removal from the EHR Incentive Programs.

(ii) Electronic Versus Paper-Based Objectives and Measures

In Stage 1 and Stage 2, we require or allow providers the option to include paper-based formats for certain objectives and measures, including the provision of a non-electronic summary of care document for a transition or referral, at § 495.6(j)(14)(i) for EPs and for eligible hospitals and CAHs at § 495.6(l)(11)(i), and the provision of paper-based patient education materials, at § 495.6(j)(12)(i) for EPs and § 495.6(l)(9)(i) for eligible hospitals and CAHs. For these objectives and measures, providers would print, fax, mail, or otherwise produce a paper document and manually count these actions to include in the measure calculation. We proposed to discontinue this policy for Stage 3; paper-based formats would not be required or allowed for the purposes of the objectives and measures for Stage 3 of meaningful use.

This does not imply that we do not support the continued use of paper-based materials in a practice setting. We strongly recommend that providers continue to

provide patients with visit summaries, patient health information, and preventative care recommendations in the format that is most relevant for each individual patient and easiest for that patient to access.

Comment: Many commenters on the Stage 3 proposed rule stated they enthusiastically support this requirement. Requiring or even allowing paper-based methods, such as faxing of summaries of care at transitions or referrals, may be hindering some providers from adopting digital technologies (for example, direct addresses) that support the overarching goal of meaningful use, which is to use technology to improve patient outcomes.

Response: We appreciate your feedback in support of eliminating paper-based methods of reporting in order to be a meaningful user in Stage 3 and we agree that limiting the focus of the program to only health IT solutions may encourage adoption as well as spurring further innovation among IT developers. As stated in the Stage 3 proposed rule (80 FR 16742) our goal is to focus on advanced use of EHRs. While we do not in any way seek to limit the methods by which a provider may engage with a patient or share information, we do not believe that requiring providers to measure paper-based actions is consistent with the long-term goals of the program. We believe that the requirements and focus of the program should be exclusively on leveraging HIT to support clinical effectiveness and patient safety, HIE, and quality improvement.

Comment: Many commenters requested that we keep paper-based measures in place, stating that CMS should not encourage electronic processes exclusively until consumers are ready to accept them.

Response: As noted in the Stage 3 proposed rule (80 FR 16742), our policy to no longer require or allow providers to record and report paper-based actions does not imply that we do not support the continued use of paper-based materials in a practice setting. Some patients may prefer to receive a paper version of their clinical summary or may want to receive education items or reminders on paper or some other method that is not electronic. Our proposal would simply no longer require or allow providers to manually count and report on these paper-based exchanges.

Comment: Another commenter stated this proposal to eliminate paper-based formats will cause extreme hardship for providers who serve geriatric populations and will negatively impact the quality of care their elderly patients will receive. Many geriatric patients and their caretakers do not have access to internet or computers and do not have any other means of receiving electronic health information.

Response: We strongly recommend that providers continue to provide patients with visit summaries, patient health information, and preventative care recommendations in the format that is most relevant for each individual patient and easiest for that patient to access. In some cases, this may include the continued use of non-IT based resources. However, we proposed this method would no longer be required or allowed for manual measurement in order to meet the requirements of the Medicare and Medicaid EHR Incentive Programs.

Comment: A commenter stated there must be a focus on standards to ensure that EHRs are collecting the appropriate and relevant clinical data. If printed, the electronic versions of visit summaries should be presented in a clinically relevant manner. In

addition, because the commercial payer community is not impacted by the requirements of the EHR Incentive Programs, many providers continue to prefer a paper-based information format, with electronic formats limited to practice management software. A commenter also stated that if the EHR systems do not adequately populate necessary information, paper-based formats are necessary to track actions and measure calculations.

Response: We respectfully disagree. Paper-based formats are not necessary to populate information that CEHRT systems capture. CEHRT stores data in a structured format that allows patient information to be easily retrieved and transferred. The removal of paper-based actions is intended to support the discontinuation of manual paper-based calculation and chart abstraction. If a provider's EHR is not accurately capturing and allowing for the retrieval and transfer of data, the provider should work with their EHR developer to correct the error. The provider should also ensure that all staff entering information into the EHR have the necessary training to input patient data, just as staff were previously trained to input data correctly into a paper record or administrative or billing system. We believe this will also eliminate redundancy for providers in clinical and administrative processes. As noted in the Stage 3 proposed rule, we consider redundant objectives and measures to include those where a viable health IT-based solution may replace paper-based actions (80 FR 16741).

After consideration of the public comments, we are finalizing our proposal that paper-based formats will not be required or allowed for the purposes of the objectives and measures for Stage 3 of meaningful use.

(iii) Advanced EHR Functions

In the Stage 3 proposed rule (80 FR 16742), we proposed to simplify requirements for meaningful use through an analysis of existing objectives and measures for Stages 1 and 2 to determine if they are redundant, duplicative, or "topped out". We noted that some of the objectives and measures which meet these criteria involve EHR functions that are required by the statutory definition of "certified EHR technology" (see section 1848(o)(4) of the Act, which references the definition of "qualified EHR" in section 3000(13) of the Public Health Service Act) which a provider must use to demonstrate meaningful use. We stated that it was our intent that the objectives and measures proposed for Stage 3 would include uses of these functions in a more advanced form. For example, patient demographic information is included in an electronic summary of care document called a consolidated clinical document architecture (C-CDA) provided during a transition of care in the Stage 2 Summary of Care objective and measures (77 FR 54013 through 54021), which represents a more advanced use of the EHR function than in the Stage 1 and 2 objective to record patient demographic information (77 FR 53991 through 53993).

We received the following comments on this proposal and our response follows.

Comment: Many commenters applauded this proposal noting that it made no sense to require providers to track the capture of data when providers were also tracking the use of that exact same data in other objectives and measures. Providers specifically noted that items such as vital signs and smoking status were not only used in multiple other objectives (for example, they must be included in a summary of care document), but that they are also included in CQMs which allow providers more insight into the

clinical relevance of the data.

Some commenters objected to removing duplicative data capture from the program— specifically citing the measures for patient demographics, structured lab results, vital signs, advance directives, and smoking status— because they believe the measures should continue to be independently captured. One commenter requested clarification on how Stage 2 measures like family health history and electronic progress reports are incorporated into Stage 3. A commenter suggested that there needs to be more clarity with respect to how those measures which are duplicative of more advanced processes are still required for use and potentially tracked through other means, such as in the common clinical data set (CCDS).

Response: As stated previously in this final rule with comment period, we note that we sought to identify the objectives and measures which measure only the capture data in a structured format without any additional requirement on the use of that data within the measure. We also note that this was an important factor in reviewing those measures which were identified as potentially topped out (section II.B.2.b.(4)(a)(i)). In other words, most measures selected for removal were both topped out and also redundant or paper-based (as discussed previously in section II.B.2.b.(4)(a)(ii)), or duplicative of more advanced use objectives. We understand some providers may still find value in independently setting goals for data capture of structured data elements; however, we believe it is appropriate to no longer require reporting to CMS on these redundant or duplicative measures. We believe this will allow providers to focus on the use of the technology and the use of the data to support care coordination and quality

improvement rather than monitoring the simple capture of that data for a measure which has already reached high capture rates.

We note that family health history is still a required data field within the definition of CEHRT at § 495.4. This means it will still be part of CEHRT available for provider use. This measure in particular was identified as having high performance, but also representing a significant burden for counting and measurement purposes.

According to provider recommendations, family health history should not be recorded in an EHR in episodic fashion but should allow for linear capture as structured data that can be leveraged by more advanced functions, such as the Patient Specific Education measure under the Patient Electronic Access objective. Electronic notes are similar use cases within the CEHRT, as are the standards for advance directives and smoking status. In addition, the requirements for the fields within an electronic summary of care document, the C-CDA, include structured data elements such as demographics, medication list, medication allergy list, vital signs, and structure lab results, among others, which are required as part of the electronic summary of care document C-CDA a provider must send in conjunction with a transition of care or referral in support of effective care coordination. For further information, we refer readers to the ONC 2015 Edition Certification Criteria final rule published elsewhere in this Federal Register.

Comment: A commenter on the Stage 3 proposed rule stated that although it is implied, it does not appear to be clearly stated that vocabularies and standards associated with the topped out, redundant, or duplicative measures are still required for use.

Response: We did not propose to remove the required use of standards associated

with structured data capture within the CEHRT. CEHRT must still include the functions and capabilities that are part of the overall definition of requirements for CEHRT for the Medicare and Medicaid EHR Incentive Programs, including LOINC standards, HL7 standards, and SNOMED standards, among others, as established in the ONC certification criteria for CEHRT. These structured data elements must also be part of the C-CDA in an electronic exchange and the information provided to a patient through the view, download, and transmit functions of CEHRT. For further information, we refer readers to the ONC 2015 Edition Certification Criteria final rule published elsewhere in this Federal Register.

After consideration of the public comments received, we are finalizing our proposed approach for analyzing the objectives and measures to identify and maintain and promote the advanced use of health IT for Stage 3 of meaningful use.

(b) Considerations in Defining the Objectives and Measures of Meaningful Use for 2015 through 2017

In the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20354), we stated that we analyzed the existing objectives and measures of meaningful use to consider if they should be modified for the program beginning in 2015. Using the approach 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 also considered the functions and standards included the technology certified to 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.

Our analysis of the objectives and measures of meaningful use Stage 1 and Stage 2 identified a number of measures that met the criteria as either redundant, duplicative, or topped out, with new participants consistently performing at a statistically comparable rate to returning participants. Table 2 identifies the current objectives and measures that met the criteria. Therefore, we proposed (80 FR 20355) to no longer require providers to attest to these objectives and measures as currently codified in the CFR under § 495.6 in order to meet program requirements beginning in 2015.

TABLE 2: OBJECTIVES AND MEASURES IDENTIFIED BY PROVIDER TYPE THAT ARE REDUNDANT, DUPLICATIVE, OR TOPPED OUT

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

We noted 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 encouraged 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 withdrawal of an endorsement for these best practices or to discourage providers from conducting and tracking these activities for their own quality improvement goals. 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.

Comment: The majority of commenters for the EHR Incentive Programs in 2015 through 2017 proposed rule were in support of removing the objectives and measures that are considered redundant, duplicative, or "topped out," including patient reminders, recording vital signs, smoking status, structured lab results, patient lists, imaging results, family health history, and demographics. Some commenters stated they agree that many of the measures no longer provided enough value to remain part of the program. Limiting the number of objectives to those that can truly impact the biggest issues facing healthcare technology is an appropriate and much needed direction.

Other commenters stated they believe this will have the effect of simplifying the EHR Incentive Programs and easing the administrative burdens associated with the attestation process. Other commenters support the idea of encouraging providers to continue to conduct these activities if it suits their practice and the preferences of their patient population—but not be required to attest to these measures in order to meet the requirements of the program.

Response: As we stated in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 16741), we proposed the removal of these measures, or measures that are no longer useful in gauging performance, in order to reduce the reporting burden on providers for measures already achieving widespread adoption.

Comment: Some commenters on the EHR Incentive Programs in 2015 through 2017 proposed rule indicated some objectives still require some of the same structured

data elements scheduled to be retired and some may still be of value to an organization in meeting other initiatives or regulatory requirements and are, therefore, worth retaining. A commenter disagreed with removal of the vital signs measure, as other measures may not fully capture vital sign information on all patients and keeping the measure incentivizes providers not only to collect these important data points but also to ensure that vital signs data is input into the EHR. Another commenter stated that not providing clinical summaries could have the adverse effect of decreasing patient engagement, especially if patients are not using patient portals. Some commenters indicated exempting laboratory data is especially damaging to the creation of EHRs because structured laboratory data provides the best opportunity to load results automatically into an EHR, given the degree of coding and structure, and prevents duplicate ordering. Other commenters are concerned that an EHR will not allow providers to create their own patient lists so they can assess which of their patients may require additional clinical attention. Another commenter was opposed to the removal of electronic notes, stating when providers must continually find the paper chart in order to know what is going on with the patient, it slows them down and they do not get optimal value out of an EHR.

Some commenters opposed the removal of specific objectives or measures, such as the imaging results measure, stating it should be retained as a menu set choice or as an alternate choice to implementing reporting for a second public health measure in addition to immunization reporting. Other commenters are concerned with the removal of the family history measure because this data can be a strong indicator for preventative services. A few commenters are concerned with the removal of the record demographics

measure and stated, if removed, adherence may drop and reporting will be less useful.

Response: We agree that functions and standards related to measures that are no longer required for the EHR Incentive Programs could still hold value for some providers and organizations. As stated in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20355), we encourage providers to continue to use the information as best suits their practice and the preferences of their patient population. The removal of these measures from the EHR Incentive Programs is not intended as a withdrawal of an endorsement of the use of the standards, the capture of the data, the implementation of best practices, or to discourage providers from conducting and tracking the information for their own quality improvement goals. Additionally, the data standards and functions will remain part of CEHRT for provider use. As part of our effort to reduce complexity, reduce reporting burden, and streamline the EHR Incentive Programs, we proposed to remove the core and menu structure established in previous rules. We do not believe the continuation of an optional menu objective for simple data capture provides better support for the standard than the support provided by requiring the inclusion of the standard in CEHRT and the use of that data within a more advanced objective.

As noted previously, we support the continued use of structured data within a certified EHR to support advanced clinical processes, care coordination, and quality improvement. The capture of this data in a structured format allows the provider to use the data for these processes and supports the efficacy of quality measurement and quality improvement. The removal of the requirement to count simple data capture allows providers to shift the focus of their use of technology to support effective use of the data.

Comment: A commenter on the EHR Incentive Programs in 2015 through 2017 proposed rule requested CMS clarify further the reasons why objectives and measures were removed.

Response: As we noted in the Stage 3 proposed rule (80 FR 16741 through 16742), we reviewed performance data submitted by providers through attestation to determine topped out measures. We applied the following criteria to determine topped out measures: (1) statistically indistinguishable performance at the 75th and 99th percentile, and (2) performance distribution curves at the 25th, 50th, and 75th percentiles as compared to the required measure threshold. We then compared the identified measures to other meaningful use objectives that use the data in a more advanced function. We also proposed to remove measures that are paper-based for the reasons stated previously. We encourage commenters to review the performance data on our website under EHR Incentive Programs Objective and Measure Performance Report for additional information³.

After consideration of the public comments received, we are finalizing, as proposed, the list of objectives and measures in Table 2 identified as redundant, duplicative, or topped out and will no longer require these objectives and measures for meaningful use beginning with an EHR reporting period in 2015. The removal of these measures is reflected in the final objectives and measures adopted in the regulation text at § 495.22.

(i) Changes to Objectives and Measures for 2015 through 2017

³ CMS EHR Incentive Programs Data and Reports at [www.CMS.gov/EHR Incentive Programs](http://www.CMS.gov/EHR%20Incentive%20Programs)

In the EHR Incentive Programs in 2015 through 2017 proposed rule, we noted that in order to implement the proposed changes to the program to align with long-term goals; there are a number of changes that must be made to other requirements of meaningful use (80 FR 20355). These changes fall into the following two major categories--

- Changes to streamline the structure in 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 demonstrate meaningful use for an EHR reporting period in 2015.

We recognized and considered the stakeholder and provider representatives' concerns in implementing the patient engagement objectives requiring patient action (see the Stage 2 final rule at 77 FR 54046 under the Health Outcomes Policy Priority "Engage patients and families in their care"), which include barriers to successful implementation of the required health IT or CEHRT functions necessary to support the measures. We proposed changes to these objectives to allow providers to focus on improvements without jeopardizing their ability to successfully fulfill the requirements of the EHR Incentive Programs.

(ii) Structural Requirements of Meaningful Use in 2015 through 2017

In the EHR Incentive Programs in 2015 through 2017 proposed rule, we proposed to eliminate the distinction between core and menu objectives and purported that all retained objectives 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 (80 FR 20356). 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

Furthermore, we stated that the objectives and measures retained in each case for all providers would be the Stage 2 objectives and measures and proposed to establish alternate exclusions and specifications to mitigate any additional burden on providers for an EHR reporting period in 2015 (80 FR 20356).

For the public health reporting objectives and measures, we proposed 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 because we believe it allows for greater flexibility for providers and supports continued efforts to engage providers and public health agencies in the essential data capture and information exchange that 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. For the consolidated public health reporting objective in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20366), we proposed that EPs report on any combination of two of the five available options, while eligible hospitals and CAHs report on any combination of three of the six available options. If a provider is scheduled

to attest to Stage 1 of meaningful use in 2015, we proposed to allow EPs to report on only one of the five available options outlined and the eligible hospitals or CAHs to report on any combination of two of the six available options for an EHR reporting period in 2015 (80 FR 20366).

Therefore, we proposed that the structure of meaningful use for 2015 through 2017 would be nine required objectives for EPs using the Stage 2 objectives for EPs, with alternate exclusions and specifications for Stage 1 providers in 2015. We proposed that the structure of meaningful use for 2015 through 2017 would be eight required 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 two measures from the public health reporting objective or meet the criteria for exclusion from up to five measures; eligible hospitals and CAHs would be required to report on a total of three measures from the public health reporting objective or meet the criteria for exclusion from up to six measures.

TABLE 3: 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 2 public health 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 3 public health objectives	8 core objectives 1 public health objective (3 measure options)
	Current Stage 2 Structure	Retained Objectives	Proposed Structure
EP	17 core objectives including public health objectives 3 of 6 menu objectives	9 core objectives 0 menu objectives 4 public health 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	7 core objectives 1 menu objective 3 public health objectives	8 core objectives 1 public health objective (3 measure options)

We received public comment on this proposal and our response follows.

Comment: Many commenters on the EHR Incentive Programs in 2015 through 2017 proposed rule relayed their support of program consolidation with transition to a single stage, as well as the removal of core and menu objectives and measures.

Other commenters believe that such changes will make it much easier for all providers to attest, for providers to know what Stage they are in, and for CMS to track providers who are in different reporting years. Some commenters stated that the transition to a single stage of meaningful use would drastically reduce the administrative burden, provide simplicity that will benefit EHR developers and users, and facilitate meeting interoperability goals. Other commenters stated that by reducing the amount of effort that a participant has to exert – especially for measures that are already a matter of clinical routine – participants will have an experience that is significantly less intrusive.

Response: We appreciate the commenters' feedback and support for our proposal

to transition to a single stage of meaningful use. In this final rule with comment period, we are making changes to the requirements for Stage 1 and Stage 2 for 2015 through 2017 to align with the approach for Stage 3 in 2018 and subsequent years. This includes a simplified structure and focus on objectives and measures with sustainable growth potential aligned to the programs' foundational goals prior to the full implementation of Stage 3 in 2018.

Comment: Some commenters on the EHR Incentive Programs in 2015 through 2017 proposed rule stated that eliminating the core and menu structure does not mean that choice should be eliminated from the structure of reporting. Other commenters requested that the original core and menu structure be kept in the program.

Response: The proposed removal of the core and menu structure is part of our focus to simplify the reporting requirements and decrease complexity in response to stakeholder feedback. We proposed this change to refocus program requirements on those objectives and measures that represent advanced use of CEHRT.

We disagree that the commenters' suggestion to retain a core and menu structure offers value to supporting program goals or to promoting flexibility in a meaningful way. Retaining a menu of objectives that includes topped out, redundant, or duplicative measures for the sole purpose of allowing providers to continue to choose among them is counter-productive to efforts to reduce program complexity and ease the reporting burden on providers. It also offers no benefit to CMS to continue to require reporting on measures that no longer represent a statistical value for measurement or a means of differentiating provider performance. The only other method by which a menu could be

implemented would be to make formerly required objectives optional. As stated in the EHR Incentive Programs in 2015 through 2017 proposed rule(80 FR 20386), we do not believe that approach supports program goals or meets our statutory duty to require more stringent measures of meaningful use over time.

Furthermore, we believe the objectives that we proposed to retain represent the functions that any provider should apply to leverage HIT in support of improved outcomes for their patients. We believe that the existing exclusions for each measure are adequate to allow flexibility for providers. Additionally, we have proposed to include alternate exclusions and specifications for Stage 1 providers in 2015 to allow them to continue the workflows they have already established for 2015 and give them time to move forward with the more advanced measures.

After consideration of public comments received, we are finalizing the changes to the structure as proposed.

(iii) Alternate Exclusions and Specifications for Stage 1 Providers for Meaningful Use

We proposed (80 FR 20357) several alternate exclusions and specifications for providers scheduled to demonstrate Stage 1 of meaningful use in 2015 that 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 that have a lower threshold or other measure differences between Stage 1 and Stage 2;
- Establishing exclusion for Stage 2 measures that 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 that would now be otherwise required.

For the first category, we proposed 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 noted that for an EHR reporting period beginning in 2016, we proposed that all providers must attest to the specifications (including the measure thresholds) associated with the Stage 2 measure. For the second category, we proposed the alternate exclusions outlined for providers would only apply for an EHR reporting period in 2015. For an EHR reporting period in 2016, we proposed that 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.

The proposed 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 in the EHR Incentive Programs in 2015 through 2017 proposed rule(80 FR 20358 through 20374).

Comment: Many commenters were supportive of allowing alternate exclusions for Stage 1 providers in 2015. Some stated that if the proposal to shift to a single set of measures for 2015 were adopted, providers who were planning to attest to Stage 1 in 2015 in accordance with the current policies would certainly require accommodations. Other commenters stated that these exclusions should also be considered optional for Stage 1 providers who want to move to Stage 2 immediately. Many commenters stated that it would benefit the provider if they were able to indicate the Stage that they were

scheduled to demonstrate for 2015 in the attestation system.

Response: We thank you for your support of our proposal to establish alternate exclusions and specifications to ease the transition to a single stage of meaningful use. We proposed to accommodate eligible providers previously scheduled to demonstrate Stage 1 in 2015 by allowing alternate exclusions and specifications for certain objectives or measures. Providers scheduled to be in Stage 1 may opt to use the alternate exclusions and specifications, but they are not required to use them. The Medicare and Medicaid EHR Incentive Programs registration and attestation system will automatically identify those providers who are eligible for alternate exclusions and specifications. Upon attestation, these providers will be offered the option to attest to the Stage 2 objective and measure and the option to attest to the alternate specification or claim the alternate exclusion if available. The provider may independently select the option available to them for each measure for which an alternate specification or exclusion may apply.

Comment: A commenter requested clarification on how providers should document that they did not intend to attest to a menu objective or clarification that this is not something that will be/should be audited.

Response: We understand that intent or lack thereof may be difficult for a provider to document and will not require documentation that a provider did not plan to attest to a menu objective for the provider to claim the alternate exclusion.

Comment: A number of commenters strongly recommended that CMS keep the alternate specifications and exclusions proposed for 2015 available for providers meant to be in Stage 1 in 2016 and 2017 to allow more recent participants the same progression

through the stages of the EHR Incentive Programs as those who entered the program earlier. Other commenters suggested that while the Stage 2 objectives are achievable with prior planning by 2017, retaining the alternate exclusions alternate in 2016 would allow providers to obtain and effectively implement any necessary software required to meet certain Stage 2 measures that they may not currently have in place. These commenters noted that for some objectives and measures, the need to obtain and implement CEHRT that they do not already possess would require time to ensure privacy and security protocols and patient safety measures are effectively implemented. Commenters noted this is especially true with the functions, clinical workflows, and staff training that would be required to effectively implement electronic prescribing and computerized provider order entry, which may present a significant risk to patient safety if the technology is implemented incorrectly in order to meet an expedited timeline.

Response: We understand the commenters' concerns that meeting the Modified Stage 2 requirements may be challenging for some providers for those objectives and measures that would require the implementation of additional CEHRT modules they did not previously possess because they were not scheduled to be in Stage 2 or because they did not intend to attest to the menu objective. In general, the timing to implement these new technologies would not necessary be prohibitive for a provider to successfully participate in 2016; however, as some commenters mentioned there are patient safety risks associated with the effective implementation of the technology and the supportive workflows which are of concern for certain objectives. To accommodate these concerns, we will allow providers who would otherwise be scheduled for Stage 1 in 2016 to claim

the alternate exclusions for the Modified Stage 2 objectives and measures that would require the effective implementation of CEHRT modules for an EHR reporting period in 2016 that the provider does not currently possess. Specifically, we believe this includes measures 2 and 3 (lab and radiology orders) of the Computerized Provider Order Entry Objective for EPs, eligible hospitals, and CAHs, as well as the Electronic Prescribing Objective for eligible hospitals and CAHs. However, we do not believe this extension should include the Health Information Exchange Objective for a number of reasons. First, we have already proposed additional flexibility for that objective in 2015 through 2017 regarding the CEHRT requirement for the transmission of an electronic summary of care document. Second, we believe the threshold of 10 percent associated with the Health Information Exchange Objective and measure is achievable within a calendar year. Finally, we believe that the ability of all providers to successfully exchange health information electronically is enhanced by greater participation among providers as a whole. We also do not believe that providers who otherwise would be scheduled for Stage 1 in 2016 should be allowed to use for an EHR reporting period in 2016 the alternate specifications that we proposed for 2015, as these are only applicable for measures that already have both a Stage 1 and Stage 2 equivalent and are supported by measures using the same CEHRT functions and standards. We direct readers to each objective in section II.B.2.a of this final rule with comment period for a full discussion of the details pertaining to the requirements for the alternate exclusions and specifications for the applicable objectives and measures.

After consideration of the public comments, we finalize the structure of the objectives and measures for the EHR Incentive Programs in 2015 through 2017 as proposed. In addition, we are finalizing as proposed the proposal for alternate exclusions and specifications for certain providers in 2015. We finalize that providers that were scheduled to demonstrate Stage 1 in 2015 or 2016 (for certain exclusions only) may choose the alternate exclusions and specifications where applicable or may attest to the modified Stage 2 objectives and measures. We finalize that EPs, eligible hospitals and CAHs that were scheduled to be in Stage 1 in 2016 may claim an alternate exclusion for an EHR reporting period in 2016 for the Computerized Provider Order Entry Objective Measures 2 and 3 (lab and radiology orders) or choose the modified Stage 2 objective and measures. We finalize that eligible hospitals and CAHs that were scheduled to be in Stage 1 in 2016 may claim an alternate exclusion for an EHR reporting period in 2016 for the Electronic Prescribing Objective or choose the modified Stage 2 Objective. For further detail, we direct readers to the individual objectives and measures for the EHR Incentive Programs in 2015 through 2017 in section II.B.2.a of this final rule with comment period. We refer readers to Table 1 in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20352) for an illustration of our policy on the prior progression of stages and whether a provider is scheduled to be in Stage 1 in 2015 or 2016.

(iv) Changes to Patient Engagement Requirements for 2015 through 2017

As discussed in the EHR Incentive Program for 2015 through 2017 proposed rule (80 FR 20357), we proposed to make changes to two objectives that have measures

related to patient engagement. We proposed to remove the threshold requirement for these two measures that count patient action in order for the provider to meet the measure. While we support patient engagement and believe that providers have a role in influencing patient behavior and supporting improved health literacy among their patients, data analysis on the measures supports concerns expressed by providers that significant barriers exist that heavily impact a provider's ability to meet the patient action measures. Therefore, we proposed to remove the thresholds for these two measures in order to allow for further maturity of the technology, greater saturation in the market, and increased awareness among patient population. We believe this allows for the necessary time for providers to work toward patient education and 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 that specifically contain measures requiring a provider to track patient action. We proposed to modify these measures as follows:

- Patient Action to View, Download, or Transmit (VDT) 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.

++ 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.

- 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.a of this final rule with comment period. We note that these changes are intended to allow providers to work toward meaningful patient engagement through HIT using the methods best suited to their practice and their patient population. Furthermore, we note that beginning in 2018 (and optionally in 2017); providers are required to meet an objective exclusively focused on patient engagement that has an expanded set of measures and increased thresholds. (For further information on that proposed objective, we direct readers to 80 FR 16755 through 16758.)

(c) Considerations in Defining the Objectives and Measures of Meaningful Use Stage 3

After analysis of the existing Stage 1 and Stage 2 objectives and measures as described in section II.B.1.b.(4)(a) and review of the recommendations of the HIT Policy Committee and the foundational goals and requirements under the HITECH Act, we identified in the Stage 3 proposed rule (80 FR 16743) eight key policy areas that represent the advanced use of EHR technology and align with the program's foundational goals and overall national health care improvement goals, such as those found in the CMS National

Quality Strategy.⁴ These eight policy areas provide the basis for the proposed objectives and measures for Stage 3. They are included in Table 4 as follows:

TABLE 4: OBJECTIVES AND MEASURES FOR MEANINGFUL USE IN 2017 AND SUBSEQUENT YEARS

Program Goal/Objective	Delivery System Reform Goal Alignment
Protect Patient Health Information	Foundational to the EHR Incentive Program and Certified EHR Technology* Recommended by HIT Policy Committee
Electronic Prescribing (eRx)	Foundational to the EHR Incentive Program National Quality Strategy Alignment
Clinical Decision Support (CDS)	Foundational to Certified EHR Technology Recommended by HIT Policy Committee National Quality Strategy Alignment
Computerized Provider Order Entry (CPOE)	Foundational to Certified EHR Technology National Quality Strategy Alignment
Patient Electronic Access to Health Information	Recommended by HIT Policy Committee National Quality Strategy Alignment
Coordination of Care through Patient Engagement	Recommended by HIT Policy Committee National Quality Strategy Alignment
Health Information Exchange (HIE)	Foundational to the EHR Incentive Program and Certified EHR Technology Recommended by HIT Policy Committee National Quality Strategy Alignment
Public Health and Clinical Data Registry Reporting	Recommended by HIT Policy Committee National Quality Strategy Alignment

*See, for example, sections 1848(o)(2) and (4) of the Act

In the Stage 3 proposed rule (80 FR 16743), we proposed that providers must successfully attest to these eight objectives and the associated measures (or meet the exclusion criteria for the applicable measure) to meet the requirements of Stage 3 in the Medicare and Medicaid EHR Incentive Programs. These objectives and measures include advanced EHR functions, use a wide range of structured standards in CEHRT, employ

⁴The National Quality Strategy: "HHS National Strategy for Quality Improvement in Health Care" <http://www.ahrq.gov/workingforquality/about.htm>

increased thresholds over similar Stage 1 and Stage 2 measures, support more complex clinical and care coordination processes, and require enhanced care coordination through patient engagement through a flexibility structure of active engagement measures.

Comment: Many commenters supported the approach for identifying the key priorities for the EHR Incentive Programs over the long term. Commenters' opinions on the top priorities varied, with some supporting greater patient engagement, some supporting a stronger shift towards outcomes-based quality measurement and quality improvement, and others encouraging continued support of interoperability and health information exchange infrastructure. Several commenters agreed with the specific selection of high priority goals identified by CMS. Other commenters noted that the priority goals are too broad and not specific enough to outcomes and chronic disease management or that many may not be universally relevant across all patient populations. Commenters also submitted comments on specific objectives or noted that across the board the measures associated with these objectives are not measuring improvements in patient outcomes.

Several commenters appreciated the removal of the core and menu structure of the objectives, while establishing a single set of objectives and measures in Stage 3, and believed it would reduce the program's complexity.

Response: We thank the commenters for their input both on our selection process and on the eight key policy areas we identified as well as on the structure of Stage 3. We agree with commenters who note that a wide range of high priority health conditions, as well as specific specialties and characteristics of unique patient populations, are not

explicitly recognized in our proposals or identified in the eight key policy areas. We note that we sought to establish a broad spectrum of key policy areas, which may include many varied projects, initiatives, and outcomes-based impact goals within their scope. The eight key policy areas here identified are intentionally broad in scope because, as noted in the proposed rule, we are seeking to align with overarching national health care improvement and delivery system reform goals and establish methods by which HIT can be leveraged by individual providers to support their efforts toward these key policy goals in their unique implementation.

In response to commenters who specifically cited a need to focus on outcomes and quality improvement based on outcomes measurement, we agree with this assessment. We note that the goal of the EHR Incentive Program is largely to spur the development and adoption of health HIT solutions that support these broader goals. We believe that technology itself cannot improve care coordination or patient outcomes, but the use of that technology can be a tool for providers to work toward these key policy areas. HIT can provide efficiencies in administrative processes which support clinical effectiveness, leveraging automated patient safety checks, supporting clinical decision making, enabling wider access to health information for patients, and allowing for dynamic communication between providers. That is why we proposed a set of priorities for Stage 3 that focus on these concepts. However, it is also the reason behind our efforts to align the EHR Incentive Program with the National Quality Strategy and with CMS quality measurement and quality improvement programs like PQRS, CPCI, Pioneer ACOs and Hospital IQR and HVBP programs. We welcome continued input from providers and

stakeholder groups as we continue our efforts to support and promote patient-centered delivery system reform.

We note that public comments received on specific objectives and responses to comments for these objectives are included in the discussion of each objective and its associated measures in section II.B.2.b of this final rule with comment period.

After consideration of the comments received, we are finalizing our approach for setting the eight key policy areas for Stage 3 as proposed. We address the individual objectives and measures in section II.B.2.b of this final rule with comment period.

(d) Flexibility within Meaningful Use Objectives and Measures

We proposed to incorporate flexibility within certain objectives for Stage 3 for providers to choose the measures most relevant to their unique practice setting. As a result, as part of successfully demonstrating meaningful use, providers would be required to attest to the results for the numerators and denominators of all measures associated with an objective. However, a provider would only need to meet the thresholds for two of the three associated measures. The proposed Stage 3 objectives including flexible measure options are as follows:

- Coordination of Care through Patient Engagement – Providers must attest to the numerators and denominators of all three measures, but must only meet the thresholds for two of three measures.
- Health Information Exchange – Providers must attest to the numerators and denominators of all three measures, but must only meet the thresholds for two of three measures.

- Public Health Reporting – EPs must report on three measures and eligible hospitals and CAHs must report on four measures.

For the objectives that allow providers to meet the thresholds for two of three measures (for example, the Coordination of Care through Patient Engagement objective and the Health Information Exchange objective), we proposed that if a provider claims an exclusion for a measure the provider must meet the thresholds of the remaining two measures to meet the objective. If a provider meets the exclusion criteria for two measures for such an objective, the provider may exclude those measures and must meet the threshold of the remaining measure to meet the objective. If a provider meets the exclusion criteria for all three measures for such an objective, the provider may exclude those measures and would still meet the objective.

Comment: We received comments supporting the flexibility proposed within certain objectives for Stage 3. Several commenters requested also allowing flexibility within other objectives not included in our proposal such as Computerized Provider Order Entry (CPOE) and CDS in order to accommodate specialties who may have low numbers of orders or who have limited applicable CQMs to pair with a CDS. We also received recommendations to change our approach toward flexibility including allowing providers to attest to only 2 of the 3 measures for which they meet the threshold to meet the objective, allowing providers to attest to all 3 measures and meet only 1 threshold to meet the objective, and variations on those concepts.

Response: We thank the commenters and note that we did not propose flexibility for other objectives such as CPOE and CDS because we believe there are already

accommodations within these objectives for specialists. For CPOE these are in the form of exclusions and for CDS providers may elect to focus their selection on high priority health conditions within their specialty if they do not believe they have adequate CQM pairings to implement. We thank those commenters who provided recommendations on the number of measures required for attestation and for the thresholds. We note that our intent to require attestation to all three is to ensure that the functions for all measures are available for provider use and to provide CMS with valuable data on performance from all providers on these measures.

After consideration of the public comments received, we are finalizing our proposal to provide flexibility within certain measures as proposed.

(e) EPs Practicing in Multiple Practices/Locations

For Stage 3, we proposed to maintain the policy from the Stage 2 final rule (77 FR 53981) that states that to be a meaningful user, an EP must have 50 percent or more of his or her outpatient encounters during the EHR reporting period at a practice/location or practices/locations equipped with CEHRT. An EP who does not conduct at least 50 percent of their patient encounters in any one practice/location would have to meet the 50 percent threshold through a combination of practices/locations equipped with CEHRT. In the Stage 2 final rule at (77 FR 53981), we defined patient encounter as any encounter where a medical treatment is provided or evaluation and management services are provided.

In addition, in the Stage 2 final rule at (77 FR 53981) we defined a practice/location as equipped with CEHRT if the record of the patient encounter that

occurs at that practice/location is created and maintained in CEHRT. We stated that this can be accomplished in the following three ways:

- CEHRT could be permanently installed at the practice/location.
- The EP could bring CEHRT to the practice/location on a portable computing device.
- The EP could access CEHRT remotely using computing devices at the practice/location.

We proposed to maintain these definitions for Stage 3.

Comment: We received a number of comments requesting clarification for providers practicing in certain settings as to how they should calculate the percentage of their patient encounters occurring in a location equipped with CEHRT. Specifically, a commenter requested guidance on how to calculate the percentage for providers who practice in a long-term care facility but for whom these patient encounters represent less than 50 percent of their total. Another commenter requested clarification on how the calculation works with regards to a hardship exception from a payment adjustment.

Response: Our policy is the same across practice settings: to be a meaningful EHR user, an EP must have 50 percent or more of his or her outpatient encounters during the EHR reporting period at a practice/location or practices/locations equipped with CEHRT. Thus, EPs who practice in long-term care settings must track their outpatient encounters across their practice settings during the EHR reporting period and meet the 50 percent threshold. EPs who practice in multiple locations and lack control over the availability of CEHRT may consider applying for a hardship exception.

After consideration of the public comments received, we are finalizing our proposal to maintain this policy as finalized in the Stage 2 final rule at (77 FR 53981).

(f) Denominators

In the Stage 3 proposed rule (80 FR 16744), we note that the objectives for Stage 3 include percentage-based measures wherever possible. In the Stage 2 final rule, we included a discussion of the denominators used for the program that included the use of one of four denominators for each of the measures associated with the meaningful use objectives outlined in the Stage 2 final rule (77 FR 53982 for EPs and 77 FR 53983 for eligible hospitals and CAHs).

For EPs, the references used to define the scope of the potential denominators for measures include the following:

- Unique patients seen by the EP during the EHR reporting period.
- Office visits.
- All medication, laboratory, and diagnostic imaging orders created during the reporting period.
- Transitions of care and referrals including:

++ When the EP is the recipient of the transition or referral, first encounters with a new patient and encounters with existing patients where a summary of care record (of any type) is provided to the receiving EP.

++ When the EP is the initiator of the transition or referral, transitions and referrals ordered by the EP.

For the purposes of distinguishing settings of care in determining the movement

of a patient, we proposed that a transition or referral may take place when a patient is transitioned or referred between providers with different billing identities, such as a different National Provider Identifier (NPI) or hospital CMS Certification Number (CCN). We also proposed that in the cases where a provider has a patient who seeks out and receives care from another provider without a prior referral, the first provider may include that transition as a referral if the patient subsequently identifies the other provider of care.

For eligible hospitals and CAHs, the references used to define the scope of the potential denominators for measures include the following:

- Unique patients admitted to the eligible hospital's or CAH's inpatient or emergency

department during the EHR reporting period.

- All medication, laboratory, and diagnostic imaging orders created during the reporting

Period.

- Transitions of care and referrals including:

++ When the hospital is the recipient of a transition or referral, all admissions to the inpatient and emergency departments.

++ When the hospital is the initiator of the transition or referral, all discharges from the inpatient department, and after admissions to the emergency department when follow-up care is ordered by authorized providers of the hospital.

We proposed that the explanation of the terms "unique patients," "transitions of

care," and "referrals" stated previously for EPs would also apply for eligible hospitals and CAHs, and we refer readers to the discussion of those terms in the hospital context in the Stage 2 final rule (77 FR 53983 and 53984). We proposed for Stage 3 to maintain the policy that admissions may be calculated using one of two methods (the observation services method and the all emergency department method), as described for Stage 2 at 77 FR 53984. We stated that all discharges from an inpatient setting are considered a transition of care. We also proposed for transitions from an emergency department, that eligible hospitals and CAHs must count any discharge where follow-up care is ordered by an authorized provider regardless of the completeness of information available to the receiving provider.

Comment: We received a few comments noting that we inadvertently left out the hospital denominator termed "inpatient bed days," which was discussed in the Stage 2 final rule.

Response: We thank the commenters for their assistance and note that this was not an oversight but a deliberate omission. In the Stage 2 final rule, we stated that while inpatient bed days was a potential useful inclusion in defining discharge calculations, it was not in use for any objective or measure (77 FR 53984). As the denominators are specific to the language used in the objectives and measures, we did not include inpatient bed days in our proposal.

Comment: Multiple commenters requested clarification on when patients whose records are not maintained in CEHRT may be excluded from the denominator for a measure.

Response: Each objective includes a specific designation regarding whether the denominator or denominators for the associated measures may be limited to only those records maintain in the CEHRT. We direct readers to the definition of each objective in § 495.22 for 2015 through 2017 and § 495.24 for Stage 3, respectively.

Comment: Several commenters offered suggestions on an approach for calculation for the numerators related to any measure or objective using the “unique patient” denominator (for example, patient specific education). These commenters requested clarification for measures which are based on actions for unique patients and if they may occur before, during, or after the reporting period. Some commenters specifically mentioned FAQ 8231⁵ which specified the timing required to measure actions for the numerator for measures which do not explicitly state the timing in the numerator. The FAQ stated these actions may occur before, during or after the EHR reporting period if the EHR reporting period is less than one full year, but could not be counted if they occurred prior to the beginning of the year or after the end of the year. Commenters noted that prior interpretation used by many developers contradicted this guidance and interpreted the lack of a time distinction in the numerator to mean that the action could occur at any point and was not constrained to the EHR reporting period or even the calendar or fiscal year. Commenters requested that CMS allow a continuation of the prior interpretation until 2015 Edition technology is required in order to not force developers to change systems to a different calculation.

Response: We note that we do not agree with an interpretation of the unique

⁵ FAQ #8231 <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/FAQ.html>
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patient denominator that allows for an action in previous reporting years to count in the numerator for a measure (such as the patient specific education objective and measure) in perpetuity. We believe that this not only skews the accuracy of the measure, it also is counter to the intention of establishing a benchmark of performance in each reporting period. We require these actions because we believe they should be regularly performed as part of a provider's meaningful use of CEHRT. In addition, this method of measurement suggested would cause drastic variations between providers over time based on their specialty, patient population, and frequency of repeat visits. We do, however, understand the desire to minimize the need for developers to change EHR technology already certified to the 2014 Edition or to require recertification. We address the issue of specification on timing directly in the applicable objectives in section II.B.2.a of this final rule with comment period.

Comment: One commenter requested the removal of the qualifying language regarding encounters with a new patient for the denominator for transitions and referrals for an EP. The commenter expressed concern that it was burdensome to include all new patients as a referral and that in many cases there was no referring provider initiating the first encounter with the patient.

Response: We appreciate the commenter's concern, but note that these denominators and definitions are for the purposes of defining the objectives and measures for the Medicare and Medicaid EHR Incentive Programs and that for the objectives where this language is included, we believe it is appropriate to include all new patients. Specifically, this denominator is used in objectives that relate to reconciling important

patient health information including medications the patient may be taking and any medication allergies the patient may have. We believe that it is essential that a provider include all new patient encounters (even those where there is no referring provider) in these important objectives that impact patient safety. Furthermore, we note that these definitions in the Stage 3 proposed rule at 80 FR 16744 are continuations of the Stage 2 definitions previously finalized for the Medicare and Medicaid EHR Incentive Programs in the Stage 2 final rule at 77 FR 53984.

After consideration of the public comments received, we are finalizing these denominators and the related explanations of terms as proposed.

(g) Patient Authorized Representatives

In the Stage 3 proposed rule at 80 FR 16745 we proposed the inclusion of patient-authorized representatives in the numerators of the Coordination of Care through Patient Engagement objective and the Patient Electronic Access objective as equivalent to the inclusion of the patient. We expect that patient-authorized representatives with access to such health information will always act on the patient's behalf and in the patient's best interests and will remain free from any potential or actual conflict of interest with the patient. Furthermore, we expect that the patient-authorized representatives would have the patient's best interests at heart and will act in a manner protective of the patient.

Comment: Commenters were supportive of the inclusion of a patient-authorized representative in the Stage 3 objectives and measures related to patient electronic access and patient engagement. A commenter expressed approval of our proposal to include the

patient-authorized representative in the meaningful use numerators as equivalent to the patient, believing this will encourage physicians to treat the authorized representative in the same fashion as the patient. The commenter noted that this is particularly important for providers serving patient populations where a large percent have cognitive limitations or dementia and the role of the caregiver or authorized representative is critical. Another commenter noted that many patients trust and rely on their representatives to help them navigate the health care system, coordinate their care, and comply with treatment plans. Inclusion of patient-authorized representatives recognizes the importance of these individuals in the care and treatment of many patients. A number of commenters also noted that this would prove a substantial benefit to providers caring for parents of young children and working to engage the parent using these tools in relation to the child who is their patient.

Response: We thank the commenters for their support and insight into how this policy supports the overall goals to expand the concept of patient engagement and support the communication continuum between provider and patient with the clear focus on patient-centered care.

After consideration of the public comments received, we are finalizing this policy as proposed. We direct readers to the individual objectives and measures outlined in section II.B.2.b of this final rule with comment period for further discussion of this provision within the applicable objectives and measures.

(h) Discussion of the Relationship of the Requirements of the EHR Incentive Programs to CEHRT

We proposed to continue our policy of linking each objective to the CEHRT definition and to ONC-established certification criteria. As with Stage 1 and Stage 2, EPs, eligible hospitals, and CAHs must use technology certified to the certification criteria in the ONC HIT Certification Program to meet the objectives and associated measures for Stage 3.

We received no comments specific to this proposal and are finalizing as proposed. We direct readers to the individual objectives and measures outline in section II.B.2. of this final rule with comment period for further discussion of this provision within the applicable objectives and measures and to section II.B.3 of this final rule with comment period for discussion of the definition of CEHRT for the Medicare and Medicaid EHR Incentive Programs.

(i) Discussion of the Relationship Between a Stage 3 Objective and the Associated Measure

We proposed to continue our Stage 1 and Stage 2 policy that regardless of any actual or perceived gaps between the measure of an objective and full compliance with the objective, meeting the criteria of the measure means that the provider has met the objective in Stage 3.

We received no comments specific to this proposal and are finalizing as proposed. We direct readers to the individual objectives and measures outlined in section II.B.2. of this final with comment period rule for further discussion of this provision within the

applicable objectives and measures.

2. Meaningful Use Objectives and Measures

a. Meaningful Use Objectives and Measures for 2015, 2016, and 2017

In the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20358), we proposed the following objectives and measures for EPs, eligible hospitals, and CAHs to demonstrate meaningful use for an EHR reporting period in 2015 through 2017. We noted that there are nine proposed objectives for EPs plus one consolidated public health reporting objective, and eight proposed objectives for eligible hospitals and CAHs plus one consolidated public health reporting objective. We proposed these objectives would be mandatory for all providers for an EHR reporting period beginning in 2016 and proposed to allow alternate exclusions and specifications for some providers in 2015 depending on their prior participation.

Objective 1: Protect Patient Health Information

In the EHR Incentive Programs in 2015 through 2017 proposed rule, we proposed at 80 FR 20358 to retain, with certain modifications, the Stage 2 objective and measure for Protect Electronic Health Information for meaningful use in 2015 through 2017. In the Stage 2 final rule (77 FR 54002 through 54003), we discussed the benefits of safeguarding ePHI, as doing so is essential to all other aspects of meaningful use. Unintended and/or unlawful disclosures 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 EHRs may present.

We note that we were inconsistent with our naming of this objective calling it

"protect patient health information" and alternately "protect electronic health information". The former matches the Stage 3 Objective (section II.B.2.b.i) while the latter is what we called it in our Stage 2 final rule.

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

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 ePHI created or maintained 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 EP, eligible hospital, or CAH's 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.

The HHS Office for Civil Rights (OCR) has issued guidance on conducting a security risk analysis in accordance with the Health Insurance Portability and Accountability Act of 1996 (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 in CEHRT. However, we noted that other ePHI may be subject to the HIPAA rules, and we refer providers to those rules for additional security requirements.

Comment: The vast majority of commenters expressed support for the inclusion of this objective. These commenters recognized the importance of protecting patient health information and agreed that this protection should consist of administrative, technical, and physical safeguards. A commenter stated that the measure is onerous for small practices because the elements of what constitutes a risk analysis are not necessarily clear. A commenter suggested an exclusion for small practices.

Another commenter noted that larger healthcare networks have a dedicated IT staff; small practices do not, making it difficult and costly to meet the standards of an annual security risk analysis and implementing security changes.

Response: We appreciate the commenters' support for the continued inclusion of this objective and measure.

We disagree that the elements of what constitutes a security risk analysis are not clear. In the proposed rule, we identified the specific requirements in the CFR and provided links to free tools and resources available to assist providers, including an SRA Tool developed by ONC and OCR. We decline to consider exclusions, including for small practices, as we believe it is of utmost importance for all providers to protect ePHI.

We maintain that a focus on protection of electronic personal health information is necessary for all providers due to the number of breaches reported to HHS involving lost or stolen devices.

Comment: A commenter believes that these requirements are actually redundant with existing expectations for security risk assessment under HIPAA Security Rule compliance. The current HIPAA Security Rule requirement to conduct or review a security risk assessment is comprehensive and clearly requires providers to comply with all of its provisions. Thus, it seems unnecessary and overly burdensome to require attestation under the Medicare and Medicaid EHR Incentive Programs.

Response: As we have stated previously, this objective and measure are only relevant for meaningful use and this program, and are not intended to supersede what is separately required under HIPAA and other rulemaking. We do believe it is crucial that all EPs, eligible hospitals, and CAHs evaluate the impact CEHRT has on their compliance with HIPAA and the protection of health information in general.

Comment: A commenter requested clarification that only one risk assessment is required by their organization per year. The commenters noted that their organization has multiple groups of EPs with multiple 90-day reporting periods in a year.

Several commenters suggested that we incorporate the language from one of our frequently asked questions (FAQs) into the final rule— that the security risk assessment "may be completed outside of the EHR reporting period timeframe but must take place no earlier than the start of the EHR reporting year and no later than the provider attestation date."

Many commenters suggested that we update our frequently asked questions that relate to security risk assessments.

Response: As noted in the Stage 3 proposed rule (80 FR 16746) (in which we

proposed to maintain this Stage 2 objective even into Stage 3 with clarification on the timing for the requirements), the existing policy is that an analysis or review must be conducted annually for each EHR reporting period. We note that the security risk assessment is not an "episodic" item related only to a snapshot in time, but should cover the entirety of the year for which the analysis or review is conducted. Therefore, it is acceptable for the security risk analysis to be conducted outside the EHR reporting period if the reporting period is less than one full year. However, the analysis or review must be conducted within the same calendar year as the EHR reporting period, and if the provider attests prior to the end of the calendar year, it must be conducted prior to the date of attestation. An organization may conduct one security risk analysis or review which is applicable to all EPs within the organization, provided it is within the same calendar year and prior to any EP attestation for that calendar year. However, each EP is individually responsible for their own attestation and for independently meeting the objective. Therefore, it is incumbent on each individual EP to ensure that any security risk analysis or review conducted for the group is relevant to and fully inclusive of any unique implementation or use of CEHRT relevant to their individual practice.

We intend to update our FAQs to reflect policy changes and clarifications that flow from this final rule with comment period. Prior versions of FAQs and those related to past program years will be archived and maintained for public access on our website at www.cms.gov/EHRIncentivePrograms.

Comment: A commenter stated that the scope of the risk assessment in the proposed rule appears to be limited to ePHI created or maintained via CEHRT. The

commenter questioned whether this scope is more limited than in prior meaningful use requirements.

Response: The scope of the security risk analysis for the Medicare and Medicaid EHR Incentive Programs relates to ePHI created or maintained using CEHRT. We did not propose to change the scope of this objective and measure from the Stage 2 requirements.

Comment: Several commenters requested a national educational campaign sponsored by the federal government to help physicians ensure that they are adequately equipped to protect electronic patient information.

Response: We will continue to work with OCR and ONC on educational efforts related to protecting electronic health information. We agree that this will require ongoing education and outreach.

After consideration of public comments received, we are finalizing this objective and measure as proposed with a minor modification to adopt the title “Protect Patient Health Information” for EPs, eligible hospitals and CAHs as follows:

Objective 1: Protect Patient Health Information

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

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 by 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 EP, eligible hospital, or CAH's risk management process.

We are adopting Objective 1: Protect Patient Health Information at § 495.22(e)(1)(i) for EPs and § 495.22(e)(1)(ii) for eligible hospitals and CAHs. We further specify that in order to meet this objective and measure, an EP, eligible hospital, or CAH must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 2: Clinical Decision Support

In the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20358), we proposed to retain the Stage 2 objective and measures for Clinical Decision Support (CDS) for meaningful use in 2015 through 2017 such that CDS would be used to improve performance on high-priority health conditions. This is a consolidated objective, which incorporates the Stage 1 objective to implement drug-drug and drug-allergy interaction checks. It would be left to the provider's clinical discretion to select the most appropriate CDS interventions for his or her patient population.

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

We proposed that CDS interventions selected should be related to four or more of the 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.

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, we 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.

Proposed Alternate Exclusions and Specifications for Stage 1 Providers for Meaningful

Use in 2015

For an EHR reporting period in 2015 only, we proposed 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 as follows:

- Proposed 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.

Comment: Many commenters expressed support of the Clinical Decision Support Objective in its entirety. Several noted that the inclusion of this objective in the EHR Incentive Program in 2015 through 2017 requirements ensures the continued implementation of these important supports for providers. In addition, commenters agree that it is best for CDS interventions to be implemented at the point in patient care that best enhances clinical decision making before taking an action on behalf of a patient. Some noted appreciation for the continued requirement for drug-drug and drug-allergy interaction checking. They also believe that it is a significant benefit to patient care.

A commenter was supportive of the flexibility provided by CMS and ONC in the use of homegrown alerts and for nurturing a supportive environment for those providers developing their own homegrown alerts and not deterring this type of innovation with overly onerous measure definitions or certification requirements. Many commenters expressed that the use of CDS will have a positive impact on the quality, safety, and efficiency of care. They also supported the proposed objective and measures to use CDS to improve performance on high-priority health conditions.

Response: We greatly appreciate and thank commenters' support for this objective.

Comment: A few commenters expressed concern about the work and strain and the substantial cost involved in implementing, training, maintenance, and updating of the tools to meet the clinical decision support requirements.

A commenter expressed concern that the requirement for every EP to have five CDS elements pertaining to his or her scope of work may be overly burdensome for large organizations with highly specialized EPs where there may be circumstances necessary to build CDS tools that would only be useful for a few individuals.

Additionally, a commenter stated there is a struggle to interpret whether or not each of our implemented features meet ONC's referential link and source attribute requirements.

Response: We recognize commenters' concerns regarding implementation of the necessary tools to meet the CDS requirements. The companion ONC standards and certification criteria final rule for the 2014 Edition certification (77 FR 54163 through 54292) as well as the 2015 Edition certification criteria in the 2015 Edition final rule published elsewhere in this Federal Register, provide further information regarding the standards for CDS within CEHRT. With each incremental phase of meaningful use, CDS systems progress in their level of sophistication and ability to support patient care. It is our expectation that, at a minimum, providers will select CDS interventions to drive improvements in the delivery of care for the high-priority health conditions relevant to their patient population. Continuous quality improvement requires an iterative process in the implementation and evaluation of selected CDS interventions that will allow for ongoing learning and development. In this final rule with comment period, we will consider a broad range of CDS interventions that improve both clinical performance and the efficient use of healthcare resources, and as noted in the Stage 2 final rule (77 FR 53995 through 53996), we believe sufficient CDS options exist to support

providers' implementation of five total. Given the wide range of CDS interventions currently available and the continuing development of new technologies, we do not believe that any EP, eligible hospital, or CAH would be unable to identify and implement five CDS interventions, as previously described. Therefore, we did not establish an exclusion for the first measure of this objective based on specialty in the Stage 2 final rule and we did not propose to change that policy.

Comment: A commenter suggested we eliminate the drug-drug and drug-allergy interaction checks as a topped out measure.

Other commenters requested the removal of the language requiring participants to have CDS enabled for "the entire reporting period," as it is challenging for participants to meet. A commenter suggested that we change the requirement to provide that CDS be enabled within the first 45 days of the reporting period and remain enabled throughout the reporting period.

Another commenter believes that the level of interaction checks should be determined by the organizational directives, as well as the discretion of the clinical team.

Response: We noted our belief that automated drug-drug and drug-allergy checks provide important information to advise the provider's decisions in prescribing drugs to a patient. Because this functionality provides important CDS that focuses on patient health and safety, we proposed to continue to include the use of this functionality within CEHRT as part of the objective for using CDS and maintain our belief that this function should be enabled, as previously finalized, for the duration of the EHR reporting period. We note that the provider has discretion to implement the CDS for drug-drug and drug-

allergy checks in a manner that is most appropriate for their organization and clinical needs.

Comment: A commenter requested clarification on the exclusion and for similar exclusions that include the language "fewer than 100 (medication orders, office visits, etc.)." Commenters requested further clarification that the 100 would be over the course of the full year and requested confirmation that providers using a shorter reporting period should pro-rate this total for that reporting period.

Response: The policy is fewer than 100 during the EHR reporting period and this language is used consistently in both Stage 1 and Stage 2 objectives and measures that include a similar exclusion. There is no distinction based on the length of the EHR reporting period and no option to pro-rate.

Comment: Commenters additionally expressed concern about the requirement to track compliance with CDS and recommended that we allow them to retain the freedom to use whatever forms of CDS make sense for their practice including the timing of the interventions. A commenter stated that tracking compliance puts increased emphasis on pop-up type support over other types where tracking compliance does not necessarily happen easily and noted that provider responses to some types of CDS (like creating order sets for different conditions and providing health maintenance suggestions) are not easily tracked, and not within their certified system.

Some commenters requested that CDS should be enabled to address conditions relevant to the EP's scope of practice. Others stated that children's hospitals or specialty providers should have the same level of choice that is available to adult hospitals and

general practitioners, while others requested the removal of the link to CQMs completed. Still others requested that the five CDS interventions be related either to CQMs or to other metrics included in a nationally recognized quality improvement registry or a qualified clinical database registry.

One commenter on the EHR Incentive Programs for 2015 through 2017 proposed rule specifically requested clarification whether an example used in the Stage 3 proposed rule (for example, the appropriate use criteria for imaging services example at 80 FR 16750) could also be used to satisfy the CDS objective for the EHR Incentive Programs in 2015 through 2017.

Response: We appreciate the comments and note that in Stage 1, we allowed providers significant leeway in determining the CDS interventions most relevant to their scope of practice. In Stage 2 and later, we are continuing to provide the flexibility for providers to identify high-priority health conditions that are most appropriate for CDS. We expect that providers will implement many CDS interventions, and providers are free to choose interventions in any domain that is a priority to the EP, eligible hospital, or CAH.

We also agree with the commenter that providers should be allowed the flexibility to determine the most appropriate CDS intervention and timing of the CDS. The CDS measure for EPs, eligible hospitals, and CAHs allows this flexibility by allowing the implementation at a relevant point in patient care that refers to a relevant point in clinical workflows when the intervention can influence clinical decision making before diagnostic or treatment action is taken in response to the intervention. Further, many

providers may associate CDS with pop-up alerts. However, these alerts are not the only method of providing CDS. CDS should not be viewed as simply an interruptive alert, notification, or explicit care suggestion. Well-designed CDS encompasses a variety of workflow optimized information tools, which can be presented to providers, clinical and support staff, patients, and other caregivers at various points in time. We believe that the examples outlined in the Stage 3 proposed rule and further discussed in the Stage 3 objective in section II.B.2.b.iii of this final rule with comment period are applicable for CDS in general and would apply for the EHR Incentive Programs in 2015 through 2017. We refer readers to the CDS objective description in the Stage 3 proposed rule for further information (80 FR 16749 through 16750).

After consideration of the public comments received, we are finalizing the objective, measures, exclusions, and alternate objective and measure as proposed for EPs, eligible hospitals, and CAHs as follows:

Objective 2: Clinical Decision Support

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

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.

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

Alternate Objective and Measure: For an EHR reporting period in 2015 only, an EP, eligible hospital or CAH who is scheduled to participate in Stage 1 in 2015 may satisfy the following in place of 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 are adopting Objective 2: Clinical Decision Support at § 495.22(e)(2)(i) for EPs and § 495.22(e)(2)(ii) for eligible hospitals and CAHs. We further specify that in order to meet this objective and measures, an EP, eligible hospital, or CAH must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 3: Computerized Provider Order Entry

In the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20359), we proposed to retain the Stage 2 objective and measures for CPOE for meaningful use in 2015 through 2017, with modifications proposed for alternate

exclusions and specifications for Stage 1 providers for an EHR reporting period in 2015.

Proposed Objective: Use computerized provider order entry for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional that 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 the 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 proposed to retain the three distinct measures of the Stage 2 objective to calculate a separate percentage threshold for all three types of orders: medication, laboratory, and radiology. We proposed 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:

- Proposed Measure 1: Medication Orders

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.

- Proposed Measure 2: Laboratory Orders

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.

- Proposed Measure 3: Radiology Orders

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.

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

We proposed alternate exclusions and alternate specifications for this objective

and measures for Stage 1 providers in 2015.

Proposed 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.

Proposed 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.

Proposed 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.

Comment: A number of commenters supported the inclusion of the objective into the proposed rule; some supported the thresholds and agreed with the alternative specifications and exclusions. A few commenters stated the thresholds for all three measures are realistically achievable if scribes and clinical staff with proper orders are allowed to perform CPOE. A few commenters appreciated the clarification around who may enter orders using CPOE for purposes of this objective. Another commenter believed that the use of CPOE in conjunction with the Clinical Decision Support for

interaction checking greatly benefits patient safety initiatives and reduces medication errors.

Response: We appreciate the many comments of overall support for the CPOE objective, thresholds and alternate specifications and exclusions. We believe our explanation in the proposed rule at 80 FR 20359 of which staff may enter orders using CPOE for purposes of this objective will alleviate some of the burden associated with providers' confusion. This explanation was in response to feedback from stakeholders requesting further information.

Comment: A commenter opposed the objective indicating although there are exclusions for providers who write less than 100 orders per EHR reporting period for any of the measures, it still may be a high bar for providers new to the program or who have just completed their first year. Other commenters believe that Stage 1 participants would have difficulty meeting the objective. Another commenter requested lower thresholds related to CEHRT issues.

Response: Under our proposals for 2015, new participants in the program or those scheduled to demonstrate Stage 1 in 2015 may attest to an alternate measure 1, which is the equivalent of the current Stage 1 measure. Additionally, we proposed alternate exclusions for these providers for the measures for laboratory and radiology orders (measures 2 and 3) under CPOE. We believe the alternate specifications and exclusions provide ample flexibility for meeting the requirements in 2015.

Comment: A few commenters stated that the definition of credentialed user is difficult to isolate and varies from state to state. Another commenter stated the physician

using an EHR should be able to dictate who enters orders on their behalf.

Other commenters stated they disagreed with the requirement that only credentialed staff may enter orders for CPOE, as not all medical assistants are required to be credentialed to practice. They further suggested that if a standard for medical assistant CPOE is required, then the standard should be that the medical assistant must be appropriately trained for CEHRT use (including CPOE) by the employer or CEHRT vendor in order to be counted.

Other commenters recommended that we allow medical assistants who were hired and handling the paper -based equivalent of CPOE prior to the Stage 2 final rules (September 2012), and still with the same employing organization (as of September 2012), to be referred to as "Veteran Medical Assistants" and be permitted to enter CPOE.

Another commenter proposed that the rule be revised to allow orders placed by licensed healthcare providers, medical interns, and certified medical assistants in the numerator of the measure.

A commenter requested clarification as to whether CEHRT entries completed by scribes are eligible for CPOE. Another commenter inquired as to whether orders entered by non-physician staff through the means of standing orders are eligible as CPOE. A commenter requested clarification on whether phone orders from physicians can be considered CPOE if they are entered at the time of the call by a licensed healthcare professional that is authorized to enter orders based on the state regulations.

Response: In the Stage 2 final rule (77 FR 53986) and in subsequent guidance in

FAQ 9058⁶, we explained for Stage 2 that a licensed health care provider or a medical staff person who is a credentialed medical assistant or is credentialed to and performs the duties equivalent to a credentialed medical assistant may enter orders. We maintain our position that medical staff must have at least a certain level of medical training in order to execute the related CDS for a CPOE order entry. We defer to the provider to determine the proper credentialing, training, and duties of the medical staff entering the orders as long as they fit within the guidelines we have proscribed. We believe that interns who have completed their medical training and are working toward appropriate licensure would fit within this definition. We maintain our position that, in general, scribes are not included as medical staff that may enter orders for purposes of the CPOE objective. However, we note that this policy is not specific to a job title but to the appropriate medical training, knowledge, and experience.

Further, we note that we did not propose to change our prior policy on allowing providers to exclude standing orders as finalized in the Stage 2 final rule at 77 FR 53986.

Finally, we believe that a circumstance involving tele-health or remote communication may be included in the numerator as long as the order entry otherwise meets the requirements of the objective and measures.

Comment: A commenter stated that CPOE does not help ensure patient safety or encourage continuity of care, which is the premise of the program. They stated "reputable labs" are not equipped to accept online orders. The commenter also indicated that interoperability issues are also a concern with meeting this measure. They stated that

⁶ CMS.gov Frequently Asked Questions #9058 [EHR Incentive Programs]
<https://questions.cms.gov/faq.php?id=5005&faqId=9058>

many specialists practice in private office settings and many do not share the same EHR system as hospitals, laboratories, and imaging facilities.

Response: We respectfully disagree with the commenter's feedback. As noted in the proposed rule, we believe CPOE improves quality and safety. For example, a CPOE for medications may trigger a clinical decision support checking for potential medication allergies or drug interactions at the point of the order and therefore, influences the appropriateness of initial order decision. In addition, we maintain our position that CPOE improves safety and efficiency by automating aspects of the ordering process to reduce the possibility of communication and other errors. However, we note that the inclusion of the order into the patient's electronic record allows for the exchange of that information electronically, while paper-based order entry systems do not.

Comment: A commenter requested clarification on the definition of "exclusionary criteria."

Response: Exclusionary criteria are merely the exclusions listed for each of the measures. We specifically stated that we proposed 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.

Comment: A commenter requested a combined measure for CPOE rather than the requirement that the measures be broken down by lab, meds, and imaging and stated that a 60 percent overall threshold for all orders, regardless of type, would be less burdensome to report.

Response: We respectfully disagree. As stated in the Stage 2 final rule

(77 FR 53987), we believe providers implement CPOE for packages of order types which are handled similarly and so we do not believe it is appropriate to measure CPOE universally for all order types in one process. We also expressed concerns in the Stage 2 proposed rule about the possibility that an EP, eligible hospital, or CAH could create a test environment to issue the one order and not roll out the capability widely or at all. For these reasons, we finalized percentage thresholds for all three types of order medications, laboratory, and radiology, rather than one consolidated measure.

Comment: A commenter recommended that we clarify in the preamble of the final rule that EPs can exclude "protocol" or "standing orders" from the denominators of the measures under the CPOE objective, as this explanation was provided in the preamble of the proposed rule for Stage 3, but not in the 2015 through 2017 proposed rule.

Response: We did not propose changes to our policy on "protocol" or "standing orders" from Stage 2. We reiterate from the Stage 2 final rule that we agree that this category of orders warrant different considerations than orders that are due to a specific clinical determination by the ordering provider for a specific patient. Therefore, we allow providers to exclude orders that are predetermined for a given set of patient characteristics or for a given procedure from the calculation of CPOE numerators and denominators. Note this does not require providers to exclude this category of orders from their numerator and denominator (77 FR 53986).

Comment: A commenter requested clarification defining what constitutes an "order"(for example, whether an order is equivalent to a single transaction or if each order code in the single transaction represents an individual)order. The commenter also

inquired whether a laboratory panel/profile test is counted as one order.

Response: Each order that is associated with a specific code would count as one order. Multiple tests ordered at the same time count individually if they fall under a different order code. For example, a laboratory panel, which consists of one order code but multiple tests, would only count as one order for the purposes of CPOE. If those tests were ordered individually with each having its own order code, each test would count as an order.

Comment: Several commenters requested that for CPOE measure 2 lab orders, we modify the exclusion criteria to include circumstances where there are no receiving centers for electronic radiology orders or lab orders in case there are no local or regional imaging centers that are set up to receive or transmit CPOE . Another commenter believed there should be an additional exclusion for measure 2 to address instances in which the lab does not want to connect electronically due to the low number of lab orders submitted by the physician. One commenter stated CPOE measures are not relevant or valuable for physician office or outpatient settings and should be limited only to inpatient settings such as hospitals.

Some commenters stated that the CPOE objective should be considered topped out.

Response: We respectfully disagree with the commenters. CPOE is the entry of the order into the patient's EHR that uses a specific function of CEHRT. CPOE does not otherwise specify how the order is filled or otherwise carried out. Therefore, whether the ordering of laboratory or radiology services using CPOE in fact results in the order being

transmitted electronically to the laboratory or radiology center conducting the test does not affect a provider's performance on the CPOE measures. CPOE is a step in a process that takes place in both hospital and ambulatory settings, and we continue to believe it is relevant to both settings.

Additionally, we note that when we analyzed attestation data from 2011 through 2013, provider performance on the CPOE measures is high, but high performance is not the only consideration in determining whether to retain an objective or measure in the program. We also review provider performance across varying levels of participation, the variance between provider types at different quartiles, stakeholder feedback on the potential value add of the objective and measure, and other similar considerations. Based on these factors, we believe the CPOE objective should be maintained in the program as it promotes patient safety and clinical efficiency. In addition, we believe there is room for significant improvement on measure performance.

Comment: A commenter suggested replacing "radiology orders" with "imaging orders" to better align with the Stage 3 objective.

Response: We appreciate the feedback and suggestion. In the proposed rule, we sought 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. However, as stated in the proposed rule, we also sought to avoid proposing new requirements that would require changes to the existing technology certified to the 2014 Edition certification criteria, and therefore, retained the three measures of the current Stage 2 objective (medication, laboratory, and radiology) as finalized in Stage 2 (77 FR 53987)

Comment: A commenter specifically requested an exclusion for providers who are using a 90-day reporting period of less than 25 medication orders for the 90-day reporting period.

Response: We decline to change the exclusion criteria. The policy is fewer than 100 orders during the EHR reporting period and this language is used consistently in both Stage 1 and Stage 2 objectives and measures that include a similar exclusion. There is not a distinction based on the length of the EHR reporting period.

After consideration of public comments received, we are finalizing the alternate exclusions and specifications with the following modifications based on the final policy we adopted in section II.B.1.b.(4)(b)(iii) of this final rule with comment period. We note that providers who would otherwise have been scheduled for Stage 1 in 2016 may be required to implement technology functions for certain Stage 2 measures if they do not already have these functions in place because there is no Stage 1 equivalent to the Stage 2 measure. In certain cases, the improper implementation of these functions could represent a patient safety issue and therefore we are finalizing an alternate exclusion in 2016 in order to allow sufficient time for implementation in these circumstances. The Stage 2 CPOE objective measure for lab orders and the measure for radiology orders both require functions that a provider who was expecting to be in Stage 1 in 2016 may not be able to safely implement in time for an EHR reporting period in 2016. Therefore a provider may elect to exclude from these two measures for an EHR reporting period in 2016 if they were previously scheduled to be in Stage 1 in 2016.

We are finalizing the objective, measures, exclusions and alternate specifications

and exclusions for EPs, eligible hospitals, and CAHs as follows:

Objective 3: Computerized Provider Order Entry

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

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.

- 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: 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.

- 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: 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.

- 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.

Alternate Exclusions and Specifications:

- Alternate Measure 1: For Stage 1 providers in 2015, 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: Providers scheduled to be in Stage 1 in 2015 may claim an exclusion for measure 2 (laboratory orders) of the Stage 2 CPOE objective for an EHR reporting period in 2015; and, providers scheduled to be in Stage 1 in 2016 may claim an exclusion for measure 2 (laboratory orders) of the Stage 2 CPOE objective for an EHR reporting period in 2016.

Alternate Exclusion for Measure 3: Providers scheduled to be in Stage 1 in 2015 may claim an exclusion for measure 3 (radiology orders) of the Stage 2 CPOE objective for an EHR reporting period in 2015; and, providers scheduled to be in Stage 1 in 2016 may claim an exclusion for measure 3 (radiology orders) of the Stage 2 CPOE objective for an EHR reporting period in 2016.

We are adopting the Objective 3: Computerized Provider Order Entry at § 495.22(e)(3)(i) for EPs and § 495.22(e)(3)(ii) for eligible hospitals and CAHs. We further specify that in order to meet this objective and measures, an EP, eligible hospital, or CAH must use the

capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 4: Electronic Prescribing

In the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20360), we proposed 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 proposed the objective would be required for 2015 through 2017, with an exception for Stage 1 eligible hospitals and CAHs for an EHR reporting period in 2015.

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

As noted in the Stage 2 final rule at 77 FR 54035, the use of electronic prescribing has several advantages over having the patient carry the prescription or the provider directly faxing handwritten or typewritten prescriptions to the pharmacy. These advantages include: providing decision support to promote safety and quality in the form of adverse interactions and other treatment possibilities; 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; reduction of communication errors; and automatic comparisons of the medication order to others the pharmacy or third parties

have received for the patient. We proposed to maintain these policies in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20361).

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 CEHRT.

We proposed 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.

We also proposed 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.

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

We proposed 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.

Proposed Alternate EP Measure: More than 40 percent of all permissible prescriptions written by the EP are transmitted electronically using CEHRT.

We proposed no alternate exclusions for this EP objective.

Comment: We received a number of comments in support of this objective including commenters who stated that clinicians support electronic prescribing if it is efficient and does not interfere with workflows. Of those who supported the objective, most believe that electronic prescribing has clear patient and provider benefits, specifically with helping to reduce prescription errors. Some commenters also supported the proposal to continue to exclude over-the-counter medications from the definition of prescription for the purposes of the electronic prescribing objective. Commenters

specifically stated support, noting that the use of electronic prescribing will reduce the number of prescription drug related adverse events, deter the creation of fraudulent prescriptions, and decrease the opportunity for prescription drug misuse and abuse. Finally, a commenter noted that the inclusion of the drug formulary query will support CMS' efforts to reduce the financial burden to the patient.

Response: We thank the commenters for their insight and support of this objective.

Comment: One topic of concern expressed by commenters was how controlled substances would be addressed in this final rule with comment period given that there are certain state restrictions on how providers can prescribe controlled substances. Commenters stated that in the past, previous mandates stated that prescriptions for controlled substances were required have to be written, not electronically prescribed. Many commenters indicated they believe the inclusion of controlled substances should remain optional and depend on whether or not the state allows the electronic prescription submission of these types of drugs. However, other commenters noted that many states now allow controlled substances to be electronically prescribed either for all prescriptions or for certain circumstances and types of drugs. These commenters noted that controlled substances should be included where feasible, as the inclusion would reduce the paper - based prescription process often used for such prescriptions, as long as the inclusion of these prescriptions are permissible under in accordance with state law.

Response: We appreciate the feedback on the inclusion of controlled substances and agree that at present this should remain an option for providers, but not be required.

As the commenters note, many states have varying policies regarding controlled substances and may address different schedules, dosages, or types of prescriptions differently. Given these developments with states easing some of the prior restrictions on electronically prescribing controlled substances, we believe it is no longer necessary to categorically exclude controlled substances from the term “permissible prescriptions.” Therefore the continued inclusion of the term "controlled substances" in the denominator may no longer be an accurate description to allow for providers seeking to include these prescriptions in the circumstances where they may be included. We will define a permissible prescription as all drugs meeting our current Stage 2 definition of a prescription (77 FR 53989) with a modification to allow the inclusion of controlled substances where feasible and allowed by law as proposed in Stage 3 (80 FR 16747) in the denominator of the measure. We will no longer distinguishing between prescriptions for controlled substances and all other prescriptions, and instead will refer only to permissible prescriptions (consistent with the definition for Stage 3 at Section II.B.2.b.ii). Therefore, we are changing the measure for this objective to remove the term controlled substances from the denominator and instead changing the denominator to read "permissible prescriptions". We note this is only a change in wording and does not change the substance of our current policy for Stage 2 –which providers have the option, but are not required, to include prescriptions for controlled substances in the measure – which we will maintain for 2015 through 2017. For the purposes of this objective ,we are adopting that prescriptions for controlled substances may be included in the definition of permissible prescriptions where the electronic prescription of a specific medication or

schedule of medications is permissible under state and federal law.

Comment: A number of providers commented on the inclusion of the query for the drug formulary, noting that this process takes time, interrupts provider workflows, is burdensome for providers to conduct for patients who are uninsured, and often requires additional paperwork or manual processing in order to comply with the requirement that each prescription must complete a query in order to count in the numerator. Some providers noted a gap in the CEHRT function for this measure.

Response: If no formulary is available for a prescription, the provider may still count the patient in the numerator for the measure. However, we understand that the formulary query may prove burdensome in some instances, especially when it requires additional action beyond the automated function in CEHRT. We believe that the query of a formulary can provide a benefit, and our long-term vision is the progress toward fully automated queries using universal standards in real time. In order to balance the potential benefit of this function with the current burden on providers, we provide the following guidance on how providers may count the query of a formulary. Providers may count a patient in the numerator where no formulary exists to conduct a query, providers may also limit their effort to query a formulary to simply using the function available to them in their CEHRT with no further action required. This means that if a query using the function of their CEHRT is not possible or shows no result, a provider is not required to conduct any further manual or paper-based action in order to complete the query, and the provider may count the prescription in the numerator.

After consideration of the public comments received, we are finalizing changes to

the language to continue to allow providers the option to include or exclude controlled substances in the denominator where such medications can be electronically prescribed. We are finalizing that these prescriptions may be included in the definition of "permissible prescriptions" at the providers discretion where allowable by law. We are modifying the measure language to maintain "permissible prescriptions" and remove the "or all prescriptions" language and changing the denominator to read "Number of permissible prescriptions written for drugs requiring a prescription in order to be dispensed during the EHR reporting period" in accordance with this change. We are finalizing the alternate specifications for providers scheduled to demonstrate Stage 1 of meaningful for an EHR reporting period in 2015 as proposed.

We are finalizing the objective, measure, exclusions and alternate specifications for EPs as follows:

Objective 4: Electronic Prescribing

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

Measure: More than 50 percent of permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT.

- Denominator: Number of permissible prescriptions written during the EHR reporting period for drugs requiring a prescription in order to be dispensed.
- 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 Specifications:

Alternate EP Measure: For Stage 1 providers in 2015, more than 40 percent of all permissible prescriptions written by the EP are transmitted electronically using CEHRT.

We are adopting Objective 4: Electronic Prescribing at § 495.22(e)(4)(i) for EPs. We further specify that in order to meet this objective and measure, an EPm must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

(B) 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 how 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 allows 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 (80 FR 20361).

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 CEHRT.

We proposed 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.

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

We proposed 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 proposed that eligible hospitals and CAHs scheduled to report Stage 2 objectives for an EHR reporting period in 2015 that were not intending to attest to the eRx menu objective and measure may also claim an exclusion.

Proposed Alternate Eligible Hospital/CAH Exclusion: Provider may claim an exclusion for the eRx objective and measure for an EHR reporting period in 2015 if 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.

We proposed no alternate specifications for this eligible hospital and CAH objective.

Comment: Commenters were divided in terms of opposition to or support of the

proposed objective for eligible hospitals and CAHs. Those in support expressed agreement with the concept of the requirement that discharge prescriptions be transmitted electronically, citing improvements in patient safety and reducing medication errors. Those in opposition predominantly cited concern over their ability to adopt the necessary technology by 2016.

A commenter noted that electronic prescribing would cause medication errors because the hospital often makes numerous changes to a patient's prescription at the time of discharge, and incorrect prescriptions (with the wrong medication or dosage) written on paper can simply be torn up rather than requiring a new prescription to be sent and causing confusion for the patient. Other commenters also stated similar scenarios related to current workflows, which would need to be changed in order to comply with electronic prescribing requirements.

Response: We thank the commenters for their input and consideration of this proposal. We agree that the successful implementation of electronic prescribing for eligible hospitals and CAHs would require changes to technology implementation and workflows. However, we believe the opportunity for efficiencies and improvements in patient safety outweigh these concerns. We will finalize the proposed objective and measure for eligible hospitals and CAHs. However, we will maintain the alternate exclusion through 2016 in order to allow adequate time to update systems and workflows to support successful and safe implementation.

Comment: A number of commenters on the hospital measure also noted concerns over the formulary and controlled substances. As commenters on the EP objective noted,

there are currently challenges involved in effectively completing a query of a drug formulary universally which may cause an additional burden on providers. Commenters also noted that the ability to include or exclude controlled substances should be continued but made more flexible to reflect the changes regarding the allowance and feasibility of electronic prescribing for these medications. Some commenters noted this would be especially important for eligible hospitals and CAHs serving patients in a wide geographic region which may overlap multiple jurisdictions. These commenters noted that a change around the language to make it more flexible would allow them to include prescriptions for controlled substance based on an organizational policy that addressed any potential discrepancies. Other commenters requested clarification on the approach for internal pharmacies and drugs dispensed on site.

Finally, other commenters provided feedback on the request for comment regarding refill prescriptions and continued medications and whether the measure language should be modified to only mention "new prescriptions" or "new or changed prescriptions" rather than the proposed continuation of including new, changed, and refilled prescriptions. The vast majority of commenters did not support including refilled prescriptions noting that these prescriptions should be included and monitored by the original prescriber. Commenters were divided on whether to include or exclude changed prescriptions. Some noting, again, that changed prescriptions should be monitored by the original prescriber while others noted that the change constitutes accountability for the prescription by the eligible hospital.

Response: We agree these concerns are applicable for both the EP and the

eligible hospital/CAH measures. The guidance we provided above regarding how providers may count the query of a formulary for the EP measure is also applicable for the eligible hospital/CAH measure. For controlled substances, based on public comment received we are finalizing similar changes to the denominator for the eligible hospital objective as were adopted for the EP objective to allow for the inclusion or exclusion of these prescriptions at provider discretion where allowable by law. We further note that prescriptions from internal pharmacies and drugs dispensed on site may be excluded from the denominator. Finally, we thank the commenters for their insight and will exclude refill prescriptions but maintain other prescription types. We agree with the rationale stated by commenters; however we note that many EHRs may be programmed to automatically include these prescriptions and a change in the definition could cause unintended negative consequences for EHR system developers and providers if the change required significant modifications to the software. Therefore we will modify the measure language to remove the requirement for refill prescriptions, but we will allow providers discretion over including or excluding these prescriptions rather than requiring providers to exclude them.

After consideration of the public comments received, we are modifying our proposal and finalizing changes to the language to continue to allow providers the option to include or exclude controlled substances in the denominator where such medications can be electronically prescribed. We are finalizing that these prescriptions may be included in the definition of "permissible prescriptions" at the providers discretion where allowable by law. We are modifying the denominator to read "Number of permissible

new, changed, or refill prescriptions written for drugs requiring a prescription in order to be dispensed for patients discharged during the EHR reporting period" in accordance with this change.

Finally, we proposed that some of the Stage 2 objectives and measures do not have an equivalent Stage 1 measure and so for 2015 we proposed to allow providers to exclude from these measures. However, the eligible hospital electronic prescribing objective was included in this policy for both Stage 1 providers and Stage 2 providers in 2015 because it was previously a menu measure so many Stage 2 providers may not be able to meet the measure in 2015 if they had not prepared to do so. As noted in section II.B.1.b.(4)(c)(iii), based on public comment we determined to also allow alternate exclusions in 2016 for certain measures. We determined this to be necessary because, for certain measures providers may not have the specific CEHRT function required to support the measure if they were not prepared to attest to that measure in 2015. These providers may not be able to successfully obtain and fully and safely implement the technology in time to succeed at the measure for an EHR reporting period in 2016. In the case of electronic prescribing, accelerating the implementation of the technology in a short time frame could present a patient safety risk, and so therefore for the eligible hospital objective we are finalizing an alternate exclusion in 2016 for eligible hospitals scheduled for Stage 1 or Stage 2 in 2016. We believe this change will provide the time necessary to safely implement the technology for eligible hospitals and CAHs. Therefore, we are finalizing the alternate exclusion for providers scheduled to demonstrate meaningful for an EHR reporting period in 2015 with an extension of the exclusion into

2016.

We are finalizing the objective, measure, exclusions, and alternate exclusion for eligible hospitals and CAHs as follows:

Objective 4: Electronic Prescribing

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

Measure: More than 10 percent of hospital discharge medication orders for permissible prescriptions (for new and changed prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.

- Denominator: Number of new or changed permissible prescriptions written for drugs requiring a prescription in order to be dispensed 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.
- Exclusions: 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 Exclusion:

Alternate Eligible Hospital/CAH Exclusion: The eligible hospital or CAH may

claim an exclusion for the eRx objective and measure if for an EHR reporting period in 2015 if 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 objective for an EHR reporting period in 2015; and, the eligible hospital or CAH may claim an exclusion for the eRx objective and measure for an EHR reporting period in 2016 if they were either scheduled to demonstrate Stage 1 in 2016 or if they are scheduled to demonstrate Stage 2 but did not intend to select the Stage 2 eRx objective for an EHR reporting period in 2016.

We are adopting the Objective 4: Electronic Prescribing at § 495.22(e)(4)(ii) for eligible hospitals and CAHs. We further specify that in order to meet this objective and measure, an eligible hospital or CAH must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 5: Health Information Exchange

For Objective 5: Summary of Care (here retitled to Health Information Exchange), we proposed to retain only the second measure of the existing Stage 2 Summary of Care objective for meaningful use in 2015 through 2017 (80 FR 20361) and directed readers to the full description 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.

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 proposed 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 proposed 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 important information that the patient may not have been able to provide. This 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. Previously, the measure specified the manner in which the summary of care must be electronically transmitted stating: 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 Nationwide Health Information Network(NwHIN) Exchange participant or in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network. We proposed 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's 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 CEHRT and 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.

Proposed Alternate Exclusions and Specifications for Stage 1 Providers for Meaningful

Use in 2015

We proposed 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 because there is not an equivalent Stage 1 measure.

Proposed 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.

We proposed no alternate specifications for this objective.

Comment: Many commenters supported our efforts towards interoperability and continuity of care. Commenters' general opposition to our original Stage 2 efforts included concerns about building the direct tool into existing systems being difficult and expensive, as well as the lack of receiving facilities capable of direct exchange. Commenters provided a number of general recommendations, including suggestions for keeping data private, allowing providers more freedom regarding which information is included in the summary of care documents, and permitting more alternative technologies to meet the measure. In addition, many commenters expressed the need for a more coordinated effort towards data integration on a national scale, such as a centralized data registry and national standards for interaction and interfacing with data through CEHRT.

Response: We appreciate the comments provided and the wide range of subjects raised in the comments. We agree with the general sentiment that a continued push for improved infrastructure, flexibility, and interoperability among data systems is necessary and appreciate the continued efforts of providers to play a role in this ongoing effort to modernize health care information systems and promote better care coordination through electronic health information exchange.

Comment: Some commenters expressed a general confusion that there was not a list of

the required data elements for the C-CDA in the proposed rule. Some commenters expressed an assumption that because we did not restate the previously finalized list, we are allowing providers to determine the data and information to include in the summary of care document. Other commenters noted that in the numerator discussion for the summary of care, the problem list, medication list and medication allergy list requirement is not reflected, but in subsequent text in the proposed rule the required inclusion of these data elements is clearly identified. These commenters suggest clarification of this point.

Finally, some commenters asked if the omission was intentional and if we intended that the data elements would still be available for providers to use discretion on a case-by-case basis. Other commenters did not express confusion about the requirement, but did not think some flexibility would be welcome as their trading partners are often overwhelmed by the amount of unnecessary information they receive, especially in relation to extensive laboratory test results. The commenters suggested that allowing individual providers some flexibility to determine what is important and relevant to send to the next provider in care would allow receiving providers to process and use the information more effectively.

Response: First, we note that we did not intend to cause this confusion. As stated in the EHR Incentive Program in 2015 through 2017 proposed rule at (80 FR 20361) we proposed to maintain the second measure of the Stage 2 Summary of Care Objective with certain modifications. For efficiency and to reduce the overall length of the proposed rule, we focused our discussion on the proposed modifications and referenced the full description of the measure in the Stage 2 final rule at 77 FR 54013 through 54021. The

only modifications that we intended to make were those that we expressly discussed, and unless we indicated otherwise, our intention was to maintain the existing Stage 2 policies for the measure. This includes maintaining the requirements for the data elements included in the summary of care document at 77 FR 54016 as follows:

"All summary of care documents used to meet this objective must include the following information if the provider knows it:

- Patient name.
- Referring or transitioning provider's name and office contact information (EP only).
- Procedures.
- Encounter diagnosis
- Immunizations.
- Laboratory test results.
- Vital signs (height, weight, blood pressure, BMI).
- Smoking status.
- Functional status, including activities of daily living, cognitive and disability status
- Demographic information (preferred language, sex, race, ethnicity, date of birth).
- Care plan field, including goals and instructions.

- Care team including the primary care provider of record and any additional known care team members beyond the referring or transitioning provider and the receiving provider.

- Discharge instructions (Hospital Only)
- Reason for referral (EP only)

In circumstances where there is no information available to populate one or more of the fields listed previously, either because the EP, eligible hospital, or CAH can be excluded from recording such information (for example, vital signs) or because there is no information to record (for example, laboratory tests), the EP, eligible hospital, or CAH may leave the field(s) blank and still meet the objective and its associated measure.

In addition, all summary of care documents used to meet this objective must include the following in order to be considered a summary of care document for this objective:

- Current problem list (providers may also include historical problems at their discretion),
- Current medication list, and
- Current medication allergy list.

An EP or hospital must verify these three fields for current problem list, current medication list, and current medication allergy list are not blank and include the most recent information known by the EP or hospital as of the time of generating the summary of care .document"

We intend to maintain this policy of the required data elements for the C-CDA as

previously finalized. However, we do understand provider concern over the ability to exercise some discretion over the amount of data transmitted, and as noted in the Stage 3 proposed rule (80 FR 16760) we recognize there may be reasons to apply a policy of determining clinical relevance for the amount of data in the lab results field and clinical notes field which should be included in the summary of care document. Specifically, it may be beneficial for a provider to limit the lab results transmitted in the record of an extended hospital stay to those which best represent the patient status upon admission, any outliers or abnormal results, and the patient status upon discharge. Further, we note that this is only one example and other definitions of clinical relevance for lab results may apply in other clinical settings and for other situations. We are therefore adopting a similar policy for this measure as the one outlined for Stage 3; however, we are limiting this policy to lab results. We are therefore requiring that a provider must have the ability to send all laboratory test results in the summary of care document, but that a provider may work with their system developer to establish clinically relevant parameters based on their specialty, patient population, or for certain transitions and referrals which allow for clinical relevance to determine the most appropriate results for given transition or referral. We further note that a provider who limits the results in a summary of care document must send the full results upon the request of the receiving provider or upon the request by the patient. For discussion of this proposal in relation to the Stage 3 objective in this final rule with comment period we direct readers to section II.B.2.b.vii.

Comment: Many commenters supported the modified objective removing the 50 percent measure for providing a summary of care record by any means, as well as the

measure's widening of the pathways acceptable for transmitting Summary of Care records. These commenters noted that the relaxation of requirements for manual transmission will allow them to better tailor the contents of the summary of care document to the transport mechanism and will, in fact, encourage the electronic adoption because of the ease of obtaining a full range of information on a patient as compared to non-electronic transport mechanisms.

Response: As noted previously, the general movement away from requiring reporting on paper-based measures is intended to allow providers to focus efforts on the use of CEHRT to support health information exchange. We agree that limiting the EHR Incentive Program objectives and measures exclusively to electronic transmissions while simultaneously expanding the options by which such exchange may occur will allow developers, providers, and the industry as a whole to focus on the support of HIE infrastructure while supporting innovation in interoperable health IT development.

Comment: Many commenters expressed opposition to the objective noting a lack of participation by EPs to whom the referrals are made. A large number of commenters believe that they should not be penalized for other EPs inability to receive electronic delivery, something over which they state they have no control. In addition, some primary care doctors believe they are unfairly being held responsible for communicating with specialists who can claim an exclusion for referring less than 100 times. Many commenters requested that we reduce the threshold or change the measure to a yes/no attestation due to the lack of control over other EPs and eligible hospitals/CAHs without receiving capabilities. Many recommendations about the denominator varied, with some

suggesting that the denominator referrals should exclude providers who are not EPs, eligible hospitals, or CAHs under the EHR Incentive Programs or should exclude patients who do not choose a specific provider for their recommended referral service.

Commenters also requested various exclusions, including exclusions for transitions to pediatric providers, referrals to therapists, and for those in areas where there are not enough EPs participating in Stage 2. Commenters requested clarifications on the measure regarding what constitutes "transfer of care" and what defines electronic transmissions.

Response: We appreciate the commenters' concern about a lack of participation by EPs to whom the referrals are made and note that this is one reason behind the relatively low 10 percent threshold for this measure. We also note that in the proposed rule, we expressed a concern that a key factor influencing successful HIE is the active participation of a large number of providers in the process. We note that those providers who did participate in electronic exchange through Stage 2 in 2014 performed reasonably well on the measure, but through letters and public comment expressed a need for wider participation among providers to ensure a significant number of trading partners are available for electronic exchange. This is a driving influence behind our continued support of this measure and the move to require all providers to participate in this objective and measure beginning in 2016. The definition of a transition of care for this objective was finalized in the Stage 2 final rule where we outline the denominators for the various objectives and measures (77 FR 53984). We subsequently further defined (80 FR 16759) a transition of care for electronic exchange as one where the referring

provider is under a different billing identity within the Medicare and Medicaid EHR Incentive Programs than the receiving provider and where the providers do not share access to the EHR. In cases where the providers do share access to the EHR, a transition or referral may still count toward the measure if the referring providers creates the summary of care document using CEHRT and sends the summary of care document electronically. If a provider chooses to include such transitions to providers where access to the EHR is shared, they must do so universally for all patient and all transitions or referrals.

Comment: Some commenters requested an extension of the alternate exclusion for Stage 1 providers into 2016 rather than only making this allowance for 2015.

Response: We do not believe that extending the alternate exclusion into 2016 serves the goals of the program to promote interoperability, an expanded HIT infrastructure, and the use of HIT to support care coordination. As noted previously, one of the biggest concerns expressed by providers seeking to engage in HIE is the need to increase overall participation to ensure an adequate pool of trading partners exists within the industry. We believe that requiring all participating providers to exchange health information electronically when transitioning or referring a patient to a new setting of care, but maintaining the reasonably low threshold at 10 percent, represents a reasonable balance between promoting participation and setting an achievable goal for providers.

We acknowledge that in some cases we have decided to extend the alternate exclusion for 2015 into 2016 where a provider may not have the appropriate CEHRT functions in place for a measure. However, we have limited those instances to those

cases where rushed implementation of the function could present a risk to patient safety. We do not believe this objective and measure pose such a risk, and further maintain our assertion from the Stage 3 proposed rule (80 FR 16739) that overall success on in health information exchange is enhanced by increased participation.

Comment: Many commenters supported the modified objective and the flexibility proposed around the pathways acceptable for transmitting Summary of Care records. Some commenters noted this change will facilitate queried exchange and encourage providers to push information to an HIE. Another commenter believes that this update will enhance the growth and utilization of the electronic exchange of information while upholding the same security standards as DIRECT or NwHIN.

Some commenters requested that we initiate the mandatory reporting of direct address directories to a central repository so that established standards will help providers meet future requirements in Stage 3.

Response: The intent behind the expansion of the potential transport mechanism proposed is to drive interoperability across care settings and encourage further innovation in electronic health information exchange and care coordination. We agree that the retention of the document standards for health information exchange will help to support interoperability, while allowing providers a wider range of options for the electronic transport mechanism. This will also mitigate difficulties for providers whose most common referrals may be to other caregivers who are not using a Direct transport mechanism. We note that CEHRT is required to be able to receive a C-CDA, but that the potential to use a wider range of transport mechanisms will allow for greater diversity of

information exchange.

While we encourage the use of query -based exchange for many use cases, we note that to count in the numerator the sending provider must have reasonable certainty of receipt of the summary of care document. This means that a “push” to an HIE which might be queried by the recipient is insufficient. Instead, the referring provider must have confirmation that a query was made to count the action toward the measure. We further specify that the exchange must comply with the privacy and security protocols for ePHI under HIPAA.

We thank the commenters for the suggestion around the concept of an information exchange address repository. We agree that a potential model which might allow for easier access to health information exchange contact information could be a positive step toward supporting interoperability and an improved care continuum. We refer readers to section II.D.3 of this final rule with comment period for further discussion of the collection of direct addresses or health information exchange information for potential inclusion in a nationwide healthcare provider directory. After consideration of public comments received, we are finalizing this objective, measure, exclusion, and alternate exclusion as proposed for EPs, eligible hospitals, and CAHs as follows:

Objective 5: Health Information Exchange

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.

Measure: The EP, eligible hospital or CAH that transitions or refers their patient to

another setting of care or provider of care must-- (1) use CEHRT to create a summary of care record; and (2) electronically transmit such summary to a receiving provider for more than 10 percent of transitions of care and referrals.

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 CEHRT and 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 Exclusion:

Alternate Exclusion: Provider may claim an exclusion for the Stage 2 measure that 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.

We are adopting Objective 5: Health Information Exchange at § 495.22(e)(5)(i) for EPs and § 495.22(e)(5)(ii) for eligible hospitals and CAHs. We further specify that in order to meet this objective and measures, an EP, eligible hospital, or CAH must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct

readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 6: Patient-Specific Education

In the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20362), we proposed to retain the Stage 2 objective and measure for Patient-Specific Education for meaningful use for 2015 through 2017.

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

In the Stage 2 proposed rule (77 FR 54011), 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 maintained 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 use CEHRT in a manner in which the technology suggests patient-specific educational resources based on the information created or maintained in the CEHRT. CEHRT 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 eligible 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 CEHRT 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 proposed 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 be counted in the numerator. We do not intend through this requirement to limit the education resources provided to patients 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 CEHRT.

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 CEHRT.

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.

Proposed 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, the same objective is a mandatory core objective in Stage 2. 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 proposed 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.

Proposed Alternate Exclusion: Providers 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.

We proposed no alternate specifications for this objective.

Comment: The vast majority of commenters expressed support for the inclusion of the Patient-Specific Education objective in the EHR Incentive Programs for 2015 through 2017 proposed rule. They recognized the importance of supplying patients with materials about their conditions and summaries about their visits.

Response: We thank the commenters for their support of this objective.

Comment: Those who opposed the objective believe that the inclusion of the objective in the EHR Incentive Programs for 2015 through 2017 proposed rule increased administrative burden on providers. Some commenters opposed to the objective believe that physicians should have flexibility regarding the sources and types of materials they can provide to their patients, rather than being limited to those identified by CEHRT.

Response: We appreciate the insight from providers and note that the intent of the objective is to promote wider availability of patient-specific education leveraging the function of CEHRT, as noted in the similar, electronic-only Stage 3 proposed measure. We note that this should in no way limit the provider's selection of patient-specific education materials or provision of paper-based education materials for patients if the

provider deems such an action beneficial and of use to the patient. We are simply not requiring providers to count and report any such provision that falls outside the definition for the EHR Incentive Programs for 2015 through 2017 as described in this objective and measure.

Comment: Multiple commenters requested clarification of the timeframe in which the information should be shared with the patient. Commenters specifically requested additional clarity on FAQ 8231⁷ released by CMS, stating the actions taken would need to fall within the reporting year, even if they fall outside of the reporting period. For the patient education measure of this objective, some commenters believe requiring the action to occur during the reporting period promotes wasted resources and functions from the provider. Specialty providers who are providing long -term care for a patient would need to send out patient education for what would amount to the same problem each year. This education could have been provided in a previous year to the patient, and the FAQ is stating the patient be provided the education again in order to count for the numerator in the current reporting year. Commenters further noted that many specialist EPs provide education at the beginning of an engagement with a patient appropriate to their condition with the intent that it be applicable to the entire duration of the treatment of the patient's condition. Commenters expressed concern that the policy would require the provider to either provide repetitive education or identify additional educational opportunities in order to count the action in the numerator. The commenters state that allowing for any prior action to count would reduce the unnecessary burden

⁷ FAQ #8231: CMS Frequently Asked Questions: EHR Incentive Programs
<https://questions.cms.gov/faq.php?faqId=8231>

placed on physicians, and the waste of resources to provide the patient with repetitive information.

Response: As discussed in section II.B.1.b.(4), some measures in the Stage 2 final rule did not include a specification on the timing when an action must occur for inclusion in the numerator. The Stage 2 patient-specific education objective did not contain language stating that the provision of patient-specific education must occur within the office visit or during the hospital stay. For EPs the measure states only that the patient had an office visit during the EHR reporting period and was provided patient-specific education. This could refer to materials provided during an office visit or at another point in time.

However, we disagree with the recommendation to allow any action to count in perpetuity. We note that this measure refers to a single action for each unique patient seen during the EHR reporting period. This means that if a provider meets the minimum action, even for those patients who have multiple office visits within an EHR reporting period, the provider would be providing educational information a single time each year for only just over 10 percent of their patients. We strongly disagree that this represents an unreasonable burden or that this action should not be required to continue on an annual basis. We disagree with the commenter's suggestion that patient specific education is not useful or relevant for a patient for each year in which they receive medical care. We further disagree with the examples provided for specialists or other providers providing long -term care or working with a patient to manage a chronic disease that a single provision of patient specific education should be counted for the numerator in

perpetuity. Research shows that continued patient engagement and education positively impacts patient outcomes, especially for patients with a chronic disease and patients who may experience health disparities.⁸ In addition, as a patient ages, or as their health condition changes, their needs for education about their care may also change.

Therefore, as indicated in FAQ 8231, we believe that while the patient-specific education resources may be provided outside of the EHR reporting period, this action must occur no earlier than the start of the same year as the EHR reporting period if the EHR reporting period is less than one full calendar year and no later than the date of attestation. For the eligible hospital and CAH measure, the numerator includes the qualifier "subsequently" which indicates the patient-specific education resources must be provided after the patient's admission to the hospital, and consistent with FAQ 8231, no later than the date of attestation. As noted in section II.B.1.b.(4)(b), some EHRs may have previously been designed and certified to calculate this measure based on a prior assumption, and for that reason we will not require this method of calculation until the EHR reporting period in 2017 in order to allow sufficient time for the calculation to be updated in systems.

Comment: Other commenters were concerned that the exclusion for providers who were scheduled for Stage 1 but "did not intend to select the Stage 1 Patient Education menu objective" is vague and will lead to audit problems.

Response: We refer readers to the discussion of intent in section

⁸ "Patient Education and Empowerment Can Improve Health Outcomes for Diabetes" NY Presbyterian DSME study August 2014: <http://www.nyp.org/news/hospital/2014-education-diabetes.html>.

Keolling, Todd M., MD; Monica L. Johnson, RN; Robert J. Cody, MD; Keith D. Aaronson, MD, MS: "Discharge caEducation Improves Clinical Outcomes in Patients with Chronic Heart Failure" Heart Failure: AHA Journals: <http://circ.ahajournals.org/content/111/2/179.full>

II.B.1.b.(4).(b)(iii) of this final rule with comment period where we acknowledge that it may be difficult for a provider to document intent and will not require such documentation.

Comment: Multiple commenters recommended that we add the Patient-Specific Education objective to the list of topped -out measures. Another group of commenters recommended that we provide an alternate measure for eligible hospitals/CAHs/EPs that were scheduled to be in Stage 1 in 2015 and desired to select patient education as a menu objective utilizing the current Stage 1 measure definition. Others recommended we require that providers have multi-lingual and low-literacy patient portals.

Response: We respectfully disagree that the measure is topped out and believe there is value in continued measurement especially in light of the inclusion of the similar electronic measure within Stage 3. We also disagree with the recommendation to include an alternate specification for the measure in addition to the alternate exclusion. While the policy would allow some providers to attest, it adds an additional level of complexity and makes no accommodation for those providers in 2015 who have not been engaged in the measure at all, as they did not intend to attest to that menu selection. Finally, we appreciate the recommendation on the inclusion of multi-lingual and low-literacy patient portals to provide and support patient education for a wider range of patients. We note that it is a priority of CMS and ONC to continue to foster interoperability between assistive technologies, portals such as those recommended by the commenters, applications leveraging multi-media supports, and other accessible tools and CEHRT. Unfortunately, while we strongly encourage adoption of these resources and support the

development of standards and testing, we believe the requirement of these tools for all providers in the Medicare and Medicaid EHR Incentive Programs is premature based on the current availability of such interoperable resources in the EHR marketplace.

Comment: Some commenters requested clarification if the transitive effect described in FAQ 7735 and FAQ 9686 applies for the patient-specific education objective as well. These commenters note that if patient-specific education is provided via a patient portal, it is very difficult to measure as attributable to a specific provider within a group practice or even across settings if providers are sharing an EHR.

Response: FAQ7735 and FAQ 9686 refer to the Patient Electronic Access Objective measures 2 and the Secure Electronic Messaging Objective respectively,⁹ and allow for a single action by a patient to count in the numerator for multiple providers under certain circumstances if each of the providers has the patient in their denominator for that EHR reporting period. In each case, this policy is intended to facilitate calculation in circumstances where accurate calculation and attribution of the action to a single provider may be impossible. This is not inherently the case with the patient-specific education objective which is why this objective is not included in either FAQ. The Stage 2 Patient-specific Education Objective (80 FR 20362) does not limit the measure to education provided via a patient portal and therefore a universal policy allowing the "transitive effect" would not be appropriate. For example, if a provider gives a patient a paper-based educational resource during their office visit, that instance is only

⁹ CMS.gov Frequently Asked Questions: EHR Incentive Programs FAQ 7735: <https://questions.cms.gov/faq.php?id=5005&faql=7735> and FAQ 9686: <https://questions.cms.gov/faq.php?id=5005&faql=9686>

attributable to that provider and should not be counted in the numerator for other providers within the group practice. However, if the resource is provided electronically and such attribution is impossible, it may be counted in the numerator for any provider within the group sharing the CEHRT who has contributed information to the patient's record, if that provider also has the patient in their denominator for the EHR reporting period. We recognize that this may result in a process of manual calculation if both electronic and paper-based resources are used. While we are seeking to avoid manual calculation and paper-based actions, we must also balance avoiding unintended negative consequences which may result from changing the specifications for this measure for providers who are currently using paper-based methods. For information on the fully electronic Patient-specific Education measure included in the Stage 3 proposed rule, we direct readers to section II.B.2.b.vi of this final rule with comment period.

After consideration of public comments received, we are finalizing the objective, measures, exclusions, and alternate exclusion as proposed for EPs, eligible hospitals and CAHs.

The final objective is as follows:

Objective 6: Patient-Specific Education

Objective: Use clinically relevant information from CEHRT to identify patient-specific education resources and provide those resources to the patient.

EP Measure: Patient-specific education resources identified by CEHRT 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.

- 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 CEHRT.
- 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.

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) during the EHR reporting period are provided patient-specific education resources identified by CEHRT.

- 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 Exclusion:

Alternate Exclusion: Providers 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.

We are adopting Objective 6: Patient-Specific Education at § 495.22(e)(6)(i) for

EPs and § 495.22(e)(6)(ii) for eligible hospitals and CAHs. We further specify that in order to meet this objective and measures, an EP, eligible hospital, or CAH must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 7: Medication Reconciliation

In the EHR Incentive Programs for 2015 through 2017 proposed rule (80 FR 20363), we proposed to retain the Stage 2 objective and measure for Medication Reconciliation for meaningful use in 2015 through 2017. 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.

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.

In the Stage 2 proposed rule at 77 FR 54012 through 54013, 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, as information included in the

process 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. In the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20363), we proposed to maintain these definitions without modification.

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).

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.

Proposed Alternate Exclusions and Specifications for Stage 1 Providers for Meaningful

Use in 2015

We proposed 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.

Proposed 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.

We proposed no alternate specifications for this objective.

Comment: One commenter requested clarification of whether CMS intends to limit the denominator of this proposed measure to transitions of care, or if certain referrals would also continue to be included as was the case prior to this rulemaking. Another commenter stated that they believe their CEHRT incorrectly includes encounters in the denominator where no actual transition of care is occurring or where the encounter is not a face-to-face encounter with the patient.

Many commenters provided recommendations for additional exclusions for the objective including exclusions for providers who do not have office visits; and providers who have fewer than 10 or 100 transitions of care rather than limiting the exclusion to providers who not the recipient of any transition or referral. Another commenter believes that medication reconciliation is out of scope for his practice while others requested excluding referrals for reading certain tests or imaging services. Commenters also requested that we revise the measure to allow an exclusion for providers with fewer than

100 transitions or referral received electronically or to limit the denominator to only those transitions or referrals where an electronic summary of care document was received.

Finally, one commenter stated a belief that the requirements for medication reconciliation objective depend upon the interoperability of EHR systems and may pose a significant burden to providers.

Response: We reiterate that in the EHR Incentive Program for 2015 through 2017 (80 FR 20363), we proposed to maintain the denominators finalized through rulemaking in the Stage 2 final rule (77 FR 54012 through 54013 and 53982 through 53984), including the current definition of a transition of care for inclusion in the denominator of this measure. We note that the denominator includes when the provider is the recipient of the transition or referral, first encounters with a new patient and encounters with existing patients where a summary of care record (of any type) is provided to the receiving provider (77 FR 53984).

In addition, for those EPs who note that they have no office visits, or face-to-face encounters, and therefore should not have to include patient encounters for these services (such as only reading an EKG); we refer readers to the description in the Stage 2 final rule (77 FR 53982) which notes that a provider may choose to include these encounters in the denominator or to exclude them. However, if the provider chooses to include or exclude these encounters they must apply the policy universally across all such encounters and across all applicable measures. A provider should consider how the policy will affect their ability to meet all applicable measures, and then work with their EHR vendor to ensure that the calculation of denominators and numerators matches the

provider's decision.

In terms of additional or expanded exclusions or concerns over scope of practice, we note that we did not propose any such changes and disagree that any such changes are necessary or beneficial. We believe medication reconciliation is an important part of maintaining a patient's record, that it is integral to patient safety, and that maintaining an accurate list of medications may be relevant to any provider's plan of care for a patient.

In addition, robust health information exchange is of great assistance to medication reconciliation, but an electronic summary of care document is not required for medication reconciliation. Nor is electronic HIE the only way EHRs can assist with medication reconciliation. Medication reconciliation may take many forms, from automated inclusion of ePHI to review of paper records, to discussion with the patient upon intake or during consultation with the provider. Going back to Stage 1 we have noted that medication reconciliation may become more automated as technology progresses, but may never reach a point of full automation as these other methods continue to offer value—especially conversation with the patient which may remain an important part of that process (75 FR 44362). Furthermore, while the measure does involve health information exchange, we see no value in limiting the medication reconciliation measure to only those patients for whom a record is received electronically. We believe that it is appropriate and important to conduct medication reconciliation for each patient regardless of the method that reconciliation may require. Therefore, while we believe that medication reconciliation will become easier as health information exchange capability increases and that robust health information exchange

supports medication reconciliation, it is not a prerequisite to performing medication reconciliation. Further, we believe the continued inclusion of a broad requirement for medication reconciliation will encourage developers and providers to continue to focus on how HIT can be designed and leveraged to better support provider medication reconciliation workflows through innovative new tools and resources. .

Comment: A commenter recommended that we require medication reconciliation when a provider receives a Summary of Care that is not a duplicate document and only reconcile if there are changes to the medication list. Another commenter requested that automated results should only be counted if there are medications in the queried document so it is possible to "compare the medical record to an external list of medications obtained from a patient, hospital, or other provider."

Response: We note that we discuss the denominator for a transition of care in section II.B.1.b.(4)(f) of this final rule with comment period and that in the EHR Incentive Programs in 2015 through 2017 proposed rule at (80 FR 20363) we proposed to maintain the definition for this objective from the Stage 2 final rule when the EP is the recipient of the transition or referral, first encounters with a new patient and encounters with existing patients where a summary of care record (of any type) is provided to the receiving EP (77 FR 53984). We note that the reconciliation occurs with the transition or referral, not with the receipt of the summary of care document. Therefore, if a provider receives duplicate summaries for a single referral such an action must only be counted once. In addition, the action of reviewing the medication list to determine if there are changes or confirm that there are no changes would meet the requirements of the

objective to count as an action in the numerator.

Comment: Commenters requested that CMS define what a "new" patient is for the purposes of the definition of a transition or referral. For example, one commenter noted that in their billing practices they define a patient as "new" if they have not been seen in 2 years. The commenter noted that using this definition in the denominator would include a greater number of relevant patient encounters than our current definition which uses patients who were never before seen by the provider. The commenter suggested this definition would ensure that these patients records were also updated which would be a significant benefit.

Response: In the EHR Incentive Programs in 2015 through 2017 proposed rule(80 FR 20363) as in the Stage 2 final rule (77 FR 54013), we consider a patient to be a new patient if he or she has never before been seen by the provider. We agree that the commenter's definition of "new patient" may capture a wider range of patients for whom medication reconciliation would be relevant and beneficial. While we will not change the denominator for this existing objective, a provider may use an expanded definition which includes a greater number of patients for whom the action may be relevant within their practice. We intend that our description of a new patient is a baseline that a provider must meet; however, if that requirement is met the provider may include further actions or addition encounters relevant to their practice and patient population, so long as the approach is applied universally across all such encounters, all settings and for the duration of the EHR reporting period.

Comment: A commenter requested clarification of whether the denominator of

medication reconciliation includes first encounters with all new patients (in other words, "encounters in which the provider has never before encountered the patient" as specified in the Stage 3 proposal) or only those new patients that are accompanied by a summary of care record.

Response: For providers who are on the receiving end of a transition of care or referral, the denominator includes first encounters with a new patient and encounters with existing patients where a summary of care record (of any type) is provided to the receiving provider.

Comment: A commenter requested clarification of whether CMS intends to limit the denominator of this proposed measure to transitions of care, or if certain referrals would also continue to be included as was the case prior to this rulemaking.

Response: For the purposes of this measure, we continue 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. 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. Thus, the denominator includes both transitions of care and referrals in which the provider was the transferring or referring provider.

Comment: The proposal to allow exclusion for this measure if a provider was scheduled for Stage 1 but "did not intend to select the Stage 1 Medication Reconciliation menu objective" is vague and will lead to audit problems. It should just be clearly stated that this is exclusion for Stage 1 EPs.

Response: As explained in section II.B.1.b.(4)(b)(iii) of this final rule with comment period where we acknowledge that it may be difficult for a provider to document intent and will not require such documentation.

Comment: While the commenter agrees that medication reconciliation is a critical patient care requirement when patients move from one setting of care to another, they encourage us to specify that transitions from physicians who furnish services in POS 22 code should not be considered "transitions of care" for purposes of this objective and measure.

Response: We note that we make no distinction between settings nor do we reference any POS code for the party transitioning the patient. We consider a transition as the movement of a patient from one care setting to another. We reference POS in this objective only with regard to the inclusion of patients admitted to either the Inpatient or Emergency Department (POS 21 and 23) in the denominator. We see no reason that patients referred from a provider billing under a POS 22 should not be included in the definition of a transition or referral.

After considerations of public comments received, we are finalizing as proposed the objective, measure, exclusion and alternate exclusions for EPs, eligible hospitals, and CAHs as follows:

Objective 7: Medication Reconciliation

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 performs medication reconciliation.

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).

- 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 Exclusion:

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.

We are adopting Objective 7: Medication Reconciliation at § 495.22(e)(7)(i) for EPs and § 495.22(e)(7)(ii) for eligible hospitals and CAHs. We further specify that in order to meet this objective and measures, an EP, eligible hospital, or CAH must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct

readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 8: Patient Electronic Access

We proposed to retain the Stage 2 objective for Patient Electronic Access for meaningful use in 2015 through 2017. We proposed to retain the first measure of the Stage 2 objective without modification. We proposed to retain the second measure for the Stage 2 objective with modification to the measure threshold.

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 their health information within 36 hours of hospital discharge.

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 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, or who require assistive technology to do so. Additionally, other health information may not be accessible. Finally, we noted that providers who are covered by civil rights laws, including the Americans with Disabilities Act, Section 504 of the Rehabilitation Act of 1973, or Section 1577 of the Affordable Care Act, must provide individuals with disabilities equal access to information and appropriate auxiliary aids and services as provided in the applicable statutes and regulations. For a useful reference of how to meet these obligations, we suggest covered providers reference the Department of Justice's Effective Communications guidance at <http://www.ada.gov/effective-comm.htm>.

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.

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:

- Proposed 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.

- Proposed 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.

- Proposed 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.

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:

- Proposed 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.

- Proposed 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.

- Proposed 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.

Proposed Alternate Exclusions and Specifications for Stage 1 Providers for Meaningful

Use in 2015

We proposed 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 because there is not an equivalent Stage 1 measure defined at 42 CFR 495.6.

Proposed Alternate Exclusion Measure 2: Providers 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.

We proposed no alternate specifications for this objective.

Comment: Many commenters appreciate the proposed modifications to the objective's measures that rely on patient's actions. Many respondents believe the flexibility provided in the modifications will provide more time for both providers and patients to become more comfortable accessing and using patient portals, and will not penalize providers for failing to meet thresholds based on patient actions they cannot control.

Response: We thank the commenters for their feedback concerning this proposed change in the EHR Incentive Programs in 2015 through 2017.

Comment: A number of commenters opposed our proposal to modify the second measure requiring that patients taking action to view, download, or transmit their health information. These commenters stated concern that the change will have a negative effect on patients access to their health record because it will allow providers to stop investing in the workflows, training, and patient education needed to support patient access.

Other commenters urged CMS to "preserve the existing thresholds for patient online access and secure ,messaging" stating that requiring that only one patient has access is not meaningful enough. These commenters included statements advocating for patients to have the ability to access their EHR and that we should not reduce the threshold to let providers off the hook.

Response: We appreciate the commenters' advocacy for patients and agree that patient electronic access to health information is essential to improving the quality of care. However, we disagree that reducing the patient action measure will negatively impact the workflows, training, and patient education for patient access because the patient access measure is still fully in place: that is, measure 1 which requires providers to ensure that more than 50 percent of patients are provided access to their health information. This measure requires that providers ensure that patients have all the information they need to access their record, even for patients who may choose to opt out, so a provider cannot stop doing the workflows, training, and patient education for patient access and still meet the requirements of meaningful use for measure one of this objective.

For the commenters who state that one patient having access is not meaningful enough, we believe these commenters may have misunderstood which measure we proposed to modify. As noted, we proposed no changes to the first measure under the Patient Electronic Access objective which is required for all providers in Stage 1 and Stage 2, in Medicare and Medicaid, and for both EPs, eligible hospitals, and CAHs. For this measure, each provider must demonstrate that more than 50 percent of their unique

patients during the EHR reporting period have access to view, download, and transmit their health information. In the proposed rule, we proposed only to modify the second measure (which measures the patient's action, not the provider) from a threshold of 5 percent to at least one patient.

Comment: While some commenters supported EP Measure 1 as proposed, many more were concerned with patients' general ability to access their health information. A portion of respondents in disagreement with Measure 1 were concerned the 50 percent threshold will be unattainable because their patient population is elderly, ill, low-income, and/or located in remote, rural areas. These patients do not have access to computers, Internet and/or email and are concerned with having their health information online. Several others believe Measure 1 is unnecessary, as patients must use the access provided in order for an EP, eligible hospital or CAH to meet Measure 2 of this objective. A number of commenters also disagreed with the requirement for the provision of new information within 36 hours for eligible hospitals and CAHs (four business days for EPs) stating that it was either too long a time for patients to wait or too short a time for providers to respond.

Response: We have proposed no changes to the first measure and reiterate our intent to maintain the first measure as previously finalized in the Stage 2 final rule. We note that providing access to patients to view, download, and transmit their information is a top priority for patient engagement, patient-centered care, and care coordination. We note that in the EHR Incentive Programs, the specifications for the measure allow the provision of access to take many forms and do not require a provider to obtain an email

address from the patient. We understand that many CEHRT products may be designed in that fashion, but it is not by the program.

If a provider's CEHRT does require a patient email address, but the patient does not have or refuses to provide an email address or elects to "opt out" of participation, that is not prohibited by the EHR Incentive Program requirements nor does it allow the provider to exclude that patient from the denominator. Instead, the provider may still meet the measure by providing that patient all of the necessary information required for the patient to subsequently access their information, obtain access through a patient-authorized representative, or otherwise opt-back-in without further follow up action required by the provider. We note that we have proposed no changes to the timeframe for provision of new information and maintain that 36 hours (for eligible hospitals and CAHs) and 4 business days (for EPs) is a reasonable time limit because it allows for immediate access (if feasible) and a reasonable amount of time for providers to review any information necessary before it is made available to the patient.

Comment: A commenter noted that the patient access measure 1 needs clarification as to when it must occur in relation to the EHR reporting period. The commenter further stated that once a patient has been provided access there is no need to provide additional access unless the patient originally opted out of receiving electronic access. The commenter further noted that active, ongoing access that preceded the EHR reporting period should always count in the numerator for a patient seen during the EHR reporting period. The commenter also states that when a patient opts out of electronic access, as long as the patient was properly educated on the portal and how to gain access,

there should be no need to count access again.

Further commenters referenced EHR Incentive Programs FAQ 8231¹⁰ and recommended that we clarify measure one and measure 2, and suggested that all measure with a denominator referencing unique patient should allow a provider to count actions from any time period before the reporting period or reporting year to count in the numerator.

Response: We believe the confusion on this issue for the first measure may relate to the ways in which different EHRs are set up to initiate access for a patient the first time. The measure does not address the enrollment process or how the initiation process to “turn on” access for a patient within an EHR system should function. The measure is addressing the health information itself. To count in the numerator, this health information needs to be made available to each patient for view, download, and transmit within 4 business days of its availability to the provider for each and every time that information is generated whether the patient has been "enrolled" for three months or for three years. We note that a patient needs to be seen by the EP during the EHR reporting period or be discharged from the hospital inpatient or emergency department during the EHR reporting period in order to be included in the denominator.

For example, if a provider's CEHRT uses an enrollment process to issue a user ID to the patient, a provider does not need to create a new user ID for a patient each time the patient has an office visit. That initial enrollment can occur any time as it is not governed by the measure. What the measure addresses is the health information that results from

¹⁰FAQ 8231. www.cms.gov/ehrincentiveprograms CMS Frequently Asked Questions: EHR Incentive Programs (archived).

care (e.g. from an office visit or a hospital admission). The measure timeline for making any health information available resets to 36 hours for an eligible hospital or CAH and 4 business days for an EP each time new information is available to which the patient should be provided access. Therefore, although a provider does not need to enroll a unique patient a second time if the patient has a second office visit during the EHR reporting period, the provider must continue to update the information accessible to the patient each time new information is available. In addition, if the provider fails to provide access to a patient upon an initial visit during the EHR reporting period, but provides access on a subsequent visit, the patient cannot be counted in the numerator because the patient did not have timely online access to health information related to the first visit. Similarly, the patient cannot be included in the numerator if access is provided on the first visit, but the provider fails to update the information within the time period required after the second visit. In short, a patient who has multiple encounters during the EHR reporting period, or even in subsequent EHR reporting periods in future years, needs to have access to the information related to their care for each encounter where they are seen by the EP or discharged from the eligible hospital or CAH's inpatient or emergency department.

In relation to the suggestion that the second measure should be allowed to be calculated including any action in any time period before the EHR reporting period to count in the numerator, we strongly disagree. We do not believe a single instance of a patient accessing their record should be counted in perpetuity for the measure. The calculation may include actions taken before, during, or after the EHR reporting period if

the period is less than one full year; however, consistent with FAQ 8231, these actions must be taken no earlier than the start of the same year as the EHR reporting period and no later than the date of attestation. We understand, as discussed in section II.B.1.b.(4), that some certified EHRs may not calculate the numerator in this fashion and therefore we will allow providers to use an alternate calculation for an EHR reporting period in 2015 and 2016 if that calculation is a part of their CEHRT to allow sufficient time to upgrade the calculation prior to providers attesting to data for an EHR reporting period in 2017.

Comment: Those commenters in support of the changes to measure 2 of this objective supported our incorporation of stakeholder and participant feedback into the modifications of this measure. Supporting commenters agreed with the proposed patient engagement threshold reduction, stating that it is currently unattainable for their practice due to a patient population that is elderly, ill, low-income, and/or located in remote, rural areas. For these sites, commenters believe lowering the threshold will permit them flexibility in working with their vendors and developing new approaches to increase their patient engagement.

Response: We thank the commenters for their contribution. We believe that continued efforts to raise awareness and provide access through a wider range of electronic means (such as the inclusion of APIs in the Stage 3 measure) will help to expand the adoption of this technology over time.

Comment: The majority of commenters concerned about the modifications of Measure 2 believe lowering the patient engagement threshold is counter-productive for

improving patient outcomes and moving the meaningful use program forward.

Commenters worry the new threshold is much too low to incentivize providers to encourage patient access to the electronic health records that are central to the overarching goal of meaningful use.

Some commenters disagreed with the modifications to Measure 2 and are concerned with the large jump to meet the proposed Stage 3 meaningful use VDT requirement in 2018. Several commenters believe that the reduction of the patient engagement threshold will slow momentum of this measure leaving providers ill-prepared for the future of meaningful use. Many commenters believed that lowering the requirement to only one patient viewing, downloading, or transmitting their health information is counterproductive to improving patient outcomes nationally. Engaging patients by using technology is a critical path to move the healthcare system forward and demonstrate the core value of meaningful use. Several commenters recommended a phased approach for the threshold for the measure, increasing over time to the proposed Stage 3 level. They recommended a phased approach that recognizes the challenges that some providers are encountering as they try to get their patient population more engaged with viewing, downloading or transmitting their information to a third party. They believe that a higher measure threshold will be easier to achieve as the technology becomes even more user-friendly and patients begin to see the value in becoming more involved in their own care and taking these actions. Overall, they believe a phased-in approach for the patient electronic access objective would be an appropriate and balanced step forward.

Response: We agree that providers have a role in promoting behavioral change among patients in regard to engaging with their health information and increasing health literacy and that provider influence may be a factor. However, as noted in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20357), statistical analysis of measure performance shows a wide variance, and further analysis in comparison to the first measure does not show a correlation between provider action and patient response¹¹. Through our analysis we found that neither high nor low performance on the first measure nor an overall increase or decrease in the number of patients who have access to their data, had a strong or moderate correlation to performance on patient action either for high performers or low performers. This suggests that other external factors currently impact performance on the objective. This may include a lag in the adoption of technologies by patients, patient self-selection, or other unknown factors related to the IT environment and the patients themselves. We believe that continued efforts to raise awareness and provide access through a wider range of electronic means (such as the inclusion of APIs in the Stage 3 measure) will help to expand the adoption of this technology over time, and we maintain that providers should be supported in that effort rather than having additional burden added for factors outside their control.

We wish to reiterate that we understand the concerns voiced by providers regarding patient populations that are unable to engage in their health care information electronically due to various factors, which include income, age, technological capabilities, or comprehension. We agree with the phased approach recommended by the

¹¹ EHR Incentive Programs Performance Data: Program Data and Reports: [www.cms.gov/EHR Incentive Programs](http://www.cms.gov/EHR%20Incentive%20Programs)

commenters who noted that it provides additional time for the adoption of technology by patients, but also maintains the importance of the measure. We believe this approach will allow providers to set a progressive goal with incremental increases in performance through 2018. We believe this approach is in line with our policy to build from basic to advanced use and to increase measure thresholds over time and that it will also maintain the incentive for providers to focus on methods and approaches to increase patient engagement. Therefore, we are finalizing a change from our proposal for 2015 through 2017 to build toward the Stage 3 measure threshold required in 2018. We are setting the measure threshold at 1 patient for 2015 and 2016 and 5 percent in 2017 to work toward the increased threshold for Stage 3 in 2018 (see also section II.B.2.b.(vi) for the Stage 3 objective).

After consideration of public comment received, we are finalizing the objective and the alternate exclusion to Measure 2 as proposed for EPs, eligible hospitals and CAHs.

We are finalizing Measure 1 with modifications to improve the clarity of the measure language based on stakeholder feedback and Measure 2 with modifications to the thresholds and to specify the timing of the action for EPs to match the eligible hospital and CAH measure. We are maintaining our prior policy for the information that must be provided to the patient for the objective as proposed.

We are adopting the objective as follows:

Objective 8: Patient Electronic Access

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.

EP Measure 1: More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely access to view online, download, and transmit to a third party 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 access to view online, download and transmit their health information within 4 business days after the information is available to the EP.
- Threshold: The resulting percentage must be more than 50 percent in order for an EP to meet this measure.

EP Measure 2:

For an EHR reporting period in 2015 and 2016, at least one patient seen by the EP during the EHR reporting period (or patient-authorized representative) views, downloads or transmits to a third party his or her health information during the EHR reporting period.

- Denominator: Number of unique patients seen by the EP during the EHR reporting period.
- Numerator: The number of patients in the denominator (or patient-authorized representative) who view, download, or transmit to a third party their health information.
- Threshold: The numerator and denominator must be reported, and the numerator must be equal to or greater than 1.
- Exclusions: Any EP who--

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

For an EHR reporting period in 2017, more than 5 percent of unique patients seen by the EP during the EHR reporting period (or his or her authorized representatives) view, download or transmit to a third party their health information during the EHR reporting period.

- Denominator: Number of unique patients seen by the EP during the EHR reporting period.
- Numerator: The number of patients in the denominator who view, download, or transmit to a third party their health information.
- Threshold: The resulting percentage must be greater than 5 percent.
- Exclusions: Any EP who--
 - Neither orders nor creates any of the information listed for inclusion as part of the measures; or
 - 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.

Eligible Hospital/CAH Objective: Provide patients the ability to view online, download,

and transmit their health information within 36 hours of hospital discharge.

Eligible Hospital/CAH Measure 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 are provided timely access to view online, download and transmit to a third party their health information.

- 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 who have access to view, download, and transmit their health information within 36 hours after the information is available to the eligible hospital or CAH.
- 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:

For an EHR reporting period in 2015 and 2016, at least 1 patient who is discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH (or patient-authorized representative) views, downloads or transmits to a third party his or her health information during the EHR reporting period.

- Denominator: Number of unique patients discharged from the inpatient or emergency department (POS 21 or 23) of the eligible hospital or CAH during the EHR reporting period.
- Numerator: The number of patients (or patient-authorized representative) in the denominator who view, download, or transmit to a third party their health information.

- Threshold: The numerator and denominator must be reported and the numerator must be equal to or greater than 1.
- 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.

For an EHR reporting period in 2017, more than 5 percent of unique patients discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH (or patient-authorized representative) view, download or transmit to a third party their health information during the EHR reporting period.

- Denominator: Number of unique patients discharged from the inpatient or emergency department (POS 21 or 23) of the eligible hospital or CAH during the EHR reporting period.
- Numerator: The number of patients (or patient-authorized representative) in the denominator who view, download, or transmit to a third party their health information.
- Threshold: The resulting percentage must be greater than 5 percent.
- 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 Exclusion: Providers 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.

We are adopting Objective 8: Patient Electronic Access at § 495.22(e)(8)(i) for EPs and § 495.22(e)(8)(ii) for eligible hospitals and CAHs. We further specify that in order to meet this objective and measures, an EP, eligible hospital, or CAH must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 9: Secure Electronic Messaging (EP Only)

We proposed to retain the EP Stage 2 objective for secure electronic messaging with modifications to the measure for meaningful use in 2015 through 2017.

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

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

We proposed 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 Federal Communications Commission (FCC).

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

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

We proposed 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.

- 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.

We proposed 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.

Comment: Some commenters expressed their general support for secure messaging, stating their appreciation for the convenience and ease with messaging their EPs electronically. Numerous commenters also agreed with exclusions for EPs with no office visits during the EHR reporting period and recommended a higher number than zero. A commenter expressed support for the alternate exclusion and requested the extension of this exclusion beyond 2015.

Commenters expressing general opposition to secure messaging cited their patients' reluctance to sign up for the portal due to data breach fears, lack of internet

familiarity, and overall lack of access. Other commenters also recommended continuing the reduced requirement in the future.

Response: We thank the commenters for their insight. We believe that given the proposed changes to the measure, the current exclusions are adequate and that the proposed alternate exclusion does not need to be extended beyond 2015.

Comment: Many commenters disagreed with the proposal to lower the threshold, with some believing that it takes momentum away from patient engagement. Some commenters conflated the proposals and stated the same concerned opposition for secure messaging as for the patient action measure discussed in section II.B.2.a.(viii) stating that "one patient" for secure messaging is not meaningful enough.

Response: We appreciate the commenters' advocacy for patients and applaud their efforts to promote patient engagement and raise awareness about the need for accessibility of health information. We agree with the intent behind the policy and support the policy goal of promoting enhanced patient and provider engagement, and leveraging HIT solutions to enhance patient and provider communications. We direct readers to the proposed measure we included for the Stage 3 Objective for Coordination of Care through Patient Engagement in section II.B.2.b.vi of this final rule with comment period. We would like to highlight some key differences between the Stage 3 proposed objective and the current objective, which are the result of lessons learned through feedback over the past few years from providers about their efforts to implement the requirements of the EHR Incentive Program. We believe this will help to illustrate why we proposed to reduce the threshold for this Secure Messaging objective and how we are

seeking to maintain the policy of moving patient engagement forward.

As noted in the Stage 3 proposed rule (80 FR 16756) and for the Stage 3 objective in section II.B.2.b.vi of this final rule with comment period, we included proposals for bi-directional communication and communications among and between the patient and multiple providers in a care team. We also expanded the potential role of patient-authorized representatives, and we sought to adopt a wider range of communications methods that could support and promote patient-centered care coordination. We proposed this objective because we believe that leveraging health IT to support care team communications in which a patient is actively engaged can lead to better care coordination and better outcomes for the patient. However, the current Stage 2 secure messaging objective as finalized in the 2012 Stage 2 final rule (77 FR 54031) does not include this flexibility of form, method and participation. It includes only patient-initiated communication rather than provider driven engagement, and it does not promote a wide range of use cases. Comments received indicate that this is a significant shortfall in the language of the current measure supporting the identified health care delivery system reform goal. In addition, commenters note that these factors and other environmental or patient related factors create a significant burden on providers and negatively impact a provider's ability to meet the measure. This means that providers are investing a large amount of resources to achieve a measure that is flawed, does not adequately meet the intended health goal, and provides only a limited value.

We believe that the measure should be modified to better serve as a foundation for a more dynamic use of HIT for patient engagement. For this reason, we proposed to

continue support of the function and to adopt a more dynamic measure for Stage 3 that will help drive adoption and innovation to support the long-term goals of leveraging HIT for patient engagement.

Comment: General recommendations from commenters included encouraging greater definition around secure messaging, allowing for texting/voicemail/other options, adding more exclusions, and taking into consideration patients' preferences for communication with their EPs. Some commenters requested clarification on what we consider "fully enabled" when it comes to secure messaging.

In addition, some commenters opposed lowering the threshold believe that removing the current thresholds will not help or encourage providers to prepare for upcoming Stage 3 thresholds. These commenters recommended that we consider an incrementally phased-in approach towards measure thresholds to balance the challenges providers face in promoting patient engagement. These commenters suggested beginning with simple enabled functions as proposed and increasing the threshold incrementally year over year to work toward the proposed Stage 3 threshold of 35 percent rather than having a static low threshold and a sudden jump to a higher level in Stage 3.

Still other commenters requested expanding the definition of secure messaging in the current objective to reflect the options and methods proposed for the Stage 3 objective. These commenters requested that provider initiated messaging should be the action that counts toward the numerator for the current objective and that communications with a patient-authorized representative on the patient's behalf should also count toward the measure.

Response: Fully enabled means the function is fully installed, any security measures are fully enabled, and the function is readily available for patient use. We note that we have proposed no changes to the definition of secure messaging for this measure or to any of the exclusions apart from the proposed alternate exclusion for Stage 1 providers in 2015. We proposed to remove the Stage 2 threshold of 5 percent and instead require that the capability for patients to send and receive a secure electronic message is fully enabled during the EHR reporting period (80 FR 20365). However, we agree with commenters' recommendations for a phased in approach over the period of 2015 through 2017 to the Stage 3 threshold in 2018, as it will allow providers to work incrementally toward a high goal and is consistent with our past policy in the program to establish incremental change from basic to advanced use and increased thresholds over time. We will therefore finalize "fully enabled" for 2015, at least one patient for 2016, and a threshold of 5 percent for 2017 to build toward the Stage 3 threshold addressed in section II.B.2.b.6 of this final rule with comment period.

We cannot fully adopt the Stage 3 specifications as the commenters recommend because some parts, such as communications among care team members, would not be supported by EHR technology certified to the 2014 Edition certification criteria. However, we agree that it makes sense to focus the measure on provider action rather than on patient action and to allow provider initiated actions to be included in the numerator. As noted previously, we believe that a measure that more accurately reflects the policy goal for delivery system reform should include these provider initiated actions and we also agree with the inclusion of interactions involving a patient-authorized

representative as this is an important factor for many patients in coordinating care. We will therefore modify the current objective to include provider initiated communications and communications with a patient-authorized representative in the numerator. We note that this change also means that a patient-initiated message would only count toward the numerator if the provider responded to the patient as that is part of measuring the provider action rather than the patient action for this measure. As this measurement would not be required until 2016 and then at a level of only 1 patient, we believe it is reasonable to make this change in the counting methodology in the current objective.

Comment: Some commenters stated a belief that the unique patient measures, including secure messaging, should be able to pull data from any time period before the reporting period and reporting year in order to qualify in the numerator. These commenters noted that this clarification would reduce the unnecessary burden placed on physicians, and the waste of resources to provide the patient with the same information they have already been provided.

Response: We do not believe a single instance of a patient sending a secure message should be counted in perpetuity for the measure. The calculation may include actions taken before, during, or after the EHR reporting period if the period is less than one full year; however, consistent with FAQ 8231, these actions must be taken no earlier than the start of the same year as the EHR reporting period and no later than the date of attestation. We understand, as discussed in section II.B.1.b.(4)(f), that some certified EHRs may not calculate the numerator in this fashion; however, as we are also changing the threshold for the measure so that significant measurement will not be required until

2016 and then at a required level of only 1 patient, we believe that changing this calculation will not drastically impact EHR developers and providers.

After consideration of the comments received, we are finalizing as proposed the objective, exclusion, and alternate exclusion as proposed. We are finalizing the measure with the modifications to the thresholds. We are adopting the objective as follows:

Objective 9: Secure Electronic Messaging (EP Only)

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

EP Measure:

For an EHR reporting period in 2015, the capability for patients to send and receive a secure electronic message with the EP was fully enabled during the EHR reporting period.

For an EHR reporting period in 2016, for at least 1 patient seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative) during the EHR reporting period.

- Denominator: Number of unique patients seen by the EP during the EHR reporting period.
- Numerator: The number of patients in the denominator for whom a secure electronic message is sent to the patient (or patient-authorized representative), or in response to a secure message sent by the patient (or patient-authorized representative).

- Threshold: The numerator and denominator must be reported, and the numerator must be equal to or greater than 1.

For an EHR reporting period in 2017, for more than 5 percent of unique patients seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative) during the EHR reporting period.

- Denominator: Number of unique patients seen by the EP during the EHR reporting period.
- Numerator: The number of patients in the denominator for whom a secure electronic message is sent to the patient (or patient-authorized representative), or in response to a secure message sent by the patient (or patient-authorized representative).
- Threshold: The resulting percentage must be more than 5 percent in order for an EP, eligible hospital, or CAH to meet this measure.

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

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.

We are adopting Objective 9: Secure Electronic Messaging at § 495.22(e)(9)(i) for EPs. We further specify that in order to meet this objective and measures, an EP must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 10: Public Health and Clinical Data Registry Reporting

In the EHR Incentive Programs in 2015 through 2017 proposed rule 80 FR 20366, we proposed to adopt a modified version of the consolidated Public Health and Clinical Data Registry Reporting objective proposed in the Stage 3 proposed rule for all providers to demonstrate meaningful use for an EHR reporting period in 2015 through 2017.

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 CEHRT, except where prohibited and in accordance with applicable law and practice.

In the EHR Incentive Programs for 2015 through 2017 proposed rule 80 FR 20366, we highlighted our intention to align with the Stage 3 proposed rule and remove the prior ongoing submission requirement and replace it with an "active engagement" requirement. We reiterated our definition of "active engagement" as defined in the Stage 3 proposed rule at (80 FR 16739 and 16740) and noted our proposal to adopt the

same definition for the Modified Stage 2 objective proposed for 2015 through 2017 as we believe this change is more aligned with the process providers undertake to report to a clinical registry or public health agency.

At (80 FR 20366), we proposed that "active engagement" may be demonstrated by any of the following options:

Proposed 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.

Proposed 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.

Proposed 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 noted 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.

Comment: Many commenters expressed concern regarding whether provider and developers would have adequate time to implement a new active engagement requirement in place of the ongoing submission requirement in time to successfully attest for an EHR reporting period in 2015.

Response: We note that while the active engagement options included in the EHR Incentive Program for 2015 to 2017 replace the "ongoing submission" requirement included in the Stage 2 final rule, they should not be considered mutually exclusive. We note that for providers who have already planned for and/or acted toward meeting any of the Stage 1 or Stage 2 public health reporting objectives, those actions would count toward meeting the active engagement options.

For clarification on the rationale behind this change, we note that over the past few years, we have received feedback on the Stage 1 and Stage 2 public health reporting objectives through letters, public forums, and individual inquiries from both providers/provider representatives and from public health agencies. The common trend in these communications is that the difference between the Stage 1 and Stage 2 requirements and the "ongoing submission" structure for the Stage 2 objectives created confusion around both the actions required and the timing of those actions for providers.

The active engagement requirement clarifies what is expected of a provider who seeks to meet the measures within this objective and more accurately describes the actions necessary to meet each option within the structure. This does not mean that actions a provider has already taken in an attempt to meet the "ongoing submission" requirement would not be acceptable under the new objective. Any action which would be acceptable under the Stage 1 and Stage 2 public health reporting objectives would fit within the definition of the "active engagement" options. In addition, because of the similarity between the substantive requirements of the "ongoing submission" requirement and the "active engagement" requirement options included in this final rule with comment period, we do not believe that significant time will be needed to implement the updated requirement.

For example, in Stage 2 a provider could register their intent to submit data to successfully meet a measure in one of the public health reporting objectives. Our proposal in the EHR Incentive Programs for 2015 through 2017 proposed rule includes the exact same requirement under "Active Engagement Option 1: Completed Registration to Submit Data."

We also believe that the flexibility within the active engagement options enables a provider additional time to determine the option that is best suited to their practice. For example, in Active Engagement Option 1, we also proposed that a provider would be required to register to submit data to the PHA within 60 days of the beginning of the EHR reporting period and not on the first day of the EHR reporting period. We believe that this 60-day timeframe will benefit providers who seek to determine whether Option 1

best captures their reporting status, or whether Option 2 or Option 3 are more appropriate.

We further note that this requirement would allow a provider to begin their registration prior to the start of their EHR reporting period if such were necessary, so long as the action was completed within 60 days of the start of the EHR reporting period.

Comment: Commenters requested clarification on whether a provider needed to register each year under the active engagement option 1. Commenters noted that requiring registration each year would result in duplicative registrations. Commenters also requested clarity on whether registration is required for each measure. A commenter noted that they recommend that clarity be provided regarding whether registration is required for measures that the provider has not registered for previously (for example, measures not included in Stage 2).

Response: As we have noted elsewhere in this final rule with comment period, under the proposed active engagement requirement, providers would only need to register once with a public health agency or a clinical data registry and could register before the reporting period begins. In addition, we note that previous registrations with a public health agency or clinical data registry that occurred in a previous stages of meaningful use could count toward Active Engagement Option 1 for any of the EHR reporting periods in 2015, 2016, or 2017. We clarify that providers must register with a PHA or CDR for each measure they intend to use to meet meaningful use. Further, we also clarify that to meet Active Engagement Option 1, registration with the applicable PHA or CDR is required where a provider seeks to meet meaningful use using a measure they have not successfully attested to in a previous EHR reporting period.

Comment: Commenters also requested clarification regarding whether a provider can successfully attest to meaningful use using proof of active engagement collected by their organization, or whether a provider must demonstrate that they independently engaged with the PHA or CDR.

Response: Providers can demonstrate meaningful use by using communications and information provided by a PHA or CDR to the provider directly. A provider also may demonstrate meaningful use by using communications and information provided by a PHA or CDR to the practice or organization of the provider as long as the provider shares the same CEHRT as the practice or organization.

Comment: Some comments requested clarification of the definition of production under Active Engagement Option 3.

Response: To meet any of the measures using Active Engagement - Option 3 (production), we proposed that a provider only may successfully attest to meaningful use when the receiving PHA or CDR moves the provider into a production phase. We recognize that live data may be sent during the Testing and Validation phase of Active Engagement: Option 2, but-in such a case the data received in Option 2 is insufficient for purposes of meeting Option 3 unless the PHA and CDR is actively accepting the production data from the provider for purpose of reporting.

Proposed Measures: We proposed a total of six 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 proposed measures are as shown in Table 5. We proposed that 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.

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*	2	3
Measure 5 - Clinical Data Registry Reporting**	2	3
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 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 to meet the number of measures required to meet the objective.

For EPs, we proposed 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 proposed 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 proposed 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 also proposed 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.

Comment: Commenters requested clarification regarding the number of measures that a provider would be required to meet for the EHR reporting periods covered by the EHR Incentive Program in 2015 through 2017 requirements.

Response: In the EHR Incentive Program for 2015 through 2017 proposed rule (80 FR 20356), we proposed that for providers scheduled to attest to Stage 1 in 2015, EPs would be required to successfully attest to one measure and eligible hospitals and CAHs would be required to successfully attest to any combination of two measures. We also proposed that for providers scheduled to attest to Stage 2 in 2015 and for all providers in 2016 and 2017, EPs would be required to successfully attest to any combination of two measures and eligible hospitals and CAHs would be required to successfully attest to any combination of three measures. Finally, we proposed that EPs may select from measures 1 through 5 while eligible hospitals and CAHs may select from measures 1 through 6.

To calculate the measures:

- Proposed 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 proposed that to successfully meet the requirements of this measure, bi-directional data exchange between the provider's CEHRT system and the

immunization registry/IIS is required.

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 its 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 CAH at the start of the EHR reporting period.

Comment: For Measure 1 – Immunization Registry Reporting, the vast majority of commenters noted that the addition of bi-directionality during the EHR Incentive Program 2015 through 2017 period would be burdensome to accomplish. A commenter noted that bi-directional capability is newly proposed for Stage 3 and as part of the 2015 Edition proposed rule, and is not currently part of the Stage 2 or 2014 Edition rule requirements. The commenter noted that adding in this requirement would require significant development and implementation effort and that most states are not yet able to engage in this functionality.

Response: We appreciate commenters' concerns regarding the addition of a

bi-directionality requirement for the EHR reporting periods covered by the modified Stage 2 requirements. We agree with commenters that additional time may be needed for both public health agencies and providers to adopt the necessary technology to support bi-directional functionality. Therefore, we are not finalizing the bi-directionality proposal in the EHR Incentive Programs for 2015 through 2017.

- Proposed 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 where the jurisdiction accepts syndromic data from such settings and the standards are clearly defined for EPs, or an emergency or urgent care department for eligible hospitals and CAHs (POS 23).

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.

Comment: For Measure 2 – Syndromic Surveillance Reporting, many commenters noted that jurisdictions are not able to receive ambulatory syndromic surveillance data and that, the standards for ambulatory syndromic surveillance in 2014 CEHRT for reporting are vague. A comment noted that few PHAs appear to be able to accept non-emergency or non-urgent care ambulatory syndromic surveillance data electronically. These commenters recommended that the syndromic surveillance measure should be removed from the objective.

Response: We disagree with commenters who suggest that the syndromic surveillance measure should be removed from the EHR Incentive Programs for 2015 through 2017. While some jurisdictions are not currently accepting syndromic surveillance data from ambulatory care providers, there are other providers who have been able to report in their jurisdictions and who have successfully attested to this measure. We believe that removing the syndromic surveillance measure as an option

would negatively impact such providers. We also believe that maintaining this measure for 2015 through 2017 allows additional providers to choose this measure in the future. We remind commenters that syndromic surveillance reporting is one option available to providers. If this option is not suitable for the provider, additional options are available and exclusions for this measure are also available. We are modifying the proposed EP exclusion which states “does not treat or diagnose or directly treat any disease or condition associated with a syndromic surveillance system in his or her jurisdiction” to better indicate that the registry may or may not allow the EP to report based on their category rather than on whether they treat or diagnose specific diseases or condition for syndromic surveillance reporting. For eligible hospitals and CAHs, almost all jurisdictions currently accept syndromic surveillance data. Finally, we note that some eligible professionals are already submitting syndromic surveillance data which is allowable under Stage 2. Therefore, we are adopting a modification that allows all eligible professionals to submit syndromic surveillance data for an EHR reporting period in 2015 through 2017.

- Proposed 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.

Proposed Exclusions: 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.

Comment: Some commenters noted that case reporting is not mature enough to be included in meaningful use for 2015, 2016, or 2017. A commenter noted that the majority of eligible providers operate in jurisdictions where PHAs are not able to receive electronic case reporting data and have not developed the infrastructure to support such reporting. The commenters noted that the 2015 Edition proposed rule does not include certification criteria on case reporting. These commenters recommended removing this measure from the objective for 2015 through 2017.

Response: We appreciate commenter concerns regarding the readiness of standards and functionality for case reporting and believe that technology may not yet be sufficiently mature. Based on public comment received, it is clear that many public health jurisdictions have not yet built the infrastructure to receive electronic case reports, and while a few public health jurisdictions have infrastructure to accept case reports, many of these are not able to accept case reports in a standard format. Building new infrastructure to support electronic case reporting across multiple public health jurisdictions and to support certification may not be feasible for EHR Incentive Program

reporting periods in 2015, 2016, and 2017. We continue to believe that case reporting is a core component of public health reporting and to health improvement around the country and, as noted elsewhere, are maintaining this measure for Stage 3. However, for purposes of the EHR Incentive Program for 2015 through 2017, we believe additional time is needed across the HIT landscape to develop the technology and infrastructure to support case reporting and we are not finalizing this measure as proposed.

If a provider chooses to participate in Stage 3 in 2017, they must meet the requirements defined for the Stage 3 Public Health and Clinical Data Registry Reporting objective which may include the case reporting measure defined for the Stage 3 objectives discussed in section II.B.2.b.viii of this final rule with comment period.

- Proposed 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.

As noted in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20368), in the Stage 2 final rule, we were purposefully general in our use of the term "specialized registry" (other than a cancer registry) for the Stage 2 Specialized Registry Reporting Objective 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 proposed to carry forward the concept behind this broad category from Stage 2, but also proposed 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 in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20367). We proposed 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 proposed 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).

In the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20367), we reiterated 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.

We further noted 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. In the EHR Incentive Program in 2015 through 2017 proposed rule (80 FR 20369), we proposed that EPs would have the option of counting cancer case reporting under the public health registry reporting measure, but 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.

Proposed 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.

Comment: Some commenters noted that for Measure 4 - Public Health Registry Reporting, public health registries that would fall within this measure would need additional time to implement the applicable standards identified in the 2015 Edition rule,

which would be applicable to providers seeking to attest to meaningful use in 2015, 2016, or 2017. Commenters specifically noted that the certification requirements for public health registries are not identified in the 2014 Edition rule and that the technology and infrastructure to support such registries is not yet mature.

Many commenters recommended changing this measure and the clinical data registry reporting measure back to the prior Stage 2 requirements for the specialized registry reporting objective for 2015 through 2017 instead of splitting that objective into two measures as proposed. Commenters noted that if the language in the Stage 2 specialized registry reporting objective were changed to include the "Active engagement" definition, it would provide a wide range of options which offers a value for providers and especially for certain EP specialties who may otherwise be excluding from all available measures. In addition, commenters note that maintaining the existing specialized registry reporting objective would provide continuity for providers and not inadvertently penalize providers who had selected to report to a registry under the specialized registry reporting objective which may not qualify under the definition of a public health registry or a clinical data registry from the proposed rule.

Response: We appreciate commenters concerns regarding the public health registry reporting measure proposed. We agree that the standards for public health registry reporting are part of the 2015 Edition rule and are not currently part of 2014 Edition Rule that providers are required to use in 2015 and may use in 2016 and 2017. We understand commenter concerns that requiring public health registry reporting could present a challenge for developers and for public health jurisdictions seeking to support

such reporting. Furthermore, we agree that our proposal to split the Specialized Registry Reporting objective into two measures may inadvertently cause some providers to no longer use their current reporting option to meet the measure. We are therefore not finalizing our proposal to split specialized registry reporting into two measures as proposed.

Instead, we will maintain for 2015 through 2017 a unified specialized registry reporting measure which adopts the change from "ongoing submission" to "active engagement". We believe that this will allow providers flexibility to continue in the direction they may have already planned for reporting while still allowing for a wide range of reporting options in the future. We further note that we have previously supported the inclusion of a variety of registries under the specialized registry measure, including Prescription Drug Monitoring Program reporting and electronic case reporting. We agree that a variety of registries may be considered specialized registries, which allows providers the flexibility to report using a registry that is most helpful to their patients. Therefore, we will continue to allow these registries to be considered specialized registries for purposes of reporting the EHR Reporting period in 2015, 2016, and 2017. However, we will modify the exclusion not only to reflect the change from public health registry to specialized registry but also to allow an exclusion if the provider does not collect the data relevant to a specialized registry within their jurisdiction.

We are also finalizing our proposed policy to incorporate cancer case reporting into the measure for EPs only. Therefore, EPs who were previously planning to attest to the cancer case reporting objective, may count that action toward the Specialized

Registry Reporting measure. We believe this change is necessary to support continued provider reporting to cancer case registries. However, we note that EPs who did not intend to attest to the cancer case reporting menu objective are not required to engage in or exclude from cancer case reporting in order to meet the specialized registry reporting measure. We further note that providers may use electronic submission methods beyond the functions of CEHRT to meet the requirements for the Specialized Registry Reporting measure. Finally, we are adopting our proposal that providers may count the measure more than one time if they report to multiple specialized registries as proposed. For the Stage 3 public health registry reporting measure within the Public Health and Clinical Data Registry Reporting Objective, we direct readers to section II.B.2.b.viii of this final rule with comment period.

- Proposed 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 proposed 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 proposed 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^[1]. We proposed 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.

We proposed 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 CEHRT 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.

Comment: Some commenters noted that for Measure 5 - Clinical Data Registry Reporting, the potential registries will need additional time to implement the applicable standards in the 2015 Edition rule. Other commenters disagreed with our proposal to split the Specialized Registry Reporting Objective into two measures for reporting in 2015 through 2017 citing unintended negative consequences on providers who have planned for and acted toward meeting the prior requirements, especially on the short term in 2015 and 2016. These commenters recommended retaining the prior specifications for the objective instead of adopting two new measures.

Response: We agree that the standards for clinical data registry reporting are not currently part of the 2014 CEHRT definition requirements and understand commenter concerns that without clarity on the functionality needed to support this measure, it would be difficult for providers to implement. As noted in relation to the proposed public health reporting measure, we also agree with commenters who state that there would potentially be unintended negative consequences for providers in 2015 and 2016 especially if we adopt the proposal to split the Specialized Registry Reporting Objective into two separate measures. As noted previously, we are not adopting this policy for the public health reporting measure, and we are also therefore not adopting the policy for a separate clinical data registry reporting measure. We are therefore not adopting this measure as

proposed.

As noted previously, we are not finalizing our proposal to split the measure from the Stage 2 Specialized Registry Reporting Objective (77 FR 54030) into two measures. Therefore, we are not finalizing the clinical data registry reporting measure for 2015, 2016, and for 2017 for those providers who are not demonstrating Stage 3. If a provider chooses to participate in Stage 3 in 2017, they must meet the requirements defined for the Stage 3 Public Health and Clinical Data Registry Reporting objective as discussed in section II.B.2.b.viii of this final rule with comment period.

- Proposed 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 (ELR) results. We proposed this measure for eligible hospitals and CAHs only.

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.

Comment: For Measure 6 - ELR, commenters agreed with the continuation of this measure but requested that it also be included as an option for EPs that maintain in-house laboratories.

Response: We thank commenters for their support of this measure. However, we do not agree that this measure should be extended to EPs. We note that in-house laboratories of EPs do not perform the types of tests that are reportable to public health jurisdictions. For example, many in-house laboratories focus on tests such as rapid strep tests that test for strep throat. The rapid strep tests are not reportable to public health agencies.

After consideration of public comments received, for EHR reporting periods in 2015 through 2017, we are finalizing the objective with a modification to the name to state Public Health Reporting Objective and to remove the reference to clinical data registries. We are finalizing the measures with modifications. For Measure 1, we remove the requirement for bi-directional data exchange and note that providers will not be required to receive a full immunization history and will not be required to display an immunization forecast from an Immunization Information System (IIS) to meet the measure. Providers will only need to electronically submit immunization data to the appropriate public health jurisdiction's IIS. For Measure 2, we are adopting a modification to the final policy to allow all EPs to submit syndromic surveillance data and to modify the exclusions to reflect that different categories of providers may or may not be able to report based on the requirements of the registry. . For Measure 3, we are

not finalizing the proposed case reporting measure. For Measure 4, we are not finalizing our proposal to split specialized registry reporting into two distinct measures. Instead, we will maintain a unified specification for specialized registry reporting which adopts the change from "ongoing submission" to "active engagement" and includes reporting for eligible hospitals and CAHs for 2015 through 2017..We include cancer case reporting as an option for EPs only under the adopted specialized registry reporting measure. We are redesignating this measure as "Measure 3". For Measure 5, we are not finalizing the proposed clinical data registry reporting measure. For Measure 6, we are finalizing the measure language as proposed and redesignating the measure as “Measure 4”.

For the explanation of terms, we are finalizing the definition of active engagement with the additional clarification provided through response to public comment. We are finalizing that EPs must meet at least 2 measures with a modification to reference the selection from measures 1 through 3 (rather than 1 through 5). Similarly, we are finalizing that eligible hospitals and CAHs must meet at least 3 measures from measures 1 through 4 (rather than 1 through 6). We are also finalizing the alternate specification that in 2015 Stage 1 EPs may meet one measure to meet the threshold and Stage 1 eligible hospitals and CAHs may meet two measures to meet the threshold.

For EPs, we are finalizing 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 are finalizing 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.

Finally, we note that a provider may report to more than one specialized registry and may count specialized registry reporting more than once to meet the required number of measures for the objective.

We are adopting the final objective, measures, exclusions, and alternate specification as follows:

Objective 10: Public Health Reporting

Objective: The EP, eligible hospital or CAH is in active engagement with a public health agency to submit electronic public health data from CEHRT except where prohibited and in accordance with applicable law and practice.

Measure 1 – Immunization Registry Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit immunization data.

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 its 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 CAH 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.

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--

- Is not in a category of providers from which ambulatory syndromic surveillance data is collected by their jurisdiction's syndromic surveillance system;
- 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–Specialized Registry Reporting - The EP, eligible hospital, or CAH is in active engagement to submit data to a specialized registry.

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

- Does not diagnose or treat any disease or condition associated with or collect relevant data that is required by a specialized registry in their jurisdiction during the EHR reporting period;
- Operates in a jurisdiction for which no specialized 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 specialized 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 4 – Electronic Reportable Laboratory Result Reporting: The eligible hospital or CAH is in active engagement with a public health agency to submit electronic reportable laboratory (ELR) results.

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.

Alternate Specification: An EP scheduled to be in Stage 1 in 2015 may meet 1 measure and an eligible hospital or CAH scheduled to be in Stage 1 in 2015 may meet two measures.

TABLE 6 - PUBLIC HEALTH REPORTING OBJECTIVE MEASURES FOR EPS, ELIGIBLE HOSPITALS, AND CAHs IN 2015 THROUGH 2017

Measure Number and Name	Measure Specification	Maximum times measure can count towards the objective
Measure 1 – Immunization Registry Reporting	The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit immunization data.	1
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.	1
Measure 3 – Specialized Registry Reporting	The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit data to a specialized registry.	2 for EP, 3 for eligible hospital/CAH
Measure 4- Electronic	The eligible hospital or	N/A

Reportable Laboratory Results Reporting	CAH is in active engagement with a public health agency to submit ELR results.	
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We are adopting Objective 10: Public Health Reporting at § 495.22(e)(10)(i) for EPs and § 495.22(e)(10)(ii) for eligible hospitals and CAHs. We further specify that providers must use the functions and standards as defined for CEHRT at § 495.4 where applicable; however, as noted for measure 3, providers may use functions beyond those established in CEHRT in accordance with state and local law. We direct readers to section II.B.3. of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

TABLE 7: ELIGIBLE PROFESSIONAL (EP) OBJECTIVES AND MEASURES FOR 2015 THROUGH 2017

Objectives for 2015, 2016 and 2017	Measures for Providers in 2015, 2016 and 2017	Alternate Exclusions and/or Specifications for Certain Providers
Objective 1: Protect Patient Health Information	<u>Measure:</u> 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 by 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’s risk management process.	NONE
Objective 2: Clinical Decision Support	<ul style="list-style-type: none"> • <u>Measure 1:</u> 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 EPs scope of 	If for an EHR reporting period in 2015, the provider is scheduled to demonstrate Stage 1: <u>Alternate Objective and Measure 1:</u> <u>Objective:</u> Implement one clinical

Objectives for 2015, 2016 and 2017	Measures for Providers in 2015, 2016 and 2017	Alternate Exclusions and/or Specifications for Certain Providers
	<p>practice or patient population, the clinical decision support interventions must be related to high-priority health conditions</p> <ul style="list-style-type: none"> • <u>Measure 2:</u> The EP has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period. 	<p>decision support rule relevant to specialty or high clinical priority, along with the ability to track compliance with that rule.</p> <p><u>Measure:</u> Implement one clinical decision support rule.</p>
<p>Objective 3: Computerized Provider Order Entry CPOE</p>	<ul style="list-style-type: none"> • <u>Measure 1:</u> More than 60 percent of medication orders created by the EP during the EHR reporting period are recorded using computerized provider order entry. • <u>Measure 2:</u> More than 30 percent of laboratory orders created by the EP during the EHR reporting period are recorded using computerized provider order entry. • <u>Measure 3:</u> More than 30 percent of radiology orders created by the EP during the EHR reporting period are recorded using computerized provider order entry. 	<ul style="list-style-type: none"> • <u>Alternate Measure 1:</u> For Stage 1 providers in 2015 only, 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 more than 30 percent of medication orders created by the EP during the EHR reporting period during the EHR reporting period, are recorded using computerized provider order entry. • <u>Alternate Exclusion for Measure 2:</u> Providers scheduled to be in Stage 1 in 2015 may claim an exclusion for measure 2 (laboratory orders) of the Stage 2 CPOE objective for an EHR reporting period in 2015; and, providers scheduled to be in Stage 1 in 2016 may claim an exclusion for measure 2 (laboratory orders) of the Stage 2 CPOE objective for an EHR reporting period in 2016. • <u>Alternate Exclusion for Measure 3:</u> Providers scheduled to be in Stage 1 in 2015 may claim an exclusion for measure 3 (radiology orders) of the Stage 2 CPOE objective for an EHR reporting period in 2015; and, providers scheduled to be in Stage 1 in 2016 may claim an exclusion for measure 3 (radiology orders) of the Stage 2 CPOE objective for an EHR reporting period in 2016
<p>Objective 4: Electronic Prescribing</p>	<p><u>EP Measure:</u> More than 50 percent of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using</p>	<p><u>Alternate EP Measure:</u> For Stage 1 providers in 2015 only, More than 40 percent of all permissible prescriptions written by the EP are transmitted</p>

Objectives for 2015, 2016 and 2017	Measures for Providers in 2015, 2016 and 2017	Alternate Exclusions and/or Specifications for Certain Providers
	CEHRT.	electronically using CEHRT.
Objective 5: Health Information Exchange	<u>Measure:</u> The EP 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.	<u>Alternate Exclusion:</u> 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.
Objective 6: Patient-Specific Education	<u>EP Measure:</u> Patient-specific education resources identified by CEHRT 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.	<u>Alternate Exclusion:</u> 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.
Objective 7: Medication Reconciliation	<u>Measure:</u> 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.	<u>Alternate Exclusion:</u> 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.
Objective 8: Patient Electronic Access (VDT)	<ul style="list-style-type: none"> ● <u>EP Measure 1:</u> More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely access to view online, download, and transmit to a third party their health information subject to the EP's discretion to withhold certain information. ● <u>EP Measure 2:</u> For 2015 and 2016: At least 1 patient seen by the EP during the EHR reporting period (or patient-authorized representative) views, downloads or transmits his or her health information to a third party during the EHR reporting period. For 2017: More than 5 percent of unique patients seen by the EP during the EHR reporting period (or patient-authorized representative) views, downloads or transmits their health information to a third party during the EHR reporting period. 	<u>Alternate Exclusion Measure 2:</u> Providers 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.
Objective 9:	<u>Measure:</u>	<u>Alternate Exclusion:</u> An EP may claim

Objectives for 2015, 2016 and 2017	Measures for Providers in 2015, 2016 and 2017	Alternate Exclusions and/or Specifications for Certain Providers
Secure Messaging	<p>For 2015: For an EHR reporting period in 2015, the capability for patients to send and receive a secure electronic message with the EP was fully enabled.</p> <p>For 2016: For at least 1 patient seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or patient-authorized representative), or in response to a secure message sent by the patient (or patient-authorized representative) during the EHR reporting period.</p> <p>For 2017:For more than 5 percent of unique patients seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative) during the EHR reporting period.</p>	<p>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>
Objective 10: Public Health	<ul style="list-style-type: none"> ● <u>Measure 1 – Immunization Registry Reporting:</u> The EP is in active engagement with a public health agency to submit immunization data. ● <u>Measure 2 – Syndromic Surveillance Reporting:</u> The EP is in active engagement with a public health agency to submit syndromic surveillance data. <u>Measure 3 – Specialized Registry Reporting</u> – The EP is in active engagement to submit data to a specialized registry. 	<p>Stage 1 EPs in 2015 must meet at least 1 measure in 2015, Stage 2 EPs must meet at least 2 measures in 2015, and all EPs must meet at least 2 measures in 2016 and 2017.</p>

TABLE 8: ELIGIBLE HOSPITAL AND CAH OBJECTIVES AND MEASURES FOR 2015 THROUGH 2017

Objectives for 2015, 2016 and 2017	Measures for Providers in 2015, 2016 and 2017	Alternate Exclusions and/or Specifications for Certain Providers
Objective 1: Protect Patient Health	<p><u>Measure:</u> Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1),</p>	<p>NONE</p>

Objectives for 2015, 2016 and 2017	Measures for Providers in 2015, 2016 and 2017	Alternate Exclusions and/or Specifications for Certain Providers
Information	including addressing the security (to include encryption) of ePHI created or maintained in CEHRT 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 eligible hospital or CAHs risk management process.	
Objective 2: Clinical Decision Support	<ul style="list-style-type: none"> ● <u>Measure 1</u>: 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. ● <u>Measure 2</u>: The eligible hospital or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period. 	<p>If for an EHR reporting period in 2015, the provider is scheduled to demonstrate Stage 1:</p> <p><u>Alternate Objective and Measure 1</u>:</p> <p><u>Objective</u>: Implement one clinical decision support rule relevant to specialty or high clinical priority, along with the ability to track compliance with that rule.</p> <p><u>Measure</u>: Implement one clinical decision support rule.</p>

Objectives for 2015, 2016 and 2017	Measures for Providers in 2015, 2016 and 2017	Alternate Exclusions and/or Specifications for Certain Providers
<p>Objective 3: Computerized Provider Order Entry CPOE</p>	<ul style="list-style-type: none"> ● <u>Measure 1:</u> 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. ● <u>Measure 2:</u> 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. ● <u>Measure 3:</u> 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. 	<ul style="list-style-type: none"> ● <u>Alternate Measure 1:</u> For Stage 1 providers in 2015 only, 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 more than 30 percent of medication orders created by the EP during the EHR reporting period, are recorded using computerized provider order entry. ● <u>Alternate Exclusion for Measure 2:</u> Providers scheduled to be in Stage 1 in 2015 may claim an exclusion for measure 2 (laboratory orders) of the Stage 2 CPOE objective for an EHR reporting period in 2015; and, providers scheduled to be in Stage 1 in 2016 may claim an exclusion for measure 2 (laboratory orders) of the Stage 2 CPOE objective for an EHR reporting period in 2016. ● <u>Alternate Exclusion for Measure 3:</u> Providers scheduled to be in Stage 1 in 2015 may claim an exclusion for measure 3 (radiology orders) of the Stage 2 CPOE objective for an EHR reporting period in 2015; and, providers scheduled to be in Stage 1 in 2016 may claim an exclusion for measure 3 (radiology orders) of the Stage 2 CPOE objective for an EHR reporting period in 2016
<p>Objective 4: Electronic Prescribing</p>	<p><u>Eligible Hospital/CAH Measure:</u> More than 10 percent of hospital discharge medication orders for permissible prescriptions (for new and changed prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.</p>	<p><u>Alternate EH Exclusion:</u> The eligible hospital or CAH may claim an exclusion for the eRx objective and measure if for an EHR reporting period in 2015 if 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 objective for an EHR reporting period in 2015; and, the eligible hospital or CAH may claim an exclusion for the eRx objective and measure if for an EHR reporting period in 2016 if they were either scheduled to demonstrate Stage 1 in 2015 or 2016, or if they are scheduled to demonstrate Stage 2</p>

Objectives for 2015, 2016 and 2017	Measures for Providers in 2015, 2016 and 2017	Alternate Exclusions and/or Specifications for Certain Providers
		but did not intend to select the Stage 2 eRx objective for an EHR reporting period in 2015.
Objective 5: Health Information Exchange	<u>Measure:</u> The 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.	<u>Alternate Exclusion:</u> 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.
Objective 6: Patient-Specific Education	<u>Eligible Hospital/CAH Measure:</u> 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 CEHRT.	<u>Alternate Exclusion:</u> 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.
Objective 7: Medication Reconciliation	<u>Measure:</u> 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).	<u>Alternate Exclusion:</u> 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.
Objective 8: Patient Electronic Access (VDT)	<ul style="list-style-type: none"> ● <u>Eligible Hospital/CAH Measure 1:</u> 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 are provided timely access to view online, download and transmit their health information to a third party their health information. ● <u>Eligible Hospital/CAH Measure 2:</u> For 2015 and 2016: At least 1 patient who is discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH (or patient-authorized representative) views, downloads, or transmits to a third party his or her health information during the EHR reporting period. For 2017: More than 5 percent of unique patients discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH (or patient-authorized representative) view, download, or transmit to a third party their health information during the EHR reporting period. 	<u>Alternate Exclusion Measure 2:</u> 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.

Objectives for 2015, 2016 and 2017	Measures for Providers in 2015, 2016 and 2017	Alternate Exclusions and/or Specifications for Certain Providers
Objective 9: Secure Messaging	Not applicable for eligible hospitals and CAHs	Not applicable for eligible hospitals and CAHs
Objective 10: Public Health	<ul style="list-style-type: none"> ● <u>Measure 1 – Immunization Registry Reporting</u>: The eligible hospital or CAH is in active engagement with a public health agency to submit immunization data ● <u>Measure 2 – Syndromic Surveillance Reporting</u>: The eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data ● <u>Measure 3 –Specialized Registry Reporting</u>: The eligible hospital, or CAH is in active engagement to submit data to a specialized registry. ● <u>Measure 4 – Electronic Reportable Laboratory Result Reporting</u>: The eligible hospital or CAH is in active engagement with a public health agency to submit ELR results. 	Stage 1 eligible hospitals and CAHs must meet at least 2 measures in 2015, Stage 2 eligible hospitals and CAHs must meet at least 3 measures in 2015, all eligible hospitals and CAHs must meet at least 3 measures in 2016 and 2017.

b. Objectives and Measures for Stage 3 of the EHR Incentive Programs

Objective 1: Protect Patient Health Information

In the Stage 3 proposed rule at 80 FR 16745 through 16747, we noted that, consistent with HIPAA and its implementing regulations and both the Stage 1 and Stage 2 final rules (75 FR 44368 through 44369 and 77 FR 54002 through 54003), protecting electronic protected health information(ePHI) remains essential to all aspects of meaningful use under the EHR Incentive Programs. We remain cognizant that unintended or unlawful disclosures of ePHI could diminish consumer confidence in EHRs and the overall exchange of ePHI. Therefore, in both the Stage 1 and 2 final rules, we created a meaningful use core objective aimed at protecting patients' health care information. Most recently, we finalized at (77 FR 54002 and 54003), a Stage 2 meaningful use core objective requiring providers to "protect ePHI created or maintained

by the certified EHR technology through the implementation of appropriate technical capabilities." The measure for this objective requires providers to 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), implementing security updates as necessary, and correcting identified security deficiencies as part of the provider's risk management process. For further detail on this objective, we refer readers to the Stage 2 proposed and final rules (77 FR 13716 through 13717 and 77 FR 54002).

In the Stage 3 proposed rule, we noted that public comments on the Stage 2 final rule and subsequent comments received through public forums, suggest some confusion remains among providers between the requirements of this meaningful use objective and the requirements established under 45 CFR 164.308(a)(1), 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3) of the HIPAA Security Rule. Although we stressed that the objective and measure finalized relating to ePHI are specific to the EHR Incentive Programs, and further added that compliance with the requirements in the HIPAA Security Rule falls outside the scope of this rulemaking, we nonetheless continued to receive inquiries about the relationship between our objective and the HIPAA Rules. Therefore, for Stage 3, in order to alleviate provider confusion and simplify the EHR Incentive Program, we proposed maintaining the previously finalized Stage 2 objective on protecting ePHI. However, we proposed further explanation of the security risk

analysis timing and review requirements for purposes of meeting this objective and associated measure for Stage 3.

Proposed Objective: Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards.

For the proposed Stage 3 objective, we added language to the security requirements for the implementation of appropriate technical, administrative, and physical safeguards. We proposed to include administrative and physical safeguards because an entity would require technical, administrative, and physical safeguards to enable it to implement risk management security measures to reduce the risks and vulnerabilities identified. Technical safeguards alone are not enough to ensure the confidentiality, integrity, and availability of ePHI. Administrative safeguards (for example, risk analysis, risk management, training, and contingency plans) and physical safeguards (for example, facility access controls, workstation security) are also required to protect against threats and impermissible uses or disclosures to ePHI created or maintained by CEHRT.

Comment: Most commenters supported the inclusion of this objective and many appreciate the addition of "administrative and physical safeguards" to the objective because it aligns with HIPAA. Most commenters appreciated our clarification of the timing and content of the security risk assessments. Several commenters appreciated the clarification that the requirements of this measure are narrower than what is required by HIPAA.

Some commenters noted in their support of the objective that it is essential for privacy protection and consumer confidence in EHRs as electronic personal health information is vulnerable to unauthorized access, theft, tampering, and corruption. Several commenters noted the rise in data breaches and the importance of this objective in keeping health information well secured.

A commenter suggested triggers to remind providers to conduct the security risk assessment. Many commenters supported the requirement that providers conduct a security risk analysis upon installation or upgrade of CEHRT.

Response: We appreciate the support for this measure. As we stated in our proposal, we included administrative and physical safeguards because an entity would require them in addition to technical safeguards to implement security measures to reduce the risks and vulnerabilities identified. Technical safeguards alone are not enough to ensure the confidentiality, integrity, and availability of ePHI.

Proposed Measure: Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (including 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), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process.

As noted in the proposed rule, a risk analysis must assess the risks and vulnerabilities to ePHI created or maintained by the CEHRT and must be conducted or reviewed for each EHR reporting period, and any security updates and deficiencies

identified should be included in the provider's risk management process and implemented or corrected as dictated by that process.

To address inquiries about the relationship between this measure and the HIPAA Security Rule, we explained that the requirement of the proposed measure is narrower than what is required to satisfy the security risk analysis requirement under 45 CFR 164.308(a)(1). The requirement of the proposed measure is limited to annually conducting or reviewing a security risk analysis to assess whether the technical, administrative, and physical safeguards and risk management strategies are sufficient to reduce the potential risks and vulnerabilities to the confidentiality, availability, and integrity of ePHI created by or maintained in CEHRT. In contrast, the security risk analysis requirement under 45 CFR 164.308(a)(1) must assess the potential risks and vulnerabilities to the confidentiality, availability, and integrity of all ePHI that an organization creates, receives, maintains, or transmits. This includes ePHI in all forms of electronic media, such as hard drives, floppy disks, CDs, DVDs, smart cards or other storage devices, personal digital assistants, transmission media, or portable electronic media.

In the Stage 3 proposed rule at 80 FR 16746 through 16747, we further proposed that the timing or review of the security risk analysis to satisfy this proposed measure must be as follows:

- EPs, eligible hospitals, and CAHs must conduct the security risk analysis upon installation of CEHRT or upon upgrade to a new Edition. The initial security risk analysis and testing may occur prior to the beginning of the first EHR reporting period

using that Edition of CEHRT.

- In subsequent years, a provider must review the security risk analysis of the CEHRT and the administrative, physical, and technical safeguards implemented, and make updates to its analysis as necessary, but at least once per EHR reporting period.

Comment: A commenter suggested that "mandatory consequential insurance" be required of all parties involved in data handling, storage, and dissemination.

Response: We thank the commenter for their suggestion and we will share the suggestion with other programs and agencies, which deal directly with the business requirements established under the HIPAA security rules.

Comment: Several commenters stated that inclusion of this objective was superfluous and redundant, as it is already required by HIPAA. Another suggested that we accept compliance with the HIPAA Security Rule as fulfillment of this objective. A commenter noted that it is confusing when there are requirements from more than one oversight agency. They noted that protecting patient health information is in the purview of the OCR.

Response: We disagree. In fact, in our audits of providers who attested to the requirements of the EHR Incentive Program, this objective and measure are failed more frequently than any other requirement. We have included this objective in all Stages because of the importance of protecting patients' ePHI. Although OCR does oversee the implementation of the HIPAA Security Rule and the protection of patient health information, we believe it is important and necessary for a provider to attest to the specific actions required to protect ePHI created or maintained by CEHRT in order to

meet the EHR Incentive Program requirements.

Comment: Several commenters stated that the proposed measure is "too comprehensive" and would be very difficult, time consuming, and expensive.

Many commenters requested clarification about the requirement to perform a security risk analysis when CEHRT is upgraded or patched. Others noted that requiring a security risk analysis whenever software is updated is particularly burdensome.

A commenter recommended changing the requirement of "conduct or review a security risk analysis" to "conduct and review a security risk analysis," to ensure both the behavior and the review of a security risk analysis will be completed. Several commenters requested further clarification of the timing for completion of the security risk assessment.

Response: We disagree with the concept that the objective as proposed is too comprehensive. We believe that the proposed addition of administrative and technical safeguards to this measure enables providers to implement risk management security measures to reduce the risks and vulnerabilities identified. Administrative safeguards (for example, risk analysis, risk management, training, and contingency plans) and physical safeguards (for example, facility access controls, workstation security) are also required to protect against threats and impermissible uses or disclosures to ePHI created or maintained by CEHRT.

The proposed requirement is to perform the security risk analysis upon installation of CEHRT or upon upgrade to a new Edition. Thus, it would be required when a provider upgraded from EHR technology certified to the 2014 Edition to EHR

technology certified to the 2015 Edition as established by ONC. We note that the second part of the requirement states a review must be conducted at least on an annual basis, and additional review may be required if additional implementation changes are subsequently made that were not included and planned for in the initial review.

We note that a security risk analysis is not a discrete item in time, but a comprehensive analysis covering the full period of time for which it is applicable; and the annual review of such an analysis is similarly comprehensive. In other words, the analysis and review are not merely episodic but should cover a span of the entire year, including a review planning for future system changes within the year or a review of prior system changes within the year. Therefore, we believe the commenters' concerns may be a semantic misunderstanding of the nature of an analysis and annual review. We proposed to maintain the previously finalized Stage 2 objective on protecting ePHI, which includes the statement "conduct or review" for both the EHR Incentive Programs in 2015 through 2017 and for Stage 3.

We note that for the proposed objective and measure, the measure must be completed in the same calendar year as the EHR reporting period. If the EHR reporting period is 90 days, it must be completed in the same calendar year. This may occur either before or during the EHR reporting period; or, if it occurs after the EHR reporting period, it must occur before the provider attests or before the end of the calendar year, whichever date comes first. Again, we reiterate that the security risk analysis and review should not be an episodic "snap-shot" in time, but rather include an analysis and review of the protection of ePHI for the full year no matter at what point in time that analysis or review

are conducted within the year. In short, the analysis should cover retrospectively from the beginning of the year to the point of the analysis and prospectively from the point of the analysis to the end of the year.

Comment: A commenter noted that the measure only addresses compliance and risk and should also address usability. They suggested that the analysis of security should look at how the data is used and if patients can readily access the data.

Response: We note that other objectives in the EHR Incentive Program, as well as other certification requirements around the technology, include functions related to patient access to health data as well as the sharing of health data with patients and other providers. Inherent in these objectives is the requirement to use certification criteria in the action or process of information sharing. Therefore, these actions and functions are part of the CEHRT and ePHI protections, which should be included in the provider's security risk analysis and review. We note that providers should employ a security risk analysis that is most appropriate to their own organization, which may include several resources for strategies and methods for securing ePHI. Completing a security risk analysis requires a time investment, and may necessitate the involvement of security, HIT, or system IT staff or support teams at your facility. The OCR provides broad scale guidance on security risk analysis requirements at:

<http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/rafinalguidancepdf.pdf>.

In addition, other tools and resources are available to assist providers in the process. For example, the ONC provides guidance and an SRA tool created in conjunction with OCR on its website at: <http://www.healthit.gov/providers->

[professionals/security-risk-assessment-tool](#).

Comment: Commenters questioned if the SRA Tool is only for providers and professionals in small and medium sized practices asking for further information on the definitions of small, medium, and large practices. Another commenter requested the identification of additional guidance for solo or small group practices.

Several commenters recommended that CMS collaborate with the OCR to develop more robust guidance on conducting security risk assessments and understanding and implementing encryption. A commenter suggested a national education campaign to help ensure that they are adequately equipped to protect ePHI.

Response: We decline to define practice size in this final rule with comment period. Instructions for the SRA tool notes its usefulness to small and medium practices because it was intended to provide support to organizations, which often have more limited staff and organizational knowledge on ePHI than larger organizations. However, the SRA Tool information is applicable to and may be useful for organizations of any size.

In the Stage 3 proposed rule (80 FR 16747), we did note that OCR provides broad scale guidance on security risk analysis requirements and that other tools and resources are available to assist providers in the process. In addition, CMS and ONC will continue to work to provide tools and resources, tip sheets, and to respond to FAQs from providers and developers on the privacy and security requirements.

Comment: A commenter requested clarification of the term "correcting identified security deficiencies" as not all risks can be corrected. Commenters requested information on identity proofing, authentication, and authorization. Another commenter requested

more than a passing mention of encryption.

Response: At minimum, providers should be able to show a plan for correcting or mitigating deficiencies and that steps are being taken to implement that plan. Our discussion of this measure as it relates to 45 CFR 164.308(a)(1) is only relevant for purposes of the EHR Incentive Program requirements and is not intended to supersede or satisfy the broader, separate requirements under the HIPAA Security Rule and other rulemaking. For information on identity proofing, authentication, authorization, and encryption, we refer readers to the OCR website, www.hhs.gov/ocr.

As noted in the Stage 1 final rule(75 FR 44314 at 44368), while this objective is intended to support compliance with the HIPAA Privacy and Security Rules, we maintain that meaningful use is not the appropriate regulatory tool to ensure compliance with the HIPAA Privacy and Security Rules. In addition, as noted in the Stage 2 final rule, the scope of the security risk analysis for purposes of this meaningful use measure applies only to data created or maintained by CEHRT and does not apply to data centers that are not part of CEHRT (77 FR 53968 at 54003).

After consideration of the comments received on this objective and measure, we are finalizing the objective as proposed and finalizing the measure with a modification to replace the word “stored” with the phrase “created or maintained.” We are adopting this change to correct a discrepancy between the text of the objective and the measure as well as between the measure (the objective reads “created and maintained”) and to better reflect the HIPAA security rules. We are finalizing the objective and measure as follows:

Objective 1: Protect Patient Health Information

Objective: Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards.

Measure: Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (including encryption) of data created or maintained by CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process.

We are adopting Objective 1: Protect Patient Health Information at § 495.24(d)(1)(i) for EPs and § 495.24(d)(1)(ii) for eligible hospitals and CAHs. We further specify that in order to meet this objective and measures, an EP, eligible hospital, or CAH must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 2: Electronic Prescribing

In the Stage 3 proposed rule (80 FR 16747 through 16749), we proposed to maintain the objective and measure finalized in the Stage 2 final rule (77 FR 53989 through 53990) for electronic prescribing for EPs, with minor changes. We also proposed to maintain the previous Stage 2 menu objective for eligible hospitals and CAHs as a required objective for Stage 3 with an increased threshold.

Proposed Objective: EPs must generate and transmit permissible prescriptions electronically, and eligible hospitals and CAHs must generate and transmit permissible discharge prescriptions electronically (eRx).

We proposed to continue to define "prescription" as the authorization by a provider to dispense a drug that would not be dispensed without such authorization. This includes authorization for refills of previously authorized drugs. We proposed to continue to generally define a "permissible prescription" as all drugs meeting the definition of prescription not listed as a controlled substance in Schedules II-V (DEA website at <http://www.deadiversion.usdoj.gov/schedules/index.html>) (77 FR 53989), with a slight modification to allow for inclusion of scheduled drugs where such drugs are permitted to be electronically prescribed. We proposed that providers who practice in a state where controlled substances may be electronically prescribed who wish to include these prescriptions in the numerator and denominator may do so under the definition of "permissible prescriptions" for their practice. If a provider chooses to include such prescriptions, they must do so uniformly across all patients and across all allowable schedules for the duration of the EHR reporting period. We proposed to continue to exclude over-the-counter (OTC) medicines from the definition of a prescription, although we encouraged public comments on whether OTC medicines should be included in this objective for Stage 3.

In the Stage 2 final rule at (77 FR 53989), we discussed several different workflow scenarios that are possible when an EP prescribes a drug for a patient and that these differences in transmissions create differences in the need for standards. For Stage

3, we proposed to maintain this policy for Stage 3 for EPs and extend it to eligible hospitals and CAHs so that only a scenario in which a provider (1) Prescribes the drug; (2) transmits it to a pharmacy independent of the provider's organization; and (3) The patient obtains the drug from that pharmacy requires the use of standards to ensure that the transmission meets the goals of electronic prescribing. In that situation, standards can ensure the whole process functions reliably. In all cases under this objective, the provider needs to use CEHRT as the sole means of creating the prescription, and when transmitting to an external pharmacy that is independent of the provider's organization, such transmission must be pursuant to ONC HIT Certification Program criteria.

Comment: Some commenters recommended that OTC medications should be excluded in the definition of prescription, as they are not typically prescribed electronically.

Response: We thank commenters for their input and agree that OTC medications should continue to be excluded from the definition.

Proposed EP Measure: More than 80 percent of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT.

We proposed to maintain for Stage 3 the exclusion from Stage 2 for EPs who write fewer than 100 permissible prescriptions during the EHR reporting period. We also proposed to maintain for Stage 3 the exclusion from Stage 2 if no pharmacies within a 10-mile radius of an EP's practice location at the start of his or her EHR reporting period accept electronic prescriptions (77 FR 53990). This is 10 miles in any straight line from

the practice location independent of the travel route from the practice location to the pharmacy. For EPs practicing at multiple locations, they are eligible for the exclusion if any of their practice locations equipped with CEHRT meet this criterion. 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.

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 80 percent in order for an EP to meet this measure.

Exclusions: Any EP who: (1) writes fewer than 100 permissible prescriptions during the EHR reporting period; or (2) does not have a pharmacy within their 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.

Proposed Eligible Hospital/CAH Measure: More than 25 percent of hospital discharge medication orders for permissible prescriptions (for new and changed

prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.

We proposed to limit this measure for Stage 3 to only new and changed prescriptions and invited public comment on whether a hospital would issue refills upon discharge for medications the patient was taking when they arrived at the hospital and, if so, whether distinguishing those refill prescriptions from new or altered prescriptions is unnecessarily burdensome for the hospital.

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

Denominator: The number of new or changed 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 25 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 there are no pharmacies that accept electronic prescriptions within 10 miles at the start of their EHR reporting period.

In the proposed rule, we recognized that not every patient will have a formulary that is relevant to him or her. If a relevant formulary is available, then the information can be provided. If there is no formulary for a given patient, the comparison could return

a result of formulary unavailable for that patient and medication combination, and the provider may count the prescription in the numerator if they generate and transmit the prescription electronically as required by the measure.

Comment: A few commenters were in support of the e-prescribing objective because it is an important priority in quality reporting efforts.

Response: We appreciate the support and note as we have previously stated, transmitting the prescription electronically promotes efficiency and patient safety through reduced communication errors.

Comment: Many commenters expressed concerns about requiring e-prescribing for hospitals where the objective was previously a menu option. Some noted that the shift from optional to required, combined with an increased threshold for Stage 3, makes the objective difficult to achieve for eligible hospitals and CAHs.

Response: We thank the commenters for sharing their concerns. However, we believe the potential benefits of electronic prescribing are substantial. As discussed in the Stage 2 final rule (77 FR 53989), transmitting the prescription electronically promotes efficiency and patient 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, which works in conjunction with clinical decision support interventions enabled at the generation of the prescription. In addition, we note that, as required by the HITECH Act, e-prescribing has been a required part of the EHR Incentive Programs for EPs since 2011. As noted in the Stage 3 proposed rule, eligible hospital and CAH performance on electronic prescribing in 2014 was well over the

threshold. We believe that the continued expansion of the infrastructure and 3 years to transition toward incremental increases via the objective in place for 2015 through 2017 will support hospitals in succeeding on this measure.

Comment: Some commenters requested exclusions for eRx because they have less than 100 office visits (in concurrence with previous requirements) or have an average low census. Others simply stated that they could not meet the measure.

Response: We note that we proposed to maintain for Stage 3 the exclusion from Stage 2 for EPs who write fewer than 100 permissible prescriptions during the EHR reporting period. We also proposed to maintain for Stage 3 the exclusion from Stage 2 if no pharmacies within a 10-mile radius of an EP's practice location at the start of his or her EHR reporting period accept electronic prescriptions. For eligible hospitals and CAHs in Stage 3, there is an exclusion if they do not have an internal pharmacy that can accept electronic prescriptions and there are no pharmacies that accept electronic prescriptions within 10 miles at the start of their EHR reporting period. We do not agree with setting an exclusion based on office visits, as the denominator for the measure is based not on office visits but on permissible prescriptions.

Comment: Several commenters stated that the threshold of over 80 percent for EPs is too high. Commenters cited this high threshold as a potential patient safety risk for providers switching products, since systems issues could occur from inappropriately expediting implementation in order to meet the high threshold.

Some of these commenters expressed that if the provider is required to query a drug formulary, the provider cannot be expected to meet the 80 percent threshold.

Further commenters discussed the disconnect between the various options for formulary queries and discussed the ongoing evolution of standards specifically referencing the following issues:

- Formulary queries where no formulary exists may generate errors on some systems;
- Formulary queries of formularies with access restrictions, either technological restrictions or proprietary restrictions limit the ability to query even where such a formulary is available;
- Static formularies are often not fully electronic, are not a format that can be queried, or are updated infrequently so they provide limited benefit;
- Real time formulary query standards are split with as many as three primary options available in the industry.

Despite these concerns, many commenters noted that they agree with the concept of an automated, real-time formulary query. Commenters stated that they believe it provides a value for patients when the query is feasible and successful.

Response: As we noted in the proposed rule (80 FR 16747), our analysis of the attestation data indicates the majority of EPs have already been exceeding this threshold; however, we note that each year a small but significant portion of EPs may struggle to meet this measure if they are engaged in a transition from one EHR product to another or in a full upgrade of CEHRT to a new Edition. For many functions, the potential risk to patient safety during these transitions may be easily mitigated; however, because the appropriate management of prescribed medications can be critical for both acute and

chronic patient care, the risk for electronic prescribing during transitions may be significant. We are therefore finalizing a threshold of 60 percent rather than the 80 percent proposed. We agree with the provider commenter concerns regarding the drug formulary query and reiterate that the long-term goal is to move toward real-time automated queries using a unified standard. For the short term, as noted for the electronic prescribing objective and measure for 2015 through 2017 in section II.B.2.a(iv), we believe that the query function should be maintained. However, providers are only required to meet this part of the measure to the extent that such a query is automated by their CEHRT and to the extent that a query is available and can be automatically queried by the provider. This means that if a query using the function of their CEHRT is not possible or shows no result, a provider is not required to conduct any further manual or paper-based action in order to complete the query, and the provider may count the prescription in the numerator.

Comment: Commenters noted that controlled substances should be included where feasible, as the inclusion would reduce the paper based prescription process often used for such prescriptions, as long as the inclusion of these prescriptions were permissible in accordance with state law. Commenters noted that the ability to electronically prescribe controlled substances provides prescribers with a way to manage treatments for patients with pain electronically and also deters creation of fraudulent prescriptions, which is a major concern in combating opioid misuse and abuse.

Response: We agree with commenters that the eventual progression toward universal inclusion of controlled substances in electronic prescribing is a desired goal. However, as

stated previously we believe that at present this should remain an option for providers, but not be required. As many states have now have eased some of the prior restrictions on electronically prescribing controlled substances, we believe it is no longer necessary to categorically exclude controlled substances from the term “permissible prescriptions.” Therefore we will define a permissible prescription as all drugs meeting our current definition of a prescription as the authorization by a provider to dispense a drug that would not be dispensed without such authorization and we will no longer distinguishing between prescriptions for controlled substances and all other prescriptions. Instead will refer only to permissible prescriptions consistent with the proposed definition for Stage 3 (80 FR 16747) as all drugs meeting the definition of prescription not listed as a controlled substance in Schedules II–V¹² (77 FR 53989) with a modification to allow for inclusion of scheduled drugs where such drugs are permissible to be electronically prescribed. Therefore the continued inclusion of the term "controlled substances" in the denominator may no longer be an accurate description to allow for providers seeking to include these prescriptions in the circumstances where they may be included. We are modifying the denominator to remove this language. Again, we note this is only a change in wording and does not change the substance of our current policy that providers have the option, but are not required, to include prescriptions for controlled substances in the measure for Stage 3. For the EHR Incentive Programs in 2015 through 2017, we note that the inclusion of controlled substances under permissible prescriptions is optional under the Electronic Prescribing Objective (see section II.B.2.a.iv). For Stage 3, while we intended

12 (DEA Web site at <http://www.deadiversion.usdoj.gov/schedules/index.html>)

to maintain this option, based on public comment received and the progress of states toward acceptance of electronic prescribing of controlled substances we are modifying this policy that the inclusion of controlled substances should be required where it is feasible to electronically prescribe the drug and where allowable by law. We believe the reduced threshold of 60 percent will help to mitigate the additional effort to meet this requirement and that the benefit outweighs this increased burden.

Therefore, we are changing the measure for this objective to remove the language regarding controlled substances. Instead, we are adopting that under "permissible prescriptions" for the Stage 3 objective providers must may include electronic prescriptions of controlled substances in the measure where creation of an electronic prescription for the medication is feasible using CEHRT and where allowed by law for the duration of the EHR reporting period.

After consideration of the comments received, we are adopting the objective and exclusion for electronic prescribing as proposed. We will continue to define "prescription" as the authorization by a provider to dispense a drug that would not be dispensed without such authorization. This includes authorization for refills of previously authorized drugs. We are finalizing changes to the language to continue to allow providers the option to include or exclude controlled substances in the denominator where such medications can be electronically prescribed. We are finalizing that these prescriptions may be included in the definition of "permissible prescriptions" at the providers discretion where allowable by law.

We will not include OTC medicines in the definition of a prescription for this objective.

We are maintaining the different workflow scenarios that are possible as discussed in the Stage 2 final rule at (77 FR 53989). We are maintaining this policy for Stage 3 for EPs and extending it to eligible hospitals and CAHs.

For EPs, eligible hospitals and CAHs we are finalizing the objective as follows:

Objective 2: Electronic Prescribing

Objective: EPs must generate and transmit permissible prescriptions electronically, and eligible hospitals and CAHs must generate and transmit permissible discharge prescriptions electronically (eRx).

EP Measure: More than 60 percent of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT.

- 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 60 percent in order for an EP to meet this measure.
- Exclusions: Any EP who: (1) writes fewer than 100 permissible prescriptions during the EHR reporting period; or (2) does not have a pharmacy within their 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.

Eligible Hospital/CAH Measure: More than 25 percent of hospital discharge medication orders for permissible prescriptions (for new and changed prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.

- Denominator: The number of new or changed 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 25 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 there are no pharmacies that accept electronic prescriptions within 10 miles at the start of their EHR reporting period.

We are adopting Objective 2:Electronic Prescribing at § 495.24(d)(2)(i) for EPs and § 495.24(d)(2)(ii) for eligible hospitals and CAHs. We further specify that in order to meet this objective and measures, an EP, eligible hospital, or CAH must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 3: Clinical Decision Support

Clinical decision support at the relevant point of care is an area of HIT in which significant evidence exists for substantial positive impact on the quality, safety, and efficiency of care delivery. For Stage 3 of the EHR Incentive Programs, we proposed to maintain the Stage 2 objective with slight modifications and further explanation of the relevant point of care, the types of CDS allowed, and the selection of a CDS applicable to a provider's scope of practice and patient population.

First, we offered further explanation of the concept of the relevant point of care and note that providers should implement the CDS intervention at a relevant point in clinical workflows when the intervention can influence clinical decision making before diagnostic or treatment action is taken in response to the intervention. Second, many providers may associate CDS with pop-up alerts. However, these alerts are not the only method of providing CDS. CDS should not be viewed as simply an interruptive alert, notification, or explicit care suggestion. Well-designed CDS encompasses a variety of workflow-optimized information tools, which can be presented to providers, clinical and support staff, patients, and other caregivers at various points in time. These may include but are not limited to: computerized alerts and reminders for providers and patients; information displays or links; context-aware knowledge retrieval specifications which provide a standard mechanism to incorporate information from online resources (commonly referred to as InfoButtons); clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support; and contextually relevant reference information. These functionalities may be

deployed on a variety of platforms (that is, mobile, cloud-based, installed).¹³ We continue to encourage innovative efforts to use CDS to improve care quality, efficiency, and outcomes. Health IT functionality that builds upon the foundation of an EHR to provide persons involved in care processes with general and person-specific information, intelligently filtered and organized, at appropriate times, to enhance health and health care. CDS is not intended to replace clinician judgment, but rather is a tool to assist care team members in making timely, informed, and higher quality decisions.

Proposed Objective: Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.

We proposed to retain both measures of the Stage 2 objective for Stage 3 and that these additional options stated previously on the actions, functions, and interventions may constitute CDS for purposes of the EHR Incentive Programs and would meet the measure requirements outlined in the proposed measures.

Comment: Most commenters agreed that clinical decision support should be included as an objective in Stage 3, and many expressed appreciation for the consistency between the existing Stage 2 objective and Stage 3. Some commended CMS' emphasis on clinical decision support tools in the proposed rule. Others were also pleased that CMS is aligning this objective with the HHS National Quality Strategy goals by emphasizing preventive care, chronic condition management, and heart disease and hypertension as areas of focus for quality improvement. A commenter acknowledged the

¹³FDASIA Health IT report available on the FDA website at: <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM391521.pdf>

value of CDS available in EHR technology in improving patient safety and care quality, and believes that this requirement has become obsolete as an attestation measure. Others similarly suggest that this measure is "topped out" because most participants in the Medicare and Medicaid EHR Incentive Program have many more than 5 CDS implemented in their EHRs, but they believed that CDS is a statutory requirement.

Response: We appreciate the support for this objective. As we stated in the proposed rule, clinical decision support at the relevant point of care is an area of health IT in which significant evidence exists for substantial positive impact on the quality, safety, and efficiency of care delivery. We believe these factors outweigh the potential reporting burden in place for providers who have significantly more than 5 CDS interventions in place for whom the measurement may no longer be required.

Proposed Measures: EPs, eligible hospitals, and CAHs must satisfy both measures in order to meet the objective:

Measure 1: Implement 5 clinical decision support interventions related to four or more CQMs at a relevant point in patient care for the entire EHR reporting period. Absent 4 CQMs 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.

Exclusion: For the second measure, any EP who writes fewer than 100

medication orders during the EHR reporting period.

Where possible, we recommend providers implement CDS interventions that relate to care quality improvement goals and a related outcome measure CQM. However, for specialty hospitals and certain EPs, if there are no CQMs that are outcome measures related to their scope of practice, the provider should implement a CDS intervention related to a CQM process measure; or if none of the available CQMs apply, the provider should apply an intervention that he or she believes will be effective in improving the quality, safety, or efficiency of patient care.

Comment: Many commenters supported Measure 1(period), with a significant number supporting CMS for acknowledgement of the wide variety of innovative clinical decision tools that can be used. Some acknowledged "alarm fatigue" and the subsequent ignoring of alerts, so they appreciated the alternatives to pop-up alerts. As an alternative to alerts, one provider suggested that information display as links for condition-specific order sets, diagnostic support, and contextually relevant reference information, which seem to be more user-friendly support tools. A commenter stated that the multiple tools available to meet the requirements of CDS may be difficult and there could be substantial costs associated with the tools.

Other commenters requested clarification of the types of resources that will count towards meeting the requirements of the EHR Incentive Programs related to CDS. Specifically, commenters asked about the InfoButton standard, and the requirement that RCERHT enable users to review the attributes of CDS resources.

Response: Our examples are intended to illustrate that CDS encompasses a

variety of workflow-optimized information tools. The examples are meant to be illustrative and not a requirement to utilize all of the options.

We proposed to embrace a broad definition of CDS, including (but not limited to) resources such as: computerized alerts and reminders for providers and patients, clinical guidelines, condition-specific order sets, documentation templates, focused patient data reports and summaries, and contextually relevant reference information. We posted a tip sheet and guidance on the CMS website, www.cms.hhs.gov/ehrincentive, which includes several examples of CDS and information on the general intent of this requirement, and referencing best practices for using CDS to improve care. The guidance also clarifies that CDS need not necessarily be presented during a patient encounter, or be limited to interventions targeted at physicians, and is not limited to interruptive alerts or reminders. CDS is often an integrated part of the provider's EHR system, but may also present in a variety of other mechanisms, including but not limited to: pharmacy systems, patients' personal health records (PHRs), or Patient portals provided by the practice.

The InfoButton standard can be used to provide hyperlinks to information, such as clinical guidelines or patient data summaries, at the relevant point in the care continuum and therefore represents one type of CDS that EPs, eligible hospitals, and CAHs may use to meet the EHR Incentive Programs CDS requirements. There are also likely to be cases where it makes sense for a CDS resource to display certain attributes at the time of presentation, or for a resource to include an InfoButton linking to additional information with CDS attributes. The potential workflows and implementations of these resources within a CDS is varied and should be tailored to best meet the provider's needs. However,

please note that in this example, the use of the InfoButton would not count as a separate or additional CDS intervention, but rather would be a supporting part of the one CDS of which it is a part.

Comment: For Measure 1, many commenters appreciated the strengthened connection of CQMs to CDS. However, some commenters recommended removing the requirement to link CDS to CQMs in favor of high-priority safety and quality improvement objectives. A commenter clarified that eliminating the link would enable them to meet their system quality improvement goals and would remove the measurement burden of tracking links between CDS and CQMs. Some commenters noted a lack of CQMs for some provider types and referenced pediatricians. Another stated that if the EHR developer limits the number of CQMs that are included in the CEHRT, it may limit a providers' ability to implement CDS. A commenter inquired about changes to CQMs that could relate to selected CDS. Another recommended that CDS interventions be grandfathered in for a year after a CQM change.

Many commenters requested clarification of "high-priority health conditions." A commenter suggested that "high-priority health conditions" be replaced with "conditions relevant to the EP's scope of practice". Another suggested that the CDS be related to 4 or more CQMs or high-priority health conditions. Yet another commenter stated that the high priority health conditions are not related to many of the specialties, including surgery, pediatrics, or medical subspecialties. They recommended that we allow providers to link to clinical guidelines relevant to their practice or a clinical registry that can provide real-time specialty-specific data on their scope of practice if there are not

four relevant CQMs. A commenter urged us to include immunization forecasting as a measure of CDS. Another commenter requested that we consider behavioral health as an additional priority area. A commenter does not believe CDS interventions are applicable to providers servicing elderly patient populations, specifically those in nursing homes with cognitive deficit since their mental functions are limited and life expectancy short.

Response: For providers linking CDS to CQM selections, we proposed that providers are allowed the flexibility to implement CDS interventions that are related to any of the CQMs that are finalized for the EHR Incentive Program. They are not limited to the CQMs they choose to report and we note that we have a recommended set of CQMs for EPs, which includes both a set for adult population and for pediatric populations, which may serve as a guide¹⁴. As we stated when we finalized this measure for Stage 2 of the EHR Incentive Programs (77 FR 53996), it is our expectation that, at a minimum, providers will select CDS interventions to drive improvements in the delivery of care for the high-priority health conditions relevant to their patient population. CQMs may be changed on an annual basis through the PFS or IPPS rulemaking. As CQMs are still required as part of a provider's demonstration of meaningful use, providers should modify their CDS selections if CQMs change over time.

Providers who are not able to identify CQMs that apply to their scope of practice or patient population may implement CDS interventions that they believe are related to high-priority health conditions relevant to their patient population and will be effective in

¹⁴ EHR Incentive Programs Recommended Core Set Adult and Pediatric Clinical Quality Measure Tables available at: https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/2014_ClinicalQualityMeasures.html

improving the quality, safety or efficiency of patient care. These high priority conditions must be determined prior to the start of the EHR reporting period in order to implement the appropriate CDS to allow for improved performance. We proposed to require a minimum number of CDS interventions, and providers must determine whether a greater number of CDS interventions are appropriate for their patient populations.

Comment: A commenter recommended an exclusion for physicians who face challenges implementing 5CDS interventions. Another requested that only 3CDS interventions be required. A commenter recommended an exclusion for highly specialized EPs and a reduction in the number of interventions required for each individual EP.

Response: We believe that CDS at the point of care is an area of health IT in which significant evidence exists for its substantial positive impact on the quality, safety, and efficiency of care delivery. Therefore, we did not propose exclusion for this measure. In addition, we proposed to offer considerable flexibility in the selection of the CDS interventions.

Comment: A commenter questioned if all the CDS tools suggested are required. Another commenter recommended that HHS support research that would help providers identify the most valuable CDS interventions and the most effective placement of such interventions in provider workflows.

Response: We offered a list of workflow optimized information tools to illustrate some examples in the Stage 3 proposed rule (80 FR 16749). It is not meant to be list of required tools, nor is it an exhaustive list of all the options available. Also in the Stage 3

proposed rule (80 FR 16750), CMS and ONC have provided examples of CDS interventions as well as program models such as Million Hearts, which may offer suggestions to providers and raise awareness of the possibilities available. CMS and ONC will consider providing further guidance as to CDS options, CDS and CQM pairings, and industry research on various CDS implementations.

Comment: A commenter requested a clarification on the relationship between the functions that are included in the definition of CEHRT and the actions that are required for the EHR Incentives Programs. Some commenters expressed concern that EPs and eligible hospitals and CAHs might be limited only to CDS that ONC had certified. Several commenters also expressed concern that the CDS requirements for the EHR Incentive Program objectives do not match the standards for certification and question if the certification requirements for health IT would limit the types or utility of CDS a provider might use to meet the Clinical Decision Support Objective.

Response: CMS does not certify CDS functions or resources, but instead defines that a provider must use CDS resources and that those resources must meet the ONC certification criteria to meet the definition of CEHRT. The EHR Incentive Programs do not otherwise restrict a provider's ability to choose any CDS option or resource to meet their unique needs. For the certification criteria for CDS, the ONC 2015 Edition proposed rule (80 FR 16804 through 16921) proposed the functionalities that health IT developers would build into their "CDS module" to meet the certification criteria. These "CDS modules" are what meet the CEHRT definition for the EHR Incentive Programs. However, while the certification rule specifies that the "CDS module" that is certified to

the CDS standard must have certain capabilities to provide or enable CDS for provider use, it does not certify the supports or resources themselves. This means that the ONC health IT certification criteria are designed to ensure that the "CDS module" implemented by EPs and eligible hospitals and CAHs will enable them to meet the CDS Objective requirements without limiting the potential use and innovation of a wide range of options for providers.

Comment: Several commenters recommended removing the "entire EHR reporting period" from the measure specifications to limit unnecessary measurement burden. Another commenter was concerned that the requirement for CDS interventions to be in place for the entire reporting year would make it impossible for EPs, eligible hospitals, and CAHs to change CEHRT mid-year and remain eligible.

Response: We disagree. We believe that having providers implement improvements in clinical performance for high-priority health conditions will result in improved patient outcomes and believe CDS should be in place for the entire EHR reporting period. We note that we understand reasonable downtime as may be expected with any health IT systems to ensure security or fix any issues which arise is acceptable. We intend for the implementation of 5 five CDS interventions to be a minimum. We do not intend to limit the number of interventions that may be implemented if an organization chooses to implement more than 5five. The same interventions do not have to be implemented for the entire EHR reporting period as long as the threshold of 5is maintained for the duration of the EHR reporting period. For example, if a provider identifies quality improvement goals that change the quality improvement and CDS

implementation plan over the course of the year, they may make these changes as long as the total number of CDS interventions implemented at any given time during the EHR reporting period is 5 or more. In fact, we expect that EPs, eligible hospitals, and CAHs will regularly update and adjust their portfolios of CDS interventions – fine-tuning them to evolving patient population needs and in response to each intervention's observed impact on the related CQM(s).

Comment: Many commenters were concerned about the documentation required for audit to demonstrate that a specific CDS is implemented for the duration of the reporting period. Another commenter suggested reducing the audit burden while several commenters suggested a clarification be added to reduce the audit burden by only requiring documentation showing the CEHRT has the functionality.

Several commenters requested clarification in the area of audit readiness and guidance related to expectations for the use of specific CDS at the individual level. They requested that we consider identifying this objective as an organizational or group objective rather than a specific eligible professional objective and allow the organization's efforts to meet the requirements for each provider practicing in that organization.

Response: We disagree with the suggestion to allow CDS attestations at a group level. While certain CDS may support providers in a wide range of specialties, others may be designed for particular patient populations or specialties and the selection of CQMs may also be related to the priorities for an individual provider. For example, the Million Hearts campaign may provide CDS models for many providers, but may not be

relevant for certain specialties. Providers should be selecting and implementing CDS within their practice based on their priorities to promote quality improvement and positive outcomes for patients, not to avoid a potential audit failure. Furthermore, we note that we will provide guidance to the auditors to support their understanding of the wide scope of CDS interventions available to providers.

Comment: Most commenters supported the second measure related to drug-drug and drug-allergy interaction checks. A commenter suggested clarifying that the use of the word "enabled" signifies that the provider is actively using the functionality as opposed to just having the functionality available. Another appreciated the inclusion of this measure because it is a huge benefit to patient care.

However, a commenter recommended that we allow exclusions from the drug-drug and drug-allergy interaction checks if the EP is a low-volume prescriber.

Response: We appreciate the support for this measure. We meant by “enabled” that the provider should be actively using the function for the duration of the EHR reporting period at the relevant point in care. For the second measure, we did propose an exclusion for any EP who writes fewer than 100 medication orders during the EHR reporting period.

Comment: Several commenters stated that for the second measure they believe it is burdensome to require eligible hospitals, CAHs, and EPs to enable and implement the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

Response: We believe that this measure is an important component of the EHR

Incentive Programs and offers the opportunity for positive impact on quality, efficiency of care delivery, and especially patient safety. We believe that the functionality for drug-drug and drug-allergy interaction checks should be enabled and implemented for the duration of the EHR reporting period with the exception of limited unavoidable downtime if a system issue should arise.

After consideration of the public comments received, we are finalizing the objective, measures and exclusion as proposed for EPs, eligible hospitals and CAHs as follows:

Objective 3: Clinical Decision Support

Objective: Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.

Measure 1: Implement five clinical decision support interventions related to four or more CQMs at a relevant point in patient care for the entire EHR reporting period. Absent four CQMs 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.

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

We are adopting Objective 3: Clinical Decision Support at § 495.24(d)(3)(i) for

EPs and § 495.24(d)(3)(ii) for eligible hospitals and CAHs. We further specify that in order to meet this objective and measures, an EP, eligible hospital, or CAH must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 4: Computerized Provider Order Entry

In the Stage 2 final rule, we expanded the use of computerized provider order entry (CPOE) from the Stage 1 objective requiring only medication orders to be entered using CPOE to include laboratory orders and radiology orders. For a full discussion of this expansion, we direct readers to (77 FR 53985 through 53989). We maintain CPOE continues to represent an opportunity for providers to leverage technology to capture these orders to reduce error and maximize efficiencies within their practice, therefore we proposed to maintain the use of CPOE for these orders as an objective of meaningful use for Stage 3.

Proposed Objective: Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.

We proposed to continue our policy from the Stage 2 final rule that the orders to be included in this objective are medication, laboratory, and radiology orders. However,

we proposed to expand the third measure of the objective to include diagnostic imaging. This change was intended to address the needs of specialists and allow for a wider variety of clinical orders relevant to particular specialists to be included for purposes of measurement.

For Stage 3, we proposed to continue our policy from the Stage 2 final rule that the orders to be included in this objective are medication, laboratory, and radiology orders as such orders are commonly included in CPOE implementation and offer opportunity to maximize efficiencies for providers. However, for Stage 3, we proposed to expand the objective to include diagnostic imaging, which is a broader category including other imaging tests such as ultrasound, magnetic resonance, and computed tomography in addition to traditional radiology. This change addressed the needs of specialists and allowed for a wider variety of clinical orders relevant to particular specialists to be included for purposes of measurement.

We further proposed to continue the policy from the Stage 2 final rule at 77 FR 53986 that orders entered by any licensed healthcare professional or credentialed medical assistant would count toward this objective. A credentialed medical assistant may enter orders if they are credentialed to perform the duties of a medical assistant by a credentialing body other than the employer. If a staff member of the eligible provider is appropriately credentialed and performs assistive services similar to a medical assistant, but carries a more specific title due to either specialization of their duties or to the specialty of the medical professional they assist, orders entered by that staff member would be included in this objective. We further noted that medical staff whose

organizational or job title, or the title of their credential, is other than medical assistant may enter orders if these staff are credentialed to perform the equivalent duties of a credentialed medical assistant by a credentialing body other than their employer and perform such duties as part of their organizational or job title. We deferred to the provider's discretion to determine the appropriateness of the credentialing of staff to ensure that any staff entering orders have the clinical training and knowledge required to enter orders for CPOE. This determination must be made by the EP or representative of the eligible hospital or CAH based on--

- Organizational workflows;
- Appropriate credentialing of the staff member by an organization other than the employing organization;
- Analysis of duties performed by the staff member in question; and
- Compliance with all applicable federal, state, and local laws and professional guidelines.

However, as stated in the Stage 2 final rule at 77 FR 53986, it is apparent that the prevalent time when CDS interventions are presented is when the order is entered into CEHRT, and that not all EHRs also present CDS when the order is authorized (assuming such a multiple step ordering process is in place). This means that the person entering the order would be required to enter the order correctly, evaluate a CDS intervention either using their own judgment or through accurate relay of the information to the ordering provider, and then either make a change to the order based on the information provided by the CDS intervention or bypass the intervention. The execution of this role represents

a significant impact on patient safety; therefore, we continued to maintain for Stage 3 that a layperson is not qualified to perform these tasks. We believe that the order must be entered by a qualified individual. We further proposed that if the individual entering the orders is not the licensed healthcare professional, the order must be entered with the direct supervision or active engagement of a licensed healthcare professional.

We proposed to maintain for Stage 3 our existing policy for Stages 1 and 2 that the CPOE function should be used the first time the order becomes part of the patient's medical record and before any action can be taken on the order. The numerator of this objective also includes orders entered using CPOE initially when the patient record became part of the CEHRT, but does not include paper orders entered initially into the patient record or orders entered into technology not compliant with the CEHRT definition and then transferred into the CEHRT at a later time.

In addition, we proposed to maintain for Stage 3 that "protocol" or "standing" orders may but are not required to be excluded from this objective.

We proposed to maintain the Stage 2 description of "laboratory services" as any service provided by a laboratory that could not be provided by a non-laboratory for the CPOE objective for Stage 3 (77 FR 53984). We also proposed to maintain for Stage 3 the Stage 2 description of "radiologic services" as any imaging service that uses electronic product radiation (77 FR 53986). Even though we proposed to expand the CPOE objective from radiology orders to all diagnostic imaging orders, this description would still apply for radiology services within the expanded objective.

We received public comment on our proposals and our response follows.

Comment: The majority of commenters supported the inclusion of this objective. Some of the commenters appreciated the consistency with the previous Stage 2 objective. A commenter requested that we clarify that there are no changes to the objective or to the definition of terms except for "diagnostic imaging."

Response: We appreciate the support for the objective. We proposed to maintain the Stage 2 CPOE policies except that the third measure would be expanded from radiology orders to diagnostic imaging orders and the thresholds for the measures would be increased.

Comment: Commenters requested clarification of "medical staff member credentialed to perform the equivalent duties of a credentialed medical assistant" and requested clarification on a number of potential roles including an in-house phlebotomist, an ophthalmological assistant, a medical student in residency, and other health care professionals. Other commenters requested clarification on the phrase "under the direct supervision or active engagement of a licensed healthcare professional."

Response: As noted in the Stage 3 proposed rule (80 FR 16751), we require that the person entering the orders be a licensed health care professional or credentialed medical assistant (or staff member credentialed to the equivalency and performing the duties equivalent to a medical assistant). We defer to the provider's discretion to determine the appropriateness of the credentialing of staff to ensure that any staff entering orders have the clinical training and knowledge required to enter orders for CPOE.

However, the descriptive phrase "direct supervision or active engagement" was not meant to capture a hierarchical organizational or contractual arrangement, but rather to signify that any required assistance and direction to assess and act upon a CDS and ensure the order is accurately entered should be provided in real time.

Comment: A commenter disagreed that only "certified" medical assistants are capable of entering orders and requested clarification on the specific certification required. Another commenter stated that in Massachusetts, medical assistants are not required to be credentialed in order to practice and there is no local credentialing body for medical assistants. The commenter suggested that if a standard for medical assistant CPOE is required, then the standard should be that the medical assistant must be appropriately trained for CEHRT use (including CPOE) by the employer or CEHRT vendor in order to be counted.

Response: We thank the commenter for their feedback and suggestion. We believe there may be some confusion related to the term "Certified Medical Assistant" which is not used by CMS in our proposed rules or guidance with reference to the credentialed medical assistant or the credentialed medical staff equivalent of a medical assistant. We reiterate that CMS does not require any specific or general "certification" and note that credentialing may take many forms including, but not limited to, the appropriate degree from a health training and education program from which the medical staff matriculated.

We note that a simple search online returns dozens of medical assistant training and credentialing programs as well as local industry associations for Medical Assistants

offering resources on training in the Commonwealth of Massachusetts. We note that any such program which met a provider's requirements for their practice would also be an example of an acceptable credentialing for the purposes of this objective.

We disagree that the training on the use of CEHRT is adequate for the purposes of entering an order under CPOE and executing any relevant action related to a CDS. We believe CPOE and CDS duties should be considered clinical in nature, not clerical. Therefore, CPOE and CDS duties, as noted, should be viewed in the same category as any other clinical task, which may only be performed by a qualified medical or clinical staff.

Proposed Measures: An EP, eligible hospital or CAH must meet all three measures.

Proposed Measure 1: More than 80 percent of medication orders created by the EP or authorized providers of the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry;

Proposed Measure 2: More than 60 percent of laboratory orders created by the EP or authorized providers of the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry; and

Proposed Measure 3: More than 60 percent of diagnostic imaging orders created by the EP or authorized providers of the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using

computerized provider order entry.

We proposed to continue a separate percentage threshold for all three types of orders: medication, laboratory, and diagnostic imaging. We continue to believe that an aggregate denominator cannot best capture differentiated performance on the individual order types within the objective, and therefore maintain a separate denominator for each order type. We proposed to retain exclusionary criteria from Stage 2 for those EPs who so infrequently issue an order type specified by the measures (write fewer than 100 of the type of order), that it is not practical to implement CPOE for that order type.

We proposed to retain exclusionary criteria from Stage 2 for those EPs who so infrequently issue an order type specified by the measures (write fewer than 100 of the type of order), that it is not practical to implement CPOE for that order type.

Finally, we sought public comment on whether to continue to allow, but not require, providers to limit the measure of this objective to those patients whose records are maintained using CEHRT.

Comment: A few commenters supported not requiring providers to limit the measure of this objective to patients whose records are maintained using CEHRT.

Response: We believe that the majority of providers will store their patient records in CEHRT by the beginning of Stage 3. However, as noted previously, a certain percentage of charts may still be maintained outside of CEHRT (such as workers compensation or other special contracts).

After consideration of public comments received, we maintain the distinction between measures that include only those patients whose records are maintained using

CEHRT and measures that include all patients. Providers may continue to limit the denominator to those patients whose records are maintained using CEHRT for measures with a denominator other than unique patients seen by the EP during the EHR reporting period or unique patients admitted to the eligible hospital or CAH inpatient or emergency department during the EHR reporting period.

Proposed Measure 1: To calculate the percentage, CMS and ONC have worked together to define the following for this measure:

Denominator: Number of medication orders created by the EP or authorized providers in the eligible hospital or CAH 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 80 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.

Proposed Measure 2: To calculate the percentage, CMS and ONC have worked together to define the following for this measure:

Denominator: Number of laboratory orders created by the EP or authorized providers in the eligible hospital or CAH 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 laboratory orders during the EHR reporting period.

Proposed Measure 3: To calculate the percentage, CMS and ONC have worked together to define the following for this measure:

Denominator: Number of diagnostic imaging orders created by the EP or authorized providers in the eligible hospital or CAH 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 diagnostic imaging orders during the EHR reporting period.

We further sought public comment on if there are circumstances which might warrant an additional exclusion for an EP, such as a situation representing a barrier to successfully implementing the technology required to meet the objective. We also sought comment on if there are circumstances where an eligible hospital or CAH, which focuses on a particular patient population or specialty, may have an EHR reporting period where the calculation results in a zero denominator for one of the measures, how often such circumstances might occur, and whether an exclusion would be appropriate.

Comment: A few commenters noted potential barriers for cost of a system if the provider conducts very few orders of a specific type. Many providers noted they believe that CPOE saves money and delivers process improvement benefits in a relatively short and easily measureable cycle and so saw a strong benefit from the objective.

Many commenters noted that the change from radiology orders to diagnostic imaging orders increases relevance for specialty hospitals. A few commenters requested clarification around the inclusion of diagnostic imaging and how this is different from Stage 2. .

Some commenters stated that the increase in thresholds, especially for laboratory and radiology orders, were appropriate and they would be able to meet them. Some commenters supported the increased thresholds noting that our inclusion of this objective provided additional pressure on their organization to work toward a higher goal and maximize the potential benefits CPOE offers. However, some commenters noted that the 80 percent threshold could present a problem for providers who are transitioning between certified EHR technologies within a reporting period. These commenters noted that for CPOE medication orders, and the related CDS interventions for drug-drug and medication-allergies, it is extremely important to allow adequate time for product and process implementation to ensure patient safety and minimize the risk of serious adverse events.

Response: In relation to the potential costs associated, we believe the proposed exclusions would allow providers with significantly low numbers of a certain type or types of orders to exclude the related measure and therefore avoid any unnecessary

expenditure. . We believe CPOE continues to represent an opportunity for providers to leverage technology to capture these orders to reduce error and maximize efficiencies within their practice.

We appreciate the support for the inclusion of diagnostic imaging for measure 3. We proposed the expansion for diagnostic imaging to include other imaging tests such as ultrasound, magnetic resonance, and computed tomography in addition to traditional radiology orders which were the limit of the scope of the Stage 2 objective at 80 FR 16750. We believe this change addresses the needs of specialists and allows for a wider variety of clinical orders relevant to particular specialists to be included for purposes of measurement, benchmarking, and process improvement initiatives within healthcare organizations.

Finally, we thank those commenters who supported the increased thresholds for Stage 3. We have reconsidered the increase for the medication orders measure and are in agreement with commenters who suggested this potential measure should not be raised to this level in order to avoid inadvertently encouraging rushed implementation if a provider is switching between products or implementing an upgrade to the technology. As we explained in our discussion regarding the threshold of the Electronic Prescribing Objective for Stage 3, we believe the appropriate management of medications can be critical for both acute and chronic patient care, and therefore the risk associated with CPOE for medication orders during transitions may be significant. Therefore we will maintain the Stage 2 threshold for that measure only which also aligns the three measures at the same level.

After consideration of the public comments received, at we are finalizing the objective and the measures for CPOE for laboratory orders and CPOE for diagnostic imaging orders and the exclusions for all measures as proposed. We are finalizing the measure for CPOE for medication orders with a modified threshold. We are adopting the objective for EPs, eligible hospitals and CAHs as follows:

Objective 4: Computerized Provider Order Entry

Objective: Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant, who can enter orders into the medical record per state, local, and professional guidelines.

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

- Denominator: Number of medication orders created by the EP or authorized providers in the eligible hospital or CAH 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: More than 60 percent of laboratory orders created by the EP or authorized providers of the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry; and

- Denominator: Number of laboratory orders created by the EP or authorized providers in the eligible hospital or CAH 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 laboratory orders during the EHR reporting period.

Measure 3: More than 60 percent of diagnostic imaging orders created by the EP or authorized providers of the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.

- Denominator: Number of diagnostic imaging orders created by the EP or authorized providers in the eligible hospital or CAH 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 diagnostic imaging orders during the EHR reporting period.

We are adopting Objective 4: Computerized Provider Order Entry at § 495.24(d)(4)(i) for EPs and § 495.24(d)(4)(ii) for eligible hospitals and CAHs. We further specify that in order to meet this objective and measures, an EP, eligible hospital, or CAH must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 5: Patient Electronic Access to Health Information

In the Stage 3 proposed rule (80 FR 16752), we identified two related policy goals within the overall larger goal of improved patient access to health information and patient-centered communication. The first is to ensure patients have timely access to their full health record and related important health information; and that the second is to engage in patient-centered communication for care planning and care coordination. While these two goals are intricately linked, we noted that we see them as two distinct priorities requiring different foci and measures of success. For the first goal, we proposed to incorporate the Stage 2 objectives related to providing patients with access to health information, including the objective for providing access for patients (or their authorized representatives) to view online, download, and transmit their health information and the objective for patient-specific education resources, into a new Stage 3 objective entitled, "Patient Electronic Access" (Objective 5), focused on using CEHRT to support increasing patient access to important health information. For the second goal, we proposed an objective entitled Coordination of Care through Patient Engagement

(Objective 6) incorporating the policy goals of the Stage 2 objectives related to secure messaging, patient reminders, and the ability for patients (or their authorized representatives) to view online, download, and transmit their health information using the functionality of the CEHRT.

In the Stage 3 Patient Electronic Access Objective, we proposed to incorporate certain measures and objectives from Stage 2 into a single objective focused on providing patients with timely access to information related to their care. We also proposed to no longer require or allow paper-based methods to be included in the measures (80 FR 16753) and to expand the options through which providers may engage with patients under the EHR Incentive Programs. Specifically, we proposed an additional functionality, known as application programming interfaces (APIs), which would allow providers to enable new functionalities to support data access and patient exchange.

We sought comment on what additional requirements might be needed to ensure that for the API-- (1) the functionality supports a patient's right to have his or her protected health information sent directly to a third party designated by the patient; and (2) patients have at least the same access to and use of their health information that they have under the view, download, and transmit option.

Proposed Objective: The EP, eligible hospital, or CAH provides access for patients to view online, download, and transmit their health information, or retrieve their health information through an API, within 24 hours of its availability.

We continue to believe that patient access to their electronic health information, and to important information about their care, is a high priority for the EHR Incentive

Programs.

We noted that for this objective, the provider is only required to provide access to the information through these means; the patient is not required to take action in order for the provider to meet this objective. We also stated that to "provide access" means that the patient has all the tools and information they need to gain access to their health information including, but not limited to, any necessary instructions, user identification information, or the steps required to access their information if they have previously elected to "opt-out" of electronic access. If this information is provided to the patient in a clear and actionable manner, the provider may count the patient for this objective. We further stated that providers may withhold from online disclosure any information either prohibited by federal, state, or local laws or if such information provided through online means may result in significant harm.

Further, we noted that this objective is a requirement for meaningful use and it does not affect an individual's right under HIPAA to access his or her health information. Providers must continue to comply with all applicable requirements under the HIPAA Privacy Rule, including the access provisions of 45 CFR 164.524.

We received the following comments and our response follows:

Comment: We received a number of comments requesting further clarification of the proposal to incorporate API functionality into an objective for patient electronic access. We received comments requesting clarification around how we envision the relationship between an API and the existing view, download, and transmit functionalities as well how a patient or provider might leverage an enabled API over

multiple use cases. Commenters also requested clarification on if the API would replace their patient portal or be a part of it or an additional website. Some commenters expressed concern about supporting a second patient portal.

Response: We thank the commenters and offer the following explanation of our intent for the use of an API within the patient electronic access objective as one of the potential functions through which a patient may obtain access to their health information.

First, we do not consider the API to be a "second" patient portal and that the current trend to use a patient portal to meet the view, download and transmit functions, while prevalent and acceptable, is not the only way a provider might meet the current objective. We recognize the value in these systems and support the implementation of patient portals to allow patients to engage with their health care providers for both clinical and administrative information.

However, at a basic level, the EHR Incentive Program currently requires only that providers give their patients access to their health information to be able to do three activities: view their information, download their information, and transmit their information. This is a nuanced but important distinction between the existing Stage 2 requirement and the current systems, which are used to meet it. This distinction is important, as not only do we not require a "patient portal" format for VDT, we also do not advocate such a limit on innovation in software or systems designed to allow patients to access and engage with their health information. We believe that the efficacy of the health IT environment now and the potential for future innovation, relies on the establishment of clear standards and functionality requirements paired with the flexibility

to develop differentiated technical specifications, functions, and user interface design that meet those requirements.

This proposed Stage 3 objective for Patient Electronic Access is not a "patient portal" versus "API" requirement or a requirement to support two patient portals.

Instead, this proposed objective is supporting four basic actions that a patient should be able to take:

- View their health information;
- Download their health information;
- Transmit their health information to a third party; and
- Access their health information through an API.

We also believe that these actions may be supported by a wide range of system solutions, which may overlap in terms of the software function used to do an action or multiple actions. This intent to allow for innovation and change within the scope of health IT development is part of a broader goal to lay the foundation for health care systems to support the patient and provider.

An API is a set of programming protocols established for multiple purposes. APIs may be enabled by a provider or provider organization to provide the patient with access to their health information through a third-party application with more flexibility than is often found in many current "patient portals."

From the provider perspective, an API could complement a specific provider "branded" patient portal or could also potentially make one unnecessary if patients were able to use software applications designed to interact with an API that could support their

ability to view, download, and transmit their health information to a third party.

From the patient perspective, an API enabled by a provider will empower the patient to receive information from their provider in the manner that is most valuable to the patient. Patients could collect their health information from multiple providers and potentially incorporate all of their health information into a single portal, application, program, or other software. Such a solution may be offered on a state, local, or regional basis, for instance, through a health information exchange, or through another commercial vendor. In addition, we recognize that a large number of patients consult with and rely on trusted family members and other caregivers to help coordinate care, understand health information, and make decisions. For this reason, we proposed the inclusion of patient-authorized representatives within the measures.

Comment: Commenters requested clarification on the function of the API itself, the standards in place, the potential process for determining the possible applications, which may leverage the API, and how to successfully provide patients access to their information through an API.

Response: For the provider to implement an API under our proposal, the provider would need to fully enable the API functionality such that any application chosen by a patient would enable the patient to gain access to their individual health information provided that the application is configured to meet the technical specifications of the API. Providers may not prohibit patients from using any application, including third-party applications, which meet the technical specifications of the API, including the security requirements of the API. Providers are expected to provide patients with detailed

instructions on how to authenticate their access through the API and provide the patient with supplemental information on available applications that leverage the API. We believe there are multiple paths by which a provider organization may provide this information to the patient, just as the current information for access is provided through a variety of means depending on the circumstances.

Additionally, similar to how providers support patient access to VDT capabilities, we expect that providers will continue to have identity verification processes to ensure that a patient using an application, which is leveraging the API, is provided access to their health information.

We proposed for the Patient Electronic Access objective to allow providers to enable API functionality in accordance with the proposed ONC requirements in the 2015 Edition proposed rule. The certification criteria proposed by ONC would establish API criteria, which would allow patients, through an application of their choice (including third-party applications), to pull certain components of their unique health data directly from the provider's CEHRT. This could also potentially allow a patient to pull such information from multiple providers engaged in their care. For further discussion on the technical requirements for APIs, we direct readers to the 2015 Edition proposed rule (80 FR 16840 through 16850).

Comment: A number of commenters expressed concern over the privacy and security of patient information through the use of an API. Commenters noted a number of issues including--(1) how the application would or would not be governed by HIPAA; (2) what verification mechanisms would be required to be included by the provider, the

EHR system, and the patient in order to allow the enabled API to function with the patient selected application; (3) what standards would be required for the API, the application, and any provider verification process for enrolling patients; and (4) general concern over the security of having an enabled API for an EHR.

Response: It is recognized that APIs and VDT provide access to sensitive health care material and security and privacy of patients' ePHI is of utmost importance. As has been seen in other industries where system interoperability has enabled considerable benefits for the consumer, security technology is constantly evolving to meet the changing environment. Thus, detailed monitoring, penetration testing, audits, and key management are all necessities. In addition, this changing environment requires similarly nimble guidelines and standards for privacy and security protocols. The EHR Incentive Program includes an Objective to Protect Patient Health Information (see also section II.B.2.b.1 of this final rule with comment period). This objective includes a measure requiring providers to conduct or review a security risk analysis in accordance with HIPAA requirements to ensure the protection of patient ePHI created or maintained by CEHRT. This requirement to conduct and review a security risk analysis would include the certified API enabled as a part of the provider's CEHRT. This analysis must also be done in compliance with HIPAA Security Rules, which would likewise be applicable to the provider actions related to the provision of access to the patient's health information. Beyond this baseline, we believe that evidence in similar technological transitions illustrates the need for a balanced and responsive approach to privacy and security. As noted previously, we encourage providers to innovate around enrollment structures for

patients to provide accountability for privacy and security standards; we encourage developers to incorporate security best practices in their design; and we encourage patients to employ sound practices just as they would with their online banking or other online activities regarding personal information.

Comment: Many commenters expressed concerns about successfully meeting the objective because their patient population is elderly, ill, low-income, and/or located in remote, rural areas. These patients do not have access to computers, Internet and/or email and are concerned with having their health information online. A commenter specifically requested that clinics with high elderly populations, especially those in rural areas, be exempt from meeting these patient electronic access requirements. Another commenter recommended keeping the VDT threshold to Stage 2 levels.

Several comments also included concerns about patients not using or accessing patient portals, which make it difficult for providers and hospitals to meet patient electronic access requirements. Eligible providers and hospitals do not want to be penalized if patients choose not to use the patient portal or send them secure messages. A commenter recommended that compliance with access occur when the patient has been given documentation on how to sign up for the patient portal, and that a patient's decision to opt-out be counted as compliance. The same commenter also recommended that the denominator for compliance with the portal usage measure be counted as the total number of patients in the portal, not the total number of qualified patients discharged in that period.

Many commenters supported the inclusion of patient-authorized representatives

within this objective noting that this change is essential for patient care and provides greater flexibility for providers. These commenters noted specific patient populations, such as disabled persons, elderly patients, and newborn patients or young children where the more comprehensive inclusion of non-physician caregivers, family members, and other patient-authorized representatives within the measure more accurately captures the inclusiveness of these interactions and the role that health IT can provide in supporting communications with patients and their caregivers.

Response: We note that this proposed objective is entirely focused on the provision of access to patients or their authorized representatives and does not require the provider to be accountable for the patient using that access. Additionally, the numerator is calculated based on the provision of access by the provider, not based on whether a patient possesses or can obtain technology for their own use. The provision of access by the provider is the entirety of the measurement and any subsequent barriers to access which are outside the providers control do not affect the numerator calculation. In other words, for this measure the provider must ensure the patient has been provided the information they would need to gain access whether or not the patient has the technology they need to gain access.

We believe that the overall focus of this objective on the provision of access allows providers the flexibility to work with patients with a wide range of backgrounds and IT adoption. We further believe that it prevents any negative unintended consequences of assumptions which may be placed on patients to use or not use various technologies. We believe that no patient should be excluded from access to their health

care information for any reason, especially reasons which would allow for a blanket exclusion of any patient based on a demographic factor. We note that we proposed to maintain our current policy, which applies to the Stage 2 Patient Electronic Access Objective, which requires that access be provided, even for those who choose to opt-out via providing them the information and resources they would need to opt back in. We further thank those commenters for their support of the expansion of the concept of access for patient-authorized representatives and note that this inclusion is designed to recognize the existing relationships and expand the access to information for family members and other caregivers who may serve as patient-authorized representatives. Patient-authorized representatives encompass both "personal representatives" as defined by HIPAA, as well as those authorized or designated by an individual.

Proposed Measures: EPs, eligible hospitals, and CAHs must satisfy both measures in order to meet the objective:

Proposed Measure 1: For more than 80 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):

(1) The patient (or patient-authorized representative) is provided access to view online, download, and transmit their health information within 24 hours of its availability to the provider; or

(2) The patient (or patient-authorized representative) is provided access to an ONC-certified API that can be used by third-party applications or devices to provide

patients (or patient-authorized representatives) access to their health information, within 24 hours of its availability to the provider.

We proposed that for measure 1, the patient must be able to access this information on demand, such as through a patient portal, personal health record (PHR), or API and have everything necessary to access the information even if they opt out. We proposed that all three functionalities (view, download, and transmit) or an API must be present and accessible to meet the measure. We further proposed that the functionality must support a patient's right to have his or her protected health information sent directly to a third party designated by the patient consistent with the provision of access requirements at 45 CFR 164.524(c) of the HIPAA Privacy Rule. However, we proposed that if the provider can demonstrate that at least one application that leverages the API is available (preferably at no cost to the patient) and that more than 80 percent of all unique patients have been provided instructions on how to access the information; the provider need not create, purchase, or implement redundant software to enable view, download, and transmit capability independently of the API.

To calculate the percentage, CMS and ONC worked together to define the following for the proposed measure:

Denominator: The number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of patients in the denominator who are provided access to information within 24 hours of its availability to the EP or eligible hospital/CAH.

Threshold: The resulting percentage must be more than 80 percent in order for a provider to meet this measure.

Exclusions: An EP may exclude from the measure if they have no office visits during the EHR reporting period.

Any EP that 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 may exclude the measure.

Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

Proposed Measure 2: The EP, eligible hospital or CAH must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Proposed Measure 2: To calculate the percentage, CMS and ONC worked together to define the following for this measure:

Denominator: The number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of patients in the denominator who were provided electronic access to patient-specific educational resources using clinically relevant information identified from CEHRT.

Threshold: The resulting percentage must be more than 35 percent in order for a provider to meet this measure.

Exclusions: An EP may exclude from the measure if they have no office visits during the EHR reporting period.

Any EP that 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 may exclude the measure.

Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

We proposed that both measures for this objective must be met using CEHRT.

Comment: A number of commenters expressed concern about the timeframe of

24 hours for the availability, stating that it was either too long for patients to wait or too short a time for providers to adequately review the information provided for accuracy and compliance with any concerns over disclosure of information, such as sensitive test results, mental health issues, or information which must be withheld in order to comply with state or local law.

Response: We appreciate this assessment and recognize that such a review may be required in certain cases where the disclosure or non-disclosure cannot simply be automated. We recognize that provider's workflows, especially for EPs in small practices, may be impacted in these instances where such a need arises. Therefore, we are instead finalizing that information must be included for access within 48 hours for EPs and are retaining the current 36 hours for eligible hospitals and CAHs. We note that this would allow for immediate availability for most patients where the provision of information can be automated and will provide adequate time for review processes for sensitive information by providers as necessary.

Comment: A number of commenters expressed skepticism about the maturity and security of API technology for patient electronic access, and noted that the ONC API certification process is not fully functional yet. In response to our request for comment regarding expansion of the patient engagement measures to include the use of application programming interfaces (APIs) in addition to, or in place of, a patient portal, one commenter referenced the JASON report and the Argonaut Project¹⁵ and expressed strong support the use of APIs to enhance interoperability, increase patient engagement,

¹⁵ JASON Report: http://www.healthit.gov/sites/default/files/ptp13-700hhs_white.pdf
Argonaut Project: <http://hl7.org/implement/standards/fhir/2015Jan/argonauts.html>

and ease the burden of EHR end users with respect to programming, updating, and maintenance. Some commenters expressed concern about the potential cost associated with API implementation.

Response: As noted, referencing the JASON report and Argonaut Project, the use of APIs in the health care industry represents an opportunity for both patients and providers to leverage technology to support the free flow of information in a dynamic and secure manner. This technology is already in widespread use in other industries with similar implementation challenges, such as finance, and the social IT environment includes the use of APIs in simple every day interactions. Some low-cost and even free API functions already exist in the health IT industry, and we expect third-party application developers to continue to create low-cost solutions that leverage APIs as part of their business models.

Further, we encourage health IT system developers to leverage the existing API platforms and applications as this would allow developers to immediately begin offering providers no-cost, or low-cost solutions to implement and enable an API as part of their current systems even prior to the implementation of Stage 3 in 2018.

In terms of cost, as we have stated in the past with the view, download, and transmit functions, we do not believe it would be appropriate for EPs and hospitals or CAHs to charge patients a fee for accessing their information using an API or VDT. We believe the economies of scale provided by enabling an API render the cost of use by an individual patient minimal and we do not believe that providing free access to patients represents a burden to the provider.

However, we recognize that the potential usage of APIs extends beyond the individual patient to other provider organizations, non-physician care settings, home health care, and many other uses. We recognize that under very high usage, it may be expensive to support APIs, and in those circumstances, providers may want to consider the feasibility of cost sharing arrangements with outside organizations or businesses, which frequently leverage the enabled API to support care coordination.

Comment: A few comments focused on Measure 2, the requirement to provide CEHRT-generated patient educational materials to patients. A commenter discussed how low patient adoption of portals/APIs makes it difficult to provide more than 35 percent of patients with electronic educational materials. Another commenter requested that--(1) the denominator be patients who have office visits rather than patients who are seen by an EP; and (2) providers who have less than 100 office visits during the EHR reporting period be excluded. Lastly, a commenter opposed only using CEHRT-generated patient educational materials and thought additional materials printed in-office by providers should be acceptable.

Response: We disagree that this measure threshold should be reduced or limited to office visits or that providers should be required or allowed to continue to count paper-based actions toward this measure. We believe that the provision of access to patient-specific education following a similar model as the provision of access to a patient's record will allow providers the opportunity to leverage a wide range of resources for patients and include this information in concert with the patient's electronic health record. We believe that as the technology continues to evolve providers will perform

well beyond the threshold and expect that innovative options will progress apace with this progress. We by no means intend to discourage providers from also using paper-based or other methods of providing patients with education about their health and their care. We are simply no longer requiring or allowing paper-based actions to be counted because the EHR Incentive Programs focuses on leveraging health IT to support patient engagement.

We are therefore finalizing Measure 2 as proposed for the method of delivery and with a modification to specify that for the numerator of for measure 2 for each year, the action must occur within the same calendar year as the EHR reporting period, but may occur before, during, or after the EHR reporting period if the EHR reporting period for the provider is less than a full calendar year. We note that the action must occur prior to the provider submitting their attestation if they attest prior to the end of the calendar year. For measure 1, we refer readers to the discussion on the Alternate Proposals for the measure immediately following.

Alternate Proposals:

For measure 1, we sought comment on the following set of alternate proposals for providers to meet the measure using the functions of CEHRT outlined previously in this section. These alternate proposals involve the requirements to use a view, download, and transmit function or an API to provide patients access to their health information.

Measure 1 as proposed would allow providers the option either to give patients access to the view, download, and transmit functionality, or to give patients access to an API.

Specifically, we sought comment on whether the API option should be required rather

than optional for providers, and if so, should providers also be required to offer the view, download, and transmit function.

Proposed Measure 1: For more than 80 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):

(1) The patient (or patient-authorized representative) is provided access to view online, download, and transmit their health information within 24 hours of its availability to the provider; or

(2) The patient (or the patient-authorized representative) is provided access to an ONC-certified API that can be used by third-party applications or devices to provide patients (or patient-authorized representatives) access to their health information, within 24 hours of its availability to the provider.

Alternate A: For more than 80 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):

(1) The patient (or the patient-authorized representative) is provided access to view online, download, and transmit his or her health information within 24 hours of its availability to the provider; and

(2) The patient (or patient-authorized representatives) is provided access to an ONC-certified API that can be used by third-party applications or devices to provide patients (or patient-authorized representatives) access to their health information within 24 hours of its availability to the provider.

Alternate B: For more than 80 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):

(1) The patient (or patient-authorized representative) is provided access to view online, download, and transmit their health information within 24 hours of its availability to the provider; and the patient (or patient-authorized representative) is provided access to an ONC-certified API that can be used by third-party applications or devices to provide patients (or patient-authorized representatives) access to their health information within 24 hours of its availability to the provider; or,

(2) The patient (or patient-authorized representatives) is provided access to an ONC-certified API that can be used by third-party applications or devices to provide patients (or patient-authorized representatives) access to their health information within 24 hours of its availability to the provider.

Alternate C: For more than 80 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), the patient (or patient-authorized representative) is provided access to an ONC-certified API that can be used by third-party applications or devices to provide patients (or patient-authorized representatives) access to their health information, within 24 hours of its availability to the provider.

We welcomed public comment on these proposals. We received the following comments and our response follows:

Comment: The majority of commenters who discussed APIs recommended that

the use of APIs be optional (for example, no requirement for both APIs and patient portals); most opposed making APIs mandatory. A few comments specifically noted that patient portals are already in place and it would be counterproductive and financially wasteful to force investment in APIs. Others also expressed skepticism about the maturity and security of API technology for patient electronic access, and noted that the ONC API certification process is not fully functional yet. Commenters noted that EPs, eligible hospitals, and CAHs have worked very hard to establish patient portals, and have encouraged patients to use them and that this effort has required an extraordinary effort in time and financial commitment. The commenters further stated that it would not make financial, strategic, or technical sense to abandon patient portals. They also stated that many patients who have begun to engage with their health record would not be willing to change their approach to obtaining their patient data, and while they may eventually eagerly accept and use alternatives, it will take time to transition them. Commenters requested maximum flexibility for this measure, noting that the stated goal of providing such flexibility means that the best alternative is to allow providers to choose whether to have a portal or an API, or both, but not to require both. Requiring APIs as a substitute for patient portals represents an overhaul of existing, expensive, and time-consuming technology. CMS should not require such an overhaul.

Response: As noted previously, we disagree that the API functionality cannot be implemented successfully by 2018 as the technology is already in widespread use in other industries and API functions already exist in the health IT industry. Within the Objective for Patient Electronic Access, we see the potential and need for multiple use cases, which

leverage a wide range of systems design, from the traditional patient portal to leveraged APIs, which allow providers and patients to expand information sharing among systems. Examples of these use cases could include a patient with a chronic condition seeking to combine records from multiple providers, home health care providers accessing records from multiple patients in real time, patients accessing a wide range of health information and scheduling appointments with or requesting refills from a single provider on a dedicated site, and many more. While we understand the commenters' concern about adding new technology in light of the investment already made in existing technology, we believe that patient access should not be limited to a single function, action or use case when multiple viable options are available to support a wider range of potential use. We believe that the investments that have been made in existing patient portals—serve a positive and necessary function, and those who invested in such portals should not abandon that investment. In addition, as noted previously, we believe that there are existing API options that can be leveraged to provide low-cost health IT solutions that diversify the technology pathways and expand the capacity of providers and patients to share health information. We believe these functions are compatible and complementary of each other and that the appropriate requirement is the inclusion of both concepts by supporting, all four possible actions for patients access (that is, view, download, transmit, and access data through an API).

After consideration of public comments received, we are finalizing the objective with a modification based on the change to the 24 hour requirement proposed as well as to better represent the functions of CEHRT use. For Measure 1 we are finalizing

Alternate A which includes the requirement that providers offer all four functionalities (view, download, transmit, and access through API) to their patients. We further specify that any patient health information must be made available to the patient within 48 hours of its availability to the provider for an EP and 36 hours of its availability to the provider for an eligible hospital or CAH. For measure two, we are finalizing measure a modification to the numerator to specify the timing of the action in relation to the EHR reporting period.

Objective 5: Patient Electronic Access to Health Information

Objective: The EP, eligible hospital or CAH provides patients (or patient-authorized representative) with timely electronic access to their health information and patient-specific education.

Measure 1: For more than 80 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):

- (1) The patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and
 - (2) The provider ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the provider's CEHRT.
- Denominator: The number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

- **Numerator**: The number of patients in the denominator (or patient-authorized representative) who are provided timely access to health information to view online, download, and transmit to a third party and to access using an application of their choice that is configured meet the technical specifications of the API in the provider's CEHRT.
- **Threshold**: The resulting percentage must be more than 80 percent in order for a provider to meet this measure.

Measure 2: The EP, eligible hospital or CAH must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

- **Denominator**: The number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.
- **Numerator**: The number of patients in the denominator who were provided electronic access to patient-specific educational resources using clinically relevant information identified from CEHRT during the EHR reporting period.
- **Threshold**: The resulting percentage must be more than 35 percent in order for a provider to meet this measure.

Exclusions: A provider may exclude the measures if one of the following apply:

- An EP may exclude from the measure if they have no office visits during the EHR reporting period.
- Any EP that 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 may exclude the measure.
- Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

We are adopting Objective 5: Patient Electronic Access at § 495.24(d)(5)(i) for EPs and § 495.24(d)(5)(ii) for eligible hospitals and CAHs. We further specify that in order to meet this objective and measures, an EP, eligible hospital, or CAH must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 6: Coordination of Care through Patient Engagement

For Stage 3, as previously noted, we proposed to incorporate the Stage 2 objectives related to providing patients with access to health information into a new Stage 3 objective entitled, "Patient Electronic Access" (see section II.B.2.b.v). For this objective 6 entitled "Coordination of Care through Patient Engagement," we proposed to

incorporate the policy goals of the Stage 2 objectives related to secure messaging, patient reminders, and the measure of patient engagement requiring patients (or their authorized representatives) to view, download, and transmit their health information using the functionality of the CEHRT.

Proposed Objective: Use communications functions of CEHRT to engage with patients or their authorized representatives about the patient's care.

The Stage 3 proposed rule focused on encouraging the use of EHR functionality for secure dialogue and efficient communication between providers, care team members, and patients about their care and health status, as well as important health information such as preventative and coordinated care planning. Similar to the Patient Electronic Access Objective, we also proposed to expand the options through which providers may engage with patients under the Medicare and Medicaid EHR Incentive Programs including the use of APIs. An API can enable a patient—through a third-party application—to access and retrieve their health information from a care provider in a way that is most valuable to that patient. We proposed the Coordination of Care through Patient Engagement Objective for Stage 3 to support this provider and patient engagement continuum based on the foundation already created within the EHR Incentive Programs but using new methods and expanded options to advance meaningful patient engagement and patient-centered care. We also proposed that for purposes of this objective, patient engagement may include patient-centered communication between and among providers facilitated by authorized representatives of the patient and of the EP, eligible hospital, or CAH.

We proposed three measures for this objective, which are discussed below. We proposed that providers must attest to the numerator and denominator for all three measures, but would only be required to successfully meet the threshold for two of the three proposed measures to meet the Coordination of Care through Patient Engagement Objective.

Comment: Commenters supported the concept of patient engagement and promoting communication among provider and patients. Also, commenters supported the changes we proposed to expand the technologies and methods by which providers and patients can leverage technology to support communication and care coordination. Commenters also commended us for the provision allowing providers to attest to all three measures but only meet the threshold for 2 of the 3 in order to pass the measure. Comments stated that this would allow us to collect meaningful data but not penalize providers for variation in their patient populations or other factors that might impact their performance.

Response: We thank the commenters for their support of the objective and our approach to provide flexibility while continuing to encourage a wide range of use cases for patient engagement. We agree that the open communication between provider and patient is a fundamental factor in patient-centered care and effective care coordination. This was a driver behind our proposal for this objective to improve and enhance the channels of communication through supporting health IT solutions.

Comment: Some commenters disagreed with our approach and stated that we should not enforce provider and patient communication through the use of health IT. Commenters claimed that elderly populations, economically disadvantaged populations,

patients living in rural areas, and patients with disabilities may not want to use technology to engage with their provider and this makes the requirement unfair to providers serving these patient populations.

Response: First, we disagree that any universal demographic factor would prohibit a patient from using or leveraging technology to communicate with a provider. ONC's research found that there were no significant differences in use of online medical records by age, race/ethnicity, education or setting.¹⁶ We note that assistive technologies, telemedicine technologies, and affordable mobile technologies already exist in the marketplace to serve a wide range of individuals coming from a wide range of backgrounds and we believe that health IT communications technologies will find similar utilization. Second, we recognize that technology supported communication may not be adopted by each patient, which is why we did not propose requiring that a provider ensure all patients actually take action and engage in this manner. However, we note that we do not believe that potential challenges to online or electronic communications are in any way more significant than the existing challenges to communication posed by the current limited channels available. Nor do we note a causal relationship or correlation between communications challenges and a diminished need or interest in communicating with one's provider. Therefore, we are aiming to support a wide range of communication channels, technologies, and approaches to support many use cases.

¹⁶ ONC Data Brief June 2015 healthit.gov

Proposed Measure 1: During the EHR reporting period, more than 25 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) actively engage with the electronic health record made accessible by the provider. An EP, eligible hospital or CAH may meet the measure by either:

(1) More than 25 percent of all unique patients (or patient-authorized representatives) seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period view, download or transmit to a third party their health information; or

(2) More than 25 percent of all unique patients (or patient-authorized representatives) seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period access their health information through the use of an ONC-certified API that can be used by third-party applications or devices.

Proposed Option 1: View, Download, or Transmit to a Third Party

Denominator: Number of unique patients seen by the EP, or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of unique patients (or their authorized representatives) in the denominator who have viewed online, downloaded, or transmitted to a third party the patient's health information.

Threshold: The resulting percentage must be more than 25 percent in order for an

EP, eligible hospital, or CAH to meet this measure.

Proposed Option 2: API

Denominator: The number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of unique patients (or their authorized representatives) in the denominator who have accessed their health information through the use of an ONC-certified API.

Threshold: The resulting percentage must be more than 25 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusions: Applicable for either option discussed previously, the following providers may exclude from the measure:

- Any EP who has no office visits during the EHR reporting period may exclude from the measure.
- Any EP that 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 FCC¹⁷ on the first day of the EHR reporting period may exclude from the measure.
- Any eligible hospital or CAH operating in a location that does not have 50 percent or more of its housing units with 4Mbps broadband availability

¹⁷www.broadbandmap.gov

according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measure.

For measure 1, for the API option, we proposed that providers must attest that they have enabled an ONC-certified API and that at least one application, which leverages the API, is available to patients (or the patient-authorized representatives) to retrieve health information from the provider's CEHRT. We also stated that we recognize that there may be inherent challenges in measuring patient access to CEHRT through third-party applications that utilize an ONC-certified API, and we solicited comment on the nature of those challenges and what solutions can be put in place to overcome them. We also solicited comment on suggested alternate proposals for measuring patient access to CEHRT through third-party applications that utilize an API, including the pros and cons of measuring a minimum number of patients (one or more) who must access their health information through the use of an API in order to meet the measure of this objective.

Comment: Similar to the objective in general, a large number of commenters opposed this measure stating providers should not be held accountable for patient action. However, those commenters in support of the measure concept recommended that it be measured as a combination of use cases rather than independently for each function. These commenters approved the inclusion of the API function noting that it offers greater flexibility for patients, but stated that providers should not be required to meet separate thresholds for patient use of the different functions. They stated that the use of APIs is currently self-selective among patient populations, which skew the provider's ability to

push their use universally. Additionally, they noted issues related to independently counting the usage of a function. For example, an API may not be designed to recognize individual instances of use separately over time; it may not independently recognize an action which might also meet the view, download, or transmit actions; or it may prohibit providers who wish to switch to an API assisted VDT system from being able to also meet a separate VDT threshold. However, both commenters in support of the measure and opposed to the measure suggested a lower threshold in order to ensure that providers can meet the requirements by 2018. Some commenters suggested an approach where the threshold increases over time to allow providers to work toward incrementally increased levels. Commenters noted that this would allow providers more time to innovate workflows and methods to overcome barriers to patient engagement.

Response: As noted previously, we disagree that providers have no role in influencing patient engagement. In this new measure for Stage 3, we are seeking to enhance a provider's ability to influence patient engagement by providing a wider range of technologies and methods for a patient's use. We agree with the commenters' recommendation against independent thresholds for the functions within the objective and reiterate our view that there are four actions a patient might take:

1. View their information.
2. Download their information.
3. Transmit their information to a third party.
4. Access their information through an API.

We further agree that these actions may overlap and that a provider should be able

to count any and all actions in the single numerator. Therefore, we believe it is a reasonable modification to change the first measure to state that a provider may meet a combined threshold of for VDT and API actions or if their technology functions overlap then any and view, download, transmit, or API actions taken by the patient using CEHRT would count toward the threshold.

We do agree that the threshold should represent a goal, but that we should seek to set a goal that will be attainable for providers who make the effort to achieve this measure. As noted in section II.B.1.b.(4)(b)(iv) of this final rule with comment period, we adopted a phased approach for the two measures related to patient action for reporting in 2015 through 2017 (Objective 8 - Patient Electronic Access measure 2 and the Objective 9 - Secure Electronic Messaging.) This phased approach includes a 5 percent threshold in 2017, and we believe it is appropriate to adopt a 5 percent threshold for measures 1 of this objective also (Objective 6- Coordination of Care through Patient Engagement) for an EHR reporting period in 2017. We believe that the primary barrier to performance on the measure is the lag in the adoption of technology by patients as well as the influence of self-selective participation. We further believe that these influences can be mitigated by providing additional time for the technologies to mature as noted in our rationale for adoption of the phased approach. Therefore, it is appropriate for the 5 percent threshold in 2017 to apply for all applicable measures based on the timeline established.

We believe that 10 percent is a reasonable threshold for providers participating in 2018 as compared to the proposed 25 percent threshold, and should be attainable by providers. In addition, we will continue to monitor performance on the measure to determine if any

further adjustment is needed prior to 2018 and to potentially set another incremental increase toward the proposed 25 percent threshold in a subsequent year.

Proposed Measure 2: For more than 35 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient's authorized representatives), or in response to a secure message sent by the patient (or the patient's authorized representative).

Denominator: Number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of patients in the denominator for whom a secure electronic message is sent to the patient, the patient's authorized representatives, or in response to a secure message sent by the patient.

Threshold: The resulting percentage must be more than 35 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusion: Any EP who has no office visits during the EHR reporting period may exclude from the measure.

Any EP that 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 may exclude from the measure.

Any eligible hospital or CAH operating in a location 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 may exclude from the measure.

For measure 2, we proposed that "communicate" means when a provider sends a message to a patient (or the patient's authorized representatives) or when a patient (or the patient's authorized representatives) sends a message to the provider. In patient-to-provider communication, the provider must respond to the patient (or the patient's authorized representatives) for purposes of this measure. We further proposed to include in the measure numerator situations where providers communicate with other care team members using the secure messaging function of CEHRT, and the patient is engaged in the message and has the ability to be an active participant in the conversation between care providers. However, we sought comment on how this action could be counted in the numerator, and the extent to which that interaction could or should be counted for eligible providers engaged in the communication. In addition, we sought comment on what should be considered a contribution to the patient-centered communication; for example, a contribution must be active participation or response, a contribution may be viewing the communication, or a contribution may be simple inclusion in the communication.

We specified that the secure messages sent should contain relevant health information specific to the patient in order to meet the measure of this objective. We believe the provider is the best judge of what health information should be considered

relevant in this context. We noted that messages with content exclusively relating to billing questions, appointment scheduling, or other administrative subjects should not be included in the numerator. For care team secure messaging with the patient included in the conversation, we also believe the provider may exercise discretion if further communications resulting from the initial action should be excluded from patient disclosure to prevent harm. We noted that if such a message is excluded, all subsequent actions related to that message would not count toward the numerator.

Comment: Commenters overwhelmingly supported our approach to the redesigned secure electronic messaging objective for Stage 3. Specifically, commenters noted that this more dynamic, multi-directional objective is a better approach for meeting the underlying goal of effective provider-patient communication than our prior Stage 2 objective.

Specifically, commenters also supported the ability for providers to select to focus on this measure rather than on measure 1 as for some specialists, the ability to quickly and effectively communicate with a patient and other care team members is paramount. These commenters noted that for their patients, the information they provide through VDT is often duplicative of that provided by the patient's primary care provider. However, they note they often receive request for clarification around specific results or recommendations so the ability to provide that support through secure messaging with the patient and other care team members is a significant benefit.

Some commenters opposed the measure in general, again highlighting that providers should not be held accountable for patient action. Still others disagreed with

the requirement that a provider must respond to a patient-initiated communication in order for such an action to count in the numerator.

Again, commenters both opposed to and in support of the measure suggested a lower threshold to ensure the measure is attainable for providers who make the effort to engage in this action. Finally, some commenters requested clarity about what the content of the message needs to be to count toward the numerator.

Response: We appreciate the support and agree with the commenters' assessment that the Stage 2 objective did not fully meet the intended goal of secure messaging. We agree that this proposed objective supports a wider range of use and a more effective method of communication for providers and patients.

We disagree that this proposed measure holds providers accountable for patient action, as the Stage 3 proposed measure specifically puts the control over communications in the hands of the provider. For this measure, we proposed to include provider-initiated communications, provider-to-provider communications if the patient is included, and allows the provider to count any patient-initiated communication if the provider responds to the patient (80 FR 16757). We disagree that the provider should not be required to respond to the patient in order to meet the measure, the goal of the measure is to promote provider-patient communication where the action driving the communication rests with provider initiated communication. We note that this does not require the provider to respond to every message received if no response is necessary. In addition, the denominator is not based on the number of messages received from the patient nor are patient-initiated messages required to meet the measure. Therefore we

believe that it is reasonable to only allow providers to count messages in the numerator when the provider participates in the communication, in this case by responding to the patient.

Again, we do agree that the threshold should represent a goal, but that we should seek to set a goal that will be attainable for providers who make the effort to achieve this measure. As discussed for Measure 1, we adopted a phased approach for the two measures related to patient action for reporting in 2015 through 2017 (Objective 8 - Patient Electronic Access measure 2 and the Objective 9 - Secure Electronic Messaging.) This phased approach includes a 5 percent threshold in 2017 and we believe it is appropriate to adopt a 5 percent threshold for measures 2 of this objective (Stage 3 Objective 6 - Coordination of Care through Patient Engagement) for an EHR reporting period in 2017. In this case, it is not the barrier of patient action which is a potential risk factor, as the measure itself has been changed, but instead the adoption of new CEHRT and implementing the related workflows which would be required for providers participating in Stage 3 in 2017. We also believe a 25 percent threshold would be an attainable goal for providers in 2018 because the measure focuses on provider-initiated action and offers multiple paths for success; while the reduction from 35 percent reduces the risk of failure for those providers who may require additional time to implement the functions and workflows within their practice. As stated in the Stage 3 proposed rule (80 FR 16757), the types of communications which cannot count toward the measure are communications dealing exclusively with billing, appointment scheduling, or other administrative processes.

Proposed Measure 3: Patient-generated health data or data from a non-clinical setting is incorporated into the CEHRT for more than 15 percent of all unique patients seen by the EP or discharged by the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Denominator: Number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of patients in the denominator for whom data from non-clinical settings, which may include patient-generated health data, is captured through the CEHRT into the patient record.

Threshold: The resulting percentage must be more than 15 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusion: Any EP who has no office visits during the EHR reporting period may exclude from the measure.

Any EP that 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 may exclude from the measure.

Any eligible hospital or CAH operating in a location 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 may exclude from the measure.

For measure 3, we noted that the use of the term "clinical" means different things in relation to place of service for billing for Medicare and Medicaid services. However, for purposes of this measure only, we proposed that a non-clinical setting be defined as a setting with any provider who is not an EP, eligible hospital or CAH as defined for the Medicare and Medicaid EHR Incentive Programs and where the care provider does not have shared access to the EP, eligible hospital, or CAH's CEHRT. This may include, but is not limited to, health and care-related data from care providers such as nutritionists, physical therapists, occupational therapists, psychologists, and home health care providers, as well as data obtained from patients themselves. We specifically noted this last item and referred to this sub-category as patient-generated health data, which may result from patient self-monitoring of their health (such as recording vital signs, activity and exercise, medication intake, and nutrition), either on their own, or at the direction of a member of the care team.

We sought comment on how the information for measure 3 could be captured, standardized, and incorporated into an EHR. For the purposes of this measure, the types of data that would satisfy the measure is broad. It may include, but is not limited to, social service data, data generated by a patient or a patient's authorized representative, advance directives, medical device data, home health monitoring data, and fitness monitor data.

We also sought comment on whether this proposed measure should have a denominator limited to patients with whom the provider has multiple encounters, such as unique patients seen by the provider two or more times during the EHR reporting period.

We also sought comment on whether this measure should be divided into two distinct measures—for example, (1) patient-generated health data, or data generated predominantly through patient self-monitoring rather than by a provider; and (2) all other data from a non-clinical setting. This would result in the objective including four measures, with providers having an option of which two measures to focus on for the EHR reporting period.

We also sought comment on whether the third measure should be proposed for eligible hospitals and CAHs, or remain an option only for eligible professionals. For those commenters who believe it should not be applicable for eligible hospitals and CAHs, we sought further comment on whether eligible hospitals and CAHs should then choose one of the remaining two measures or be required to attest to both. We received the following comments and our response follows:

Comment: Commenters were supportive of the concept of the measure with a specific emphasis on the ability to incorporate this type of data into a patient record. Commenters felt this measure specifically supports chronic disease management and care coordination. Commenters recommended that the denominator be limited to two or more visits in a year, which would make the measure more relevant for hospitals and CAHs as well as some types of specialists. Commenters recommended against splitting the measure into two parts and noted that the threshold proposed is too high for a measure that is entirely new.

A number of commenters opposed the measure, expressed concern over the efficacy of data originating from a source other than a clinician, stated that patient

generated data is not relevant to their practice, or stated that all data is patient generated so the measure is useless.

Most commenters requested further information on what types of data would count toward the measure. Some commenters asked if provider questionnaires sent via secure message might count while others asked if patient self-assessment screenings done in the physician's office may count. Some commenters questioned whether a patient that provided information on family health history may count toward the measure if the information were provided outside an office visit via an electronic means. Finally, commenters requested an episodic designation for the measure to identify when the inclusion of such information must occur and if the inclusion must be repetitive for each EHR reporting period.

Response: We thank the commenters for their input. We agree with the recommendation to maintain a single measure as we believe this best represents the goal of the policy to support the use of CEHRT to incorporate many kinds of data into a comprehensive record for each patient. We are declining the recommended changes to limit the denominator as we believe a wider range is more suitable. However, we agree with the recommendation to reduce the required threshold for this new measure and function to promote adoption with an attainable goal. We are therefore reducing the threshold to 5 percent for the measure. For the purposes of this measure, we note our intent as stated in the Stage 3 proposed rule (80 FR 16757) that the types of data that would satisfy the measure are broad. It may include, but is not limited to, social service data, data generated by a patient or a patient's authorized representative, advance

directives, medical device data, home health monitoring data, and fitness monitor data. In addition, the sources of data vary and may include mobile applications for tracking health and nutrition, home health devices with tracking capabilities such as scales and blood pressure monitors, wearable devices such as activity trackers or heart monitors, patient-reported outcome data, and other methods of input for patient and non-clinical setting generated health data. We emphasized that these represent several examples of the data types that could be covered under this measure. We note that providers in non-clinical settings may include, but are not limited to, care providers such as nutritionists, physical therapists, occupational therapists, psychologists, and home health care providers. Other key providers in the care team such as behavioral health care providers, may also be included, and we encourage providers to consider ways in which this measure can incorporate this essential information from the broader care team. We also note, as stated in the Stage 3 proposed rule, while the scope of data covered by this proposed measure is broad, it may not include data related to billing, payment, or other insurance information (80 FR 16757).

We also disagree with the suggestion that the data may be information the patient provides to the EP, eligible hospital or CAH on location during the office visit or hospital stay as such data does not meet the intent of the measure to support care coordination and patient engagement in a wide range of settings outside the provider's immediate scope of practice. However, we agree that if a patient separately provides clinical information including family health history and the information noted previously through other means, that such information may count toward the numerator if it is incorporated into

the patient record using the adopted specifications for CEHRT for the measure.

With regard to the efficacy of the data, we do not specify the manner in which providers are required to incorporate the data. Providers may work with their EHR developers to establish the methods and processes which work best for their practice and needs. We note that in cases where the data provided can be easily incorporated in a structured format or into an existing field within the EHR (such as a C-CDA or care team member reported vital signs or patient reported family health history and demographic information) the provider may elect to do so. Alternately, a provider may maintain an isolation between the data and the patient record and instead include the data by other means such as attachments, links, and text references again as best meets their needs. We believe there may be a wide range of potential methods by which a provider may ensure the data is relevant for their needs and that provenance and purpose are identified.

Finally, we note that measure 3 includes longitudinal measurement within the EHR reporting period, rather than purely episodic measurement. This means that for more than 5 percent of unique patients during the EHR reporting period, this information must be included. If information is obtained and incorporated for a patient following their first visit during the EHR reporting period, the provider may count the patient in the numerator even if no further information is provided after a subsequent visit.

After consideration of public comments received, we are finalizing the objective with a modification to remove the reference to communications functions due to the adoption of the use of an API (which is broader than a communication function). We are finalizing the exclusions as proposed and the measures with the modifications for the

threshold as previously discussed. We are finalizing that providers must attest to all three measures and must meet the thresholds for at least two measures to meet the objective.

We are adopting finalizing the objective and measures as follows:

Objective 6: Coordination of Care through Patient Engagement

Objective: Use CEHRT to engage with patients or their authorized representatives about the patient's care.

Measure 1: During the EHR reporting period, more than 10 percent of all unique patients (or their authorized representatives) seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) actively engage with the electronic health record made accessible by the provider and either:

- (1) view, download or transmit to a third party their health information; or
- (2) access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's CEHRT; or
- (3) a combination of (1) and (2).

- Denominator: Number of unique patients seen by the EP, or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.
- Numerator: The number of unique patients (or their authorized representatives) in the denominator who have viewed online, downloaded, or transmitted to a third party the patient's health information during the EHR reporting period and the number of unique patients (or their authorized representatives) in the denominator who have accessed their health information through the use of an API during the EHR reporting period.
- Threshold for 2017: The resulting percentage must be more than 5 percent.

- Threshold for 2018 and Subsequent Years: The resulting percentage must be more than 10 percent.

Measure 2: For more than 25 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient or their authorized representative. For an EHR reporting period in 2017, the threshold for this measure is 5 percent rather than 25 percent.

- Denominator: Number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.
- Numerator: The number of patients in the denominator for whom a secure electronic message is sent to the patient (or patient-authorized representative) or in response to a secure message sent by the patient (or patient-authorized representative), during the EHR reporting period.
- Threshold in 2017: The resulting percentage must be more than 5 percent in order for an EP, eligible hospital, or CAH to meet this measure
- Threshold in 2018 and Subsequent Years: The resulting percentage must be more than 25 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Measure 3: Patient generated health data or data from a nonclinical setting is incorporated into the CEHRT for more than 5 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department

(POS 21 or 23) during the EHR reporting period.

- Denominator: Number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.
- Numerator: The number of patients in the denominator for whom data from non-clinical settings, which may include patient-generated health data, is captured through the CEHRT into the patient record during the EHR reporting period.
- Threshold: The resulting percentage must be more than 5 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusions: A provider may exclude the measures if one of the following apply:

- An EP may exclude from the measure if they have no office visits during the EHR reporting period.
- Any EP that 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 may exclude the measure.
- Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

We are adopting Objective 6: Coordination of Care Through Patient Engagement at § 495.24(d)(6)(i) for EPs and § 495.24(d)(6)(ii) for eligible hospitals and CAHs. We

further specify that in order to meet this objective and measures, an EP, eligible hospital, or CAH must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 7: Health Information Exchange

In the Stage 3 proposed rule 80 FR 16758, we stated that improved communication between providers caring for the same patient can help providers make more informed care decisions and coordinate the care they provide. Electronic health records and the electronic exchange of health information, either directly or through health information exchanges, can reduce the burden of such communication. We noted that the purpose of the proposed objective is to ensure a summary of care record is transmitted or captured electronically and incorporated into the EHR for patients seeking care among different providers in the care continuum, and to encourage reconciliation of health information for the patient. We further stated that the proposed objective promotes interoperable systems and supports the use of CEHRT to share information among care teams.

Proposed Objective: The EP, eligible hospital, or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, retrieves a summary of care record upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of CEHRT.

In the Stage 2 final rule at 77 FR 53983, we described transitions of care as the movement of a patient from one setting of care (hospital, ambulatory primary care practice, ambulatory specialty care practice, long-term care, home health, rehabilitation facility) to another. For additional information, see section II.B.1.b.(4).(f) of this final rule with comment period. Referrals are cases where one provider refers a patient to another provider, but the referring provider also continues to provide care to the patient. We also recognized there may be circumstances when a patient refers himself or herself to a setting of care without a provider's prior knowledge or intervention. These referrals may be included as a subset of the existing referral framework and they are an important part of the care coordination loop for which summary of care record exchange is integral. Therefore, a provider should include these instances in their denominator for the measures if the patient subsequently identifies the provider from whom they received care. In addition, the provider may count such a referral in the numerator for each measure if they undertake the action required to meet the measure upon disclosure and identification of the provider from whom the patient received care.

In the Stage 2 final rule, we indicated that a transition or referral within a single setting of care does not qualify as a transition of care (77 FR 53983). We received public comments and questions requesting clearer characterization of when a setting of care can be considered distinct from another setting of care. For example, questions arose whether EPs who work within the same provider practice are considered the same or two distinct settings of care. Similarly, questions arose whether an EP who practices in an outpatient setting that is affiliated with an inpatient facility is considered a separate entity.

Therefore, in the Stage 3 proposed rule at 80 FR 16759 for the purposes of distinguishing settings of care in determining the movement of a patient, we explained that for a transition or referral, it must take place between providers which have, at minimum, different billing identities within the EHR Incentive Programs, such as different National Provider Identifiers (NPI) or hospital CMS Certification Numbers (CCN) to count toward this objective.

Please note that a "referral" as defined here only applies to the EHR Incentive Programs and is not applicable to other federal regulations.

We stated in the Stage 2 final rule at 77 FR 13723 that if the receiving provider has access to the medical record maintained by the provider initiating the transition or referral, then the summary of care record would not need to be provided and that patient may be excluded from the denominators of the measures for the objective. We further noted that this access may vary from read-only access of a specific record, to full access with authoring capabilities, depending on provider agreements and system implementation among practice settings. In many cases, a clinical care summary for transfers within organizations sharing access to an EHR may not be necessary, such as a hospital sharing their CEHRT with affiliated providers in ambulatory settings who have full access to the patient information. However, public comments received and questions submitted by the public on the Stage 2 Summary of Care Objective reveal that there may be benefits to the provision of a summary of care document following a transition or referral of a patient, even when access to medical records is already available. For example, a summary of care document would notify the receiving provider of relevant

information about the latest patient encounter as well as highlight the most up-to-date information. In addition, the "push" of a summary of care document may function as an alert to the recipient provider of the transition that a patient has received care elsewhere and would encourage the provider to review a patient's medical record for follow-up care or reconciliation of clinical information.

Therefore, we proposed to revise this objective for Stage 3 to allow the inclusion of transitions of care and referrals in which the recipient provider may already have access to the medical record maintained in the referring provider's CEHRT, as long as the providers have different billing identities within the EHR Incentive Program. We noted that for a transition or referral to be included in the numerator, if the receiving provider already has access to the CEHRT of the initiating provider of the transition or referral, simply accessing the patient's health information does not count toward meeting this objective. However, if the initiating provider also creates and sends a summary of care document, this transition can be included in the denominator and the numerator, as long as this transition is counted consistently across the organization.

Proposed Measures: We proposed that providers must attest to the numerator and denominator for all three measures, but would only be required to successfully meet the threshold for two of the three proposed measures to meet the Health Information Exchange Objective.

Proposed Measure 1: For more than 50 percent of transitions of care and referrals, the EP, eligible hospital or CAH that transitions or refers their patient to another

setting of care or provider of care: (1) creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.

Proposed Measure 2: For more than 40 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP, eligible hospital or CAH incorporates into the patient's EHR an electronic summary of care document from a source other than the provider's EHR system.

Proposed Measure 3: For more than 80 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP, eligible hospital, or CAH performs a clinical information reconciliation. The provider must implement clinical information reconciliation for the following three clinical information sets:

- Medication. Review of the patient's medication, including the name, dosage, frequency, and route of each medication.

- Medication allergy. Review of the patient's known medication allergies.

- Current Problem list. Review of the patient's current and active diagnoses.

For the first measure, we maintained the requirements established in the Stage 2 final rule to capture structured data within the certified EHR and to generate a summary of care document using CEHRT for purposes of this measure (77 FR 54014). For purposes of this measure, we required that the summary of care document created by CEHRT be sent electronically to the receiving provider.

In the Stage 2 final rule at 77 FR 54016, we specified all summary of care documents must include the following information in order to meet the objective, if the provider knows it:

- Patient name.
- Referring or transitioning provider's name and office contact information

(EP only).

- Procedures.
- Encounter diagnosis.
- Immunizations.
- Laboratory test results.
- Vital signs (height, weight, blood pressure, BMI).
- Smoking status.
- Functional status, including activities of daily living, cognitive and disability

status.

- Demographic information (preferred language, sex, race, ethnicity, date of

birth).

- Care plan field, including goals and instructions.
- Care team including the primary care provider of record and any additional

known care team members beyond the referring or transitioning provider and the receiving provider.

- Discharge instructions (Eligible hospitals and CAHs Only).
- Reason for referral (EP only).

For the 2015 Edition proposed rule, ONC proposed a set of criteria called the Common Clinical Data Set that include the required elements for the summary of care document, the standards required for structured data capture of each, and further definition of related terminology and use. Therefore, for Stage 3 of meaningful use we proposed that summary of care documents used to meet the Stage 3 Health Information Exchange objective must include the requirements and specifications included in the CCDS specified by ONC for certification to the 2015 Edition proposed rule.

In the Stage 3 proposed rule (80 FR 16760), we stated that the CCDS may include additional fields beyond those initially required for Stage 2 of meaningful use as new standards are developed to accurately capture vital information on patient health. For example, the 2015 Edition proposed rule includes a criterion and standard for capturing the unique device identifier (UDI) for implantable medical devices .As we noted in the Stage 3 proposed rule at 80 FR 16760, we believe the inclusion of the UDI in the CCDS reflects the understanding that UDIs are an important part of patient information that should be exchanged and available to providers who care for patients with implanted medical devices. The documentation of UDIs in a patient medical record and the inclusion of that data field within the CCDS requirements for the summary of care documents is a key step toward improving the quality of care and ensuring patient safety. This example highlights the importance of capturing health data in a structured format using specified, transferable standards. For further information on the CCDS standards , please see ONC's 2015 Edition final rule, published elsewhere in this issue of the **Federal Register**. In circumstances where there is no information available to

populate one or more of the fields included in the CCDS, either because the EP, eligible hospital, or CAH can be excluded from recording such information (for example, vital signs) or because there is no information to record (for example, laboratory tests) the EP, eligible hospital, or CAH may leave the field blank and still meet the requirements for the measure.

However, all summary of care documents used to meet this objective must be populated with the following information using the CCDS certification standards for those fields:

- Current problem list (Providers may also include historical problems at their discretion).
- Current medication list.
- Current medication allergy list.

We defined allergy in the proposed rule as an exaggerated immune response or reaction to substances that are generally not harmful (80 FR 16760). Information on problems, medications, and medication allergies could be obtained from previous records, transfer of information from other providers (directly or indirectly), diagnoses made by the EP or hospital, new medications ordered by the EP or in the hospital, or through querying the patient.

We proposed to maintain that all summary of care documents contain the most recent and up-to-date information on all elements. In the event that there are no current diagnoses for a patient, the patient is not currently taking any medications, or the patient has no known medication allergies; the EP, eligible hospital, or CAH must record or

document within the required fields that there are no problems, no medications, or no medication allergies recorded for the patient to satisfy the measure of this objective. The EP or hospital must verify that the fields for problem list, medication list, and medication allergy list are not blank and include the most recent information known by the EP, eligible hospital, or CAH as of the time of generating the summary of care document.

In the Stage 3 proposed rule 80 FR 176760, we encouraged providers to send a list of items that he or she believes to be pertinent and relevant to the patient's care, rather than a list of all problems, whether active or resolved, that have ever populated the problem list. While a current problem list must always be included, the provider can use his or her judgment in deciding which items historically present on the problem list, medical history list (if it exists in CEHRT), or surgical history list are relevant given the clinical circumstances.

Similarly, we noted comments from stakeholders and through public forums and correspondence on the potential of allowing only clinically relevant laboratory test results and clinical notes (rather than all laboratory tests results and clinical notes) in the summary of care document for purposes of meeting the objective. We stated our belief that while there may be a benefit and efficiency to be gained in the potential to limit laboratory test results or clinical notes to those most relevant for a patient's care; a single definition of clinical relevance may not be appropriate for all providers, all settings, or all individual patient diagnosis. Furthermore, we noted that should a reasonable limitation around a concept of "clinical relevance" be added, a provider must still have the CEHRT functionality to include and send all labs or clinical notes. Therefore, we proposed to

defer to provider discretion on the circumstances and cases in which a limitation around clinical relevance may be beneficial and note that such a limitation would be incumbent on the provider to define and develop in partnership with their health IT developer as best fits their organizational needs and patient population. In the Stage 3 proposed rule 80 FR 16760 we further specified our proposal that while the provider has the discretion to define the relevant clinical notes or relevant laboratory results to send as part of the summary of care record, to state that providers must be able to provide all clinical notes or laboratory results through an electronic transmission of a summary of care document if that level of detail is subsequently requested by a provider receiving a transition of care or referral or the patient is transitioning to another setting of care. We noted that this proposal would apply for lab results, clinical notes, problem lists, and the care plan within the summary of care document.

For the second measure, we proposed to address the other end of the transition of care continuum. In the Stage 2 final rule, we limited the action required by providers to sending an electronic transmission of a summary of care document (77 FR 54017 through 54018). We did not have a related requirement for the recipient of that transmission. We did not adopt a certification requirement for the receiving end of a transition or referral or for the measure related to sending the summary, as that is a factor outside the sending provider's immediate control. However, in Stage 3 of meaningful use, we proposed a measure for the provider as the recipient of a transition or referral requiring him or her to actively seek to incorporate an electronic summary of care document into the patient record when a patient is referred to them or otherwise transferred into their care. This

proposal was designed to complete the electronic transmission loop and support providers in using CEHRT to support the multiple roles a provider plays in meaningful health information exchange.

For the purposes of defining the cases in the denominator, we proposed that what constitutes "unavailable" and, therefore, may be excluded from the denominator, will be that a provider--

- Requested an electronic summary of care record to be sent and did not receive an electronic summary of care document; and
- Queried at least one external source via HIE functionality and did not locate a summary of care for the patient, or the provider does not have access to HIE functionality to support such a query.

We sought comment on whether electronic alerts received by EPs from hospitals when a patient is admitted, seen in the emergency room or discharged from the — hospital--so called "utilization —alerts"--should be included in measure 2two, or as a separate measure. Use of this form of health information exchange is increasingly rapidly, driven by hospital and EP efforts to improve care transitions and reduce readmissions. We also sought comment on which information from a utilization alert would typically be incorporated into a patient's record and how this is done today.

For both the first and second measures, we proposed that a provider may use a wide range of health IT systems for health information exchange to receive or send an electronic summary of care document, but must use their certified EHR technology to create the summary of care document sent or to incorporate the summary of care

document received into the patient record. We also proposed that the receipt of the summary of care document may be passive (provider is sent the C-CDA and incorporates it) or active (provider requests a direct transfer of the C-CDA or provider queries an HIE for the C-CDA). In the Stage 2 proposed rule, we noted the benefits of requiring standards for the transport mechanism for health information exchange consistently nationwide (77 FR 13723). In the Stage 2 final rule, a governance mechanism option was included in the second measure for the summary of care objective at 77 FR 54020. In the Stage 3 proposed rule 80 FR 16762, we again sought comment on a health information exchange governance mechanism. Specifically we sought comment on whether providers who create a summary of care record using CEHRT for purposes of Measure 1 should be permitted to send the created summary of care record either —(1) through any electronic means; or (2) in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network. We additionally sought comment on whether providers who are receiving a summary of care record using CEHRT for the purposes of Measure 2 should have a similar requirement for the transport of summary of care documents requested from a transitioning provider. Finally, we sought comment on how a governance mechanism established by ONC at a later date could be incorporated into the EHR Incentive Programs for purposes of encouraging interoperable exchange that benefits patients and providers, including how the governance mechanism should be captured in the numerator, denominator, and thresholds for both the first (send) and second (receive) measures of this HIE objective.

For the third measure, we proposed a measure of clinical information reconciliation, which incorporates the Stage 2 objective for medication reconciliation and expands the options to allow for the reconciliation of other clinical information. Clinical information such as medication allergies and problems will allow providers additional flexibility in meeting the measure in a way that is relevant to their scope of practice. In the Stage 2 final rule, we outlined the benefits of medication reconciliation, which enables providers to validate that the patient's list of active medications is accurate (77 FR 54011 through 54012). This activity improves patient safety, improves care quality, and improves the validity of information that the provider shares with others through health information exchange. We believe that reconciliation of medication allergies and problems affords similar benefits.

For this proposed measure, we specified that the EP, eligible hospital, or CAH that receives the patient into their care should conduct the clinical information reconciliation. It is for the receiving provider that up-to-date information will be most crucial to make informed clinical judgments for patient care. We reiterated that this measure does not dictate what subset of information must be included in reconciliation. Information included in the process is determined by the provider's clinical judgment of what is most relevant to patient care.

For this measure, we proposed to define clinical information reconciliation as the process of creating the most accurate patient-specific information in one or more of the specified categories using the clinical information reconciliation capability of certified EHR technology, which will compare the "local" information to external/incoming

information that is being incorporated into the certified EHR technology from any external source. We referred providers to the standards and certification criteria for clinical information reconciliation proposed in ONC's 2015 Edition proposed rule at 80 FR 16831 through 16833.

As with medication reconciliation, we believe that an electronic exchange of information following the transition of care of a patient is the most efficient method of performing clinical information reconciliation.

We recognized that workflows to reconcile clinical information vary widely across providers and settings of care, and we requested comment on the challenges that this objective might present for providers, and how such challenges might be mitigated, while preserving the policy intent of the measure. In particular, we solicited comment on the following:

- Automation and Manual Reconciliation. The Stage 2 measure does not specify whether reconciliation must be automated or manual. Some providers have expressed concern over the automatic inclusion of data in the patient record from referring providers, while others have indicated that requiring manual reconciliation imposes significant workflow burden. We also sought comment on whether the use and display of meta-tagged data could address concerns related to the origin of data and thereby permit more automated reconciliation of these data elements.

- Review of Reconciled Information. Depending on clinical setting, this measure could be accomplished through manual reconciliation or through automated functionality. In either scenario, should the reconciliation or review of automated functionality be

performed only by the same staff allowed under the Stage 3 requirements for the CPOE objective?

- What impact would the requirement of clinical information reconciliation have on workflow for specialists? Are there particular specialties where this measure would be difficult to meet?

- What additional exclusions, if any, should be considered for this measure?

We also encouraged comment on the proposal to require reconciliation of all three clinical information reconciliation data sets, or if we should potentially require providers to choose 2 of 3 information reconciliation data sets relevant to their specialty or patient population. We explained that we expect that most providers would find that conducting clinical information reconciliation for medications, medication allergies, and problem lists is relevant for every patient encountered. We solicited examples describing challenges and burdens that providers who deliver specialist care or employ unique clinical workflow practices may experience in completing clinical information reconciliation for all three data sets and whether an exclusion should be considered for providers for whom such reconciliation may not be relevant to their scope of practice or patient population. Additionally, we solicited comments around the necessity to conduct different types of clinical information reconciliation of data for each individual patient. For example, it is possible that the data for certain patients should always be reviewed for medication allergy reconciliation, when it may not be as relevant to other patient populations.

We proposed that to meet this objective, a provider must attest to the numerator

and denominator for all three measures but would only be required to successfully meet the threshold for two of the three proposed measures.

Measure 1: To calculate the percentage of the first measure, CMS and ONC worked together to define the following for this measure:

Denominator: Number of transitions of care and referrals during the EHR reporting period for which the EP or eligible hospital or CAH 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 exchanged electronically.

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

Exclusion: An EP neither transfers a patient to another setting nor refers a patient to another provider during the EHR reporting period.

Any EP that 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 may exclude the measures.

Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

Measure 2: To calculate the percentage of the second measure, CMS and ONC worked together to define the following for this measure:

Denominator: Number of patient encounters during the EHR reporting period for which an EP, eligible hospital, or CAH was the receiving party of a transition or referral or has never before encountered the patient and for which an electronic summary of care record is available.

Numerator: Number of patient encounters in the denominator where an electronic summary of care record received is incorporated by the provider into the certified EHR technology.

Threshold: The percentage must be more than 40 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusion: Any EP, eligible hospital or CAH for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period is excluded from this measure.

Any EP that 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 may exclude the measures.

Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps

broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

Measure 3: To calculate the percentage, CMS and ONC worked together to define the following for this measure:

Denominator: Number of transitions of care or referrals during the EHR reporting period for which the EP or eligible hospital or CAH inpatient or emergency department (POS 21 or 23) was the recipient of the transition or referral or has never before encountered the patient.

Numerator: The number of transitions of care or referrals in the denominator where the following three clinical information reconciliations were performed: medication list, medication allergy list, and current problem list.

Threshold: The resulting percentage must be more than 80 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusion: Any EP, eligible hospital or CAH for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period is excluded from this measure.

Any EP that 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 may exclude the measure.

Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

We received the following comments and our response follows:

Comment: Many commenters supported our proposal for the HIE Objective applauding the focus on interoperability stating the move toward a true ability to share all patient health records in real time, regardless of EHR system in use, is much needed and very valuable to both providers and patients. This would almost certainly allow better management of care, less duplication of tests and reduction of other waste elements in the system, thus reducing costs. Other commenters noted support of the use of CEHRT to transmit a summary of care record during transitions of care and acknowledges the value of incorporating a patient's summary of care record received from another provider to facilitate clinical information reconciliation and care delivery.

Some commenters specifically mentioned that people with cancer often receive fragmented and uncoordinated care because their treatments frequently require multiple clinicians including surgeons, oncologists, primary care physicians, and other specialists. These commenters noted that providing coordinated care requires access to all of a patient's data by all of his or her providers, an essential function that EHRs can provide.

Still others expressed conceptual support for the proposed objective as the measure rationally seeks to organize the care of the patient on the care continuum and takes the next step in closing the transitions of care loop by incorporating outside medical

information and promoting the reconciliation of medical data from transitioning patients. These commenters expressed a belief that the efforts to improve communication between providers for the same patient promotes better care decisions and care coordination. The ability to communicate information electronically decreases the chance of errors, missing information, or misunderstandings due to lack of standardization. Finally many commenters noted that the ability to send and receive data from other providers throughout the care continuum is imperative to transforming healthcare and improving patient care.

Response: We thank the commenters for their support and agree that this objective should be a top priority for delivery system reform to promote the real-time interoperable exchange of health information and facilitate care coordination. We also appreciate the insight on how electronic exchange can support care management through reducing errors and duplicate testing. We believe the benefits of effective health information exchange are extensive for both providers and patients and for this reason we have maintained health information exchange as a key goal of the EHR Incentive Programs.

Comment: The majority of commenters believe the thresholds for health information exchange (HIE) are too high for EPs. They pointed to various interoperability challenges, which make it difficult to meet the requirements and generally state that we are holding providers accountable for industry or national issues surrounding interoperability that are beyond their control.

Many commenters stated that there are not enough providers and practices that

can electronically receive transition of care documents because many (especially those in rural areas) do not have the capabilities needed to meet the HIE requirements (for example, Direct technologies, HIE access). Other commenters stated a lack of trading partners, including health care providers who are not subject to these regulations) as one of the main obstacles to meeting the Stage 3 HIE requirements. Several commenters requested that providers only be required to engage eligible professionals and eligible hospitals who are also working toward meeting the requirements of the EHR Incentive Programs, and that there should be exclusions based on the capabilities of surrounding practices or a lack of trading partners. Other commenters indicated statewide and regional health information exchanges are at varying levels of development and vary widely in their capabilities and sophistication. Other commenters stated the HIE technology and interoperability capabilities are not mature enough to meet these HIE requirements and will lead to provider failure or providers being held responsible for criteria they cannot control and standards they cannot meet.

Another commenter stated there are no national or regional data repositories in place for direct email addresses to be shared which has made it extremely challenging for providers to comply with this objective and measure, even if the provider has the capability to generate and transmit a C-CDA.

Response: We disagree and believe that this threshold is a reasonable and achievable goal for providers for an EHR reporting period in 2018. We understand the challenges providers and other stakeholders describe and recognize that the transition to interoperable health information exchange requires a paradigm shift across the health

care industry. We believe the work providers are already engaged in and the HIE objectives and measures from Stage 2 are helping to actualize this change. As described in the Stage 3 proposed rule (80 FR 16739), we believe that electronic exchange is more likely to succeed as a higher volume of providers are actively engaged in the sending and receiving of electronic health information. Further, we note that we have proposed more flexibility in the transport mechanism in order to support the exchange of a standardized file in a wide range of transactions. Therefore, we believe that the requirement of this objective is a challenging goal, but a challenge that can and should be achieved.

We disagree that there should be additional exclusions for this objective. As stated previously, we believe that the increased participation in the EHR Incentive Programs will help to support the overall ability for providers to electronically exchange health information. Further, we note that performance for providers in rural areas on the Stage 2 objective does not differ from the overall performance on the measure¹⁸. We also note that, as stated in the proposed rule, we define a transition of care or referral as a transition or referral to another provider of care that is recognized as a different billing entity for the EHR Incentive Programs (NPI, CCN). The inclusion or exclusion of additional provider types and transitions or referrals is at the discretion of the provider as best meets their practice needs as long as the inclusion or exclusion policy is applied universally for the duration of the EHR reporting period.

We intend to support policies that mitigate the impact that a lack of trading partners or a lack of transport mechanisms have on providers. As we note throughout

¹⁸ 18 ONC Data Brief June 2015 healthit.gov

this final rule with comment period, we are seeking to increase participation among EHR Incentive Program participants and expand the methods by which providers may exchange information. These policies are aimed at ensuring that a lack of trading partners will not continue to be a significant hurdle for providers as the widespread adoption of certified EHRs continues and new flexible innovations for transport are supported.

In addition, CMS and ONC share a mutual understanding of the issue relating to importance of provider access to health information exchange contact information and agree that a method to facilitate this access would support interoperable health information exchange. We are committed to exploring potential models and opportunities to enable providers to more readily share their own electronic exchange contact information and access the contact information of potential trading partners. It is our intent to populate the National Plan and Provider Enumeration System (NPPES) with direct addresses and/or electronic service endpoints of EHR Incentive Program participants as a means of creating a health care provider directory resource. For more information, we direct readers to section II.D.3 of this final rule with comment period.

Comment: Many commenters requested a clearer definitions for the denominators relating to the measures including:

- Transitions of care for providers with a shared EHR
- Patient-reported referrals and patient self-referrals.
- New patients and patient encounters in which the provider has never before encountered the patient

Commenters further went on to express support for the option to include providers with a shared EHR and support for the ability to include patient-self referrals as an option, and asked specific questions relating to how these items impact any variation in the denominators between the measures.

Response: We refer commenters to the Stage 2 final rule at 77 FR 53982 through 53983 as well as section II.B.1.b.(4).(f) of this final rule with comment period for further explanation of the definition of transitions of care and the definition of transition or referral, which has not been modified from Stage 2.

For our policy regarding transitions or referrals among providers with a shared EHR, in the Stage 3 proposed rule, we proposed that providers may count a transition of care or referral as long as the receiving provider would at least be considered a different provider if attesting for the EHR Incentive Programs (individual NPI or CCN level) in the denominator if they do so universally across all settings. They may also count these transitions with providers who share a certified EHR if they do so universally across all settings and for all such transitions. However, for any action to count in the numerator of a measure within this objective, the provider may not simply deem the shared access to the record sufficient, they would instead need to complete the required action associated with each measure. We maintain that this option to include or not include such transitions is entirely at the provider's discretion, but the policy must be applied universally for all transitions or referrals related to the denominator for Measure 1 and Measure 2. We believe that these transitions and referrals should not be excluded from Measure 3, as clinical information reconciliation may include actions beyond the

electronic exchange of a patient record. We further clarify that the use of the reference to a billing identity within the program is intended to establish the baseline that if a provider chooses to included exchanges with providers with a shared EHR they may do so as long as the recipient would be considered a different provider in the EHR Incentive Programs (e.g., by the EPs NPI or the eligible hospital or CAH CCN). Some examples which would be included under this policy would be one EP sending to another EP in the same group practice, an eligible hospital sending to an EP in an ambulatory setting which shares the hospital EHR, or a provider sending to a non-EP practitioner who may have shared access to the EHR but whose patient encounters are not included under the referring EPs supervision. Some examples which would be excluded under the policy are an EP in one setting referring a patient to another setting for a different service but where the same EP is the provider, an eligible hospital referring a patient from one clinical setting within the hospital to another (where they attest with the same CCN), and an EP sending to a non-EP practitioner who is under direct supervision and whose patient encounters may be included in the EPs attestation.

We note that in the Stage 3 proposed rule (80 FR 16759) we stated that we believe a provider should count a referral in the denominator in the case of patient-self referrals if the patient subsequently identifies the provider from whom they received care. We further stated that the provider may count such a referral in the numerator for each measure if they undertake the action required to meet the measure upon disclosure and identification of the provider from whom the patient received care. However, we have reconsidered this requirement based on feedback from commenters who note that

variations in timing and provider specialty might impact the feasibility and value proposition for a provider to count patient self-referrals in this manner. For example, if a primary care provider is notified of a self-referral to a specialist months after the resulting visit with the specialist has occurred, the receipt and incorporation (Measure 2) and reconciliation (Measure 3) of the summary of care record by the primary care provider from the specialist is important for the patient's continued care by the primary care provider. In this scenario, it may not make sense for Measure 1 to be required. Under measure 1 as proposed, the primary care provider would be required to send a summary of care record to the specialist. If the specialist has already seen the patient and no follow-up or continued treatment is needed, we believe the referring provider is best suited to determine whether the summary of care record should still be sent. We note that there are further examples of such instances which provide further complications for feasibility of this requirement as proposed. We are, therefore, modifying our initial proposal so that patient self-referrals may be included, but are not required, for measure 1. The provider should determine in what cases they would include or not include patient-self referrals and apply that policy across all such referrals for the duration of the reporting period. We note that providers should seek to receive or retrieve a summary of care document from the other provider of care and should seek to reconcile clinical information once the provider is identified in the same manner they would for any other transition or referral for measures 2 and 3.

For the definition of new patient and never before seen by the provider, we stated that we use the same definition of "new patient" as described in Objective 7 Medication

Reconciliation for the EHR Incentive Programs in 2015 through 2017 in section II.B.2.a.v of this final rule with comment period.

Comment: Some commenters opposed the option to allow providers to only meet the threshold for 2 of 3 objectives, suggesting this would result in slower adoption of true interoperability between providers as they pursue different goals of the EHR Incentive Programs. These commenters stated that providers need to align on common goals to successfully reach interoperability. Other commenters praised this flexibility stating that it would allow them to set internal goals and a continuous improvement process and still be able to meet program requirements if they sought to make adjustments to workflows.

Response: We appreciate the insights from the commenters and agree that the allowance to meet two of three thresholds represents a more flexible option for providers. We believe that rather than hinder participation, this flexibility will allow providers to innovate and expand their uses of HIE as best meets their organizational needs.

Comment: Many commenters supported our proposal allowing providers to limit the transmission of certain data elements based on clinical relevance. Others commended the approach of requiring the ability to send all data elements while allowing flexibility for providers to make the determination of relevance as best fits their practice and patient population.

Some commenters further suggested that providers be able to limit the C-CDA itself or not be required to send the full C-CDS on all transitions of care. Many commenters addressed the C-CDS itself stating that they support renaming the clinical

data sets from “Common MU Data Set” to a new term, as the data sets are relevant beyond the EHR Incentive Programs. Some noted that CCDS is close to C-CDA however commenters were split on if that was a problem or a benefit.

Some commenters opposed the changes to the required data set in the CCDS stating that the additional data fields that are incorporated into the proposed Stage 3 CCDS would involve significant effort to implement and transition the data elements necessary to support the standard summary of care record.

Other commenters noted agreement with the expansion of captured data elements and recommended we maintain capture of this information in a format supported by the C-CDA data structure, but that they should not be mandatory to be populated on the C-CDA in order to meet the numerator of sending an electronic summary of care. These commenters supported continuing to require that the current problem list, medication list, and medication allergy must be populated within the C-CDA.

Response: We thank the commenters and note that our proposal to allow for provider discretion over clinical relevance stemmed largely from the input from providers on how best to address issues with this measure. We also agree that it is essential to maintain the ability to send a full set of all available lab results and clinical notes. We reiterate that while the provider generally has the discretion to define the relevant clinical notes or relevant laboratory results, providers must be able to provide all clinical notes and/or laboratory results through an electronic transmission of a summary of care document. Furthermore, providers must send all clinical notes and/or all laboratory results if that level of detail is subsequently requested by a provider receiving a transition

of care or referral, or if that level of detail is requested by the patient who is transitioning to another setting of care.

We disagree with the suggestion that the C-CDA not be required and that any electronic transmission of patient health information may be accepted for attestation. Furthermore, we disagree with suggestions that the C-CDA should not include all required elements of the ONC defined CCDS for purposes of CEHRT. We note that both the CCDS and C-CDA support the interoperable exchange of data elements for provider use. Without standards, the data from one system cannot readily be translated into usable data in another system.

However, we clarify that not all elements of the CCDS are required to include data if no such data is available or known to the provider. The only three fields which must include data are the current problem list, medication list, and medication allergy list, which must at least include a reference that no such data is known or available. This is an important patient safety element finalized in the Stage 2 final rule which we maintain for Stage 3.

Comment: Some commenters noted the importance of the availability of certain information in care delivery, including sexual orientation & gender identity, disparities, behavior health, and UDI data. Some commenters specifically highlighted the importance of capturing UDI data for improved care and better reporting of adverse events as well as allowing for the ability to provide more effective corrective and preventative action in response to device recalls and alerts.

Response: We thank commenters for their comments and for their support of UDI within the program. We note that ONC's 2015 Edition final rule, published elsewhere in this issue of the **Federal Register**, includes UDIs for a patient's implantable devices in the CCDS and the corresponding implantable device list certification criterion in the Base EHR definition. We believe that incorporating UDIs, beginning with UDIs for implantable devices, in certified EHR technology will be integral to patient care, as this information can help those within a patient's care team to accurately identify the patient's devices (and associated clinically relevant information, such as a device's latex content or MRI safety) and thus be better informed and better able to care for the needs of the patient. We refer readers to the 2015 Edition final rule for further discussion of this criteria.

Certain other types of information, while not required within the CCDS, have associated standards and capabilities for data capture that are included in certification criteria that compose the Base EHR definition. As such, while these types of information are not required within the CCDS, the ability to capture this information is required under the definition of CEHRT. This distinction means the provider would have the data element available for use within their certified EHR and would have the ability to capture the data in a structured format as appropriate for their individual practice and patient population. For example, the Base EHR definition included in the 2015 Edition final rule provides for the capture of demographic data within certified EHR technology, including the capture of more granular data on race and ethnicity and of data that extends beyond a more limited understanding of clinical care data—such as the collection of social,

psychological, and behavioral health information. The ability to capture this information in CEHRT supports provider efforts to provide improved, patient-centered care and reduce health disparities.

The 2015 Edition proposed rule also included a criterion to record a patient's sexual orientation and gender identity (SO/GI) in a structured way with standardized data. Where the patient chooses to disclose this information, the inclusion of this information can help those within the patient's care team to have more information on the patient that can aid in identifying interventions and treatments most helpful to the particular patient. Additionally, sexual orientation and gender identity can be relevant to individual treatment decisions; for example, transgender men who were assigned female at birth should be offered a cervical exam, as appropriate. In the final rule, ONC is requiring that Health IT modules enable a user to record, change, and access SO/GI to be certified to the 2015 Edition "demographics" certification criterion. By doing so, SO/GI is now included in the 2015 Edition Base EHR definition, which is a part of the definition of CEHRT (see section II.B.3). We note that certification does not require that a provider collect this information; it requires only that their CEHRT enable the provider to do so. CMS and ONC believe including SO/GI in the "demographics" criterion represents a crucial step forward to improving care for LGBT communities.

We also note that we received comments specific to the composition of the CCDS and addressing the C-CDA, which are out of scope for this rule. We refer readers to the 2015 Edition final rule included elsewhere in this Federal Register for further information on the CCDS and the C-CDA, as well as for further information on provisions related to

data collection, including the collection of sexual orientation and gender identity data and behavioral, social, and psychological data.

Comment: For Measure 1, many commenters expressed similar concerns with the first measure as with HIE as a whole citing interoperability barriers and the lack of providers and other trading partners available to electronically exchange data. Commenters also considered the threshold of 50% to be too high and too far a leap from the 10% requirement in Stage 2. Additionally, commenters opposed removing the exclusion qualifier which allowed providers to exclude the measure if they conduct fewer than 100 referrals or transitions of care during the EHR reporting period. A few commenters believe measure 1 is valuable driver of interoperability within health care, but acknowledged that refinements/adjustments need to be made.

Response: We reiterate that CMS and ONC are committed to working with the industry to support and promote an expanded HIE infrastructure to facilitate health IT facilitated care coordination. We believe expanding the flexibility for the use of a wide variety of transport mechanisms, encouraging wider provider participation and continuing to support the use of standards for structured data in certified EHR technology will help to mitigate these concerns. We do not believe the threshold is too high given the past performance, the expansion of options, and the expressed need for higher overall participation. We do however note that the change to the exclusion may be problematic for providers with very few transitions in an EHR reporting period and are therefore maintaining the exclusion at 100 transitions and referrals as finalized in the Stage 2 final rule for an electronic summary of care and consistent with measures 2 and 3.

Comment: Some commenters requested clarification if any electronic means could include transmission via pdf or electronic fax, or the conversion of a C-CDA document into one of these formats. Commenters also suggested that any electronic means is not a rigorous enough definition to ensure the security of patient information in transmission.

Many commenters strongly supported the expansion of the available methods by which secure electronic exchange could occur. Some strongly encouraged us to continue to require summary of care record exchange in a manner that is consistent with a governance mechanism ONC establishes for the nationwide health information network. These commenters noted that transmission of a summary of care record could be accomplished in various ways and requested that CMS and ONC should provide resources outside the regulations to support and clarify these requirements for developers and providers.

Other commenters specifically supported the requirement for the transmission of electronic summary of care document in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network and believe that allowing any other transmission method will increase the cost and complexity of receiving and incorporating data into the EHR. Response: We note that the intent for flexibility around sending via any electronic means (so long as the provider is using the standards established for certified health IT under the ONC certification program for the creation of the electronic summary of care document) is to promote and facilitate a wide range of options and also to specifically facilitate the receipt of a summary of care document electronically. In the past, in response to inquiries by providers we developed

an FAQ which stated that an electronic summary of care document may be converted from a C-CDA to another format (e.g. SOAP, secure email, electronic fax, and etc.) by a third party intermediary, and that such a transition may still be counted in the numerator if the third party can confirm for the sending provider that the summary of care was ultimately received by the next provider of care¹⁹. However, for Stage 3 we do not intend to continue to allow this policy, as it does not drive toward the overall goal of the HIE Objective that providers send, receive or retrieve, and incorporate an electronic summary of care document for each transition or referral. This means the initiating provider must send a C-CDA document that the receiving provider would be capable of electronically incorporating as a C-CDA on the receiving end. In other words, if a provider sends a C-CDA and the receiving provider converts the C-CDA into a pdf or a fax or some other format, the sending provider may still count the transition or referral in the numerator. If the sending provider converts the file to a format the receiving provider could not electronically receive and incorporate as a C-CDA, the initiating provider may not count the transition in their numerator. We further note that for measure 1, a provider must have confirmation of receipt or that a query of the summary of care record has occurred in order to count the action in the numerator.

We further note that the security of the transmission is of paramount importance to CMS. We, therefore, remind providers and emphasize that any transmission method chosen by a provider must comply with the privacy and security protocols for ePHI

¹⁹ FAQ #10660 <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/FAQ.html>
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outlined in HIPAA.

We requested comment from providers on how the governance mechanism could be considered for purposes of the objectives and measures in Stage 3 and we thank commenters for their comments. We will continue to consider these comments as we work with ONC to address governance as it relates to health information exchange, and look forward to continuing to work with stakeholders in this area.

Comment: For Measure 2, some commenters acknowledged the potential benefit of this measure with the understanding that various challenges would need to be overcome first. Commenters felt the 40 percent threshold was too high, particularly for a new measure. They also expressed concerns with the administrative burden, workflow and time management challenges, and technological barriers involved in reviewing and incorporating data from other providers.

Response: We respectfully disagree that the threshold for the measure is too high, as the ability to retrieve, receive and incorporate an electronic summary of care document for transitions or referrals as defined by the measure is entirely within the provider's control. For example, in our proposal we allow providers to exclude a patient from the denominator where a reasonable due diligence reveals that no electronic record is available for the patient. This reduces the burden on providers to incorporate the record for only those patients for whom an electronic record is available after their effort to receive, request, or query for an electronic summary of care is successful. We believe there may be many variations in how providers accomplish this measure and believe those workflows and processes are best left to provider discretion.

Comment: Some commenters expressed that it would be unreasonable to include patients never before seen by the provider. These commenters noted that, for example, emergency department workflows are simply incompatible with requirements to try to identify outside sources of summary of care records for walk-in patients. They further noted that the infrastructure for doing this does not exist in most areas and is not likely to exist for several years to come.

Other commenters requested we add the word "electronically" to the measure language so that the measure reads "For 40 percent of transitions or referrals received electronically". Other commenters noted that a provider may have the capacity to query an HIE in their CEHRT, but is unable to do so because there is no HIE in their area or their organization is still in the process of on-boarding with a potential HIE network. These commenters expressed concern that the denominator calculation would not allow them to exclude patients for whom they were unable to query in this instance. Others expressed a similar concern over the understanding of an HIE noting that many do not require the provider to possess additional functionality, but instead allow a provider to query for a document and receive that document via direct transport from the HIE.

Response: We disagree with the commenters that it is unreasonable to include new patients and note that the example provided about the ability of a hospital to find information on a patient presenting at the emergency department is exactly the type of process that is supported by health IT rather than hindered by it.

We also decline to add the qualifier to the measure to specify only counting existing electronic transitions or referrals in the requirement to receive, request or query

for an electronic summary of care record. If we were to change the measure to read "received electronically" it eliminates any further follow up to request or query for an electronic record when an electronic record was not already received with the transition or referral. This change would fundamentally alter the measure and render it meaningless.

The proposed measure denominator already allows providers to exclude patients for whom no electronic document is available after a reasonable effort is made, such as a request to the referring provider and a query of any HIE or service. As stated in the proposed rule, for the purposes of defining the cases in the denominator, we proposed that what constitutes "unavailable" and, therefore, may be excluded from the denominator, will be that a provider —

- Requested an electronic summary of care record to be sent and did not receive an electronic summary of care document; and
- Queried at least one external source via HIE functionality and did not locate a summary of care for the patient, or the provider does not have access to HIE functionality to support such a query.

However, we do agree with commenters and are adopting a change to state that the reference to HIE functionality within the denominator calculation should be revised to reflect whether or not there is an HIE from which the provider is able to query and receive a C-CDA using their CEHRT. We are therefore adding an additional qualifier to the statement to include that the HIE functionality supporting a query for a summary of care document is not currently operational in the provider's geographic region or EHR network. Therefore, for the purposes of defining the cases in the denominator, we are

modifying our proposal to state that what constitutes , "unavailable" and therefore may be excluded from the denominator, —is as follows:

- The provider requested an electronic summary of care record to be sent and did not receive an electronic summary of care document; and
- The provider either:
 1. Queried at least one external source via HIE functionality and did not locate a summary of care for the patient, or
 2. Confirmed that HIE functionality supporting query for summary of care documents was not operational in the provider's geographic region and not available within the provider's EHR network as of the start of the EHR reporting period.

Comment: Finally, commenters requested information on what the term “incorporated” means in the numerator. Some expressed concerns over the integrity of the information if they are forced to incorporate it into their EHR.

Response: We do not define incorporate, as it may vary among recipient providers based on the providers HIE workflows, their patient population, and based on the referring provider. The record may be included as an attachment, as a link within the EHR, as imported structured data, or the provider may conduct a reconciliation of the clinical information within the record to incorporate this information into the patient record within their EHR. We note that a record cannot be considered to be incorporated if it is discarded without the reconciliation of clinical information or if it is stored in a manner that is not accessible for provider use within the EHR.

Comment: Many commenters supported Measure 3 and clinical information reconciliation with some stating that the measure should be required rather than an option within the objective. Others stated that all three types of information should be required for all care transitions because reconciliation of medications, medication allergies, and current problems is consistent with the requirement to provide the safest care. Many commenters also agreed with the threshold for the measure of more than 80 percent, with some stating that we should simply require all patients for this measure instead.

Some commenters discussed the administrative burden, various workflow challenges involved in reviewing, and incorporating data from other providers including the amount of time required to review inbound summary of care reports. Other commenters discussed how the CCDS are not helpful because they contain too much unnecessary and redundant information as well as the risk associated with receiving summary of care information that has not been reviewed by a provider in a timely manner.

Other commenters stated that not all new patient referrals require comprehensive data reconciliation. For example a dermatologist evaluating a simple skin lesion or an orthopedist evaluating a painful joint may not need to perform in depth reconciliation to provide quality care.

In addition, many commenters discussed the means of measurement for medications, problems, and allergies such as if duplicate records needed to be reconciled or if data that is verified as requiring no further update would also count toward the measure. Several commenters requested clarification on whether the reconciliation

should be automated or manual. Some requested we offer both options to allow providers to choose the means that best fits their practice. and many commenters had concerns about the liability associated with automated reconciliation.

Response: We appreciate the support for the measure; however, we did not propose that this measure should be required for the objective but rather that providers must meet the threshold for two of three measures based on the needs of their practice. We believe that many providers may conduct some form of reconciliation in conjunction with measure 2, or that providers in certain specialties may elect to conduct reconciliation of clinical information even beyond our requirement at all patient encounters. We understand from previous listening sessions and feedback from stakeholders that the summary of care documents sometimes contain an overwhelming amount of information. For this reason, we allow provider discretion to define the relevant clinical notes and/or laboratory results to send in the summary of care document, although we maintain that providers must still have the CEHRT functionality to include and send all labs or clinical notes. We believe this will provide the efficiency sought by stakeholders in their feedback.

We note that this measure builds on the existing Medication Reconciliation Objective for the EHR Incentive Programs in 2015 through 2017 (see section II.B.2.a.v). We agree that this process may include both automated and manual reconciliation to allow the receiving provider to work with both the electronic data provided with any necessary review, and to work directly with the patient to reconcile their health information. We further note that the point of reconciliation is to assist in

maintaining the most relevant, complete, and up to date information for a given patient. if no update is necessary, the process of reconciliation may consist of simply verifying that fact or reviewing a record received on referral and determining that such information is merely duplicative of existing information in the patient record. Both such examples would count toward the measure if the provider established their reconciliation process to include such verification.

Comment: Commenters requested clarification on whether data can be reconciled by non-credentialed staff or by credentialed staff only. Commenters were split on their opinions of whether reconciliation should be conducted by only credentialed medical staff like CPOE or by any staff trained to work with the EHR and enter patient information. Some recommended allowing auto reconciliation of data as long as it is reviewed by credentialed staff or provider. Other commenters stated that non-credentialed staff should be able to reconcile the data, then have it reviewed by credentialed staff.

Response: We require the person entering the order in CPOE to be credentialed medical staff because of the need to review, assess, and potentially act on a CDS based on the order entered. For further discussion, we direct readers to the CPOE objective in section II.B.2.a. of this final rule with comment period. In most cases, clinical information reconciliation may not require the same level of medical training and knowledge and a non-clinical staff person trained to accurately and completely enter patient information may be fully qualified to conduct this task. However, in some instances, further medical knowledge and training may be required, such as if a

medication reconciliation triggers a CDS drug-drug intervention. We therefore agree with commenters that non-medical staff may conduct reconciliation under the direction of the provider so long as the provider or other credentialed medical staff is responsible and accountable for review of the information and for the assessment of and action on any relevant CDS.

Comment: A few commenters supported the inclusion of electronic alerts to the EP, when their patient is seen in the emergency department or admitted and/or discharged from the hospital. Other commenters stated that the standard is too vague and the technology too immature for required use at this time and that CMS should allow providers to choose if they wish to participate in this action for the near future.

Response: We decline to finalize an inclusion of electronic alerts at this time. We will continue to review the development of the technology and standard for potential inclusion in the future.

After consideration of public comments received, we are finalizing the objective with a minor modification to the language to clarify receiving or retrieving a summary of care through query as discussed for measure 2. We are finalizing the measures and exclusions as proposed for EPs, eligible hospitals and CAHs. We are finalizing that providers must attest to all three measures and must meet the thresholds for at least two measures to meet the objective. The final objective and measures are as follows:

Objective 7: Health Information Exchange

Objective: The EP, eligible hospital, or CAH provides a summary of care record when

transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of CEHRT.

Measure 1: For more than 50 percent of transitions of care and referrals, the EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care: (1) creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.

- Denominator: Number of transitions of care and referrals during the EHR reporting period for which the EP or eligible hospital or CAH 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 exchanged electronically.
- Threshold: The percentage must be more than 50 percent in order for an EP, eligible hospital, or CAH to meet this measure.
- Exclusion: A provider may exclude from the measure if any of the following apply:
 - 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.
 - Any EP that 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 may exclude the measures.

- Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

Measure 2: For more than 40 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP, eligible hospital or CAH incorporates into the patient's EHR an electronic summary of care document.

- Denominator: Number of patient encounters during the EHR reporting period for which an EP, eligible hospital, or CAH was the receiving party of a transition or referral or has never before encountered the patient and for which an electronic summary of care record is available.
- Numerator: Number of patient encounters in the denominator where an electronic summary of care record received is incorporated by the provider into the certified EHR technology.
- Threshold: The percentage must be more than 40 percent in order for an EP, eligible hospital, or CAH to meet this measure.
- Exclusion: A provider may exclude from the measure if any of the following apply:
 - Any EP, eligible hospital or CAH for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period is excluded from this measure.
 - Any EP that 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 may exclude the measures.

- Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

Measure 3: For more than 80 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP, eligible hospital, or CAH performs a clinical information reconciliation. The provider must implement clinical information reconciliation for the following three clinical information sets:

- (1) Medication. Review of the patient's medication, including the name, dosage, frequency, and route of each medication.
 - (2) Medication allergy. Review of the patient's known medication allergies.
 - (3) Current Problem list. Review of the patient's current and active diagnoses
- Denominator: Number of transitions of care or referrals during the EHR reporting period for which the EP or eligible hospital or CAH inpatient or emergency department (POS 21 or 23) was the recipient of the transition or referral or has never before encountered the patient.
 - Numerator: The number of transitions of care or referrals in the denominator where the following three clinical information reconciliations were performed: medication list, medication allergy list, and current problem list.
 - Threshold: The resulting percentage must be more than 80 percent in order for an EP, eligible hospital, or CAH to meet this measure.

- Exclusion: Any EP, eligible hospital or CAH for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period is excluded from this measure.

We are adopting Objective 7: Health Information Exchange at § 495.24(d)(7)(i) for EPs and § 495.24(d)(7)(ii) for eligible hospitals and CAHs. We further specify that in order to meet this objective and measures, an EP, eligible hospital, or CAH must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

Objective 8: Public Health and Clinical Data Registry Reporting

In the Stage 3 proposed rule (80 FR 16763) we proposed this objective to build on the requirements set forth in the Stage 2 final rule (77 FR 54021 through 54026). We proposed this objective to include improvements to the Stage 2 measures, support innovation that has occurred since the Stage 2 final rule was released, and add flexibility in the options that an eligible provider has to successfully report.

We further noted that this objective places increased focus on the importance of the ongoing lines of communication that should exist between providers and public health agencies or as further discussed later in this section, between providers and clinical data registries. Providers' use of certified EHR technology can increase the flow of secure health information and reduce the burden that otherwise could attach to these important

communications. The purpose of this Stage 3 objective is to further advance communication between providers and public health agencies and clinical data registries, as well as strengthen the capture and transmission of such health information within the care continuum.

For Stage 3, 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. We proposed to include a new measure for electronic case reporting to reflect the diverse ways that providers can electronically exchange data with public health agencies. In addition, we used new terms such as public health registries and clinical data registries to incorporate the Stage 2 designations for cancer registries and specialized registries under these categories which are known in the health care industry to designate a broader range of registry types. We further explained the use of these terms within the specifications outlined for each applicable measure.

Proposed Objective: The EP, 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.

For Stage 3, we proposed to remove the prior "ongoing submission" requirement and replace it with an "active engagement" requirement. Depending on the measure, the ongoing submission requirement from the Stage 1 and Stage 2 final rules required the successful ongoing submission of applicable data from certified EHR technology to a

public health agency or clinical data registry for the entire EHR reporting period. As part of the Stage 2 final rule, we provided examples demonstrating how ongoing submission could satisfy the measure (77 FR 54021). However, stakeholders noted that the ongoing submission requirement does not accurately capture the nature of communication between providers and a public health agency or clinical data registry, and does not consider the many steps necessary to arrange for registry submission to a public health agency or clinical data registry. Given this feedback, we believe that "active engagement" as defined later in this section is more aligned with the process providers undertake to report to a clinical data registry or to a public health agency.

For purposes of meeting this new objective, EPs, eligible hospitals and CAHs would be required to demonstrate that "active engagement" with a public health agency or clinical data registry has occurred. Active engagement means that the provider is in the process of moving towards sending "production data" to a public health agency or clinical data registry, or is sending production data to a public health agency or clinical data registry. We noted that the term "production data" refers to data generated through clinical processes involving patient care and it is 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 proposed 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 public health agency or, where applicable, the clinical data registry 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 public health agency or clinical data registry to begin testing and validation. This option allows providers to meet the measure when the public health agency or the clinical data registry 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 public health agency or, where applicable, the clinical data registry 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 public health agency or clinical data registry.

We also proposed to provide support to providers seeking to meet the requirements of this objective by creating a centralized repository of national, state, and local public health agency and clinical data registry readiness. In the Stage 2 final rule (77 FR 54021), we noted the benefits of developing a centralized repository where a public health agency could post readiness updates regarding their ability to accept electronic data using specifications prescribed by ONC for the public health objectives. In accordance with the Paperwork Reduction Act of 1995, we also published a notice in

the **Federal Register** on February 7, 2014 soliciting public comment on the proposed information collection required to develop the centralized repository on public health readiness (79 FR 7461). We considered the comments and we proposed moving forward with the development of the centralized repository. The centralized repository is integral to meaningful use and is expected to be available by the start of CY 2017. We expect that the centralized repository will include readiness updates for public health agencies and clinical data registries at the state, local, and national level. We received the following comments and our responses follow:

Comment: Some commenters expressed concern regarding the active engagement requirement included in the proposed rule. Commenters noted that the description of active engagement is vague. Commenters also noted that additional time, beyond the 2018 requirement year, would be needed to ensure that providers could change their current framework to meet the new active engagement requirement. Other commenters requested clarification on the definition of production in Option 3. Other commenters noted that during the production phase, issues may arise that need resolution and that, similar to the testing and validation phases, processes are needed to ensure proper resolution. A commenter proposed adding a 30-day allowance to the active engagement option 3 (production) to align with the 30-day allowance included in active engagement option 2 (testing and validation).

Response: We thank the commenters for their input and note the following clarifications of intent and purpose for the change from “ongoing submission” to “active engagement.” We received feedback from a variety of stakeholders that the "ongoing

submission" structure created confusion. This feedback highlighted that providers are unsure of how ongoing submission could be achieved and whether periodic, continuous, or episodic reporting was generally required. We found that the wide variation among potential provider reporting scenarios and submission processes contributed to the difficulty in defining "ongoing submission" in a fair and universally applicable manner. Therefore our change to "active engagement" is intended to more clearly identify the progression of the requirement as well as providing a basis for defining the actions required by the provider in each step of the process. In a sense, the active engagement options are a clarification of the more basic concept of reporting which is that the provider is taking action and in communication with a public health agency in order to register, test and submit data in a progression which results in the provider successfully reporting relevant data to the public health agency.

The active engagement requirement clarifies what is expected of a provider who seeks to meet the measures within this objective and renames the requirement to better describe the provider's role in meeting each option within the structure. There is an intentional similarity between some of the broad descriptions of the Stage 2 "ongoing reporting" and the requirements for the "active engagement" options. This is both to provide continuity and to define a more comprehensive progression for providers in meeting the measure. For example, in the Stage 2 rule (77 FR 54021), we generally stated that a provider could register their intent to submit data to successfully meet a measure in the public health objective. This concept is defined with additional guidance in the Stage 3 proposed rule as Active Engagement Option 1: Completed Registration to

Submit Data.

For the commenters discussing the submission of production data as defined in Action Engagement Option 3: Production, we note that under this option a provider only may successfully attest to meaningful use when the receiving public health agency or clinical data registry moves the provider into a production phase. We recognize that live data may be sent during the Testing and Validation phase of Option 2, but the data received in Option 2 is not sufficient for purposes of meeting Option 3 unless the public health agency and clinical data registry is actively accepting the production data from the provider for purpose of reporting. We agree with commenters who noted that issues may arise that require provider action. In such a case, we require providers to respond to issues in the same manner as described in Option 2. For example, a provider in the production phase would not be able to successfully attest to Option 3 if there were issues in production where the provider fails to respond to an issue within 30 days on two occasions.

Comment: Some commenters sought clarification on whether a provider who has already registered with a public health agency or clinical data registry during a previous reporting period would have to register again in order to meet the active engagement requirement. Commenters noted that a registration requirement in such circumstances would be duplicative.

Response: As we have noted in the proposed rule, under the active engagement requirement, providers would only need to register once with a public health agency or a clinical data registry and could register before the reporting period begins. In addition,

we note that previous registrations with a public health agency or clinical data registry that occurred in a previous stage of meaningful use could count toward option 1 of the active engagement requirement for purposes of attesting to Stage 3. We clarify that providers must register with a public health agency or clinical data registry for each measure they intend to use to meet meaningful use. Further, we also clarify that to meet option 1 of the active engagement requirement, registration with the applicable public health agency or clinical data registry is required where a provider seeks to meet meaningful use using a measure they have not successfully attested to in a previous EHR reporting period.

Comment: Commenters requested clarification regarding whether a provider can successfully attest to meaningful use using proof of active engagement collected by their organization, or whether a provider must demonstrate that he or she independently engaged with the public health agency or clinical data registry.

Response: The EHR Incentive Programs are based on individual providers meeting the objectives and measures of meaningful use. Therefore an individual provider can only meet an objective or measure if they are engaged in the activity which is used to meet the measure. This means a provider can demonstrate meaningful use by using communications and information provided by a public health agency or clinical data registry to the provider directly for individual reporting. Or, a provider also may demonstrate meaningful use by using communications and information provided by a public health agency or clinical data registry to the practice or organization of the provider if the organization reports at the group level as long as the provider is

contributing to the data reported by the group. If the provider does not contribute to the data, they must claim the exclusion if applicable and/or meet another public health reporting measure. For example, a provider who does not administer immunizations should claim the exclusion even if their organization submits immunization reporting at the group level.

Comment: Commenters also expressed support for the proposed centralized repository of public health agencies and clinical data registry readiness. Commenters noted that the repository would help developers and providers consider available registry options and provide advance notice of the status of registries. Though the repository received many positive comments, some commenters noted that variability in the readiness of public health agencies presented an additional challenge for providers who seek to prepare for and meet the measures.

Response: In response to comments received and the concern that providers need advance readiness notification from public health agencies and clinical data registries to prepare and plan before the EHR reporting period begins, we are broadening the exclusions that could apply to providers seeking to meet the objective. The exclusion will allow providers more time to prepare their processes to align with what data public health jurisdictions are ready to accept. Specifically, we will not finalize the proposed requirement that public health agency and clinical data registries declare readiness on the first day of the EHR reporting period. We are instead finalizing a modified exclusion that if public health agencies have not declared 6 months before the start of the EHR reporting period whether the registry they are offering will be ready on January 1 of the upcoming

year for use by providers seeking to meet EHR reporting periods in that upcoming year, a provider can claim an exclusion. We believe that modifying the exclusion to request public health agency or clinical data registry to declare their readiness 6 months ahead of the first day of the EHR reporting period would allow providers adequate notice of public health agency and clinical data registry plans to accept data at the beginning of an EHR reporting period.

Proposed Measures: We proposed a total of six possible measures for this objective. EPs would be required to choose from measures 1 through 5, and would be required to successfully attest to any combination of three measures. Eligible hospitals and CAHs would be required to choose from measures one through six, and would be required to successfully attest to any combination of four measures. The proposed measures are as shown in Table 9. As noted, we proposed that measures four and five 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.

TABLE 9: 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 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 to meet the number of measures required to meet the objective.

For EPs, we proposed that an exclusion for a measure does not count toward the total of three measures. Instead, in order to meet this objective, an EP would need to meet three 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 three, the EP can meet the objective by meeting all of the remaining measures available to them and claiming the applicable exclusions. Available measures include ones for which the EP does not qualify for an exclusion.

For eligible hospitals and CAHs, we proposed that an exclusion for a measure does not count toward the total of four measures. Instead, in order to meet this objective an eligible hospital or CAH would need to meet four 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 four, the eligible hospital or CAH can meet the objective by meeting all of the remaining measures available to them and claiming the applicable exclusions. Available measures include ones for which the eligible hospital or CAH does not qualify for an exclusion.

We also proposed 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 also proposed allowing 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 explained that we believe that this flexibility allows for EPs, eligible hospitals, and CAHs to choose reporting options that align with their practice and that will aid the provider's ability to care for their patients.

Proposed 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).

In the Stage 3 proposed rule (80 FR 16764), we noted that the immunization registry reporting measure remains a priority 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 proposed that to successfully meet the requirements of this measure, bi-directional data exchange between the provider's certified EHR technology and the immunization registry/IIS is required. We understand that many states and local public health jurisdictions are exchanging immunization data bi-directionally with providers, and that the number of states and localities able to support bi-directional exchange continues to increase. In the 2015 Edition proposed rule, ONC proposed to adopt a bi-directional exchange standard for reporting to immunization registries/IIS. We believe this functionality is important for patient safety and improved care because it allows 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 bi-directional immunization data exchange. We welcomed comment on this proposal.

Proposed Exclusion for Measure 1: 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: (1) 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; (2) 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 (3) operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data at the start of the EHR reporting period.

Comment: Many comments supported the concept of bi-directional messaging, but some commenters requested additional background on what bi-directionality means for purpose of the measure. Many commenters expressed concern about elements of the bi-directional components of immunization registry reporting, and around jurisdictional variation and the lack of public health readiness to implement bi-directional data exchange. Many commenters expressed concern about public health readiness for bi-directional data exchange, especially during the EHR Incentive Program reporting periods of 2015 through 2017. A commenter expressed concern that immunization registries are not fully prepared to support bi-directional interfaces. Many commenters also expressed concern around accepting the immunization history and forecast from an IIS when the EHR may already perform that functionality and may have better information to perform the forecasting algorithm. A commenter expressed concern that the forecast info interface could conflict with their system's existing health maintenance functionality.

Response: Bi-directionality, as noted in the applicable implementation guide Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5 (October 2014) (“Release 1.5”), provides that certified health IT must be able to receive and display a consolidated immunization history and forecast in addition to sending the

immunization record. Some comments noted that certified EHR technology may already perform the forecast and may have better information to perform the forecasting algorithm. For clarification, we note that the provider's technology certified in accordance with the ONC Health IT Certification Program may layer additional information and recommendations on top of the forecast received from the immunization registry. The requirements of CEHRT serve only as a baseline upon which additional capabilities may be built.

Regarding the bi-directionality requirement, we note that we have modified the requirements of bi-directionality for the EHR Incentive Program for 2015 through 2017 (see section II.B.2.a.x). However, for Stage 3, we believe that the bi-directionality requirement should remain. We believe that by the time Stage 3 begins, the bi-directional components of immunization registry reporting will be ready. At the time of publication of this final rule with comment period, more than half of public health jurisdictions can support bi-directional messaging and the remaining public health jurisdictions are on their way to supporting the bi-directional capability. Therefore, we are finalizing this measure, with the modification that a provider's health IT system may layer additional information on the immunization history, forecast, and still successfully meet this measure.

Proposed 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).

In the Stage 3 proposed rule (80 FR 16764), we noted that this measure remains a policy priority because electronic syndromic surveillance is valuable for early detection of outbreaks, as well as monitoring disease and condition trends. We distinguished between EPs and eligible hospitals or CAHs reporting locations because, as discussed in the Stage 2 final rule, few public health agencies appeared to have the ability to accept non-emergency or non-urgent care ambulatory syndromic surveillance data electronically (77 FR 53979). We continued to observe differences in the infrastructure and current environments for supporting electronic syndromic surveillance data submission to public health agencies between eligible hospitals or CAHs and EPs. Because eligible hospitals and CAHs send syndromic surveillance data using different methods as compared to EPs, we defined slightly different exclusions for each setting as described later in this section.

Proposed Exclusion for EPs for Measure 2: Any EP meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure if the EP: (1) does not treat or diagnose or directly treat any disease or condition associated with a syndromic surveillance system in their jurisdiction; (2) 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 (3) 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.

Proposed Exclusion for eligible hospitals/CAHs for Measure 2: 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: (1) does not have an emergency or urgent care department; (2) 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 (3) 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.

Comment: Many commenters noted that many jurisdictions are not able to receive ambulatory syndromic surveillance data and that the standards for reporting are vague. A commenter expressed concern that requiring a provider's system to be certified to the ambulatory standard does not provide value to the industry. Another commenter noted that for the few jurisdictions accepting syndromic surveillance data from ambulatory practices, the data that these jurisdictions are accepting are not data that is commonly considered syndromic surveillance data. A commenter noted that if data is being requested or collected for use cases beyond the standard syndromic surveillance definition, the requested or collected data should be used to report to proposed Measure 4: Public Health Reporting, not this measure.

Response: We agree that few jurisdictions accept syndromic surveillance from non-urgent care eligible professionals and that at times the data that is collected may not be considered traditional syndromic surveillance data. For the EHR Incentive Programs in 2015 through 2017, we continue to offer syndromic surveillance as an option for ambulatory care providers as a few jurisdictions are already accepting such data.

Because syndromic surveillance reporting is more appropriate for urgent care settings and eligible hospitals/CAHs, we remove this measure for eligible professionals for Stage 3 with the exception of providers who are practicing in urgent care settings. For CAHs and eligible hospitals, we adopt this measure as proposed. We further note that as any provider for whom reporting is not possible, an exclusion is already available; therefore, the additional setting restriction within the measure language is duplicative and may cause confusion for providers who practice in multiple settings where the measure may have different relevance. We are therefore modifying the measure language and the exclusion to help clarify the measure for those reporting on the measure and the exclusion options for those who are not reporting on the measure.

Proposed 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 proposed new reporting option was not part of Stage 2. The collection of electronic case reporting data greatly improves reporting efficiencies between providers and the public health agency. Public health agencies collect "reportable conditions", as defined by the state, territorial, and local public health agencies, 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. However, electronic case reporting presents a core benefit to public health improvement and a variety of stakeholders 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 will support more rapid exchange of case reporting information between public health agencies and providers and can include structured questions or data fields to prompt the provider to supply additional required or care-relevant information.

Proposed Exclusion for Measure 3: 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: (1) 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; (2) 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 (3) 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.

Comment: For Measure 3, commenters overwhelmingly supported the need for electronic case reporting. Many comments expressed concern with the standards referenced and the immaturity to perform these functions, especially the ability of public health jurisdictions to accept data during the EHR Incentive program for 2015 through 2017. Some commenters noted their support for case reporting, including its potential impact on patient outcomes and the use of data elements for reporting. Another commenter supported the measure, but noted the importance of ensuring high quality data and sufficient funding for public health agencies to accept data transmissions.

Response: We note that we did not finalize the case reporting option for the EHR Incentive Program in 2015 through 2017 to allow additional time for the development of the technology and infrastructure to support the measure. We also, as described elsewhere in this final rule with comment period and as noted in the Stage 2 final rule, we did allow case reporting to continue to count under the specialized registry measure. For Stage 3, we do believe that case reporting should remain. However, to allow EPs, EHR vendors, and other entities adequate time to prepare for this new measure in Stage 3, this measure will not begin requiring electronic case reporting until 2018. By the 2018 year of Stage 3, we believe that the standards will be mature and that jurisdictions will be able to accept these types of data. Therefore, we finalize this measure as proposed to begin in 2018.

Proposed 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 the February 2014 Public Health Reporting Request for Information, we proposed to carry forward the concept behind this broad category from Stage 2, but also proposed 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 proposed to define a "public health registry" as a registry that is administered by, or on behalf of, a local, state, territorial, or national public health agency and which collects data for public health purposes. While immunization registries are a type of public health registry, we proposed 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 reiterated 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 will 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 noted that ONC adopted standards for ambulatory cancer case reporting in its final rule "2014 Edition, Release 2 EHR Certification Criteria and the

ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange" (79 FR 54468) and we 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 registry 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 proposed that EPs would have the option of counting cancer case reporting under the public health registry reporting measure. We noted that cancer case reporting is not an option for eligible hospitals and CAHs under this measure because hospitals have traditionally diagnosed or treated cancers and have the infrastructure needed to report cancer cases.

Proposed Exclusions for Measure 4: 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: (1) does not diagnose or directly treat any disease or condition associated with a public health registry in their jurisdiction during the EHR reporting period; (2) 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 (3) 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.

Comment: Many commenters noted their support for public health registries. Commenters appreciated the flexibility and additional means to meet the measure, which they noted, aids specialists. Nearly all commenters expressed specific support for the Centralized Readiness Repository noting that it is essential for providers to determine if they can attest to the measure if they should take an exclusion. Commenters also noted the specific content that should be available within the Centralized Readiness Repository.

Response: We appreciate the overall support for this measure. We agree that this measure offers flexibility for specialists and as other public health registry standards mature, additional options will be available. We also appreciate the support for the Centralized Readiness Repository and will make note of the specific requirements made by commenters, including the requirement for national as well as local and state public health registries.

Comment: Some commenters noted that there were no public health registries available for their specialty or that their state may not be ready to receive data for the registries appropriate for them. Commenters were concerned that they would not be able to meet this measure because of a lack of public health registries available to them.

Response: We appreciate the comments. We note that providers may exclude from the public health registry as noted in the exclusions if there are no public health registries available. Providers can still meet the overall objective by choosing other measures or excluding out of other measures.

Comment: Many commenters noted that public health would not be providing data back as part of the public health registries.

Response: We appreciate the comments on the bi-directional component of public health registries. We encourage associations to work with their public health colleagues to maximize the use of data flowing into, and out of, public health registries.

Comment: Many commenters expressed concern that under the proposal, specialized registries included in the Stage 2 final rule would not be available as a measure option for eligible providers seeking to attest to Stage 3. A commenter noted that the addition of specific standards for reporting to public health registries and clinical data registries is a change from the specialized registry objective in Stage 2 and may pose a problem for states that already designated specialized registries in Stage 2. Another commenter expressed concern that without a special provision in place in Stage 3, some of the existing specialized registries would not meet the requirements for Stage 3.

Response: We understand the concerns raised by these providers. The specialized registry provision included in the Stage 2 final rule was developed to provide additional flexibility to providers to choose a registry best suited for their practice. Many public health jurisdictions began to accept electronic case reporting and prescription drug monitoring during previous stages of meaningful use and these reporting options were considered specialized registries. We want to continue to encourage those providers who have already started down the path of reporting to a specialized registry as part of their participation in Stage 2. Therefore, we will allow such specialized registries to be counted for purposes of reporting to this objective in Stage 3 under the public health

registry reporting measure for Stage 3 in 2017, 2018 and subsequent years in the following manner: A provider may count a specialized registry if the provider achieved the phase of active engagement defined under Active Engagement Option 3: Production, including production data submission with the specialized registry in a prior year under the applicable requirements of the EHR Incentive Programs in 2015 through 2017. We do note that reporting to specialized registries does not require certification under the ONC Health IT Certification Program or adherence to specific implementation guides for reporting in 2015 through 2017, and we direct readers to section aII.B.2.b.x for further information on the Specialized Registry Reporting measure for 2015 through 2017.

However we note that providers would not be able to count production reporting to a specialized registry under the Public Health Reporting Objective for 2015 through 2017, if there are standards and requirements referenced in the ONC 2015 Edition regulations for Public Health and Clinical Data Registry Stage 3 Measures:

- Example 1, EPs would not receive credit for cancer reporting under the Specialized Registry measure in Stage 3; rather the EPs would need to be in active engagement with the public health agency under the Public Health Registry Measure to submit cancer case data to the PHA using the standards mandated in the 2015 Edition Certification Criteria.
- Example 2, EPs would not receive credit for case reporting under the Specialized Registry measure in Stage 3 for production data submission that started in Modified Stage 2; rather the EPs would need to be in active

engagement with the public health agency under the Case Reporting Measure using the standards mandated in the 2015 Edition Certification Criteria.

In future years, as standards are developed and referenced in future ONC regulations, CMS may require further specialized registries to meet these future requirements under the ONC Health IT Certification Program.

Proposed 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, in the Stage 3 proposed rule (80 FR 16766) we proposed 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 proposed 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.²⁰ We proposed 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

²⁰<https://download.ama-assn.org/resources/doc/cqi/x-pub/nqrn-what-is-clinical-data-registry.pdf>

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 public health agencies 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.

In the Stage 3 proposed rule, we reiterated that any EP, eligible hospital, or CAH may report to more than one clinical data registry to meet the total number of required measures for this objective. We further noted that ONC will consider the adoption of standards and implementation guides in future rulemaking and should these 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.

Proposed Exclusions for Measure 5: 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: (1) does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period; (2) 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 (3) 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.

Comment: Many commenters noted their support for clinical data registries. Commenters appreciated the flexibility and additional means to meet the measure, which they noted aids specialists. Nearly all commenters expressed specific support for the Centralized Readiness Repository noting that it is essential for providers to determine if they can attest to the measure or if they should take an exclusion. Commenters also noted the specific content that should be available within the Centralized Readiness Repository

Response: We appreciate the overall support for this measure. We agree that this measure offers flexibility for specialists and as other clinical data registry standards mature, additional options will be available. We also appreciate the support for the Centralized Readiness Repository and will make note of the specific requirements made by commenters, including the requirement for national as well as local and state public health registries.

Comment: A commenter noted that since an increasing number of clinical data registries are national in scope and are essentially "borderless," it is unclear how CMS would define a provider's "jurisdiction."

Response: Our definition of jurisdiction here is general, and the scope may be local, state, regional or at the national level. The definition will be dependent on the type of registry to which the provider is reporting. A registry that is "borderless" would be considered a registry at the national level and would be included for purposes of this measure.

Comment: Some commenters noted that there were no clinical data registries available for the specialty or that their state may not be ready to receive data for the registries appropriate for them. Commenters were concerned that they would not be able to meet this measure because of a lack of clinical data registries available to them.

Response: We appreciate the comments. We note that providers may exclude from the clinical data registry as noted in the exclusions; if there are no clinical data registries available, providers can exclude from this measure. Providers can still meet the overall objective by choosing other measures or excluding out of other measures.

Comment: Many comments noted that organizations hosting clinical data registries would not be providing data back as part of the measure.

Response: We appreciate the comments on the bi-directional component of clinical data registries. We encourage all stakeholders to work with their clinical data registry colleagues to maximize the use of data flowing into, and out of, clinical data registries.

Comment: Many commenters noted that better exclusion criteria should exist for providers in jurisdictions with limited options for reporting and in cases where registries are not able to receive data. A commenter suggested that CMS consider allowing exclusions for providers in states where electronic reporting is not possible. Other commenters noted that specialists and other providers who do not perform specific types of reporting should have better ways to exclude out of the applicable measures. Another commenter noted that for orthopedic surgeons, there are few clinical data registry reporting options.

Response: We believe that the measure and associated exclusions that we have proposed provide a variety of options for providers to successfully attest or as appropriate be excluded from the measure. We note that the measure framework allows for multiple ways to achieve successful attestation under this objective, and allow for a provider to find a reporting option that works for them. For example, the public health agency and clinical data registry measure does not limit the provider to a predetermined list of reporting options. Rather, these two measures allow a provider to consider a broad array of reporting options available from public health agencies and clinical data registries and allows for reporting options developed in the future to be used to meet this measure. Considering the multiple ways and the flexibility included in this objective, we do not believe that additional exclusions are necessary. We believe that the requirements for exclusions under this objective strike the right balance to ensure that a provider seeking to exclude from a measure is unable to meet the requirements of the measure.

Proposed 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 public health agencies is required for eligible hospitals and CAHs in Stage 2 (77 FR 54021). We proposed to retain this measure for Stage 3 to promote the exchange of laboratory results between eligible hospitals/CAHs and public health agencies for improved timeliness, reduction of manual data entry errors, and more complete information.

Proposed Exclusion for Measure 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 if the eligible hospital or CAH: (1) does not perform or order laboratory tests that are reportable in their jurisdiction during the EHR reporting period; (2) 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 (3) operates in a jurisdiction where no public health agency has declared readiness to receive electronic reportable laboratory results from an eligible hospital or CAH at the start of the EHR reporting period.

Comment: For Measure 6, Electronic Reportable Laboratory Result Reporting, commenters agreed with the continuation of this measure, but requested that it also be included as an option for EPs with in-house laboratories.

Response: We thank commenters for their support of this measure. However, we do not agree that this measure should be extended to EPs. We note that in-house laboratories of EPs do not typically perform the types of tests that are reportable to public health jurisdictions. For example, many in-house laboratories focus on tests such as rapid strep tests that test for strep throat. The rapid strep tests are not reportable to public health agencies.

Use of CEHRT for Public Health and Clinical Data Registry Reporting

Objective

As proposed previously, the Public Health and Clinical Data Registry Reporting objective requires active engagement with a public health agency to submit electronic

public health data from certified EHR technology. ONC defined the standards and certification criteria to meet the definition of CEHRT in its 2011, 2014, and 2014 Release 2 Edition EHR certification criteria rules (see section II.B. of the "2014 Edition, Release 2 EHR Certification Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange" for a full description of ONC's regulatory history (79 FR 54434)). For example, ONC adopted standards for immunization reporting (see § 170.314(f)(1) and (f)(2)), inpatient syndromic surveillance (see § 170.314(f)(3) and (f)(7)), ELR (see § 170.314(f)(4)), and cancer case reporting (see § 170.314(f)(5) and (f)(6)) in its 2014 Edition final rule.

We support ONC's intent to promote standardized and interoperable exchange of public health data across the country. Therefore, to meet all of the measures within this public health objective EPs, eligible hospitals, and CAHs must use CEHRT as we proposed to define it under § 495.4 in the proposed rule and use the standards included in the 2015 Edition proposed rule. We anticipate that as new public health registries and clinical data registries are created, ONC and CMS will work with the public health community and clinical specialty societies to develop ONC-certified electronic reporting standards for those registries so that providers have the option to count participation in those registries under the measures of this objective. ONC will look to adopt such standards, as appropriate, in future rulemaking.

Comment: Many commenters requested clarification of the CEHRT specifications for each measure.

Response: We thank the commenters for these comments and refer readers to

section II.B.3 for a discussion of the definition of CEHRT and a table referencing the certification criteria required for each objective and measure for use in 2015 through 2017 and for Stage 3 in 2017, 2018 and subsequent years.

After consideration of public comment received, we are finalizing the objectives, measures, and exclusions as proposed except for the items previously discussed in this section. Specifically we are adopting modifications to include the 6 month lead time for the declaration of readiness for all exclusions for all 6 measures, to clarify the setting specificity for syndromic surveillance reporting, and to specify electronic case reporting. We are finalizing a total of 6 measures for this objective, and EPs would be required to choose from measures 1 through 5, and would be required to successfully attest to any combination of two measures. Eligible hospitals and CAHs would be required to choose from measures one through six, and would be required to successfully attest to any combination of four measures. We are finalizing that providers may attest to measure 4 and measure 5 more than once, and that an exclusion to a measure does not count toward the total in the manner proposed. The final objective and measures are as follows:

Objective 8: Public Health and Clinical Data Registry Reporting

Objective: The EP, 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.

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).

Exclusion for Measure 1: 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: (1) 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; (2) 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 (3) operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to 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 an urgent care setting.

Exclusion for EPs for Measure 2: Any EP meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure if the EP: (1) Is not in a category of providers from which ambulatory syndromic surveillance data is collected by their jurisdiction's syndromic surveillance system; (2) 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 (3) operates in a

jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from EPs as of 6 months prior to the start of the EHR reporting period.

Exclusion for eligible hospitals/CAHs for Measure 2: 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: (1) does not have an emergency or urgent care department; (2) 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 (3) operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from eligible hospitals or CAHs as of 6 months prior to the start of the EHR reporting period.

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

Exclusion for Measure 3: 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: (1) 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; (2) 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 (3) operates in a

jurisdiction where no public health agency has declared readiness to receive electronic case reporting data as of 6 months prior to 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.

Exclusions for Measure 4: 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: (1) does not diagnose or directly treat any disease or condition associated with a public health registry in their jurisdiction during the EHR reporting period; (2) 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 (3) 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 as of 6 months prior to the start 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.

Proposed Exclusions for Measure 5: 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: (1) does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period; (2) 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 (3) 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 as of 6 months prior to the start 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.

Exclusion for Measure 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 if the eligible hospital or CAH: (1) does not perform or order laboratory tests that are reportable in their jurisdiction during the EHR reporting period; (2) 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 (3) operates in a jurisdiction where no public health agency has declared readiness to receive electronic reportable laboratory results from an eligible hospital or CAH as of 6 months prior to the start of the EHR reporting period.

We are adopting Objective 8: Public Health and Clinical Data Registry Reporting at § 495.24(d)(8)(i) for EPs and § 495.24(d)(8)(ii) for eligible hospitals and CAHs. We further specify that in order to meet this objective and measures, an EP, eligible hospital, or CAH must use the capabilities and standards of as defined for as defined CEHRT at § 495.4. We direct readers to section II.B.3 of this final rule with comment period for a

discussion of the definition of CEHRT and a table referencing the capabilities and standards that must be used for each measure.

TABLE 10: 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*	2	4
Measure 5 - Clinical Data Registry Reporting**	2	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 to meet the number of measures required to meet the objective. A specialized registry to which the EP, eligible hospital or CAH reported using Active Engagement Option 3: Production in a prior year under the EHR Incentive Programs in 2015 through 2017 public health reporting objective may also count toward the measure in 2017, 2018 and subsequent years.

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

3. Certified EHR Technology (CEHRT) Requirements

a. CEHRT Definition for the EHR Incentive Programs

The definition of CEHRT 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). Certified EHR technology is defined for the Medicare and Medicaid EHR Incentive Programs at 42 CFR 495.4 and previously referenced ONC's definition of CEHRT in 45 CFR 170.102.

In the Stage 3 proposed rule 80 FR 16767, rather than establishing a 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" at § 495.4. 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 also proposed that providers must use EHR technology certified at least to the 2014 Edition in 2016 and 2017. We further proposed that 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).

Comment: Some commenters suggested potential changes to the certification program. Some commenters suggested the current EHR incentive programs mandate the use of certified EHRs that incorporate draft standards to support program requirements, including the exchange of health information among clinicians and the format of the content exchanged. Inconsistency in the implementation of the standards by vendors has led to confusion and limited provider success in meeting regulatory requirements for information exchange. For example, Stage 2 of meaningful use established a reliance on the "direct protocol," a new standard to support the sharing of information. As a result of

inconsistent implementation among EHR vendors, the ability to use the direct protocol standard to enable information exchange varies. For example, providers are required to use the C-CDA standard to send patient care summaries in a structured template.

However, the C-CDA has proved difficult to use and has not met clinical needs to share pertinent information to support care. Finally, one commenter stated that given the complexity of the objectives proposed under Stage 3, we believe meaningful use of EHRs can only be achieved if and when data captured in various EHRs and other data systems are interoperable.

Response: We refer commenters to the ONC 2015 Edition certification criteria final rule published elsewhere in this **Federal Register** for the for the established standards for certified health IT (see also the 2015 Edition proposed rule at 80 FR 16813 through 16872). We note that in the Stage 2 rule we adopted multiple options for HIE transport, and in this final rule with comment period, we have further expanded the mechanisms by which a provider can send and receive a C-CDA. We maintain that the C-CDA standard is required, and that a single C-CDA standard serves to support the interoperable exchange of health information.

Comment: Many commenters supported the proposal to allow providers to upgrade to the 2015 Edition at their own pace with an allowance for early upgrades in 2016 and 2017. Commenters noted that with the modular certification process, providers may be able to update parts of systems beginning in late 2016 so the allowance for technology certified to a combination of Editions is necessary. Most commenters noted that, given the timing, it is unlikely that technology certified to the 2015 Edition will be

widely available in time to participate in Stage 3 in 2017 and expressed support of the flexibility to select a stage in 2017. Other commenters expressed concern citing the same reasons and noted that the time between publication and implementation of the requirements of the Stage 3 final rule is too short to require 2015 Edition and Stage 3 in 2017. Some commenters suggested that 18 months is required for the transition and suggested making Stage 3 optional in 2018 or further delaying Stage 3 to support the upgrade timing.

Response: We thank the commenters for their input and agree that the shift should allow for greater flexibility in the upgrade process for developers and providers. We note that we have changed the EHR reporting period in 2017 to 90 days for providers who choose to participate in Stage 3, which allows a longer time frame between the publication of the final rules and implementation of systems capable of supporting the Stage 3 objectives and measures. We also note that many of the standards required for Stage 3 are similar or the same in 2014 and 2015 Edition certification criteria. Finally, we reiterate the requirement that providers use the 2015 Edition in 2018 to meet the requirements for Stage 3 for an EHR reporting period in 2018 and note that this timing also allows more than 24 months to the requirement to use technology certified to the 2015 Edition for an EHR reporting period in 2018.

Comment: Some commenters expressed support for our decision to move the CEHRT definition from the ONC certification criteria rules to the EHR Incentive Programs rule. Other commenters expressed concern regarding whether moving the CEHRT definition to the Stage 3 rule would increase confusion. A commenter noted that

the Stage 3 proposed rule reference to "certified EHR technology" conflicts with use of the term "health information technology" in the 2015 Edition proposed rule.

Several commenters addressed proposals specific to the Health IT Certification Program, the scope and focus of the certification criteria and standards for health IT under consideration by the ONC, testing of health IT systems presented for certification to ONC, and the specifics on how the newly created interoperability standards apply to the certification process.

Response: CMS, in consultation with ONC, believes that placing the CEHRT definition in the Stage 3 rule increases the simplicity of the rule. We do not believe that moving the CEHRT definition will lead to program confusion. Rather, by placing the requirements of the CEHRT definition within the rule that it impacts—the Stage 3 rule—we avoid confusion regarding the scope of the CEHRT definition (which is limited to EHR Incentive Program participants) and the broader scope of the ONC Health IT Certification Program (which applies to EHR Incentive Program participants and others, and may be used by other HHS programs). We believe that placing the CEHRT definition within the Stage 3 rule is appropriate and CMS will continue to work closely with ONC on the certification requirements that would be needed to support the objectives and measures of the EHR Incentive Programs. In addition, we are committed to releasing educational materials that will ease the transition related to the move of the CEHRT definition and, as requested by many commenters, have included a chart that outlines the certification criteria that will support providers who intend to attest to Stage 3 of meaningful use.

Regarding references in to "health IT," we do not agree that the use of the term "health IT" and the use of the term "certified EHR technology" is evidence of a disconnect between the Stage 3 and the ONC Health IT Certification Program. Rather, certified EHR technology is one type of health IT and is mandated required by the HITECH Act as part of for purposes of meeting attestation requirements and becoming a meaningful user. The ONC Health IT Certification Program and the associated 2015 Edition final rule provides certification criteria and standards integral to the CEHRT definition for Stage 3, but also is designed to address the needs of a broader set of settings that use health IT functionality beyond the requirements of the CEHRT definition.

Finally, comments related to the specific certification criteria proposed in the 2015 Edition proposed rule are outside the scope of this rulemaking. We direct commenters to the 2015 Edition proposed rule published on March 30, 2015. (80 FR 16804 through 16921) and the 2015 Edition final rule published elsewhere in this Federal Register.

After consideration of public comments received, we are finalizing the provision to include a full EHR Incentive Programs specific definition of CEHRT at 495.4 as proposed.

b. Defining CEHRT for 2015 through 2017

In adopting a CEHRT definition specific for the EHR Incentive Programs, we proposed in the EHR Incentive Programs in the Stage 3 proposed rule 80 FR 16767 to include, as currently for the ONC CEHRT definition under 45 CFR 170.102, the relevant Base EHR definitions adopted by ONC in 45 CFR 170.102 and other ONC certification

criteria relevant to the EHR Incentive Programs. We referred readers to ONC's 2015 Edition proposed rule for the proposed 2015 Edition Base EHR definition and a discussion of the 2014 Edition Base EHR definition. We included the Base EHR definition(s) because, as ONC explained in the 2014 Edition certification final rule(77 FR 54443 through 54444), the "Base EHR" essentially serves as a substitute for the term "Qualified EHR" in the definition of CEHRT. The term "Qualified EHR" is defined in section 3000(13) of the Public Health Service Act (PHSA), to include certain capabilities listed in that section, and is included in the statutory definition of "certified EHR technology" for the EHR Incentive Programs (for example, see section 1848(o)(4) of the Act). The Base EHR definition(s) also includes additional capabilities as proposed by ONC that we agreed all providers should have that are participating in the EHR Incentive Programs to support their attempts to meet meaningful use objectives and measures, as well as to support interoperable health information exchange.

We also proposed to define the editions of certification criteria that may be used for years 2015 through 2017 to meet the CEHRT definition. At a minimum, EPs, eligible hospitals, and CAHs would be required to use EHR technology certified to the 2014 Edition certification criteria for their respective EHR reporting periods in 2015 through 2017. We stated that a provider may also upgrade to the 2015 Edition prior to 2018 to meet the required certified EHR technology definition for the EHR reporting periods in 2015, 2016, or 2017, or they may use a combination of 2014 and 2015 Editions prior to

2018 if they have modules from both Editions which that meet the requirements for the objectives and measures or if they fully upgrade during an EHR reporting period.

Additionally, because ONC proposed, for the 2015 Edition, to no longer require certification of Health IT Modules to capabilities that support meaningful use objectives with percentage-based measures, we proposed to include these capabilities (45 CFR 170.314(g)(1) or (2) or 45 CFR 170.315(g)(1) or (2)), as applicable, in the CEHRT definition for 2015 through 2017, so that providers have technology that can appropriately record and calculate meaningful use measures. In the EHR Incentive Program in the Stage 3 proposed rule, We noted that there are many combinations of 2014 and 2015 Edition certified technologies that could be used to successfully meet the transitions of care requirements included in the 2014 and 2015 Edition Base EHR definitions for the purposes of meeting meaningful use objectives and measures. We explained that we believe we have identified all combinations in the proposed regulation text under § 495.4 that could be used to meet the CEHRT definition through 2017 and be used for the purposes of meeting meaningful use objectives and measures. We sought comments on the accuracy of the identified available options. We received the following comments and our responses follow:

Comment: Some commenters expressed concern that there is a misalignment between the requirements of the ONC Health IT Certification Program and the objectives and measures of Stage 3. Specifically, the commenter noted that though the automated numerator recording and measure calculation are not required for a module to be certified to the 2015 Edition, it is required for Stage 3.

Response: The automated numerator recording and measure calculation are not requirements of modules seeking certification under the 2015 Edition final rule. However, this does not represent a misalignment between the ONC Health IT Certification Program and the EHR Incentive Programs. Rather, the two criteria are required for purposes of meeting meaningful use, but may not be necessary for other users of the ONC's Health IT Certification Program. For example, a non-EHR Incentive Program provider using technology certified by the ONC Health IT Certification Program to meet requirements of CMS' chronic care management program would not need the automated numerator recording and measure calculation. ONC has sought to avoid requiring non-EHR Incentive Program participants to possess technology with the criteria previously stated in this final rule with comment period. Therefore, the 2015 Edition proposed and final rule includes the criteria for developers who intend to certify their products for use by EHR Incentive Program providers, but it does not make such criteria requirements for all technology certified under the ONC Health IT Certification Program.

Comment: Some commenters requested clarification on whether 2014 Edition or 2015 Edition (or both) could be used to attest to meaningful use in 2015 through 2017.

Response: We clarify as follows:

For EHR reporting periods in 2017:

- A provider who has technology certified to the 2015 Edition may attest to Stage 3 or to the modified Stage 2 requirements identified elsewhere in this rule.
- A provider who has technology certified to a combination of 2015 Edition and 2014 Edition may attest to: (1) the modified Stage 2 requirements; or (2) potentially to

the Stage 3 requirements if the mix of certified technologies would not prohibit them from meeting the Stage 3 measures.

- A provider who has technology certified to the 2014 Edition only may attest to the modified Stage 2 requirements and may not attest to Stage 3.

For EHR reporting periods in 2018:

- All providers must use technology certified to the 2015 Edition to meet Stage 3 requirements.

Comment: Commenters expressed concern that it is unclear whether technology that is certified only to the Base EHR definition is adequate for purposes of attesting to meaningful use. Another commenter suggested that the "Base certified EHRs" should be fully capable of meeting the needs of an EHR Incentive Program participant, without having to—for example—purchase add-ons, interfaces, or pay for reporting. Some commenters noted that requiring providers to attest to meaningful use using technology certified to the 2015 Edition Base EHR definition will result in providers having to possess software that is not necessary to that provider achieving meaningful use.

Response: Technology that is certified only to the Base EHR definition would not be adequate for purposes of attesting to meaningful use in any EHR reporting period. We agree that the components of the Base EHR definition proposed in the 2015 Edition proposed rule are integral to attesting to meaningful use and include a variety of criteria including , among others, criteria related to demographics, CPOE, medication allergy lists and data portability. However, the Base EHR definition does not include criteria

related to items such as public health reporting, electronic prescribing, and drug-drug/drug-allergy checks—which also are integral to attest to meaningful use.

The Base EHR definition is designed to include specific criteria that would apply to a broad cross section of developers seeking to support provider needs. The Base EHR definition is not designed solely for the use of the EHR Incentive Programs. For this reason, a product that a provider seeks to use to attest to meaningful use must be certified to the Base EHR definition and additional criteria that is determined by (a) the requirements of this CEHRT definition and (b) the specific objectives and measures the provider intends to use to meet meaningful use. Therefore, we do not believe it is appropriate to limit the CEHRT definition to the criteria included in ONC's Base EHR definition.

In this final rule with comment period, we have specifically identified the privacy and security certification criteria that EHR technology must be certified to meet the CEHRT definition for any federal fiscal year or calendar year before 2018, when an EP, eligible hospital, or CAH is using EHR certified to both the 2014 Edition and 2015 Edition to meet the definition.

We proposed provisions in the CEHRT definition for any federal fiscal year or calendar year before 2018 that would permit the use of a mix of EHR technology certified to 2014 and 2015 editions. This was designed to account for providers upgrading from EHR technology certified to the 2014 Edition to the 2015 Edition to meet the requirements of the CEHRT definition for 2018 and subsequent years (i.e., the use of EHR technology only certified to the 2015 Edition). In most instances, providers will

have certified privacy and security capabilities because these capabilities are part of the 2014 Edition Base EHR definition. The proposal also took into account that the adoption of EHR technology certified to the 2015 Edition would likely include most, if not, all relevant privacy and security capabilities. For example, EHR technology certified only to the 2015 Edition CPOE– order medications criterion will also be required to be certified to the 2015 Edition versions of all privacy and security criteria included in the 2014 Edition Base EHR definition, except the “integrity” criterion.

Our proposal did not, however, account for the unlikely, but plausible, scenario where a new entrant to the EHR Incentive Programs in 2016 or 2017 was able to meet the CEHRT definition for a federal fiscal year or calendar year before 2018 with EHR technology only or mostly certified to the 2014 Edition that did not include the requisite privacy and security capabilities which are part of the 2014 Base EHR definition. Therefore, we have specifically included privacy and security certification criteria in the definition to guard against this possibility.

We note that we encourage providers to work closely with their developers to determine what compilation of technology certified under the ONC Health IT Certification Program would allow the provider to successfully attest to meaningful use in an EHR reporting period covered under this rule. We also have provided a chart of the technology that would be required for a provider seeking to attest to an objective or measure (See Table 2, 80 FR 16810 through 16811). In addition, we encourage providers to review the website of the ONC Health IT Certification Program and the Certified

Health IT Products List (CHPL), which include real time information on what products are certified for what functionalities (see www.healthit.gov).

We note that some commenters expressed concern regarding fraudulent statements and claims regarding the technology offered to meet meaningful use. We encourage providers to use the CHPL as a resource for identifying whether a product is certified and to contact ONC if fraudulent activity is suspected.

After consideration of public comments received, we are finalizing and adopting this provision without modification at §495.4.

c. Defining CEHRT for 2018 and Subsequent Years

In the Stage 3 proposed rule at 80 FR 16767, We proposed that starting with 2018, all EPs, eligible hospitals, and CAHs would be required to use technology certified to the 2015 Edition to meet the CEHRT definition and to demonstrate meaningful use for an EHR reporting period in 2018 and subsequent years. The CEHRT definition would include, for the reasons discussed previously, meeting the 2015 Edition Base EHR definition and having other important capabilities that include the capabilities to:

- Record or create and incorporate family health history;
- Capture patient health information such as advance directives;
- Record numerators and denominators for meaningful use objectives with percentage-based measures and calculate the percentages;
- Calculate and report clinical quality measures; and
- Any other capabilities needed to be a Meaningful EHR User.

For information on 2015 Edition certification criteria that include these capabilities and are associated with proposed Meaningful Use objectives for Stage 3, we referred readers to the 2015 Edition proposed rule. We noted that we expect that the certification criteria with capabilities that support CQM calculation and reporting would be jointly proposed with CQM reporting requirements in a separate rulemaking.

Comment: We received a variety of comments on these proposals. Some commenters agreed that technology certified to the 2015 Edition would be developed and could be implemented by providers by 2018. Other commenters expressed their concern that requiring providers to attest to Stage 3 using 2015 Edition technology in 2018 was not realistic, and did not account for the new technology that needed to be developed to support the objectives and measures in Stage 3.

Some commenters requested that providers in 2018 be allowed to use technology certified to the 2014 Edition and the 2015 Edition to meet Stage 3 requirements. A commenter expressed a concern that requiring use of 2015 Edition in 2018 may be problematic for certain providers that need radiation oncology EHR products. The commenter requested that the 2018 year be a flex year as well as 2017. Another commenter suggested that making the 2015 Edition optional in 2017 could create confusion and that we should simply adopt a single edition.

Response: We note that 2017 provides a flex year for providers to fully implement their CEHRT. Extending the flex year beyond 2017 would slow provider progression to updated technology that better enables interoperability, care coordination, and health information exchange. We appreciate commenters concerns regarding

whether technology certified to the 2015 Edition would be ready in 2018. Developers have noted that between 18 or 24 months is the necessary to develop and implement health IT technology. With the finalization of this final rule with comment period, developers and providers will have more than 24 months to develop and implement 2015 Edition technology required by this final rule with comment period.

Further, we note that many of the requirements of Stage 3 are similar to those of Stage 2 and would use the same certification criteria with slight updates to vocabulary standards. For those criteria that are new to meaningful use in Stage 3 or for which significant updates are required, we agree with developers who confirm that 18 to 24 months provide enough time to develop and implement certified technology for purposes of meaningful use. We refer readers to section III.A. Table 2 of the ONC 2015 Edition Certification Criteria final rule published elsewhere in this **Federal Register** for further information on the differences between 2014 Edition and 2015 Edition criteria.

We further note that 2018 is the required year for the use of 2015 Edition and for attesting to Stage 3. We proposed and are finalizing in this rule a 2017flex year that allows providers options in the edition of CEHRT used and the stage of meaningful use to which the provider attests. This flexibility is in place in recognition of the implementation needed for technology. However, by 2018, all providers will be required to attest to Stage 3 using 2015 Edition technology.

Comment: Some commenters requested clarification on if a provider would be required to be certified to technology needed for measures the provider does not intend to use for attestation or if there is a specific certification requirement for certain specialties.

Response: ONC certifies products not by specialty, but by each specific functionality. In some cases, intended inpatient or ambulatory use may be a factor in the product a provider chooses to possess. Beyond this distinction, the definition of CEHRT includes the requirements specific to each measure which may be independently certified and a provider may not be required to obtain and use functions for which they do not intend to attest. We recognize that there are multiple permutations that could lead to a successful attestation under the EHR Incentive Programs. For example, a provider may decide to attest to the modified Stage 2 or Stage 3 Public Health measure using reporting options other than syndromic surveillance reporting. In such a case, the provider would not need to possess technology certified to ONC's "Transmission to Public Health Agencies – Syndromic Surveillance Criterion". In contrast, in Stage 3, some objectives require a provider to attest to all three measures but only successfully meet the thresholds of two of the three measures. For such objectives, a provider would need to possess certified technology for all three measures for purposes of attesting. We further note that in the case of a provider that meets the exclusions of a measure, the provider is not required to possess technology to meet that measure.

We caution providers to carefully make determinations regarding the technology they will need to attest to meaningful use and encourage providers to work closely with their developers to ensure that the technology they possess will meet their attestation needs. Please refer to Tables 11 through 16, which we have developed in conjunction with ONC of the technology requirements that support the CEHRT definition and each measure in section II.B.3.(d). of this final rule with comment period.

We also note that the CEHRT definition provides a baseline of functionality, but a provider may choose to possess technology that goes beyond the requirements of this CEHRT definition. We encourage providers to review products available to meet their needs and to review the Certified Health IT Products List that is available online at www.healthit.gov.

Comment: Some commenters suggested that providers should not be required to possess technology that is certified to record or create and incorporate family health history.

Response: We do not agree. Family health history is an integral component in the provision of care and the criterion supports the intake of such data into a provider's health IT system. As a result, care coordination between providers and between providers and patients is improved and accessible. The CEHRT definition includes the baseline of functionality that we believe is necessary to provide better care, advance care coordination, and support interoperability. Requiring a provider to have a system that is able to capture family health history or other patient information (such as advanced directives) is a foundational element of health IT that we will continue to support. For this reason, we decline to remove family health history or the requirement to capture patient health information from the CEHRT definition.

Comment: A commenter recommended that the ability to automatically query an HIE and retrieve a summary of care document be part of the definition of CERT. Many current systems rely on an EP to download a summary of care document from an external portal and then manually upload it into their EHR.

Response: This was not a separate functionality that we proposed to be part of the CEHRT definition, and we do not intend to adopt this suggestion as part of the CEHRT definition. However, we did propose that to meet the CEHRT definition a provider must have technology certified to the "Transitions of Care" certification criterion (45 CFR 170.315(b)(1)). The criterion requires that technology be capable of sending and receiving a C-CDA. We believe this will support a provider's ability to electronically exchange interoperable health information.

After consideration of public comments received, we are finalizing and adopting this provision as proposed at §495.4.

d. Final Definition of CEHRT

To facilitate readers identifying the requirements of CEHRT for each objective and measure defined in sections II.B.2.a and II.B.2.b of this final rule with comment period, ONC and CMS have developed a set of tables providing the appropriate certification criteria reference under the 2014 Edition and 2015 Edition certification criteria for the objectives and measures of meaningful use. These tables are provided for references purposes and reflect the definition of CEHRT adopted at §495.4for each year. We note that providers must also have the capabilities defined at §495.4for clinical quality measures (1)(ii)(B) or (2)(ii)(B), privacy and security (1)(ii)(C) or (2), and the certification criteria that are necessary to be a Meaningful EHR User (1)(ii)(D) or (2)(ii)(A).

TABLE 11: EP OBJECTIVES, MEASURES, AND CERTIFICATION CRITERIA FOR 2015 THROUGH 2017

Objective	Measure(s)	2014 Edition	2015 Edition	Additional Considerations
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Objective	Measure(s)	2014 Edition	2015 Edition	Additional Considerations
Objective 1: Protect Patient Health Information	<u>Measure:</u> 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 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’s risk management process.	The requirements are included in the Base EHR Definition	The requirements are a part of CEHRT specific to each certification criterion	The requirements are a part of CEHRT specific to each certification criterion
Objective 2: Clinical Decision Support	<u>Measure 1:</u> 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.	§ 170.314(a)(8) (Clinical Decision Support)	§ 170.315(a)(9) (Clinical Decision Support)	N/A
	<u>Measure 2:</u> The EP has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.	§ 170.314(a)(2) (Drug-drug, Drug-Allergy Interaction Checks)	§ 170.315(a)(4) (Drug-drug, Drug-Allergy Interaction Checks for CPOE)	N/A

Objective	Measure(s)	2014 Edition	2015 Edition	Additional Considerations
Objective 3: Computerized Provider Order Entry CPOE	<u>Measure 1:</u> More than 60 % of medication orders created by the EP during the EHR reporting period are recorded using CPOE.	§ 170.314(a)(1) (Computerized Provider Order Entry) or § 170.314(a)(18) (Optional – Computerized Provider Order Entry – Medications)	§ 170.315(a)(1) (Computerized Provider Order Entry - Medications)	N/A
	<u>Measure 2:</u> More than 30 % of laboratory orders created by the EP during the EHR reporting period are recorded using CPOE.	§ 170.314(a)(1) (Computerized Provider Order Entry) or § 170.314(a)(19) (Optional – Computerized Provider Order Entry – Laboratory)	§ 170.315(a)(2) (Computerized Provider Order Entry - Laboratory)	N/A
	<u>Measure 3:</u> More than 30 % of radiology orders created by the EP during the EHR reporting period are recorded using CPOE.	§ 170.314(a)(1) (Computerized Provider Order Entry) or § 170.314(a)(20) (Optional – Computerized Provider Order Entry – Diagnostic Imaging)	§ 170.315(a)(3) (Computerized Provider Order Entry – Diagnostic Imaging)	N/A
Objective 4: Electronic Prescribing	<u>Measure:</u> More than 50 % of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT.	§ 170.314(b)(3) (Electronic Prescribing) § 170.314(a)(10) (Drug-	§ 170.315(b)(3) (Electronic Prescribing) § 170.315(a)(10)	EPs may use a combination of technologies certified to either the 2014 Edition or 2015 Edition.

Objective	Measure(s)	2014 Edition	2015 Edition	Additional Considerations
		Formulary and Preferred Drug List Checks)	(Drug-Formulary and Preferred Drug List Checks)	
Objective 5: Health Information Exchange	<u>Measure:</u> The EP 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% of transitions of care and referrals.	§ 170.314(b)(2) (Transitions of Care-Create and Transmit Transition of Care/Referral Summaries) or § 170.314(b)(8) (Optional - Transitions of care)	§ 170.315(b)(1) (Transitions of Care)	N/A
Objective 6: Patient-Specific Education	<u>Measure:</u> 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.	§ 170.314(a)(15) (Patient-Specific Education Resources)	§ 170.315(a)(13) (Patient-Specific Education Resources)	N/A
Objective 7: Medication Reconciliation	<u>Measure:</u> The EP performs medication reconciliation for more than 50 % of transitions of care in which the patient is transitioned into the care of the EP.	§ 170.314(b)(4) (Clinical Information Reconciliation) or § 170.314(b)(9) (Optional – Clinical Information Reconciliation and Incorporation)	§ 170.315(b)(2) (Clinical Information Reconciliation and Incorporation)	N/A
Objective 8: Patient Electronic Access (VDT)	<u>Measure 1:</u> More than 50 % of all unique patients seen by the EP during the EHR reporting period are provided timely access to view online, download, and transmit to a third party their health information subject to the EP's discretion to withhold	§ 170.314(e)(1) (View, Download, and Transmit to 3 rd Party)	§ 170.315(e)(1) (View, Download, and Transmit to 3 rd Party)	N/A

Objective	Measure(s)	2014 Edition	2015 Edition	Additional Considerations
	certain information.			
	<p><u>Measure 2:</u> For 2015 and 2016: 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, during the EHR reporting period.</p> <p>For 2017: More than 5 percent of unique patients seen by the EP during the EHR reporting period (or their authorized representatives) views, downloads, or transmits their health information to a third party, during the EHR reporting period.</p>	<p>§ 170.314(e)(1) (View, Download, and Transmit to 3rd Party)</p>	<p>§ 170.315(e)(1) (View, Download, and Transmit to 3rd Party)</p>	<p>N/A</p>
<p>Objective 9: Secure Messaging</p>	<p><u>Measure:</u> For 2015: During the EHR reporting period the capability for patients to send and receive a secure electronic message with the EP was fully enabled. For 2016: For at least 1 patient seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative) during the EHR</p>	<p>§ 170.314(e)(3) (Secure Messaging)</p>	<p>§ 170.315(e)(2) (Secure Messaging)</p>	<p>N/A</p>

Objective	Measure(s)	2014 Edition	2015 Edition	Additional Considerations
	reporting period. For 2017: :For more than 5 percent of unique patients seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative) during the EHR reporting period.			
Objective 10: Public Health Reporting	<u>Measure 1 – Immunization Registry Reporting</u>	§ 170.314(f)(1) (Immunization Information) and § 170.314(f)(2) (Transmission to Immunization Registries)	N/A	N/A
	<u>Measure 2 – Syndromic Surveillance Reporting</u>	§ 170.314(f)(3) (Transmission to Public Health Agencies – Syndromic Surveillance) or § 170.314(f)(7) (Optional – Ambulatory Setting Only – Transmission to Public Health Agencies – Syndromic Surveillance)	§ 170.315(f)(2) (Transmission to Public Health Agencies – Syndromic Surveillance) Urgent Care Settings Only	N/A

Objective	Measure(s)	2014 Edition	2015 Edition	Additional Considerations
	<p><u>Measure 3 – Specialized Registry Reporting</u></p>	<p>§ 170.314(f)(5) (Optional – Ambulatory Setting Only – Cancer Case Information) and § 170.314(f)(6) (Optional – Ambulatory Setting Only – Transmission to Cancer Registries)</p>	<p>EPs may choose one or more of the following: § 170.315(f)(5) (Transmission to Public Health Agencies – Electronic Case Reporting) § 170.315(f)(7) Transmission to Public Health Agencies – Health Care Surveys § 170.315(f)(4) Transmission to Cancer Registries</p>	<p>Certified EHR technology is not required for specialized registry reporting for 2015-2017, but EHR technology certified to the 2014 Edition or 2015 Edition may be used.</p> <p>Other non-named specialized registries unsupported by certification requirements may also be chosen.</p>

TABLE 12: ELIGIBLE HOSPITAL AND CAH OBJECTIVES, MEASURES, AND CERTIFICATION CRITERIA FOR 2015 THROUGH 2017

Objective	Measure(s)	2014 Edition	2015 Edition	Additional Considerations
<p>Objective 1: Protect Patient Health Information</p>	<p><u>Measure:</u> 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 CEHRT 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</p>	<p>The requirements are included in the Base EHR Definition</p>	<p>The requirements are a part of CEHRT specific to each certification criterion</p>	<p>The requirements are a part of CEHRT specific to each certification criterion</p>

Objective	Measure(s)	2014 Edition	2015 Edition	Additional Considerations
	security deficiencies as part of the eligible hospital or CAH's risk management process.			
Objective 2: Clinical Decision Support	<u>Measure 1:</u> 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.	§ 170.314(a)(8) (Clinical Decision Support)	§ 170.315(a)(9) (Clinical Decision Support)	N/A
	<u>Measure 2:</u> The eligible hospital or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.	§ 170.314(a)(2) (Drug-drug, Drug-Allergy Interaction Checks)	§ 170.315(a)(4) (Drug-drug, Drug-Allergy Interaction Checks for CPOE)	N/A
Objective 3: Computerized Provider Order Entry CPOE	<u>Measure 1:</u> More than 60 % 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 CPOE.	§ 170.314(a)(1) (Computerized Provider Order Entry) or § 170.314(a)(18) (Optional – Computerized Provider Order Entry – Medications)	§ 170.315(a)(1) (Computerized Provider Order Entry - Medications)	N/A
	<u>Measure 2:</u> More than 30 % 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 CPOE.	§ 170.314(a)(1) (Computerized Provider Order Entry) or § 170.314(a)(19) (Optional – Computerized Provider Order Entry – Laboratory)	§ 170.315(a)(2) (Computerized Provider Order Entry - Laboratory)	N/A

Objective	Measure(s)	2014 Edition	2015 Edition	Additional Considerations
	<p><u>Measure 3:</u> More than 30 % 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 CPOE.</p>	<p>§ 170.314(a)(1) (Computerized Provider Order Entry) or § 170.314(a)(20) (Optional – Computerized Provider Order Entry – Diagnostic Imaging)</p>	<p>§ 170.315(a)(3) (Computerized Provider Order Entry – Diagnostic Imaging)</p>	<p>N/A</p>
<p>Objective 4: Electronic Prescribing</p>	<p><u>Measure:</u> More than 10 % of hospital discharge medication orders for permissible prescriptions (for new or changed prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.</p>	<p>§ 170.314(b)(3) (Electronic Prescribing) § 170.314(a)(10) (Drug-Formulary and Preferred Drug List Checks)</p>	<p>§ 170.315(b)(3) (Electronic Prescribing) § 170.315(a)(10) (Drug-Formulary and Preferred Drug List Checks)</p>	<p>Eligible hospitals and CAHs may use a combination of technologies certified to either the 2014 Edition or 2015 Edition.</p>
<p>Objective 5: Health Information Exchange</p>	<p><u>Measure:</u> The 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 % of transitions of care and referrals.</p>	<p>§ 170.314(b)(2) (Transitions of Care-Create and Transmit Transition of Care/Referral Summaries) or § 170.314(b)(8) (Optional - Transitions of care)</p>	<p>§ 170.315(b)(1) (Transitions of Care)</p>	<p>N/A</p>
<p>Objective 6: Patient-Specific Education</p>	<p><u>Measure:</u> More than 10 % of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) are</p>	<p>§ 170.314(a)(15) (Patient-Specific Education Resources)</p>	<p>§ 170.315(a)(13) (Patient-Specific Education Resources)</p>	<p>N/A</p>

Objective	Measure(s)	2014 Edition	2015 Edition	Additional Considerations
	provided patient specific education resources identified by CEHRT.			
Objective 7: Medication Reconciliation	<u>Measure:</u> The eligible hospital or CAH performs medication reconciliation for more than 50 % 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).	§ 170.314(b)(4) (Clinical Information Reconciliation) or § 170.314(b)(9) (Optional – Clinical Information Reconciliation and Incorporation)	§ 170.315(b)(2) (Clinical Information Reconciliation and Incorporation)	N/A
Objective 8: Patient Electronic Access (VDT)	<u>Measure 1:</u> 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 are provided timely access to view online, download and transmit their health information to a third party their health information.	§ 170.314(e)(1) (View, Download, and Transmit to 3 rd Party)	§ 170.315(e)(1) (View, Download, and Transmit to 3 rd Party)	N/A
	<u>Measure 2:</u> For 2015 and 2016: 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. For 2017: More than 5 percent of unique patients discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH (or his	§ 170.314(e)(1) (View, Download, and Transmit to 3 rd Party)	§ 170.315(e)(1) (View, Download, and Transmit to 3 rd Party)	N/A

Objective	Measure(s)	2014 Edition	2015 Edition	Additional Considerations
	or her authorized representative) view, download, or transmit to a third party their information during the EHR reporting period.			
Objective 9: Secure Messaging	N/A	N/A	N/A	N/A
Objective 10: Public Health Reporting	<u>Measure 1 – Immunization Registry Reporting</u>	§ 170.314(f)(1) (Immunization Information) and § 170.314(f)(2) (Transmission to Immunization Registries)	N/A	N/A
	<u>Measure 2 – Syndromic Surveillance Reporting</u>	§ 170.314(f)(3) (Transmission to Public Health Agencies – Syndromic Surveillance)	§ 170.315(f)(2) (Transmission to Public Health Agencies – Syndromic Surveillance)	N/A
	<u>Measure 3 – Specialized Registry Reporting</u>	N/A	<p>Eligible Hospitals/CAHs may choose one or more of the following:</p> <p>§ 170.315(f)(5) (Transmission to Public Health Agencies – Electronic Case Reporting)</p> <p>§ 170.315(f)(6) Transmission to Public Health Agencies – Antimicrobial Use and</p>	<p>Certified EHR technology is not required for specialized registry reporting for 2015-2017, but EHR technology certified to the 2014 Edition or 2015 Edition may be used.</p> <p>Other non-named specialized registries unsupported by</p>

Objective	Measure(s)	2014 Edition	2015 Edition	Additional Considerations
			Resistance Reporting § 170.315(f)(7) Transmission to Public Health Agencies – Health Care Surveys	certification requirements may also be chosen.
	<u>Measure 4 – Electronic Reportable Laboratory Result Reporting</u>	§ 170.314(f)(4) (Inpatient Setting Only – Transmission of Reportable Laboratory Tests and Values/Results	§ 170.315(f)(3) (Transmission to Public Health Agencies – Reportable Laboratory Tests and Values/Results)	N/A

TABLE 13 - EP OBJECTIVES, MEASURES, AND CERTIFICATION CRITERIA FOR STAGE 3 IN 2017

Objective	Measure(s)	2014 Edition	2015 Edition	Combinations
Objective 1: Protect Electronic Health Information	<u>Measure:</u> 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 created or maintained by CEHRT 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 provider’s risk management process.	The requirements are included in the Base EHR Definition	The requirements are a part of CEHRT specific to each certification criterion	The requirements are a part of CEHRT specific to each certification criterion

Objective	Measure(s)	2014 Edition	2015 Edition	Combinations
Objective 2: Electronic Prescribing	<u>Measure:</u> More than 60% of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT.	§ 170.314(b)(3) (Electronic Prescribing) § 170.314(a)(10) (Drug-Formulary and Preferred Drug List Checks)	§ 170.315(b)(3) (Electronic Prescribing) § 170.315(a)(10) (Drug-Formulary and Preferred Drug List checks)	EPs may use a combination of technologies certified to either the 2014 Edition or 2015 Edition.
Objective 3: Clinical Decision Support	<u>Measure 1:</u> The EP must implement five clinical decision support interventions related to four or more CQMs at a relevant point in patient care for the entire EHR reporting period.	§ 170.314(a)(8) (Clinical Decision Support)	§ 170.315(a)(9) (Clinical Decision Support)	N/A
	<u>Measure 2:</u> The EP has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.	§ 170.314(a)(2) (Drug-Drug, Drug-Allergy Interaction Checks)	§ 170.315(a)(4) (Drug-Drug, Drug-Allergy Interaction Checks for CPOE)	N/A
Objective 4: Computerized Provider Order Entry (CPOE)	<u>Measure 1:</u> More than 60 % of medication orders created by the EP during the EHR reporting period are recorded using CPOE.	§170.314(a)(1) (Computerized Provider Order Entry) or §170.314(a)(18) (Optional – Computerized Provider Order Entry – Medications)	§170.315(a)(1) (Computerized Provider Order Entry–Medications)	N/A
	<u>Measure 2:</u> More than 60 % of laboratory orders created by the EP during the EHR reporting period are recorded using CPOE.	§170.314(a)(1) (Computerized Provider Order Entry) or §170.314(a)(19) (Optional – Computerized Provider Order Entry – Laboratory)	§170.315(a)(2) (Computerized Provider Order Entry–Laboratory)	N/A

Objective	Measure(s)	2014 Edition	2015 Edition	Combinations
	<p><u>Measure 3:</u>More than 60 % of diagnostic imaging orders created by the EP during the EHR reporting period are recorded using CPOE.</p>	<p>§170.314(a)(1) (Computerized Provider Order Entry) or §170.314(a)(20) (Optional – Computerized Provider Order Entry – Diagnostic Imaging)</p>	<p>§170.315(a)(3) (Computerized Provider Order Entry–Diagnostic Imaging)</p>	<p>N/A</p>
<p>Objective 5: Patient Electronic Access</p>	<p><u>Measure 1:</u>For more than 80 % of all unique patients seen by the EP: (1) The patient (or the patient authorized representative) is provided timely access to view online, download, and transmit his or her health information; and (2) The EP ensures the patient’s health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the provider’s CEHRT.</p>	<p>§170.314(e)(1) (View, Download, and Transmit to 3rd Party)</p>	<p>§170.315(e)(1) (View, Download, and Transmit to 3rd Party) §170.315(g)(7) (Application Access – Patient Selection)* §170.315(g)(8) (Application Access – Data Category Request)* §170.315(g)(9) (Application Access – All Data Request)* *The three criteria combined are the “API” certification criteria</p>	<p>EPs may use technologies certified to either the 2014 Edition or 2015 Edition VDT certification criteria (i.e., §170.314(e)(1) or §170.315(e)(1)) in 2017). The 2014 Edition does not offer “API” certification criteria. Therefore, EPs choosing to attest to the Stage 3 measures in 2017 would need to possess technology certified to §170.315(g)(7), §170.315(g)(8), and §170.315(g)(9).</p>
	<p><u>Measure 2:</u>The EP must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35% of unique</p>	<p>§ 170.314(a)(15) (Patient-Specific Education Resources)</p>	<p>§ 170.315(a)(13) (Patient-specific Education Resources)</p>	<p>N/A</p>

Objective	Measure(s)	2014 Edition	2015 Edition	Combinations
	patients seen by the EP.			
Objective 6: Coordination of Care through Patient Engagement	<p><u>Measure 1:</u>For 2017, during the EHR reporting period, more than 5% of all unique patients(or patient-authorized representative)seen by the EP actively engage with the EHR made accessible by the provider. An EP may meet the measure by either-</p> <p>(1) view, download or transmit to a third party their health information; or</p> <p>(2) access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's CEHRT; or(3) a combination of (1) and (2).</p>	<p>§170.314(e)(1) (View, Download, and Transmit to 3rd Party)</p>	<p>§170.315(e)(1) (View, Download, and Transmit to 3rd Party)</p> <p>§170.315(g)(7) (Application Access – Patient Selection)*</p> <p>§170.315(g)(8) (Application Access – Data Category Request)*</p> <p>§170.315(g)(9) (Application Access – All Data Request)*</p> <p>*The three criteria combined are the “API” certification criteria</p>	<p>EPs may use a combination of technologies certified to either the 2014 Edition or 2015 Edition VDT certification criteria (i.e., §170.314(e)(1) or §170.315(e)(1)) in 2017).</p> <p>The 2014 Edition does not offer API certification criteria. Therefore, EPs choosing to attest to the Stage 3 measures in 2017 would need to possess technology certified to §170.315(g)(7), §170.315(g)(8), and §170.315(g)(9).</p>
	<p><u>Measure 2:</u>For 2017, more than 5% of all unique patients seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative).</p>	<p>§ 170.314(e)(3) (Secure Messaging)</p>	<p>§ 170.315(e)(2) (Secure Messaging)</p>	<p>N/A</p>

Objective	Measure(s)	2014 Edition	2015 Edition	Combinations
	<p><u>Measure 3</u>:Patient-generated health data or data from a non-clinical setting is incorporated into the CEHRT for more than 5 of all unique patients seen by the EP during the EHR reporting period.</p>	N/A	<p>§ 170.315(e)(3) (Patient Health Information Capture)*</p> <p>*Supports meeting the measure, but is NOT required to be used to meet the measure. The certification criterion is part of the CEHRT definition beginning in 2018.</p>	
<p>Objective 7: Health Information Exchange</p>	<p><u>Measure 1</u>:For more than 50% of transitions of care and referrals, the EP that transitions or refers their patient to another setting of care or provider of care-- (1) creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.</p>	<p>§ 170.314(b)(2) (Transitions of Care – Create and Transmit Transition of Care/Referral Summaries)</p> <p>or</p> <p>§ 170.314(b)(8) (Optional – Transitions of Care)</p>	<p>§ 170.315(b)(1) (Transitions of Care)</p>	N/A
	<p><u>Measure 2</u>:For more than 40% of transitions or referrals received and patient encounters in which the EP has never before encountered the patient, the EP receives or retrieves and incorporates into the patient's record an electronic summary of care document.</p>	<p>§ 170.314(b)(1) (Transitions of Care-Receive, Display and Incorporate Transition of Care/Referral Summaries)</p> <p>or</p> <p>§ 170.314(b)(8) (Optional – Transitions of Care)</p>	<p>§ 170.315(b)(1) (Transitions of Care)</p>	N/A

Objective	Measure(s)	2014 Edition	2015 Edition	Combinations
	<p><u>Measure 3</u>: For more than 80% of transitions or referrals received and patient encounters in which the EP has never before encountered the patient, the EP performs clinical information reconciliation.</p>	<p>§ 170.314(b)(4) (Clinical Information Reconciliation) or § 170.314(b)(9) (Optional – Clinical Information Reconciliation and Incorporation)</p>	<p>§ 170.315(b)(2) (Clinical Information Reconciliation and Incorporation)</p>	<p>N/A</p>
<p>Objective 8: Public Health and Clinical Data Registry Reporting</p>	<p><u>Measure 1</u>: Immunization Registry Reporting</p>	<p>N/A</p>	<p>§ 170.315(f)(1) (Transmission to Immunization Registries)</p>	<p>N/A</p>
	<p><u>Measure 2</u>: Syndromic Surveillance Reporting</p>	<p>§ 170.314(f)(3) (Transmission to Public Health Agencies – Syndromic Surveillance) or § 170.314(f)(7) (Optional – Ambulatory Setting Only – Transmission to Public Health Agencies – Syndromic Surveillance)</p>	<p>§ 170.315(f)(2) (Transmission to Public Health Agencies – Syndromic Surveillance) Urgent Care Setting Only</p>	<p>N/A</p>
	<p><u>Measure 3</u>: Electronic Case Reporting</p>	<p>N/A</p>	<p>§ 170.315(f)(5) (Transmission to Public Health Agencies – Electronic Case Reporting)</p>	<p>N/A</p>
	<p><u>Measure 4</u>: Public Health Registry Reporting</p>	<p>§ 170.314(f)(5) (Optional – Ambulatory Setting Only – Cancer Case Information) and § 170.314(f)(6) (Optional – Ambulatory Setting Only – Transmission to Cancer Registries)</p>	<p>EPs may choose one or more of the following: § 170.315(f)(4) (Transmission to Cancer Registries) § 170.315(f)(7) (Transmission to Public Health Agencies – Health Care Surveys)</p>	<p>EPs may choose to use technologies certified to either the 2014 Edition or 2015 Edition certification criteria in 2017.</p>

Objective	Measure(s)	2014 Edition	2015 Edition	Combinations
	<u>Measure 5</u> :Clinical Data Registry Reporting	N/A	No 2015 Edition health IT certification criteria at this time.	N/A

TABLE 14 - ELIGIBLE HOSPITAL/CAH OBJECTIVES, MEASURES, AND CERTIFICATION CRITERIA FOR STAGE 3 IN 2017

Objective	Measure(s)	2014 Edition	2015 Edition	Combinations
Objective 1: Protect Electronic Health Information	<u>Measure</u> : 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 created or maintained by CEHRT in accordance with requirements in 45 CFR 164.312(a)(2)(i v) 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.	The requirements are included in the Base EHR Definition	The requirements are a part of CEHRT specific to each certification criterion	The requirements are a part of CEHRT specific to each certification criterion
Objective 2: Electronic Prescribing	<u>Measure</u> : More than 25% of hospital discharge medication orders for permissible prescriptions (for new and changed prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.	§ 170.314(b)(3) (Electronic Prescribing) § 170.314(a)(10) (Drug-Formulary and Preferred Drug List Checks)	§ 170.315(b)(3) (Electronic Prescribing) § 170.315(a)(10) (Drug-Formulary and Preferred Drug List Checks)	Eligible Hospitals/CAHs may use a combination of technologies certified to either the 2014 Edition or 2015 Edition.

Objective	Measure(s)	2014 Edition	2015 Edition	Combinations
Objective 3: Clinical Decision Support	<u>Measure 1:</u> The eligible hospital or CAH must implement five clinical decision support interventions related to four or more CQMs at a relevant point in patient care for the entire EHR reporting period.	§ 170.314(a)(8) (Clinical Decision Support)	§ 170.315(a)(9) (Clinical Decision Support)	N/A
	<u>Measure 2:</u> The eligible hospital or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.	§ 170.314(a)(2) (Drug-Drug, Drug-Allergy Interaction Checks)	§ 170.315(a)(4) (Drug-Drug, Drug-Allergy Interaction Checks for CPOE)	N/A
Objective 4: Computerized Provider Order Entry (CPOE)	<u>Measure 1:</u> More than 60 % of medication orders created by the 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.	§170.314(a)(1) (Computerized Provider Order Entry) or §170.314(a)(18) (Optional – Computerized Provider Order Entry – Medications)	§170.315(a)(1) (Computerized Provider Order Entry – Medications)	N/A
	<u>Measure 2:</u> More than 60%t of laboratory orders created by the authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the	§170.314(a)(1) (Computerized Provider Order Entry) or §170.314(a)(19) (Optional – Computerized Provider Order Entry – Laboratory)	§170.315(a)(2) (Computerized Provider Order Entry – Laboratory)	N/A

Objective	Measure(s)	2014 Edition	2015 Edition	Combinations
	<p>EHR reporting period are recorded using CPOE.</p> <p><u>Measure 3:</u>More than 60% of diagnostic imaging orders created by the 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.</p>	<p>§170.314(a)(1) (Computerized Provider Order Entry) or §170.314(a)(2)(0) (Optional – Computerized Provider Order Entry – Diagnostic Imaging)</p>	<p>§170.315(a)(3) (Computerized Provider Order Entry – Diagnostic Imaging)</p>	<p>N/A</p>
<p>Objective 5: Patient Electronic Access</p>	<p><u>Measure 1:</u>For more than 80 % of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):</p> <p>(1) The patient (or the patient authorized representative) is provided timely access to view online, download, and transmit his or her health information.; and</p> <p>(2) The provider ensures the patient’s health information is available for the patient (or patient-authorized representative) to access using any application</p>	<p>§ 170.314(e)(1) (View, Download, and Transmit to 3rd Party)</p>	<p>§ 170.315(e)(1) (View, Download, and Transmit to 3rd Party)</p> <p>§170.315(g)(7)* (Application Access – Patient Selection)</p> <p>§170.315(g)(8)* (Application Access – Data Category Request)*</p> <p>§170.315(g)(9) (Application Access – All Data Request)*</p> <p>*The three criteria combined are the “API” certification criteria</p>	<p>Eligible Hospitals/CAHs may use technologies certified to either the 2014 Edition or 2015 Edition VDT certification criteria (i.e., §170.314(e)(1) or §170.315(e)(1))i n 2017).</p> <p>The 2014 Edition does not offer “API” certification criteria.</p> <p>Therefore, Eligible Hospitals/CAHs choosing to attest to the Stage 3 measures in 2017 would need to possess technology certified to</p>

Objective	Measure(s)	2014 Edition	2015 Edition	Combinations
	<p>of their choice that is configured to meet the technical specifications of the API in the provider’s CEHRT.</p>			<p>§170.315(g)(7), §170.315(g)(8), and §170.315(g)(9).</p>
	<p><u>Measure 2:</u>The eligible hospital or CAH must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35% of unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.</p>	<p>§ 170.314(a)(15) (Patient-Specific Education Resources)</p>	<p>§ 170.315(a)(13) (Patient-Specific Education Resources)</p>	<p>N/A</p>
<p>Objective 6: Coordination of Care through Patient Engagement</p>	<p><u>Measure 1:</u>During the EHR reporting period, more than 10 percent of all unique patients (or their authorized representatives) discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) actively engage with the EHR made accessible by the provider and either: (1) view, download or transmit to a third party their health</p>	<p>§ 170.314(e)(1) (View, Download, and Transmit to 3rd Party)</p>	<p>§ 170.315(e)(1) (View, Download, and Transmit to 3rd Party) § 170.315(g)(7) (Application Access – Patient Selection)* § 170.315(g)(8) (Application Access – Data Category Request)* §170.315(g)(9) (Application Access – All Data Request)* *The three criteria combined are the “API” certification criteria</p>	<p>Eligible Hospitals/CAHs may use technologies certified to either the 2014 Edition or 2015 Edition VDT certification criteria (i.e., §170.314(e)(1) or §170.315(e)(1)) in 2017. The 2014 Edition does not offer “API” certification criteria. Therefore,</p>

Objective	Measure(s)	2014 Edition	2015 Edition	Combinations
	information; or (2) access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's CEHRT; or (3) a combination of (1) and (2).			Eligible Hospitals/CAHs choosing to attest to the Stage 3 measures in 2017 would need to possess technology certified to § 170.315(g)(7), § 170.315(g)(8), and § 170.315(g)(9).
	<u>Measure 2:</u> For more than 25% of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative) during the EHR reporting period.	§ 170.314(e)(3) (Secure Messaging)	§ 170.315(e)(2) (Secure Messaging)	N/A
	Measure 3:Patient-generated health data or data from a non-clinical setting is incorporated into the CEHRT for more than 5% of all unique patients discharged	N/A	§ 170.315(e)(3) (Patient Health Information Capture)* *Supports meeting the measure, but is NOT required to be used to meet the measure. The certification criterion is part of the CEHRT	N/A

Objective	Measure(s)	2014 Edition	2015 Edition	Combinations
	from the eligible hospital or CAH (POS 21 and 23) during the EHR reporting period.		definition beginning in 2018.	
Objective 7: Health Information Exchange	<u>Measure 1:</u> For more than 50% of transitions of care and referrals, the eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care-- (1) creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.	§ 170.314(b)(2) (Transitions of Care – Create and Transmit Transition of Care/Referral Summaries) or § 170.314(b)(8) (Optional – Transitions of Care)	§ 170.315(b)(1) (Transitions of Care)	N/A
	<u>Measure 2:</u> For more than 40% of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH receives or retrieves and incorporates into the patient's record in their EHR an electronic summary of care document.	§ 170.314(b)(1) (Transitions of Care – Receive, Display and Incorporate Transition of Care/Referral Summaries) or § 170.314(b)(8) (Optional – Transitions of Care)	§ 170.315(b)(1) (Transitions of Care)	N/A
	<u>Measure 3:</u> For more than 80%of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible	§ 170.314(b)(4) (Clinical Information Reconciliation) or § 170.314(b)(9) (Optional – Clinical	§ 170.315(b)(2) (Clinical Information Reconciliation and Incorporation)	N/A

Objective	Measure(s)	2014 Edition	2015 Edition	Combinations
	hospital or CAH performs clinical information reconciliation.	Information Reconciliation and Incorporation)		
Objective 8: Public Health and Clinical Data Registry Reporting	<u>Measure 1</u> :Immunization Registry Reporting	N/A	§ 170.315(f)(1) (Transmission to Immunization Registries)	N/A
	<u>Measure 2</u> :Syndromic Surveillance Reporting	§ 170.314(f)(3) (Transmission to Public Health Agencies – Syndromic Surveillance)	§ 170.315(f)(2) (Transmission to Public Health Agencies – Syndromic Surveillance)	N/A
	<u>Measure 3</u> :Electronic Case Reporting	N/A	§ 170.315(f)(5) (Transmission to Public Health Agencies – Electronic Case Reporting)	N/A
	<u>Measure 4</u> : Public Health Registry Reporting	N/A	Eligible Hospitals/CAHs may choose one or more of the following: § 170.315(f)(6) (Transmission to Public Health Agencies – Antimicrobial Use and Resistance) § 170.315(f)(7) (Transmission to Public Health Agencies – Health Care Surveys)	EPs may choose to use technologies certified to either the 2014 Edition or 2015 Edition certification criteria in 2017.
	<u>Measure 5</u> :Clinical Data Registry Reporting		No 2015 Edition health IT certification criteria at this time.	N/A
	<u>Measure 6</u> :Electronic Reportable Laboratory Result	§ 170.314(f)(4) (Inpatient Setting Only – Transmission	§ 170.315(f)(3) (Transmission to Public Health Agencies –	N/A

Objective	Measure(s)	2014 Edition	2015 Edition	Combinations
	Reporting	of Reportable Laboratory Tests and Values/Results)	Reportable Laboratory Tests and Values/Results)	

TABLE 15 - EP OBJECTIVES, MEASURES, AND CERTIFICATION CRITERIA FOR STAGE 3 IN 2018 AND SUBSEQUENT YEARS

EP Objectives, Measures, and Certification Criteria for Stage 3 in 2018 and Subsequent Years		
Objective	Measure(s)	2015 Edition
Objective 1: Protect Electronic Health Information	<u>Measure:</u> 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 created or maintained by CEHRT 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 provider’s risk management process.	The requirements are a part of CEHRT specific to each certification criterion
Objective 2: Electronic Prescribing	<u>Measure:</u> More than 60% of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT.	§ 170.315(b)(3) (Electronic Prescribing) § 170.315(a)(10) (Drug-Formulary and Preferred Drug List checks)
Objective 3: Clinical Decision Support	<u>Measure 1:</u> The EP must implement five clinical decision support interventions related to four or more CQMs at a relevant point in patient care for the entire EHR reporting period.	§ 170.315(a)(9) (Clinical Decision Support)
	<u>Measure 2:</u> The EP has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.	§ 170.315(a)(4) (Drug-Drug, Drug-Allergy Interaction Checks for CPOE)
Objective 4: Computerized Provider Order Entry (CPOE)	<u>Measure 1:</u> More than 60 % of medication orders created by the EP during the EHR reporting period are recorded using CPOE.	§170.315(a)(1) (Computerized Provider Order Entry–Medications)

EP Objectives, Measures, and Certification Criteria for Stage 3 in 2018 and Subsequent Years		
Objective	Measure(s)	2015 Edition
	<u>Measure 2:</u> More than 60 % of laboratory orders created by the EP during the EHR reporting period are recorded using CPOE.	§170.315(a)(2) (Computerized Provider Order Entry–Laboratory)
	<u>Measure 3:</u> More than 60 % of diagnostic imaging orders created by the EP during the EHR reporting period are recorded using CPOE.	§170.315(a)(3) (Computerized Provider Order Entry–Diagnostic Imaging)
Objective 5: Patient Electronic Access	<u>Measure 1:</u> For more than 80 % of all unique patients seen by the EP: (1) The patient (or the patient authorized representative) is provided timely access to view online, download, and transmit his or her health information; and (2) The EP ensures the patient’s health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the provider’s CEHRT.	§170.315(e)(1) (View, Download, and Transmit to 3 rd Party) §170.315(g)(7) (Application Access – Patient Selection)* §170.315(g)(8) (Application Access – Data Category Request)* §170.315(g)(9) (Application Access – All Data Request)* *The three criteria combined are the “API” certification criteria
	<u>Measure 2:</u> The EP must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35% of unique patients seen by the EP.	§ 170.315(a)(13) (Patient-specific Education Resources)
Objective 6: Coordination of Care through Patient Engagement	<u>Measure 1:</u> For 2017, during the EHR reporting period, more than 10% of all unique patients(or patient-authorized representative)seen by the EP actively engage with the EHR made accessible by the provider. An EP may meet the measure by either- (1) view, download or transmit to a third party their health information; or (2) access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's CEHRT; or(3) a combination of (1) and (2).	§170.315(e)(1) (View, Download, and Transmit to 3 rd Party) §170.315(g)(7) (Application Access – Patient Selection)* §170.315(g)(8) (Application Access – Data Category Request)* §170.315(g)(9)

EP Objectives, Measures, and Certification Criteria for Stage 3 in 2018 and Subsequent Years		
Objective	Measure(s)	2015 Edition
		(Application Access – All Data Request)* *The three criteria combined are the “API” certification criteria
	<u>Measure 2:</u> For 2017, more than 25% of all unique patients seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative).	§ 170.315(e)(2) (Secure Messaging)
	<u>Measure 3:</u> Patient-generated health data or data from a non-clinical setting is incorporated into the CEHRT for more than 5 of all unique patients seen by the EP during the EHR reporting period.	§ 170.315(e)(3) (Patient Health Information Capture)* *Supports meeting the measure, but is NOT required to be used to meet the measure. The certification criterion is part of the CEHRT definition beginning in 2018.
Objective 7: Health Information Exchange	<u>Measure 1:</u> For more than 50% of transitions of care and referrals, the EP that transitions or refers their patient to another setting of care or provider of care-- (1) creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.	§ 170.315(b)(1) (Transitions of Care)
	<u>Measure 2:</u> For more than 40% of transitions or referrals received and patient encounters in which the EP has never before encountered the patient, the EP receives or retrieves and incorporates into the patient's record an electronic summary of care document.	§ 170.315(b)(1) (Transitions of Care)

EP Objectives, Measures, and Certification Criteria for Stage 3 in 2018 and Subsequent Years		
Objective	Measure(s)	2015 Edition
	<u>Measure 3</u> : For more than 80% of transitions or referrals received and patient encounters in which the EP has never before encountered the patient, the EP performs clinical information reconciliation.	§ 170.315(b)(2) (Clinical Information Reconciliation and Incorporation)
Public Health and Clinical Data Registry Reporting	<u>Measure 1</u> :Immunization Registry Reporting	§ 170.315(f)(1) (Transmission to Immunization Registries)
	<u>Measure 2</u> :Syndromic Surveillance Reporting	§ 170.315(f)(2) (Transmission to Public Health Agencies – Syndromic Surveillance) Urgent Care Setting Only
	<u>Measure 3</u> :Electronic Case Reporting	§ 170.315(f)(5) (Transmission to Public Health Agencies – Electronic Case Reporting)
	<u>Measure 4</u> : Public Health Registry Reporting	EPs may choose one or more of the following: § 170.315(f)(4) (Transmission to Cancer Registries) § 170.315(f)(7) (Transmission to Public Health Agencies – Health Care Surveys)
	<u>Measure 5</u> :Clinical Data Registry Reporting	No 2015 Edition health IT certification criteria at this time.

TABLE 16 - ELIGIBLE HOSPITAL/CAH OBJECTIVES, MEASURES, AND CERTIFICATION CRITERIA FOR STAGE 3 IN 2018 AND SUBSEQUENT YEARS

Objective	Measure(s)	2015 Edition
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Objective	Measure(s)	2015 Edition
<p>Objective 1: Protect Electronic Health Information</p>	<p><u>Measure:</u> 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 created or maintained by CEHRT 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 provider’s risk management process.</p>	<p>The requirements are a part of CEHRT specific to each certification criterion</p>
<p>Objective 2: Electronic Prescribing</p>	<p><u>Measure:</u> More than 25% of hospital discharge medication orders for permissible prescriptions (for new and changed prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.</p>	<p>§ 170.315(b)(3) (Electronic Prescribing) § 170.315(a)(10) (Drug-Formulary and Preferred Drug List Checks)</p>
<p>Objective 3: Clinical Decision Support</p>	<p><u>Measure 1:</u> The eligible hospital or CAH must implement five clinical decision support interventions related to four or more CQMs at a relevant point in patient care for the entire EHR reporting period.</p>	<p>§ 170.315(a)(9) (Clinical Decision Support)</p>
	<p><u>Measure 2:</u>The eligible hospital or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.</p>	<p>§ 170.315(a)(4) (Drug-Drug, Drug-Allergy Interaction Checks for CPOE)</p>
<p>Objective 4: Computerized Provider Order Entry (CPOE)</p>	<p><u>Measure 1:</u>More than 60 % of medication orders created by the 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.</p>	<p>§170.315(a)(1) (Computerized Provider Order Entry – Medications)</p>
	<p><u>Measure 2:</u> More than 60%t of laboratory orders created by the 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.</p>	<p>§170.315(a)(2) (Computerized Provider Order Entry – Laboratory)</p>
	<p><u>Measure 3:</u>More than 60% of diagnostic imaging orders created by the authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are</p>	<p>§170.315(a)(3) (Computerized Provider Order Entry – Diagnostic Imaging)</p>

Objective	Measure(s)	2015 Edition
	recorded using CPOE.	
Objective 5: Patient Electronic Access	<p><u>Measure 1:</u>For more than 80 % of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):</p> <p>(1) The patient (or the patient authorized representative) is provided timely access to view online, download, and transmit his or her health information.; and</p> <p>(2) The provider ensures the patient’s health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the provider’s CEHRT.</p>	<p>§ 170.315(e)(1) (View, Download, and Transmit to 3rd Party)</p> <p>§ 170.315(g)(7)* (Application Access – Patient Selection)</p> <p>§ 170.315(g)(8)* (Application Access – Data Category Request)*</p> <p>§ 170.315(g)(9) (Application Access – All Data Request)*</p> <p>*The three criteria combined are the “API” certification criteria</p>
	<p><u>Measure 2:</u>The eligible hospital or CAH must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35% of unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.</p>	<p>§ 170.315(a)(13) (Patient-Specific Education Resources)</p>
Objective 6: Coordination of Care through Patient Engagement	<p><u>Measure 1:</u>During the EHR reporting period, more than 10 percent of all unique patients (or their authorized representatives) discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) actively engage with the EHR made accessible by the provider and either:</p> <p>(1) view, download or transmit to a third party their health information; or</p> <p>(2) access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's CEHRT; or</p> <p>(3) a combination of (1) and (2).</p>	<p>§ 170.315(e)(1) (View, Download, and Transmit to 3rd Party)</p> <p>§ 170.315(g)(7) (Application Access – Patient Selection)*</p> <p>§ 170.315(g)(8) (Application Access – Data Category Request)*</p> <p>§ 170.315(g)(9) (Application Access – All Data Request)*</p>

Objective	Measure(s)	2015 Edition
		<p>*The three criteria combined are the “API” certification criteria</p>
	<p><u>Measure 2:</u>For more than 25% of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative) during the EHR reporting period.</p>	<p>§ 170.315(e)(2) (Secure Messaging)</p>
	<p><u>Measure 3:</u>Patient-generated health data or data from a non-clinical setting is incorporated into the CEHRT for more than 5% of all unique patients discharged from the eligible hospital or CAH (POS 21 and 23) during the EHR reporting period.</p>	<p>§ 170.315(e)(3) (Patient Health Information Capture)*</p> <p>*Supports meeting the measure, but is NOT required to be used to meet the measure. The certification criterion is part of the CEHRT definition beginning in 2018.</p>
<p>Objective 7: Health Information Exchange</p>	<p><u>Measure 1:</u>For more than 50% of transitions of care and referrals, the eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care-- (1) creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.</p>	<p>§ 170.315(b)(1) (Transitions of Care)</p>
	<p><u>Measure 2:</u>For more than 40% of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH receives</p>	<p>§ 170.315(b)(1) (Transitions of Care)</p>

Objective	Measure(s)	2015 Edition
	or retrieves and incorporates into the patient's record in their EHR an electronic summary of care document.	
	<u>Measure 3</u> : For more than 80% of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH performs clinical information reconciliation.	§ 170.315(b)(2) (Clinical Information Reconciliation and Incorporation)
Objective 8: Public Health and Clinical Data Registry Reporting	<u>Measure 1</u> :Immunization Registry Reporting	§ 170.315(f)(1) (Transmission to Immunization Registries)
	<u>Measure 2</u> :Syndromic Surveillance Reporting	§ 170.315(f)(2) (Transmission to Public Health Agencies – Syndromic Surveillance)
	<u>Measure 3</u> :Electronic Case Reporting	§ 170.315(f)(5) (Transmission to Public Health Agencies – Electronic Case Reporting)
	<u>Measure 4</u> : Public Health Registry Reporting	<p>Eligible Hospitals/CAHs may choose one or more of the following:</p> <p>§ 170.315(f)(6) (Transmission to Public Health Agencies – Antimicrobial Use and Resistance)</p> <p>§ 170.315(f)(7) (Transmission to Public Health Agencies – Health Care Surveys)</p>
	<u>Measure 5</u> :Clinical Data Registry Reporting	No 2015 Edition health IT certification criteria at this time.

Objective	Measure(s)	2015 Edition
	<p><u>Measure 6</u>:Electronic Reportable Laboratory Result Reporting</p>	<p>§ 170.315(f)(3) (Transmission to Public Health Agencies – Reportable Laboratory Tests and Values/Results)</p>

C. Clinical Quality Measurement

1. Clinical Quality Measure (CQM) Requirements for Meaningful Use in 2015 and 2016

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 EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20375 through 20376), we proposed to maintain the existing requirements established in earlier rulemaking for the reporting of CQMs. We summarized the options for CQM submission for providers in the Medicare EHR Incentive Program as follows:

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

++ 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 EP's 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.

- **Eligible hospital and CAH Options for Medicare EHR Incentive Program**

Participation (*single program participation - EHR Incentive Program only*)

++ 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, we stated that 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 proposed 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).

Beginning in 2015, we proposed 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 proposed 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.

For 2015 only, we proposed 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 proposed a 90-day reporting period in 2015 for clinical quality measures for all EPs, eligible hospitals, and CAHs that report clinical quality measures by attestation. We proposed that EPs 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. We proposed 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 proposed 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 also met. We noted 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. We also noted that 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 one 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. For further information on the requirements for eligible

hospitals and CAHs electronically submitting CQMs for a reporting period in 2015 for the Medicare EHR Incentive Program, we referred readers to the FY 2015 IPPS final rule (79 FR 50319 through 50323).

We noted 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.

Comment: We received many comments in support of maintaining the existing CQM reporting requirements and aligning CQM requirements with other quality programs where possible, including support of our proposal to align reporting for eligible hospitals and CAHs to the calendar year. Some commenters expressed concerns over their ability to report CQMs, and some commenters requested that CMS expand the number of CQMs available to specialists.

Response: We appreciate the comments in support of our proposals and understand the concerns raised by others. CMS continues to evaluate the available CQMs for inclusion in the EHR Incentive Programs and will consider adding CQMs to the program as they are developed and found to be appropriate for inclusion. In the meantime, we understand that there are situations in which an EP, eligible hospital or CAH does not have data to report on for a particular CQM, and its EHR is not certified to additional CQMs or does not have additional CQMs available to report on. In these instances, we believe that our policy on allowing zero denominators to be reported allow these providers and specialists to meet the CQM reporting requirements of the EHR Incentive Programs (see the Stage 2 final rule 77 FR 54059 and 54079 and FY 2015 IPPS final rule 79 FR 50323).

Comment: A few commenters suggested that we further align the Medicare EHR Incentive Program with PQRS and allow EPs reporting through a Qualified Clinical Data

Registry (QCDR) to satisfy the CQM reporting requirements for meaningful use.

Response: The QCDR reporting mechanism was introduced for the Physician Quality Reporting System (PQRS) beginning in 2014. For 2015, a QCDR is a CMS-approved entity that collects medical and clinical data, or both, for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. A QCDR is different from a PQRS qualified registry in that it is not limited to reporting data on measures within the PQRS measure set or the EHR Incentive Program. We appreciate the commenters' suggestion to allow CQM reporting for the EHR Incentive Programs through the PQRS QCDR option and will consider broadening our policy to accept all QCDR submissions in future policy and rulemaking. Currently, EPs can report on CQMs through a QCDR and satisfy some of the requirements for the Medicare EHR Incentive Program, as well as PQRS requirements, if they submit CQMs using certified EHR technology and the approved QRDA-I or QRDA-III format (78 FR 74754 through 74755). We note for the Medicare EHR Incentive Program, the only CQMs that may be reported through a QCDR are those finalized in the Stage 2 final rule (77 FR 54069 through 54075), and this does not include the non-PQRS measures submitted via QCDR.

Comment: Some commenters suggested that reporting on CQMs could be removed as a requirement from the EHR Incentive Program.

Response: As we noted in the Stage 2 final rule (77 FR 54056 through 54078), CQM reporting is a statutory requirement for providers seeking to be meaningful users of certified EHR technology. In addition, as noted in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20351) and in the Stage 3 proposed rule (80 FR 16740 through 16741), the use of EHR technology to submit information on clinical quality measures is defined in the

HITECH Act as a key foundational principle and policy of meaningful use (see sections 1848(o)(2)(A) and 1886(n)(3)(A) of the Act). Additionally, we believe CQM reporting is key to the continued efforts to improve the quality of care in a patient centered delivery system reform model. We maintain our commitment to CQM reporting as part of meaningful use of certified EHR technology.

Comment: Many commenters supported our proposal to allow a 90-day reporting period for clinical quality measures for all EPs, eligible hospitals, and CAHs that report clinical quality measures by attestation. Some commenters additionally suggested that this option should be extended to every year of the EHR Incentive Programs. Some commenters noted that alignment with other quality programs such as PQRS requires full-year reporting even in 2015, and therefore this policy does not align with those quality programs. Commenters also suggested that there be a 90-day reporting period for PQRS.

Response: We appreciate the comments in support of our proposal. We note that our proposal was for 2015 only, and that we are not extending it to 2016 or subsequent years. We also acknowledge that this 90-day reporting period does not fully align with other CMS quality programs such as PQRS, and that each quality program has its own reporting requirements. While we seek to align the CMS quality programs wherever possible and as appropriate, we acknowledge that this is one area where a provider seeking to satisfy the various requirements of multiple programs would need to report data separately to each program, or choose to instead report through one of our aligned options.

After consideration of the public comments, we are finalizing all of the proposals discussed previously as proposed. We note that after these proposals were published, we published the

August 17, 2015 FY 2016 IPPS final rule (80 FR 49756 through 49761), which includes additional final policies for eligible hospitals and CAHs reporting CQMs in 2016 for the Medicare EHR Incentive Program.

2. Clinical Quality Measure (CQM) Requirements for Meaningful Use in 2017 and Subsequent Years

a. Clinical Quality Measure Reporting Requirements for EPs

In the Stage 3 proposed rule (80 FR 16768), we noted that to further our goals of alignment and avoiding redundant or duplicative reporting across the various CMS quality reporting programs, we intend to address CQM reporting requirements for the Medicare and Medicaid EHR Incentive Program for EPs for 2017 and subsequent years in the Medicare Physician Fee Schedule (PFS) rulemaking, which also establishes the requirements for PQRS and other quality programs affecting EPs. We noted that the form and manner of reporting of CQMs for Medicare EPs would also be included in the PFS, while for Medicaid we would continue to allow the states to determine form and method requirements subject to CMS approval.

We proposed to continue the policy of establishing certain CQM requirements that apply for both the Medicare and Medicaid EHR Incentive Programs, including a common set of CQMs and the reporting periods for CQMs in the EHR Incentive Programs.

Comment: Commenters supported the alignment efforts between the Medicare EHR Incentive Program and PQRS or other quality programs affecting EPs. Most commenters stated that alignment would reduce burden on EPs and streamline the quality reporting process. Some commenters also appreciated the link between the annual rulemaking cycle and updates to the

CQMs stating that aligning CQM requirements for the EHR Incentive Programs with other quality programs in annual rulemaking would require measure developers to revise their CQM specifications more frequently, helping to ensure CQMs reflect the latest clinical evidence.

Response: We appreciate the commenters' support of our proposal, and agree that aligning the Medicare EHR Incentive Program and PQRS or other quality programs affecting EPs would reduce burden on EPs. We also agree that annual rulemaking will allow CMS to ensure that CQMs used in quality reporting programs are updated regularly.

Comment: A few commenters suggested that since CQMs are a requirement of multiple EP quality programs, they could be removed from the EHR Incentive Program requirements because this CQM reporting is redundant.

Response: We appreciate the commenters' suggestion. However, as noted previously, CQM reporting for the EHR Incentive Programs is required by section 1848(o)(2)(A)(iii) of the Act and an integral part of the National Quality Strategy for CMS and HHS as a whole. We further note that in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20375) we stated our intent to maintain these CQM policies as previously finalized. We further believe that by aligning the CQM requirements of the different quality reporting programs, we are reducing burden and removing the redundancy of CQM reporting by allowing EPs to report once for multiple programs.

Comment: Some commenters expressed concerns regarding the amount of time between the publication of the PFS final rule and when the CQMs and policies would go into effect. Many expressed concern over whether their EHR vendor would have time to certify and update their system to the most recent version of the CQMs.

Response: We understand the commenters' concerns and note that CQMs referenced in the PFS rulemaking are generally updated annually, and certain updates are posted in advance of the final rule. We also note that re-certification of EHR technology is not required for the CQM annual update. Additionally, we have taken steps to align certain aspects of the various CMS quality reporting programs that include the submission of CQMs.

Comment: Other commenters expressed concern about the number of stakeholders involved in these aligned programs, and stated that it would be challenging for EPs to get answers to questions or responses from CMS due to the number of stakeholders involved in CQM submissions.

Response: We understand this concern, and we note that we also continue to align CMS help desks, feedback processes, and other resources to avoid delays in answering questions. We believe that alignment of the CQM requirements along with this coordination effort will greatly reduce burden on EPs.

Comment: While commenters acknowledged the alignment effort to address CQM policies in the PFS rule, some also requested further clarification in regard to how CQM alignment among the programs would work. Specifically, they questioned whether EPs who choose to attest in 2017 would still be required to report to other quality programs, or whether attestation could count for multiple programs.

Response: We appreciate the question and opportunity to further explain this policy, which is a current policy not a new policy. Reporting CQMs by attestation under the EHR Incentive Programs is not an acceptable method of submission for other CMS quality reporting programs because, unlike the EHR Incentive Programs, these other programs have not adopted

attestation as a reporting mechanism and also have additional requirements that relate to the results of the CQM calculation. Therefore, reporting CQMs by attestation for the EHR Incentive Programs would not count toward CQM reporting for other quality programs. EPs who choose to report CQMs for the EHR Incentive Programs by attestation in 2017 would need to separately report to other quality programs via one of the approved reporting mechanisms for the particular program.

After consideration of the public comments we received, we intend to continue our policy of establishing certain CQM requirements that apply for both the Medicare and Medicaid EHR Incentive Programs, including a common set of CQMs and the reporting periods for CQMs. We intend to address CQM reporting requirements for the Medicare and Medicaid EHR Incentive Programs for EPs in the PFS rulemaking. We intend to continue to allow the states to determine form and manner of reporting CQMs for their respective state Medicaid EHR Incentive Programs subject to CMS approval.

b. CQM Reporting Requirements for Eligible Hospitals and Critical Access Hospitals

In the Stage 3 proposed rule (80 FR 16769), similar to our intentions for EPs discussed previously, we noted that to further our alignment goal among CMS quality reporting programs for eligible hospitals and CAHs, and avoid redundant or duplicative reporting among hospital programs, we intend to address CQM reporting requirements for the Medicare and Medicaid EHR Incentive Program for eligible hospitals and CAHs for 2016, 2017, and future years, in the Inpatient Prospective Payment System (IPPS) rulemaking. We stated that we intend to include all Medicare EHR Incentive Program requirements related to CQM reporting in the IPPS

rulemaking including, but not limited to, new program requirements, reporting requirements, reporting and submission periods, reporting methods, and information regarding the CQMs.

As with EPs, for the Medicaid EHR Incentive Program we would continue to allow the states to determine form and method requirements subject to CMS approval. We proposed to continue the policy of establishing certain CQM requirements that apply for both the Medicare and Medicaid EHR Incentive Programs including a common set of CQMs and the reporting periods for CQMs in the EHR Incentive Programs.

Comment: Commenters supported the alignment efforts between the Medicare EHR Incentive Program and Hospital IQR Program. Most commenters stated that alignment would reduce burden on eligible hospitals and CAHs. Some commenters also appreciated the link between the annual rulemaking cycle and updates to the CQMs stating that aligning CQM requirements for the EHR Incentive Program with other quality programs in annual rulemaking would require measure developers to revise their CQM specifications more frequently helping to ensure that CQMs reflect the latest clinical evidence.

Response: We appreciate the commenters' support of our proposal, and agree that aligning the Medicare EHR Incentive Program and the Hospital IQR Program or other quality programs affecting eligible hospitals and CAHs would reduce burdens. We also agree that annual rulemaking will allow CMS to ensure that CQMs used in quality reporting programs are updated regularly.

Comment: Some commenters expressed concerns regarding the amount of time between the publication of the IPPS final rule and when the CQMs and policies would go into effect. Many expressed concern over whether their EHR vendor would have time to certify and update

their system to the most recent version of the CQMs, and a few went on to request that changes to CQMs and submission requirements not change from one quarter reporting period to the next.

Response: We understand the commenters' concerns and note that CQMs referenced in the IPPS rulemaking are generally updated annually, and certain updates are posted in advance of the final rule. The 2016 IPPS final rule provides flexibility to eligible hospitals and CAHs needing to update their EHR systems only for the most recent version of the CQMs. No changes to 2014 CEHRT criteria or timelines are being finalized in this final rule with comment period.

Comment: Some commenters expressed concerns related to CMS' ability to accept electronically submitted CQMs.

Response: We understand the commenters' concerns. CMS has worked to continually develop and improve its CQM receiving system for the purposes of collecting CQMs electronically.

Comment: Some commenters noted that the Hospital IQR Program is not required for CAHs and requested clarification on how the alignment of the Medicare EHR Incentive Program and Hospital IQR Program would impact CAHs seeking to electronically submit their CQM data.

Response: We agree that the Hospital IQR Program is not required for CAHs. Only subsection (d) hospitals are subject to the requirements and payment reductions of the Hospital IQR Program. For the EHR Incentive Programs, CAHs may continue to report their CQM data by attestation in CY 2016. However, we encourage CAHs to submit their CQMs electronically through the QualityNet portal. We believe electronic submission of CQMs is an important next step in the meaningful use of certified EHR technology, and encourage CAHs to begin submitting CQMs electronically in 2016. We further note that in section II.C.4 of this final rule

with comment period, we finalize our policy to require the electronic submission of CQMs starting in 2018 and thus encourage CAHs to begin electronically reporting CQMs as soon as feasible.

After consideration of the public comments we received, we intend to continue our policy of establishing certain CQM requirements that apply for both the Medicare and Medicaid EHR Incentive Programs, including a common set of CQMs and the reporting periods for CQMs. We intend to address CQM reporting requirements for the Medicare and Medicaid EHR Incentive Programs for eligible hospitals and CAHs in the IPPS rulemaking. We intend to continue to allow the states to determine form and manner of reporting CQMs for their respective state Medicaid EHR Incentive Programs subject to CMS approval.

c. Quality Reporting Data Architecture Category III (QRDA-III) Option for Eligible Hospitals and CAHs

In the Stage 3 proposed rule (80 FR 16771), we proposed to remove the QRDA-III option for eligible hospitals and CAHs, as we believe the CQM calculations, per the QRDA-III, are not advantageous to quality improvement in a hospital setting. We noted that as the EHR Incentive Programs further aligns with the Hospital IQR Program, we intend to continue utilizing the electronic reporting standard of QRDA-I patient level data that we finalized in the FY 2015 IPPS rule (79 FR 50322), which will allow the same level of CQM reporting, and use and analysis of these data for quality improvement initiatives.

We also proposed that states would continue to have the option, subject to our prior approval, to allow or require QRDA-III for CQM reporting.

We received comments regarding these proposals in response to the Stage 3 proposed

rule, as well as comments regarding the QRDA-III option in response to the FY 2016 IPPS/LTCH PPS proposed rule. We considered these comments and responded to them in the FY 2016 IPPS/LTCH PPS final rule, and we finalized our proposal to remove the QRDA-III as an option for reporting under the Medicare EHR Incentive Program. We stated that for 2016 and future years, we are requiring QRDA-I for CQM electronic submissions for the Medicare EHR Incentive Program. We also noted that states would continue to have the option, subject to our prior approval, to allow or require QRDA-III for CQM reporting. For more information, we refer readers to the discussion in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49759 through 49760).

3. CQM Reporting Period Beginning in 2017

In the Stage 3 proposed rule (80 FR 16773), we proposed to require an EHR reporting period of one full calendar year for meaningful use for providers participating in the Medicare EHR Incentive Program, with a limited exception for Medicaid providers demonstrating meaningful use for the first time (80 FR 16779). We proposed to require the same length for the CQM reporting period for EPs, eligible hospitals, and CAHs beginning in 2017. We proposed a limited exception for Medicaid providers demonstrating meaningful use for the first time who would have a CQM reporting period of any continuous 90 days that is the same 90-day period as their EHR reporting period.

a. CQM Reporting Period for EPs

We proposed to require a CQM reporting period of one full calendar year for all EPs participating in the Medicare and Medicaid EHR Incentive Program, with a limited exception for Medicaid providers demonstrating meaningful use for the first time who would have a CQM

reporting period of any continuous 90 days that is the same 90-day period as their EHR reporting period. We proposed these reporting periods would apply beginning in CY 2017 for all EPs participating in the EHR Incentive Program.

Comment: Most commenters supported one full calendar year of reporting for EPs participating in the EHR Incentive Programs. Some commenters stated that they believed this would result in more complete and accurate data. A few commenters stated that no exception should be granted for Medicaid providers demonstrating meaningful use for the first time because this exception would cause confusion. A commenter recommended that under this exception, we allow the 90-day reporting period for CQMs to be different than the 90-day EHR reporting period.

Response: We appreciate the comments in support of our proposal, and we agree that a full year of reporting would lead to more complete data. However, we believe that a 90-day CQM reporting period is appropriate for the Medicaid EHR Incentive Program when the EP is attesting to meaningful use for the first time. A 90-day CQM reporting period would allow Medicaid EPs additional time and flexibility within their first year of demonstrating meaningful use to implement certified EHR technology and otherwise integrate the meaningful use objectives into their practices. We also believe that it would reduce the burden on states to implement significant policy and system changes in preparation for Stage 3, as the 90-day period for the first year of meaningful use is consistent with our previous policies and meaningful use timelines. We agree with the commenter's recommendation that we not require the reporting period for CQMs to be the same 90-day period as the EHR reporting period under the exception proposed for Medicaid. We believe it is appropriate for the CQM reporting period to be any

continuous 90-day period in the calendar year for providers demonstrating meaningful use for the first time under the Medicaid EHR Incentive Program. This will give providers flexibility with attesting and would not require states to make system changes as there are 90-day reporting periods under the current policy.

Comment: Some commenters opposed the proposal stating that there is additional work that needs to be done to assess the feasibility, accuracy, and reliability of electronically reported data, while others stated that requiring one calendar year of electronically submitted data creates additional burden on EPs to collect that data. A few commenters suggested a 90-day reporting period for all EPs in 2018 when electronic reporting is required.

Response: We understand the commenters' concerns and note that CMS continues to assess electronically reported data for accuracy and reliability. If data is determined to be flawed, such data will be identified by CMS in order to preserve the integrity of data used for differentiating performance. Additionally we note that one calendar year of data is required for PQRS and other quality reporting programs with which we seek to align the EHR Incentive Program; this alignment reduces provider burden by allowing EPs to report once for multiple programs. We believe full year reporting is necessary for the efficacy of quality measurement and quality improvement planning, and, in fact, most CQMs are designed to be collected over a 12-month period, including multiple variables to track change over time. As mentioned in the Stage 3 proposed rule, we believe full year CQM reporting will allow for the collection of more comparable data across CMS quality programs, increase alignment across those programs, and reduce the complexity of reporting requirements for the Medicare EHR Incentive Program by streamlining the reporting timeline for providers for CQMs and meaningful use objectives and

measures (79 FR 16769). While we are allowing a 90-day EHR reporting period for EPs who demonstrate Stage 3 in 2017, we do not believe it is necessary to similarly allow returning participants who are participating in Stage 3 to also use a 90-day reporting period for CQMs for 2017. The shorter reporting period for Stage 3 participants is intended to ease the transition to the new Stage 3 objectives and measures and higher thresholds. There is no such difference between the CQM requirements for Stage 3 participation in 2017 versus participation meeting the objectives and measures outline for use in 2015 through 2017 in section II.B.2.a of this final rule with comment period.

Note that there is also a 90-day EHR reporting period permitted in 2017 for EPs participating for the first time in either the Medicare or Medicaid EHR Incentive Programs. Consistent with prior program years, we are permitting EPs participating for the first time in 2017 to use a 90-day reporting period for CQMs.

After considering the public comments we received, we are finalizing our proposal to require a CQM reporting period of one full calendar year for EPs participating in the Medicare and Medicaid EHR Incentive Programs starting in 2017. We are finalizing with modification our proposal of a limited exception for EPs demonstrating meaningful use for the first time under the Medicaid EHR Incentive Program. For these EPs, the reporting period for CQMs would be any continuous 90-day period within the CY, with the modification that it could be a different 90-day period than their EHR reporting period for the incentive payment under Medicaid.

b. CQM Reporting Period for Eligible Hospitals and CAHs

For eligible hospitals and CAHs in 2017 and subsequent years, in the Stage 3 proposed rule (80 FR 16770) we proposed to require a reporting period of one full calendar year which

consists of 4 quarterly data reporting periods for providers participating in the Medicare and Medicaid EHR Incentive Program, with a limited exception for Medicaid providers demonstrating meaningful use for the first time who would have a CQM reporting period of any continuous 90 days that is the same 90-day period as their EHR reporting period. We stated that more details of the form and manner will be provided in the IPPS rulemaking cycle.

Comment: Most commenters supported one full calendar year of reporting for eligible hospitals and CAHs participating in the EHR Incentive Programs. Some commenters stated that they believed this would result in more complete and accurate data, and others expressed support for a consistent reporting period across reporting programs. Some commenters opposed the proposal stating that there is additional work that needs to be done to assess the feasibility, accuracy, and reliability of electronically submitted data. Some commenters opposed the proposal stating that it creates additional burden on eligible hospitals and CAHs to collect the data, and some went on to suggest that CMS continue the validation pilot instead of requiring one full year of electronically submitted data in 2018. A few commenters suggested a 90-day reporting period for all eligible hospitals and CAHs in 2018 when electronic reporting is required. A commenter recommended that under the limited exemption for Medicaid eligible hospitals and CAHs, we should allow the 90-day reporting period for CQMs to be different than the 90-day EHR reporting period.

Response: We appreciate the comments we received in support of our proposal, and agree that accepting one full year of data will result in more complete and accurate data. We understand the concerns stated by commenters regarding the additional burden and efforts associated with collecting this data, but we note that providers would be able to submit one full

year of data for both the EHR Incentive Program and the Hospital IQR Program, thereby reducing provider burden. We further note that CMS continues to assess electronically submitted data for accuracy and reliability. If data is determined to be flawed, such data will be identified by CMS in order to preserve the integrity of data used for differentiating performance.

While we are allowing a 90-day EHR reporting period for eligible hospitals and CAHs who demonstrate Stage 3 in 2017, we do not believe it is necessary to similarly allow returning participants who are participating in Stage 3 to also use a 90-day reporting period for CQMs for 2017. The shorter reporting period for Stage 3 participants is intended to ease the transition to the new Stage 3 objectives and measures and higher thresholds. There is no such difference between the CQM requirements for Stage 3 participation in 2017 versus participation meeting the objectives and measures outline for use in 2015 through 2017 in section II.B.2.a. of this final rule with comment period.

Note that there is also a 90-day EHR reporting period permitted in 2017 for eligible hospitals and CAHs participating for the first time in either the Medicare or Medicaid EHR Incentive Programs. Consistent with prior program years, we are permitting eligible hospitals and CAHs participating for the first time in 2017 to use a 90-day reporting period for CQMs.

After consideration of the public comments that we received, we are finalizing our proposal to require a reporting period of one full calendar year which consists of 4 quarterly data reporting periods starting in 2017 for eligible hospitals and CAHs participating in the Medicare and Medicaid EHR Incentive Program. We are finalizing with modification our proposal of a limited exception for eligible hospitals and CAHs demonstrating meaningful use for the first time under the Medicaid EHR Incentive Program. For these eligible hospitals and CAHs, the

reporting period for CQMs would be any continuous 90-day period within the CY, with the modification that it could be a different 90-day period than their EHR reporting period for the incentive payment under Medicaid. More details of the form and manner will be provided in the IPPS rulemaking cycle.

c. Reporting Flexibility for EPs, Eligible Hospitals, and CAHs in 2017

We proposed that EPs, eligible hospitals, and CAHs would be able to have more flexibility to report CQMs in one of two ways in 2017 – via electronic reporting or attestation (80 FR 16770). First EPs, eligible hospitals, and CAHs may choose to report eCQMs electronically using the CQMs finalized for use in 2017 using the most recent version of the eCQMs (electronic specifications), which would be the electronic specifications of the CQMs published by CMS in 2016. Alternately, a provider may choose to continue to attest also using the most recent (2016 version) eCQM electronic specifications.

Comment: Commenters supported our proposal to allow more flexibility in 2017 reporting. Most commenters supported a move toward electronic reporting, and also agreed that attestation should remain an option for 2017 to provide options to, and reduce burden on EPs, eligible hospitals, and CAHs. Some commenters supported our proposal but urged CMS to make electronic reporting mandatory in 2018 or move up the timeline to require mandatory electronic reporting as soon as possible.

Response: We appreciate the comments in support of our proposal, and agree with commenters' statements that flexibility reduces burden on EPs, eligible hospitals, and CAHs. We also appreciate commenters' support of a move toward electronic reporting, and requiring electronic reporting in 2018 or moving up the timeline for mandatory electronic reporting. We

believe electronic reporting is an important step in demonstrating meaningful use of certified EHR technology and note that in section II.C.4 of this final rule with comment period, we are finalizing our proposal to require electronic reporting in 2018 where feasible.

After consideration of these public comments, we are finalizing this policy as proposed.

4. Reporting Methods for CQMs

In the Stage 3 proposed rule (80 FR 16770), starting in 2017, we proposed to continue to encourage electronic submission of CQM data for all EPs, eligible hospitals, and CAHs where feasible. However, as outlined in section II.C.1.b. of the Stage 3 proposed rule (80 FR 16770), we would allow attestation for CQMs in 2017.

For 2018 and subsequent years, we proposed that providers participating in the Medicare EHR Incentive program must electronically report where feasible and that attestation to CQMs would no longer be an option except in certain circumstances where electronic reporting is not feasible. This would include providers facing circumstances which render them unable to electronically report (such as a data submission system failure, natural disaster, or certification issue outside the control of the provider) who may attest to CQMs if they also attest that electronically reporting was not feasible for their demonstration of meaningful use for a given year. We noted that we intend to address the form and manner of electronic reporting in future Medicare payment rules.

For the Medicaid EHR Incentive Program, as in the Stage 2 rulemaking (77 FR 54089), we proposed that states would continue in Stage 3 to be responsible for determining whether and how electronic reporting of CQMs would occur, or whether they wish to continue to allow reporting through attestation. If a state does require such electronic reporting, the state is

responsible for sharing the details of the process with its provider community. We proposed for Stage 3 that the states would establish the method and requirements, subject to our prior approval, for the electronic capture and reporting of CQMs from CEHRT. We have included Table 17 in this final rule with comment period as a summary of our proposals (80 FR 16770).

TABLE 17: PROPOSED eCQM REPORTING TIMELINES FOR MEDICARE & MEDICAID EHR INCENTIVE PROGRAM

Year	2017 Only	2017 Only	2018 and Subsequent Years	2018 and Subsequent Years
Reporting Method Available	Attestation	Electronic Reporting	Attestation	Electronic Reporting
Provider Type who May Use Method	All Medicare providers Medicaid providers must refer to state requirements for reporting	All Medicare Providers Medicaid providers must refer to state requirements for reporting	Medicare Providers with circumstances rendering them unable to eReport Medicaid providers must refer to state requirements for reporting	All Medicare Providers Medicaid providers must refer to state requirements for reporting
CQM Reporting Period	1 CY for Medicare 1 CY for returning Medicaid 90 days for first time meaningful user Medicaid	1 CY for Medicare 1 CY for returning Medicaid 90 days for first time meaningful user Medicaid	1 CY for Medicare 1 CY for returning Medicaid 90 days for first time meaningful user Medicaid	1 CY for Medicare 1 CY for returning Medicaid 90 days for first time meaningful user Medicaid
eCQM Version Required (CQM electronic specifications update)	2016 Annual Update	2016 Annual Update	2016 Annual Update or more recent version	2017 Annual Update
CEHRT Edition Required	2014 Edition Or 2015 Edition	2014 Edition Or 2015 Edition	2015 Edition	2015 Edition

Comment: Most commenters supported the move to electronic reporting; however, they did so with caution. Commenters expressed their support, as well as concerns, related to the feasibility of the move to electronic reporting of CQMs citing issues with data submission and the reliability of CQMs. Some commenters expressed concerns about committing to a timeline for implementing electronic reporting of CQMs stating that they had concerns about future updates to CQMs and the difficulties eligible hospitals face in implementing CQMs currently.

Response: We appreciate the comments in support of our move to electronic reporting, and understand some of the concerns that come along with that move. CMS continues to evaluate the accuracy and reliability of CQM data received from providers. We believe that it is important to set a timeline for requiring electronic reporting and to give EPs, eligible hospitals, CAHs and their EHR vendors time to prepare for this requirement.

Comment: A few commenters requested clarification as to which CQM version would be accepted via attestation.

Response: We appreciate the comments and the opportunity to clarify our policy. For 2017 reporting, we will accept the 2016 version of the CQM specifications for both attested and electronically reported CQMs. For 2018 reporting, we will accept the 2017 version of the CQM specifications for both attested and electronically reported CQMs. For 2018, we will additionally accept the 2016 version of the CQM specifications for attestation. We note that attestation in 2018 will be allowed for providers facing circumstances which render them unable to electronically report (such as a data submission system failure, natural disaster, or certification issue outside the control of the provider) who may attest to CQMs if they also attest that electronically reporting was not feasible, and we are therefore allowing either the 2016 or 2017

version of the CQM specifications due to this exception.

Comment: A few commenters stated that since attestation to core objectives is a manual process, CQM submission should also remain a manual process and the two should not be split.

Response: We believe that electronic reporting is a valuable step in demonstrating meaningful use and helps us to reach our goal of alignment with other quality reporting programs. In addition, we note that the data received via electronic reporting is valuable and necessary for quality improvement.

Comment: A few commenters suggested that CMS should direct states on reporting method to prevent too much variation among the state and federal programs.

Response: While we appreciate the commenters' suggestion, we believe that, consistent with our policy in previous years for the EHR Incentive Programs, the reporting method for CQMs in the Medicaid EHR Incentive Program is an operational question that is best left to state discretion subject to our approval. Allowing states flexibility with respect to the reporting method for CQMs permits states to continue using attestation or to pursue other options such as electronic reporting. We believe this is appropriate given the varying capabilities and policies among states regarding CQM submission.

We are finalizing our policy as proposed, that in 2017 all providers have two options to report CQM data, either through attestation or through use of established methods for electronic reporting where feasible. Starting in 2018, providers participating in the Medicare EHR Incentive Program must electronically report where feasible and that attestation to CQMs would no longer be an option except in certain circumstances where electronic reporting is not feasible. We are also finalizing our proposal that for the Medicaid EHR Incentive Program states would

continue to be responsible for determining whether and how electronic reporting of CQMs would occur, or whether they wish to continue to allow reporting through attestation. We note that if a state does require such electronic reporting, the state is responsible for sharing the details of the process with its provider community. We also note that the states would establish the method and requirements, subject to our prior approval, for the electronic capture and reporting of CQMs from CEHRT.

5. CQM Specification and Changes to the Annual Update

In the Stage 3 proposed rule (80 FR 16771), we recognized that it may be necessary to update CQM specifications after they have been published to ensure their continued clinical relevance, accuracy, and validity. CQM specification updates may include administrative changes, such as adding the NQF endorsement number to a CQM, correcting faulty logic, adding or deleting codes as well as providing additional implementation guidance for a CQM. These changes are described through the annual updates to the electronic specifications for EHR submission published by CMS. Because we require the most recent version of the CQM specifications to be used for electronic reporting methods, we understand that EHR vendors must make CQM updates on an annual basis and providers must regularly implement those updates to stay current with the most recent CQM version.

In the Stage 3 proposed rule (80 FR 16771), we proposed no changes to our policy on updating CQM specifications. However, we stated that we will continue to evaluate the CQM update timeline and look for ways to provide CQM updates timely, so that vendors can develop, test, and deploy these updates and providers can implement those updates as necessary.

We received many comments in response to our request for comments. However, we

note that we did not make any specific proposal in regard to the annual update process for CQMs.

Comment: Many commenters expressed concerns regarding the timing and frequency of annual updates. Several stated that EHR vendors need more time to update the CQMs in their EHRs and suggested updates should be minimal, or that the new specifications for CQMs should be released well in advance of their implementation. A few commenters suggested that the CQM updates should be more frequent, such as monthly, to address changes in clinical guidance and to keep the CQMs relevant.

Response: We appreciate both perspectives on this subject and note that the CQM specifications are posted at least 6 months prior to the reporting period. We believe it is important to reflect the most recent clinical guidance in CQMs, and therefore seek to find an appropriate balance between the timing of the posting of CQM specifications and the reporting period for those CQMs.

Comment: Some commenters suggested that recertification should be required with each update to the CQMs.

Response: At this time, we do not require recertification with the annual update, but instead strongly recommend and encourage EHR vendors to test their products against CMS verification tools and receiving systems.

Comment: Some commenters suggested that CMS have some flexibility in when a CQM can be updated in order to address those situations where a CQM required an update mid-year. For example, these commenters suggested that CMS be able to update or suspend the use of that CQM at any point during the year.

Response: We appreciate all comments received in regard to the annual update process, and will take them into consideration for future rulemaking and policy development. We note that we did not make any specific proposals in the Stage 3 proposed rule, and thus are not finalizing any change to our policy at this time.

6. Certified EHR Technology Requirements for CQMs

In the 2014 Edition EHR Certification Criteria Final Rule, ONC finalized certain certification criteria to support the meaningful use objectives and CQMs set forth by CMS. In that rule, ONC also specified that in order for an EP, eligible hospital, or CAH to have EHR technology that meets the Base EHR definition, the EHR technology must be certified to a minimum of nine CQMs for EPs or 16 CQMs for eligible hospitals and CAHs (77 FR 54264 through 54265; see also 45 CFR 170.102). This is the same number required for quality reporting to the Medicare and Medicaid EHR Incentive Programs, the PQRS EHR reporting and, beginning in 2015, the electronic reporting option under the Hospital IQR Program.

As stated in the Stage 3 proposed rule (80 FR 16771 through 16772), we believe EHRs should be certified to more than the minimum number of CQMs required by one or more CMS quality reporting programs so that EPs, eligible hospitals, and CAHs have a choice of which CQMs to report, and could therefore choose to report on CQMs most applicable to their patient population or scope of practice.

We realize that requiring EHRs to be certified to more than the minimum number of CQMs required by the Medicare and Medicaid EHR Incentive Programs may increase the burden on EHR vendors. However, in the interest of EPs, eligible hospitals, and CAHs being able to choose to report eCQMs that represent their patient populations, we would like to see EP

vendors certify to all eCQMs that are in the EP selection list, or eligible hospital/CAH vendors certify to all eCQMs in the selection list for those stakeholders.

We are also considering a phased approach such that the number of CQMs required for the vendors to have certified would increase each year until EHR products are required to certify all CQMs required for reporting by EPs, eligible hospitals, and CAHs. For example, in year one of this phased plan, we might require that EHRs be certified to at least 18 of 64 available CQMs for EPs and 22 of 29 available CQMs for eligible hospitals and CAHs; in year two, we might require at least 36 CQMs for EPs and all 29 CQMs for eligible hospitals and CAHs; in subsequent years of the plan, we would increase the number of required CQMs for EPs until the EHR is certified to all applicable CQMs for EPs, eligible hospitals, and CAHs.

We have also considered alternate plans that would require EHRs to be certified to more than the minimum number of CQMs required for reporting, but would not require the EHR to be certified to all available CQMs. For example, we might require that EHRs be certified to a certain core set of CQMs plus an additional 9 CQMs for EPs, and a certain core set of CQMs plus an additional 16 CQMs for eligible hospitals and CAHs, which the EHR vendor could choose from the list of available CQMs.

We note that the specifics of this plan would be outlined in separate notice-and-comment rulemaking such as the PFS or IPPS rules. In the Stage 3 proposed rule (80 FR 16771 through 16772), we sought comment on a plan to increase the number of CQMs to which an EHR is certified.

Comment: We received many comments in support of a plan to require EHR vendors to certify to more than the minimum required CQMs, and several comments in support of a plan to

have EHR vendors certify to all CQMs. Most commenters stated that either approach would reduce burden on EPs, eligible hospitals, and CAHs by allowing them to choose which measures to report instead of being forced to report on only those CQMs to which their EHR is certified. Commenters also stated that having more CQMs to choose from would reduce the number of zero denominators that are reported to CMS because EPs, eligible hospitals, and CAHs would have better access to CQMs for which they have patient data. Some commenters also proposed alternative plans such as a requirement to have EHRs certify to "capture and export" all CQMs, but not necessarily to "calculate and report" those CQMs, or to have all consumers of CQM data, including states, private payers, etc., agree on one set of CQMs to be reported.

A few commenters opposed any plan to require a certain number of CQMs to which EHRs must be certified stating that EHR vendors should be allowed to choose CQMs based on their provider population or specialty product. Some commenters opposed the plan to certify to all CQMs because of the burden it would place on EHR vendors, and because it would force EHRs to be certified to CQMs that are not relevant to the EHR's provider population. Other commenters expressed concern about a plan to certify to all CQMs, even in a phased approach, because they were unclear about the number and quality of the CQMs to be included in future years of the EHR Incentive Program. Lastly, some commenters expressed concern about the burden this plan could place on EPs, eligible hospitals, and CAHs because of the added effort it would take to implement these measures in their provider setting.

Response: We appreciate all of the comments we received in regard to the plans we outline in the proposed rule(s). We note that we did not make any proposals to implement these plans, and we will not be finalizing any policy regarding a requirement to have EHRs certify to a

certain number of CQMs. We agree with the majority of commenters that EHRs should be required to certify to more than the minimum number of CQMs for reporting. However, we are still determining what that number should be, and will take these comments into consideration as we continue to develop that policy.

7. Electronic Reporting of CQMs

As previously stated in the Medicare and Medicaid EHR Incentive Programs Stage 2 final rule (77 FR 54051 through 54053) and restated in the Stage 3 proposed rule (80 FR 16772), CQM data submitted by EPs, eligible hospitals, and CAHs are required to be captured, calculated, and reported using certified EHR technology. We do not consider the manual abstraction of data from a patient's chart to be capturing the data using certified EHR technology. We believe that electronic information interfaced or electronically transmitted from non-certified EHR technology, such as lab information systems, automated blood pressure cuffs, and electronic scales, into the certified EHR, would satisfy the "capture" requirement, as long as that data is visible to providers in the EHR.

Comment: We received several comments regarding the manual extraction of data from a patient's chart. Specifically, a few commenters objected to the loss of opportunity to manually extract data from a patient's chart, and a few stated their need to continue extracting data from a patient's chart.

Response: We did not make any proposals on this subject in the Stage 3 proposed rule, but noted that we do not consider the manual abstraction of data from the EHR to be capturing the data using certified EHR technology (80 FR 16772). Explanation of our goal to transition from manual abstraction of data to electronic reporting for hospital reporting can be found in the

Medicare and Medicaid EHR Incentive Programs Stage 2 final rule (77 FR 54078 through 54079).

D. Demonstration of Meaningful Use and Other Issues

1. Demonstration of Meaningful Use

a. Common Methods of Demonstration in Medicare and Medicaid

In the EHR Incentive Programs for 2015 through 2017 and the Stage 3 proposed rules, we proposed to continue our common method for demonstrating meaningful use in both the Medicare and Medicaid EHR Incentive Programs (80 FR 20376 and 80 FR 16772). The demonstration methods we adopt for Medicare will automatically be available to the states for use in their Medicaid programs.

b. Methods for Demonstration of the Criteria for Meaningful Use in 2015 through 2017

As mentioned previously in section II.B.1.b.(2). of this final rule with comment period, we are redesignating the numbering of certain sections of the regulation text under part 495. In prior rules, we defined the criteria for the demonstration of meaningful use at § 495.8, which is redesignated as § 495.40. We defined the criteria for the demonstration of meaningful use at § 495.40, including references to the objectives and measures as well as the requirement to report CQMs. In order to demonstrate meaningful use in 2015 through 2017, we proposed (80 FR 20374) that the requirements at § 495.40 include a reference to the objectives and measures for 2015 through 2017 outlined at § 495.22 which the provider must satisfy (80 FR 20376).

We proposed 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 also proposed to continue the existing optional batch file process for attestation. Further, we

proposed 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 2015 and 2016 in order to avoid a payment adjustment in the subsequent year.

Comment: A number of commenters requested additional support for providers seeking to attest for an EHR reporting period in 2015 given the proposed changes for the program in 2015.

Response: We understand the need to provide information for providers as quickly as possible and will work to create educational guides, FAQs, tip sheets, and other tools to support providers seeking to meet the requirements of the EHR Incentive Program for an EHR reporting period in 2015.

After consideration of the comments received, we are finalizing our proposal to maintain attestation as the demonstration method for EHR reporting periods in 2015 through 2017 and the corresponding regulation text at § 495.40.

c. Attestation Deadlines for the EHR Incentive Programs in 2015 through 2017

In the EHR Incentive Program in 2015 through 2017 proposed rule (80 FR 20376), we proposed changes to the attestation deadlines for eligible hospitals and CAHs in connection with the proposal that these providers must complete an EHR reporting period between October 1, 2014 and the end of the calendar year (CY) on December 31, 2015, and complete an EHR reporting period for 2016 between January 1, 2016 and December 31, 2016. Specifically, we proposed changes 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, we noted that providers would not be able to attest for an EHR reporting period in 2015 prior to January 1, 2016 in order to allow adequate time to make the system changes necessary to accept attestations. 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 received the following comments and our response follows:

Comment: A number of commenters requested that CMS allow providers to attest to an EHR reporting period for 2015 prior to the finalization of the proposals contained in the EHR Incentive Programs in 2015 through 2017 proposed rule for various reasons, including concerns about the load on CMS systems in the attestation period if all providers attest at the same time. Others commenters expressed similar concerns if hospital attestations are added to that total. Finally, a number of commenters requested that systems be opened early to allow eligible hospitals that are attesting for the first time to earn an incentive payment as quickly as possible.

Response: First, we note that under the Administrative Procedure Act, we could not accept attestations for 2015 that are based solely on proposals made in a notice of proposed rulemaking. Second, as we stated in the EHR Incentive Program in 2015 through 2017 proposed rule (80 FR 20376), the majority of eligible professionals would have been attesting for an EHR reporting period in 2015 of one full year at the close of CY 2015. This means that the high

volume of attestations in January and February of 2015 has already been anticipated and preparations for that time have been made. Therefore, we do not expect the proposed changes to the attestation deadlines would significantly increase the load on CMS systems, and even with full participation among eligible hospitals and CAHs, only an additional 4,000 attestations would be received at the close of the calendar year with the shift from fiscal year to calendar year reporting for these providers.

Comment: A number of commenters requested an extension of the attestation period following the close of the year for EHR reporting periods in 2015. Some of these commenters recommended that data submission be allowed for 3 months or for 6 months following the close of the calendar year. Other commenters stated that large organizations need more time to complete attestations. A number of commenters requested that CMS allow greater flexibility in prolonging an attestation period for 2015 only. Still other commenters noted that there may be a lag after the end of the reporting period before all data can be collected and validated. These commenters suggested that we allow for a longer period of time in which to attest after the reporting period, which would allow for accurate collection, validation, documentation, and attesting to the data. Other commenters noted the volume of attestations and requested additional time, as the volume of providers that will be completing their attestations during that time period may tax the system and cause extensive delays while entering the data.

Response: We believe that an attestation period of 2 months following the close of the calendar year (February 29, 2016 for an EHR reporting period in 2015) is appropriate because it is consistent with our current policy of requiring attestation within the 2 months after the close of the fiscal year for returning eligible hospitals and CAHs or calendar year for returning EPs. We

further note that this attestation period also aligns with the submission period for CQM reporting for PQRS. We understand the concern over a high volume of attestations. However, as noted previously, we do not anticipate that the proposed changes to the attestation deadlines would significantly increase the volume over what was expected for 2015. In addition, as we have done in past years, we will monitor progress, attestation volume, and provider readiness in real time as the attestation period progresses.

Comment: A commenter requested that we clarify how the requirements of the program prior to the final rule relate to those after the effective date of the final rule in terms of the attestation windows and selection of an EHR reporting period. The commenter requested that new participants be able to attest to the current Stage 1 objectives and measures even after the effective date of this final rule with comment period for an EHR reporting period in 2015. The commenter also requested guidance on whether states will be required to take an approach consistent with CMS on this issue.

Response: Any attestations accepted by a state for the Medicaid EHR Incentive Program prior to the effective date of this final rule with comment period must meet the requirements in effect at that time for the Medicaid EHR Incentive Program. In addition, the objectives and measures of meaningful use apply to both the Medicare and Medicaid EHR Incentive Programs, and the demonstration methods we adopt for Medicare would automatically be available to the states for use in their Medicaid programs.

We refer the commenter to sections II.B.1.b.(4).(a). and II.E. of this final rule with comment period for an explanation of when in 2015 the 90-day EHR reporting period and EHR reporting period for a payment adjustment year may occur. We further note that CMS will not

be accepting attestations for an EHR reporting period in 2015 and subsequent years for any objective or measure which has been removed in this final rule with comment period in section II.B.1.b.(4).(b).

Comment: A commenter stated that providers believe that the management of attestation deadlines and payment adjustments is very complicated and difficult to follow.

Response: We note that this is part of the motive behind some of the changes to reporting periods for the Medicare and Medicaid EHR Incentive Programs. We further note that while this final rule with comment period makes additional changes to the program, we believe these changes will help to settle the program into a more regular and predictable schedule for all participants.

After consideration of the comments received, we are finalizing the attestation deadlines for meaningful use in 2015 and 2016 as proposed. We note that any EP, eligible hospital or CAH that attested to meaningful use for the first time under Medicare or Medicaid for an EHR reporting period in 2015 prior to the effective date of this final rule with comment period will not be required to submit a new attestation.

d. 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. In the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20376), we noted that we are proposing a later deadline for attestation for 2015 only to allow enough time for all

providers to complete a 90-day EHR reporting period after the anticipated effective date of the final rule. We proposed changes to the attestation deadlines for purposes of the payment adjustment years for EPs, eligible hospitals, and CAHs in the EHR Incentive Programs in 2015 through 2017 proposed rule at 80 FR 20380 and 20381. We address those proposals and respond to the comments received in section II.E.2. of this final rule with comment period.

e. Methods for Demonstration of the Stage 3 Criteria of Meaningful Use for 2017 and Subsequent Years

We proposed to continue the use of attestation as the method for demonstrating that an EP, eligible hospital, or CAH has met the Stage 3 objectives and measures. We proposed to continue the existing optional batch file process for attestation in lieu of individual Medicare EP attestation through our registration and attestation system. This batch reporting process ensures that the objectives and measures of the program and the use of certified EHR technology continues to be measured at the individual level, while promoting efficiencies for group practices that must submit attestations on large groups of individuals (77 FR 54089).

We stated that we would continue to leave open the possibility for CMS and the states to test options for demonstrating meaningful use that utilize existing and emerging HIT products and infrastructure capabilities. These options could involve the use of registries or the direct electronic reporting of measures associated with the objectives. We would not require any EP, eligible hospital, or CAH to participate in this testing in order to receive an incentive payment or avoid the payment adjustment.

For 2017 only, we proposed changes to the attestation process for the meaningful use objectives and measures, which would allow flexibility for providers during this transitional year (80 FR 16772).

Comment: A few commenters suggested that EHR Incentive Program attestation be automated. EPs, eligible hospitals, or CAHs should be able to use their certified EHR technology to directly share EHR Incentive Program performance data with CMS, eliminating the need for the manual input of data into the agency's attestation portal. Allowing automated EHR Incentive Program attestation will improve participation in the program, cut down on possible manual input errors, and be more in line with the intent of supporting interoperability and the seamless transfer of electronic health care performance data.

Response: We note that in the Stage 2 proposed rule we requested input on the potential of developing an automated electronic reporting system for the objectives and measures of the EHR Incentive Programs (77 FR 13764). We decided not to develop such a submission method at that time as the system update required could prove burdensome for providers, especially small practices and those operating proprietary systems, and we instead adopted the batch reporting option which does allow for a more automated process for large groups to submit their data to CMS (77 FR 54089). As noted in the Stage 2 final rule, we will continue to review and analyze the possibility of an electronic system to replace the current manual attestation as CMS continues to work toward program alignment with quality reporting programs, which support electronic submission of CQM data using CEHRT.

After consideration of the comments received, we are finalizing our proposal to maintain attestation as the method of demonstration of meaningful use for the EHR Incentive Programs

for 2017 and subsequent years and the corresponding regulation text at § 495.40.

(1) Meaningful Use Objectives and Measures in 2017 and CEHRT Flexibility in 2017

In the Stage 3 proposed rule (80 FR 16772), in order to allow all providers to successfully transition to Stage 3 of the EHR Incentive Programs for a full year-long EHR reporting period in 2018, we proposed to allow flexibility for the EHR Incentive Programs in 2017. We stated that this transition period would allow providers to establish and test their processes and workflows for Stage 3 of the EHR Incentive Programs prior to 2018. Specifically, for 2017, we proposed that providers may either repeat a year at their current stage or move up stage levels. We also proposed that for 2017, a provider may not move backward in their progression and that providers who participated in Stage 1 in 2016 may choose to attest to the Stage 1 objective and measures, or they may move on to Stage 2 or Stage 3 objectives and measures for an EHR reporting period in 2017. Providers who participated in Stage 2 in 2016 may choose to attest to the Stage 2 objectives and measures or move on to Stage 3 objectives and measures for an EHR reporting period in 2017. However, under no circumstances may providers return to Stage 1.

Finally, we proposed that in 2018, all providers, regardless of their prior participation or the stage level chosen in 2017, would be required to attest to Stage 3 objectives and measures for an EHR reporting period in 2018.

Comment: Many commenters supported allowing providers to choose or not choose Stage 3 in 2017. Commenters noted that the inability to select the stage of participation in prior years was a significant frustration for providers and that allowing choice and flexibility offers providers to the chance to review their performance and attest to the highest level they were able to achieve. However, many commenters were confused by this proposal and how this proposal

related to the proposals in the EHR Incentive Programs in 2015 through 2017 proposed rule which would remove the Stage 1 objectives and measures from the program.

Response: We thank the commenters for their insight and reiterate that our intent in the selection of stage for the demonstration of meaningful use is intended to offer greater flexibility for providers. We note that the proposal which includes references to Stage 1 was published prior to the publication of the EHR Incentive Programs in 2015 through 2017 proposed rule and therefore the proposal to change the stage designations at 80 FR 20352 through 20353 had not yet been made. In section II.B.2.a. of this final rule with comment period, we finalized a set of objectives and measures that all EPs, eligible hospitals, and CAHs must meet for an EHR reporting period in 2015, 2016, and 2017, unless a provider chooses to meet the Stage 3 objectives in 2017. Thus, we will not allow attestation to Stage 1 objectives and measures in 2017 regardless of prior program participation. As stated previously, CMS will not be accepting attestations for an EHR reporting period in 2015 and subsequent years for any objective or measure which has been removed in this final rule with comment period in section II.B.1.b.(4).(b).

After consideration of public comment received, we are finalizing our proposal with modifications to allow providers to attest to the Stage 3 objectives and measures defined at § 495.24 for an EHR reporting period in 2017 instead of the objectives and measures for 2015 through 2017 defined at § 495.22 if they so choose.

(2) Stage and CEHRT Flexibility in 2017

In the Stage 3 proposed rule (80 FR 16772 through 16773), we also proposed to allow providers flexible CEHRT options for an EHR reporting period in 2017 and noted that these

options may impact the selection of objectives and measures to which a provider can attest. Specifically, under the CEHRT options for 2017, we proposed that providers would have the option to continue to use EHR technology certified to the 2014 Edition, in whole or in part, for an EHR reporting period in 2017. We noted that providers who use only EHR technology certified to the 2014 Edition for an EHR reporting period in 2017 may not choose to attest to the Stage 3 objectives and measures as those objectives and measures require the support of EHR technology certified to the 2015 Edition. We further explained this proposal at 80 FR 16773 stating that providers using only EHR technology certified in whole or in relevant part to the 2014 Edition certification criteria may attest to the Stage 1 or Stage 2 objectives and measures; and, providers using EHR technology certified in whole or in relevant part to the 2015 Edition certification criteria may elect to attest to the Stage 1 or Stage 2 objectives and measures or to the Stage 3 objectives and measures if they have all the 2015 Edition functionality required to meet all Stage 3 objectives.

We noted that all providers would be required to fully upgrade to EHR technology certified to the 2015 Edition for the EHR reporting period in 2018. We also reiterated that providers may elect to attest to Stage 3 of the program using EHR technology certified to the 2015 Edition beginning in 2017. Finally, in the Stage 3 proposed rule we stressed that the use of 2011 CEHRT, although an option under the 2014 CEHRT Flexibility final rule (79 FR 52913 through 52914), is not an option under this proposal (80 FR 16773).

We sought comment on this flexibility option including alternate flexibility options and received the following comments on these proposals and our response follows:

Comment: While some commenters expressed skepticism that providers would be ready to attest to Stage 3 in 2017, the majority of commenters were in support of the flexible options for Stage 3 in 2017, especially allowing for the timeline required to fully update to EHR technology certified to the 2015 Edition. While commenters generally expressed concern that most providers may not be ready to progress to Stage 3 in 2017, they supported the proposal to allow providers to select the option for themselves in 2017, which would allow them to work toward that goal but to still successfully meet the requirements of the program in 2017, even if they do not meet the Stage 3 requirements. Additionally, some commenters noted that they would not support an alternate option or policy which required the selection of the Stage 3 objectives and measures in 2017 if the provider has fully implemented EHR technology, but that they agreed that the flexibility to select or not select Stage 3 is a benefit for providers. A number of commenters requested that this flexibility also be extended into 2018 and noted that technology certified to the 2015 Edition may not be ready in time for a reporting period in 2018.

Response: We are committed to working toward the goals outlined for Stage 3 of the EHR Incentive Programs, but we also recognize the need for balance and support of providers in making this transition. We agree that the option of participating in Stage 3 in 2017 should be encouraged but not required. Therefore, we will finalize our proposal to allow providers to choose Stage 3 participation in 2017, and will not require Stage 3 participation if the provider has fully implemented EHR technology certified to the 2015 Edition in 2017.

However, we do reiterate that a provider must have the necessary functions certified to the 2015 Edition in order to successfully demonstrate Stage 3 if they so choose. As discussed in section II.B.3. of this final rule with comment period, EHR technology certified to the 2015 Edition can support the Stage 2 objectives and measures, but EHR technology certified to the 2014 Edition on its own cannot support all of the Stage 3 objectives and measures. So even though EHR technology certified to the 2015 Edition is not required until 2018, a provider must at least have the functions of CEHRT certified to the 2015 Edition which are required to support the unique Stage 3 measures in order to participate in Stage 3 in 2017. For Stage 3 there are certain EHR technology functions which are not available within the 2014 Edition certification criteria, and if a provider chooses to attest to Stage 3 in 2017 they must use EHR technology modules certified to the 2015 Edition for those functions. These modules and module certified to the 2014 Edition can be used together in many combinations to make up the whole EHR system and meet the definition of CEHRT required for the program. We direct readers to section II.B.3. of this final rule with comment period for further information on the CEHRT definition at § 495.4. See Tables 14, 15, and 16 in section II.B.3. for more information about which modules support specific Stage 3 objectives and measures.

We believe providing flexibility in 2017 will allow for an easier transition and full scale upgrade to EHR technology certified to the 2015 Edition for participation in 2018. We did not propose an extension of this flexibility into 2018 as we are committed to moving toward a single streamlined program to support long term sustainability and reduce the overall complexity for providers participating in the EHR Incentive Programs. We note that, as mentioned in section II.B.1.b.(3). of this final rule with comment period, we are finalizing a 90-day EHR reporting

period for providers demonstrating Stage 3 in 2017 to further support providers seeking to move to Stage 3 in 2017.

After consideration of the comments received, we are finalizing a modification to our proposal to allow providers using EHR technology certified to the 2015 Edition, in whole or in part, the option to attest to Stage 3 objectives and measures if they have the relevant CEHRT modules certified to the 2015 Edition certification criteria necessary to support Stage 3. (See Tables 14, 15, 16 in section II.B.3. for more information about which modules support specific Stage 3 objectives and measures.) We further note that CMS will not be accepting attestations for an EHR reporting period in 2015 and subsequent years for any objective or measure which has been removed in this final rule with comment period in section II.B.1.b.(4).(b). Further we reiterate that certification to the 2011 Edition is no longer valid for use in the EHR Incentive Programs and a provider may not attest to a system with that certification in any year after 2014. Finally, we note that providers using only EHR technology certified to the 2014 Edition may not attest to the Stage 3 objectives and measures for an EHR reporting period in 2017. Therefore, we reiterate the following options for providers for Stage and CEHRT flexibility for an EHR reporting period in 2017:

Providers using only EHR technology certified in whole or in relevant part to the 2014 Edition certification criteria may attest to the objectives and measures of meaningful use defined at § 495.22 .

Providers using EHR technology certified in relevant parts to the 2014 Edition certification criteria and EHR technology certified in relevant parts to the 2015 Edition certification criteria may elect to:

- Attest to the objectives and measures at § 495.22.
- Attest to the Stage 3 objectives and measures at § 495.24 if they have the 2015 Edition functionality required to meet the Stage 3 objectives and measures. (See Tables 14, 15, and 16 in section II.B.3. for more information about which modules support specific Stage 3 objectives and measures.)

Providers using only EHR technology certified in whole or in relevant parts to the 2015 Edition certification criteria may elect to:

- Attest to the objectives and measures at § 495.22.
- Attest to the Stage 3 objectives and measures at § 495.24.

We are adopting these policies at § 495.40 with references to the objectives and measures outlined in § 495.22 and § 495.24 for the applicable years.

(3) CQM Flexibility in 2017

In the Stage 3 proposed rule (80 FR 16773), we proposed to allow greater flexibility by proposing to split the use of CEHRT for CQM reporting from the use of CEHRT for the objectives and measures for 2017. This means that providers would be able to separately report CQMs using EHR technology certified to the 2015 Edition even if they use EHR technology certified to the 2014 Edition for the meaningful use objectives and measures for an EHR reporting period in 2017. Providers may also use EHR technology certified to the 2015 Edition for their meaningful use objectives and measures in 2017 and use EHR technology certified to the 2014 Edition for their CQM reporting for an EHR reporting period in 2017.

For an EHR reporting period in 2017, we proposed that EPs, eligible hospitals, and CAHs may choose to report eCQMs electronically using the CQMs finalized for use in 2017 using the

most recent version of the eCQMs (electronic specifications), which would be the electronic specifications of the CQMs published by CMS in 2016, or a provider may choose to continue to attest to the CQMs established for use in 2017 also using the most recent (2016 version) eCQM electronic specifications.

Similar to our rationale under the 2014 CEHRT Flexibility final rule (79 FR 52910 through 52933), we stated that we believe the proposals outlined for attestation in 2017 would allow providers the flexibility to choose the option which applies to their particular circumstances and use of CEHRT (80 FR 16773). We proposed that upon attestation, providers may select one of the proposed options available for their participation year and EHR Edition, and the EHR Incentive Program Registration and Attestation System would then prompt the provider to attest to meeting the objectives, measures, and CQMs applicable under that option. We further proposed that auditors would be provided guidance related to reviewing attestations associated with the options for using CEHRT in 2017, as was done for 2014.

We received comments related to the reporting requirements for CQMs, which are addressed in section II.C. of this final rule with comment period. We also received a number of questions and comments on reporting clinical quality measures for the Medicaid program, which are addressed in section II.C. and II.G. of this final rule with comment period. We received no comments specific to the demonstration of these requirements beyond those previously addressed in section II.D.1.(e).(1). and (2) of this final rule with comment period in relation to the selection of stage, the selection of certified EHR technology, and the overall demonstration of meaningful use in 2017 and subsequent years via attestation.

We are finalizing as proposed the policy to allow providers the flexibility to electronically report CQMs or to attest to CQMs using either EHR technology certified to the 2014 Edition or EHR technology certified to the 2015 Edition, independently of the Edition they use for their objectives and measures for an EHR reporting period in 2017. For further discussion of this final policy, we direct readers to section II.C. of this final rule with comment period.

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

In the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20377), we proposed that certain Medicaid EPs would have the option of attesting through the EHR Incentive Program Registration and Attestation system for the purpose of avoiding the Medicare payment adjustment. This alternate method would allow EPs who have previously received an incentive payment under the Medicaid EHR Incentive Program (for either AIU or meaningful use) to demonstrate that they are meaningful EHR users in situations where they fail to meet the eligibility criteria for the Medicaid EHR Incentive Program in a subsequent year.

Comment: Many commenters agreed with our proposal to establish an alternate method of demonstrating meaningful use to allow Medicaid EPs to attest using the CMS registration and attestation system so they can avoid the Medicare payment adjustment. Some commenters questioned whether this would be available prior to February 28, 2016, to allow EPs to attest in cases where the state's attestation system was not ready by the deadline. Some commenters questioned whether attestation information submitted to CMS would be shared with the states.

Response: We intend for this alternate method of demonstrating meaningful use to be available beginning January 1, 2016 for EPs attesting for their EHR reporting period in

2015. However, we proposed this method only for Medicaid EPs who did not meet the eligibility criteria and thus would not be able to attest to the Medicaid EHR Incentive Program for the same year and receive an incentive payment.

We note that Medicaid EPs can avoid the Medicare payment adjustment by successfully demonstrating meaningful use to the state Medicaid agency under the Medicaid EHR Incentive Program, even if it occurs after the Medicare attestation period closes, as long as the attestation is accepted by the state. It would then be the state's responsibility to include that EP in the quarterly report on meaningful users, which we discuss in section II.G. of this final rule with comment period.

Attestations from Medicaid EPs that come through the CMS registration and attestation system will be treated the same as other provider attestations that are submitted to that system for purposes of data sharing. We recognize that states collect, analyze, and use EHR Incentive Program attestation information for a number of purposes, such as informing other state programs and making policy decisions. However, we will not send information from those attestations to states, consistent with preceding practice.

Comment: A commenter requested clarification regarding the reporting period for EPs who are in the Medicaid EHR Incentive Program and use the alternate method of attestation through the CMS registration and attestation system.

Response: We proposed that EPs using this alternate method would be required to demonstrate meaningful use for the applicable EHR reporting period established for the Medicare EHR Incentive Program, which would depend on the year as well as the EP's prior participation in the program and stage of meaningful use. For example, if the EP is in their first

year of demonstrating meaningful use, and the Medicare EHR Incentive Program has a 90-day EHR reporting period for EPs demonstrating meaningful use for the first time in that year, then the EP would use a 90-day EHR reporting period.

We reiterate that an EP's attestation using this alternate method would not constitute a switch from the Medicaid EHR Incentive Program to the Medicare EHR Incentive Program. For the purposes of the Medicaid EHR Incentive Program, an EP's use of this alternate method would be treated the same as if the EP had not attested to meaningful use for that year. For an EP who uses this alternate method, their EHR reporting period in a subsequent year for the Medicaid EHR Incentive Program would be determined without regard to any previous attestations using this alternate method. For example, an EP could still have a 90-day EHR reporting period for the Medicaid EHR Incentive Program for their first year of demonstrating meaningful use even though they had demonstrated meaningful use through this alternate method in a previous year.

Comment: Commenters also asked if CMS would allow this policy for providers who had not yet attested in Medicare or Medicaid as of 2015, given that Medicaid still allows incentive payments for new participants until 2016. A number of commenters requested clarification on what scenarios would providers be allowed to use the alternate attestation and where would it be prohibited, if this did apply for 2015. Specifically, these commenters inquired whether this alternate attestation option is available for providers who are attesting to AIU in 2015 or 2016 and also wish to attest to avoid the Medicare payment adjustment.

Response: We did not propose this option for 2015. However, we understand there may be new participants, and especially newly practicing EPs or new hospitals, for whom this option

might be relevant and beneficial. We have considered a number of scenarios that are consistent with our proposed policy which is to allow providers who are working toward achieving meaningful use in the Medicaid EHR Incentive Program to attest under Medicare to avoid the payment adjustment without switching if they are unable to attest under Medicaid for a given year. The option will be available for 2015 under the following scenarios:

- For an EHR reporting period 2015, an EP who has not successfully attested to AIU or meaningful use in either the Medicare or Medicaid program may use the alternate attestation option under the Medicare EHR Incentive Program to avoid a payment adjustment in 2016 and 2017. This EP cannot qualify for an incentive payment under Medicare for 2015 because 2014 is the last first year that an EP may begin receiving Medicare incentive payments under section 1848(o) of the Act. The EP may attest to meaningful use in the Medicaid program for an EHR reporting period in 2016 if they meet the eligibility and other requirements for the Medicaid EHR Incentive Program.

- A provider may not use the alternate attestation option to attest to meaningful use in Medicare to avoid a payment adjustment in conjunction with an attestation for an incentive payment for AIU in the Medicaid program in the same year.

Comment: A number of commenters requested clarification from a systems perspective on how CMS will offer the alternate attestation option and coordinate with states on implementation. Some commenters questioned if CMS is considering an option to allow the states flexibility to develop a no-payment attestation pathway as another option for the providers who are unable to switch but do not meet the thresholds for patient volume required to qualify

for a Medicaid incentive payment. Another commenter requested that we describe any operational and technical changes states may need to make to their EHR Incentive Program.

Response: We reiterate that the alternate attestation option for the purpose of avoiding a Medicare payment adjustment will be implemented within the Medicare registration and attestation system only. As mentioned previously, Medicaid EPs seeking to exercise this option must attest in the Medicare system and in accordance with the requirements for the Medicare EHR Incentive Program in order to successfully demonstrate meaningful use and avoid the Medicare payment adjustment. The only requirement for state support of this proposal is to notify EPs of their eligibility to exercise this alternate option in partnership with CMS provider education and outreach efforts. We will not require additional reporting from states, nor require states to process additional systems changes. We will work with the states to coordinate any necessary information sharing and to monitor real-time use of the alternate attestation option once implemented.

After consideration of the comments received, we are finalizing the proposal for this alternate method of demonstrating meaningful use for certain Medicaid EPs to avoid the Medicare payment adjustment with a modification allowing the alternate attestation for new participants in 2015 as described previously.

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

We proposed to continue posting Stage 1 and Stage 2 aggregate and individual performance and participation data resulting from the EHR Incentive Programs online regularly for public use. We further noted our intent to potentially publish the performance and participation data on Stage 3 objectives and measures of meaningful use in alignment with

quality programs, which utilize publicly available performance data such as Physician Compare.

In addition to the data already being collected under our regulations, as outlined in the Stage 3 proposed rule (80 FR 16774), we proposed to collect the following information from providers to ensure providers keep their information up-to-date through the system of record for their NPI in the NPES:

- Primary Practice Address (address, city, state zip, country code, etc.).
- Primary Business/Billing Address (address, city, state, zip, country code, etc.).
- Primary License information (for example, provide medical license in at least one state (or territory)).
- Contact Information (phone number, fax number, and contact email address).
- Health Information Exchange Information:
 - ++ Such as DIRECT address required (if available).
 - ++ If DIRECT address is not available, Electronic Service Information is required.
 - ++ If DIRECT address is available, Electronic Service Information is optional in addition to DIRECT address.

We did not propose any changes to the registration for the Medicare and Medicaid EHR Incentive Programs.

We received the following comments and our response follows:

Comment: We received a number of comments requesting a wider range of publically available data on the Medicare and Medicaid EHR Incentive Programs including cross-referencing Medicaid participation and performance data.

Response: We thank the commenters for their suggestions and will continue to work to promote data transparency and provide data across both programs on provider participation and performance. We refer readers to section II.G.4. of this final rule with comment period for further information on the types of information, CMS is requesting from states to support these efforts and note that we will continue to post data files for public use on the CMS website at: www.cms.gov/EHRIncentivePrograms on the data and reports section.

Comment: Some commenters noted the inclusion of the health information exchange information in the providers' record within the NPPES system. A commenter opposed the inclusion, stating that not all providers have a direct address. However, the majority support the proposed enhancements to NPPES as a step in the right direction. Some commenters requested CMS take additional steps to develop some form of "centralized national healthcare provider directory" to support health information exchange and care coordination. Some commenters made further suggestions as to how such a directory should be organized as well as the full extent of exchange information it should contain for each provider.

Response: We note that CMS and ONC are committed to exploring potential models and opportunities to support improved access to the relevant contact information to facilitate health information exchange among providers. We understand that not all providers may have a direct address. Therefore, we proposed to include other exchange information in the system of record as noted in the Stage 3 proposed rule (80 FR 16774). We also understand that not all providers who might participate in health information exchange are participating in the EHR Incentive Programs. However, we believe that this may be one step in the process to facilitate health information exchange among providers across a wide range of settings.

After consideration of the public comments received, we are finalizing these proposals as proposed.

4. Hospital-Based Eligible Professionals

As noted in the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20378), 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 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 whom 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 noted that we appreciate this feedback from stakeholders and requested public comment on our current definition of a hospital-based EP under § 495.4 for the EHR Incentive Programs. We sought public comment on whether additional place of service codes or settings should be included in our definition of a hospital-based EP. In addition, we sought 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 received the following comments and our response follows:

Comment: A number of commenters on the EHR Incentive Program in 2015 through 2017 proposed rule requested the addition of place of service code (POS 22) to the definition of hospital-based EP. Some of these comments stated that providers may practice across multiple settings and their organizational base may be the hospital outpatient setting, and as a result, they face significant challenges in meeting the requirements of the program. Some commenters stated that certain physician specialties, such as pathologists, radiologists, and even some hospitalists, have reported challenges with the existing definition and that a change in the definition of hospital-based would provide more clarity for these physicians. A commenter stated that the definition of a hospital-based provider is fundamentally flawed and suggested to define a hospital-based provider as a provider who performs 90 percent or more of their services in place of service 21, 22, and/or 23 (Inpatient Hospital, Outpatient Hospital, and Emergency Room Hospital). A commenter offered an example stating that a cardiac interventionist might not qualify as hospital-based because 90 percent of their services were not billed POS 21 or POS 23 even though they spend 100 percent of their time in the hospital setting. The commenter indicated that the interventionist treats many patients who are admitted as outpatients, reads echocardiograms for the hospital, and has no patient encounters, which are not included in the hospital EHR; but the provider also cannot independently meet the requirements of the program. Some commenters additionally requested that CMS include POS 51 (Inpatient Psychiatric Facility) in addition to POS 22 Observation Services Patients in the hospital-based determination.

On the hospital side, a commenter expressed support for a change in the hospital-based

designation because they are currently struggling with the hospital-based designation for the inclusion of services provided in hospital settings by providers who are designated EPs and that the hospital performance on the measures would be higher if these patient encounters were included. The provider recommended that all POS codes should be revisited and the requirements for hospital-based eligibility could be expanded to include all hospital-based POS codes that are rendered in the hospital settings including rehabilitation hospitals and hospital observations, which are otherwise not included in the numerators of their percentages.

Commenters in support of a change were split on when such a change should be implemented. A commenter recommended that CMS change its definition beginning with 2017. Other commenters believe that CMS should retroactively make this correction, and refund physicians who were penalized because of this issue stating physicians who use POS 22 typically are using the hospital-based EHR during the patient observation period, and should not be penalized.

Many commenters opposed any change in the hospital-based designation. Some commenters stated that this proposal could compromise the purpose of the program. A commenter stated that changing the definition of hospital-based eligible professional at this time in the program could encourage fraud. If an EP who was previously eligible for the incentive would now be ineligible for payment adjustments due to the change, this would be unfair. Some commenters stated that redefining EP by once again including POS 22 in the "hospital" definition would not be reasonable so long as provider-based billing exists. The commenter suggested considering some combination of place of service and NPPES classification which does not exclude the large base of ambulatory providers who bill provider based.

Another commenter stated that including POS 22 in the definition of a hospital-based EP could have major implications for the eligible hospital numerators and denominators. Additionally, the design and implementation of the various parts of a hospital's EHR system would have to be redesigned in order to change the status in addition to changing work flows and training to match that change, which would drastically impact the hospital's ability to meet the measures as well as their overall IT expenditures.

Some commenters stated that adding POS 22 or another change to the designation may undermine the current understanding of the program and would require additional education and guidance to ambulatory providers who have already successfully attested. A commenter stated that they do not support re-classifying services provided in an outpatient hospital (POS 22) setting as hospital-based because of a concern that expanding the hospital-based definition to reduce the number of EPs for EHR Incentives may inhibit continuous hospital investments in ambulatory EHRs. The commenter noted that the ambulatory EHR space is an important component to the overall HIT ecosystem and that CMS should encourage investment in this area by excluding outpatient services from the hospital-based calculation. The commenter stated that the current definition of a hospital-based provider is consistent with the hospital's payment calculation, which is based on inpatient discharges and emergency department services, and is consistent with the collection of EHR Incentive Program information for hospitals. The commenter continued by stating that if CMS included POS 22 services in the hospital-based provider definition, CMS would need to revisit whether the inclusion of these services affects the hospital payment calculation and collection of EHR Incentive Program encounters for hospitals. Another commenter expressed a similar concern that changing the hospital-based designation

may have unintended consequences on the hospital payment calculation, necessitating adjustments to all payments made to date if CMS chooses to make a change to the definition of hospital based.

Other commenters stated this is a very complex issue and sought further clarification on the impact of a potential change, noting organizations that have many subspecialists who see patients in the hospital outpatient setting using an office or ambulatory workflow and that these providers may be required to bill with POS 22 due to the physical location of their offices. The commenter stated that the majority of these EPs are currently meeting the requirements of the program and will continue to practice medicine in the same manner going forward. However, the commenter also noted that there are EPs who are truly "hospital-based," such as hospitalists, who are currently being held to the same standard as ambulatory providers, even though their workflow is not conducive to easily meeting such standards. The commenter then recommended that CMS allow providers who see both inpatient and ambulatory patients with a significant volume to choose whether they want to be excluded from the program or continue to participate as an individual eligible professional.

Other recommendations from commenters included a mention of hardship exceptions for POS 22-related issues, a suggestion to allow EPs the right, in an expedited fashion, to petition for a change in their hospital-based status when there is a material change in their organizational affiliation (that is, a physician leaving a hospital-based practice to join an outpatient physician practice), excluding patient encounters in POS 21 and POS 23 for an EP, and excluding the POS 21 and POS 23 encounters from Medicare payment adjustment.

Response: The scenarios and examples described by the commenters are consistent with those we have heard from providers previously. However, we are concerned that there does not seem to be an identifiable factor that has changed since the program began and caused EPs who were previously designated hospital-based to be designated otherwise. In addition, the comments both in support of and opposing a revision to the hospital-based EP definition show the wide diversity of providers who may have services billed under a different POS who fall on both sides of the argument for and against an amendment of the definition. We see no method to modify the current definition to clearly identify EPs for whom inclusion in the definition might be reasonable and those for whom inclusion in the definition might be inappropriate. Further, we are concerned that any blanket redesignation of EPs in certain settings would result in the exclusion of patient encounters in those settings being captured in an EHR. Without a clear rationale for a change, and without a clear definition to change to, we cannot proceed to change the definition of hospital-based EP at this time.

Therefore, we are not finalizing changes to the definition of hospital-based EP at this time. We will continue to consider this issue in the future as we explore program requirements for the MIPS.

5. Interaction with Other Programs

We proposed no changes to the ability of providers to participate in the Medicare and Medicaid EHR Incentive Programs and other CMS programs. We continue to work on aligning the data collection and reporting of the various CMS programs, especially in the area of clinical quality measurement. See sections II.C. of this final rule with comment period for the policies and requirements for CQM reporting.

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 EHR reporting periods beginning in FY 2015 for CAHs.

1. Statutory Basis for Payment Adjustments and Hardship Exceptions

a. Statutory Basis for Payment Adjustments and Hardship Exceptions for Eligible Professionals (EPs)

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 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 Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10) was enacted on April 16, 2015, after the publication of the Stage 3 proposed rule and the EHR Incentive Program in 2015 through 2017 proposed rule. Section 101(b)(1)(A) of MACRA amended section 1848(a)(7)(A) of the Act to sunset the meaningful use payment adjustment for EPs at the end of CY 2018. Section 101(c) of MACRA added section 1848(q) of the Act requiring the establishment of a MIPS, which would incorporate certain existing

provisions and processes related to meaningful use. The term "applicable percent" is defined in section 1848(a)(7)(A)(ii) of the Act, as amended by section 101(b)(1)(A) of MACRA, 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 2018, 97 percent.

In addition, section 1848(a)(7)(A)(iii) of the Act, as amended by section 101(b)(1)(A) of MACRA, provides that if, for CY 2018, 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.

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 EHR 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 § 495.102. We refer readers to the final rules for Stages 1 and 2 (75 FR 44447 through 44448 and 77 FR 54093 through 54102) for more information.

b. Statutory Basis for Payment Adjustments and Hardship Exceptions for Eligible Hospitals

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 will 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 fiscal year involved and the Secretary shall not take into account such reduction in computing the applicable percentage increase for a subsequent fiscal year.

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 will result in a significant hardship, such as in the case of a hospital in a rural area without sufficient internet access. This section also provided 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 412.64(d) 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.

We established regulations implementing these statutory provisions under § 412.64. We refer readers to the final rules for Stages 1 and 2 (75 FR 44460 and 77 FR 54102 through 54109) for more information.

c. Statutory Basis for Payment Adjustments and Hardship Exceptions for CAHs

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 will be made for cost EHR 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 EHR 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 EHR reporting period beginning in FY 2016, its reimbursement would be reduced to 100.33 percent of its reasonable costs. For a cost EHR reporting period beginning in FY 2017 and each subsequent fiscal year, its reimbursement would be reduced to 100 percent of reasonable costs. We

established regulations implementing these statutory provisions under § 413.70. We refer readers to the final rules for Stages 1 and 2 (75 FR 44464 and 77 FR 54110 through 54111) for more information.

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 case 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.

2. EHR Reporting Period for a Payment Adjustment Year

In the EHR Incentive Programs in 2015 through 2017 proposed rule and the Stage 3 proposed rule, we proposed 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 those rules. For an explanation of these proposals, we refer readers to 80 FR 16774 through 16779 and 80 FR 20378 through 20381.

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

As follows is a summary of the comments received on the proposals for the EHR reporting period for a payment adjustment year for EPs (80 FR 16774 through 16779 and 80 FR 20378 through 20381):

Comment: We received a few comments supporting the proposed deadline of February 29, 2016 for new participants to attest in order to avoid a payment adjustment in CY 2016 in light of the other program changes proposed in the rule. Many commenters expressed concern with our proposal to remove the 90-day EHR reporting period for new

participants. They noted that this will create an enormous barrier for new entrants and will likely deter participation in the program and others stated that new entrants need time to install and learn to use technology before beginning their first EHR reporting period. Commenters also requested an extended deadline ranging from 2 months to 6 months additional time in 2016 for attestations for EHR reporting periods in 2015. Additionally some commenters requested clarification of the early attestation deadlines for new participant EPs in 2016 and 2017.

Response: We thank you for your comments and support. For discussion of the attestation deadlines for EPs we direct readers to section II.D. of this final rule with comment period. Regarding the comments on the attestation deadlines, we proposed that for EPs 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. We refer readers to 80 FR 20380 through 20381 of the EHR Incentive Programs in 2015 through 2017 proposed rule for additional information.

We agree with the concerns expressed by commenters regarding our proposal to discontinue the 90-day EHR reporting period for a payment adjustment year for new participants who attest under Medicare beginning in 2017. We agree that a full year EHR reporting period could be a barrier for new entrants and could deter participation in the program especially as new entrants need time to install and learn to use technology before beginning their first EHR reporting period. However, we maintain that it is important to move all providers to the same EHR reporting period to simplify the program. So in 2018 all providers will attest to the Stage 3

definition of meaningful use for an EHR reporting period of the entire calendar year, with a limited exception for Medicaid providers who demonstrated AIU prior to 2017 and are demonstrating meaningful use for the first time. For these reasons, we will adopt a final policy that for EPs demonstrating meaningful use for the first time in 2017 under Medicare or Medicaid, the EHR reporting period for a payment adjustment year is any continuous 90-day period in CY 2017 and applies for purposes of the payment adjustments in CY 2018. To avoid the payment adjustment in CY 2018, the 90-day period must occur within the first three quarters of CY 2017 and the EP must attest by October 1, 2017.

Comment: Some commenters noted that new participants in 2018 would be moving to Stage 3 and should have a 90 day EHR reporting period for that purpose, not just in Medicaid but also in Medicare. Other commenters stated that any provider in their first year, and all providers in the first year of a new stage, should have a 90-day reporting period.

Response: We do not believe a 90-day EHR reporting period is necessary for new participants in 2018 as discussed in section II.B.1.b.(3).(a). of this final rule with comment period. However, we note that we are offering additional flexibility for any provider, new or returning, who elects to participate in Stage 3 in 2017 which we believe is a fair solution to support these providers' efforts to move forward in the program. As noted in section II.E.2. of this final rule with comment period, we are adopting a policy for EPs in the Medicaid program, and for eligible hospitals and CAHs who demonstrate Stage 3 in 2017, allowing a 90-day EHR reporting period. We are adopting this policy based on public comment received (as discussed in section II.B.1.b.(3)(c) of this final rule with comment period) in relation to the EHR reporting period for 2017 in order to allow these providers adequate time to upgrade to the required 2015

Edition technology and to encourage providers to select the option to participate in the Stage 3 objectives and measures which support our long term goals. For Medicaid EPs, and for new participants in Medicaid and Medicare, this 90-day EHR reporting period for Stage 3 would also apply for the purposes of avoiding the payment adjustment in 2019 for returning participants and for the payment adjustment in 2018 for new participants who attest to Stage 3 prior to October 1, 2017.

For Medicare EPs, we note that the EHR reporting period for a payment adjustment year for returning participants in 2017 and for all Medicare EPs in 2018 and subsequent years will be established through future rulemaking in association with the MIPs program discussed further in the comments and responses immediately following.

Comment: We received a number of comments requesting clarification of how the policies proposed in the EHR Incentive Program in 2015 through 2017 and Stage 3 proposed rules are affected by recent legislation modifying the HITECH Act provisions for payment adjustments for eligible professionals.

Response: As noted previously, section 101(b)(1)(A) of MACRA amended section 1848(a)(7)(A) of the Act to sunset the EHR Incentive Program payment adjustment for EPs at the end of CY 2018. Thus, we are not finalizing the proposal (80 FR 16775) that for all EPs beginning with the CY 2019 payment adjustment year, 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 example, CY 2017 as the EHR reporting period for the CY 2019 payment adjustment year). We are also not finalizing the proposed limited exception for EPs demonstrating meaningful use under the Medicaid EHR Incentive Program for the first time (80 FR 16775).

The reason we are not finalizing these proposals is because CY 2018 will be the last payment adjustment year for EPs under section 1848(a)(7)(A) of the Act, as amended by section 101(b)(1)(A) of MACRA. As noted previously, section 1848(q) of the Act, as added by section 101(c) of MACRA, requires the establishment of MIPS, which would incorporate certain existing provisions and processes related to meaningful use. We intend to implement MIPS through future rulemaking, which among other things would address the effect on Medicare Physician Fee Schedule payments in CY 2019 and subsequent years for certain EPs who are not meaningful EHR users for an applicable performance period. We encourage readers to review and respond to our request for information titled "Request for Information Regarding Implementation of the Merit-based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models" published in the October 1, 2015 **Federal Register** (80 FR 59102).

After consideration of the public comments, we are finalizing the following changes to the EHR reporting period for a payment adjustment year for EPs as proposed, with a modification for 2017. In CY 2015, the EHR reporting period for a payment adjustment year for EPs who have not successfully demonstrated meaningful use in a prior year ("new participants") is any continuous 90-day period in CY 2015. An EP who successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustments in CYs 2016 and 2017 if the EP successfully attests by February 29, 2016.

In CY 2015, the EHR reporting period for a payment adjustment year for EPs who have successfully demonstrated meaningful use in a prior year ("returning participants") is any continuous 90-day period in CY 2015. An EP who successfully demonstrates meaningful use for

this period and satisfies all other program requirements will avoid the payment adjustment in CY 2017 if the EP successfully attests by February 29, 2016.

In CY 2016, the EHR reporting period for a payment adjustment year for EPs who are new participants is any continuous 90-day period in CY 2016. An EP who successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in CY 2017 if the EP successfully attests by October 1, 2016, and will avoid the payment adjustment in CY 2018 if the EP successfully attests by February 28, 2017.

In CY 2016, the EHR reporting period for a payment adjustment year for EPs who are returning participants is the full CY 2016. An EP who successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in CY 2018 if the EP successfully attests by February 28, 2017.

In CY 2017, the EHR reporting period for a payment adjustment year for EPs who are new participants is any continuous 90-day period in CY 2017. An EP who successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in CY 2018 if the EP successfully attests by October 1, 2017.

We have revised the definition of “EHR reporting period for a payment adjustment year” under § 495.4 to reflect these final policies. Table 18 contains a summary of the final policies.

TABLE 18 - EHR REPORTING PERIODS AND RELATED PAYMENT ADJUSTMENT YEARS FOR EPs

2015			
	EHR reporting period for a payment adjustment year	Applies to avoid a payment adjustment in CY 2016	Applies to avoid a payment adjustment in CY 2017

EPs who have not successfully demonstrated meaningful use in a prior year (new participants)	Any continuous 90-day period in CY 2015	Yes, if EP successfully attests by February 29, 2016	Yes, if EP successfully attests by February 29, 2016
EPs who have successfully demonstrated meaningful use in a prior year (returning participants)	Any continuous 90-day period in CY 2015	No	Yes, if EP successfully attests by February 29, 2016
2016			
	EHR reporting period for a payment adjustment year	Applies to avoid a payment adjustment in CY 2017	Applies to avoid a payment adjustment in CY 2018
EP new participants	Any continuous 90-day period in CY 2016	Yes, if EP successfully attests by October 1, 2016	Yes, if EP successfully attests by February 28, 2017
EP returning participants	CY 2016	No	Yes, if successfully attest by February 28, 2017
2017			
	EHR reporting period for a payment adjustment year	Applies to avoid a payment adjustment in CY 2018	Applies to avoid a payment adjustment in CY 2019
EP new participants	Any continuous 90-day period in CY 2017	Yes, if EP successfully attests by October 1, 2017	N/A
EP returning participants	N/A	N/A	N/A
Medicaid EP returning participants demonstrating Stage 3	Any continuous 90-day period in CY 2017	No	Yes, if successfully attest by February 28, 2018

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

As follows is a summary of the comments received on the proposals for the EHR reporting period for a payment adjustment year for eligible hospitals (80 FR 16776 through 16778 and 80 FR 20380 through 20381):

Comment: We received a number of comments stating that new participant eligible hospitals should be allowed to attest prior to January 1, 2016 in order to earn an incentive payment and avoid the Medicare payment adjustment for 2016. We received comments in support of the proposed changes to the EHR reporting period for a payment adjustment year to allow for greater flexibility and more time for eligible hospitals to work toward successful demonstration of meaningful use.

Response: We thank the commenters and note that the attestation period will be open for all providers in January of 2016 to attest for an EHR reporting period in 2015.

Comment: Some commenters agreed with the proposal as described to align EHR reporting periods for the purpose of future payment adjustments and endorsed the proposal to continue with the current structure for these components. Some comments also supported a single deadline for new participants to attest to avoid the payment adjustments in 2017.

Response: We appreciate the commenters' feedback and support. We strongly believe this will simplify the EHR Incentive Program and further our goal to align reporting requirements under the EHR Incentive Program and the reporting requirements for various CMS quality reporting programs, to respond to stakeholders who cited difficulty with following varying reporting requirements, and to simplify HHS system requirements for data capture.

Comment: Some commenters expressed concerns about our proposal to require first-time

participants to fulfill an EHR reporting period 2 years in advance of the payment adjustment year. They believe that this policy change is unnecessarily confusing and unfairly penalizes first-time participants. They recommended that CMS retain its current policy to allow first-time participants to avoid a penalty in the subsequent year.

Some commenters noted that new participants in 2018 would be moving to Stage 3 and should have a 90 day EHR reporting period for that purpose. Other commenters stated that any provider in their first year, and all providers in the first year of a new stage, should have a 90 day reporting period.

Response: We recognize the commenters' concerns, and for the reasons stated in section II.E.2.a with regard to new participant EPs in 2017, we will adopt a final policy that for eligible hospitals demonstrating meaningful use for the first time in 2017 under Medicare or Medicaid, the EHR reporting period for a payment adjustment year is any continuous 90-day period in CY 2017 and applies for purposes of the payment adjustments in FY 2018. To avoid the payment adjustment in FY 2018, the 90-day EHR reporting period must occur within the first three quarters of CY 2017 and the eligible hospital must attest by October 1, 2017.

However, we will adopt a final policy beginning in 2018 to require eligible hospitals (new participants and returning participants) that attest to meaningful use under Medicare to complete a full CY EHR reporting period that is 2-years before the payment adjustment year. We are adopting a limited exception of a 90-day EHR reporting period the year that is 2 years before the payment adjustment year for Medicaid participants demonstrating meaningful use for the first time that previously demonstrated AIU prior to 2017 to allow these providers to earn an incentive payment in the Medicaid program for 2018 without receiving an penalty in the

Medicare program.

We disagree that the change to a full-year EHR reporting period unfairly impacts new participant. We note that the prior exception to allow a 90-day EHR reporting period favors new participants over returning participants who have no such opportunity to avoid a payment adjustment in the subsequent year. We further note that new participants could have chosen to begin the program at any time since 2011 unless they are newly practicing providers who are already afforded a hardship exception from the penalty.

After consideration of the public comments, we are finalizing the following changes to the EHR reporting period for a payment adjustment year for eligible hospitals as proposed, with a modification for the EHR reporting period in 2017. For the reasons stated in section II.E.2.a. of this final rule with comment period for Medicaid EPs participating in Stage 3 in 2017, we are finalizing a similar policy for eligible hospitals to establish a 90-day EHR reporting for Stage 3 participants in 2017 for the purposes of avoiding the payment adjustment in 2019 for returning participants and for the payment adjustment in 2018 for new participants who attest to Stage 3 prior to October 1, 2017. For further discussion of the policy related to the EHR reporting period in 2017 we direct readers to section II.B.1.b.(3).iii. of this final rule with comment period.

In CY 2015, the EHR reporting period for a payment adjustment year for eligible hospitals that have not successfully demonstrated meaningful use in a prior year (new participants) is any continuous 90-day period beginning on October 1, 2014 and ending on December 31, 2015. An eligible hospital that successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in FYs 2016 and 2017 if the eligible hospital successfully attests by February 29, 2016.

In CY 2015, the EHR reporting period for a payment adjustment year for eligible hospitals that have successfully demonstrated meaningful use in a prior year (returning participants) is any continuous 90-day period beginning on October 1, 2014 and ending on December 31, 2015. An eligible hospital that successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in FY 2017 if the eligible hospital successfully attests by February 29, 2016.

In CY 2016, the EHR reporting period for a payment adjustment year for eligible hospitals that are new participants is any continuous 90-day period in CY 2016. An eligible hospital that successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in FY 2017 if the eligible hospital successfully attests by October 1, 2016, and will avoid the payment adjustment in FY 2018 if the eligible hospital successfully attests by February 28, 2017.

In CY 2016, the EHR reporting period for a payment adjustment year for eligible hospitals that are returning participants is the full CY 2016. An eligible hospital that successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in FY 2018 if the eligible hospital successfully attests by February 28, 2017.

In CY 2017, the EHR reporting period for a payment adjustment year for eligible hospitals that are new participants is any continuous 90-day period in CY 2017. An eligible hospital that successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in FY 2018 if the eligible hospital successfully attests by October 1, 2017 and will avoid the payment adjustment in FY 2019 if the

eligible hospital successfully attests by February 28, 2018.

In CY 2017, the EHR reporting period for a payment adjustment year for eligible hospitals that are demonstrating Stage 3 is any continuous 90-day period in CY 2017. An eligible hospital that successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in FY 2019 if the eligible hospital successfully attests by February 28, 2018.

In CY 2017, the EHR reporting period for a payment adjustment year for eligible hospitals that are returning participants and are not demonstrating Stage 3, is the full CY 2017. An eligible hospital that successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in FY 2019 if the eligible hospital successfully attests by February 28, 2018.

Beginning in CY 2018, the EHR reporting period for a payment adjustment year for eligible hospitals is the entire calendar year that is two years before the payment adjustment year. For example, CY 2018 is the EHR reporting period for the FY 2020 payment adjustment year. The exception to this general rule is for eligible hospitals that successfully demonstrated AIU under the Medicaid EHR Incentive Program for a payment year prior to 2017 and are demonstrating meaningful use for the first time under the Medicaid EHR Incentive Program in the calendar year that is two years before the payment adjustment year. For those eligible hospitals, the same 90-day EHR reporting period used for the Medicaid incentive payment will also apply for purposes of the Medicare payment adjustment year 2 years after the calendar year in which the eligible hospital demonstrates meaningful use. For example, if an eligible hospital has never successfully demonstrated meaningful use in a prior year and demonstrates under the

Medicaid EHR Incentive Program that it is a meaningful EHR user for the first time in CY 2018, the EHR reporting period for the Medicaid incentive payments any continuous 90-day period within CY 2018, and the same 90-day period also serves as the EHR reporting period for the FY 2020 payment adjustment year under Medicare. An eligible hospital that successfully demonstrates meaningful use for the relevant period and satisfies all other program requirements will avoid the payment adjustment in the relevant year if the eligible hospital successfully attests by the date specified by CMS.

We have revised the definition of “EHR reporting period for a payment adjustment year” under § 495.4 to reflect these final policies. Table 19 contains a summary of the final policies, although it does not include years beyond 2018.

TABLE 19 - EHR REPORTING PERIODS AND RELATED PAYMENT ADJUSTMENT YEARS FOR ELIGIBLE HOSPITALS

2015			
	EHR reporting period for a payment adjustment year	Applies to avoid a payment adjustment in FY 2016	Applies to avoid a payment adjustment in FY 2017
eligible hospitals that have not successfully demonstrated meaningful use in a prior year (new participants)	Any continuous 90-day period from October 1, 2014 through December 31, 2015	Yes, if eligible hospital successfully attests by February 29, 2016	Yes, if eligible hospital successfully attests by February 29, 2016
eligible hospitals that have successfully demonstrated meaningful use in a prior year (returning participants)	Any continuous 90-day period from October 1, 2014 through December 31, 2015	No	Yes, if eligible hospital successfully attests by February 29, 2016
2016			
	EHR reporting period for a payment adjustment year	Applies to avoid a payment adjustment in FY 2017	Applies to avoid a payment adjustment in FY 2018
eligible hospital new participants	Any continuous 90-day period in CY 2016	Yes, if eligible hospital successfully attests by October 1, 2016	Yes, if eligible hospital successfully attests by February 28, 2017
eligible hospital returning participants	CY 2016	No	Yes, if eligible hospital successfully attests by February 28, 2017
2017			
	EHR reporting period for a payment adjustment year	Applies to avoid a payment adjustment in FY 2018	Applies to avoid a payment adjustment in FY 2019
eligible hospital new	Any continuous	Yes, if eligible	Yes, if eligible

participants	90-day period in CY 2017	hospital successfully attests by October 1, 2017	hospital successfully attests by February 28, 2018
eligible hospital Stage 3 participants	Any continuous 90-day period in CY 2017	No for returning participants	Yes, if eligible hospital successfully attests by February 28, 2018
eligible hospital returning participants	CY 2017	No	Yes, if eligible hospital successfully attests by February 28, 2018
2018			
	EHR reporting period for a payment adjustment year	Applies to avoid a payment adjustment in FY 2019	Applies to avoid a payment adjustment in FY 2020
eligible hospital new participants	CY2018	No	Yes, if eligible hospital successfully attests by February 28, 2019
eligible hospital Medicaid exception	the continuous 90-day EHR reporting period for the Medicaid incentive payment in CY 2018	No	Yes, if eligible hospital successfully attests by February 28, 2019
eligible hospital returning participants	CY 2018	No	Yes, if eligible hospital successfully attests by February 28, 2019

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

As follows is a summary of the comments received on the proposals for the EHR reporting period for a payment adjustment year for CAHs (80 FR 16777 through 16779 and 80 FR 20381):

Comment: We received a number of comments stating that CAHs should be allowed to attest in 2015 if they are demonstrating meaningful use for the first time in order to earn an incentive payment and avoid the 2015 payment adjustment. We further received requests for

clarification of whether the early attestation deadlines apply for CAHs in order to avoid future payment adjustments as first time participants.

Response: As noted in section II.D. of this final rule with comment period, some new participant CAHs have already attested to meaningful use for an EHR reporting period in 2015. The early attestation deadlines do not apply to CAHs because of the alignment of the EHR reporting period with the payment adjustment year and the use of the cost report reconciliation process to reduce a CAH's Medicare reimbursement for reasonable costs incurred if the CAH does not successfully demonstrate meaningful use for the applicable EHR reporting period. Furthermore, for the reasons stated in section II.E.2.a. of this final rule with comment period with regard to new participant EPs in 2017, we will adopt a final policy that for CAHs demonstrating meaningful use for the first time in 2017 under Medicare or Medicaid, the EHR reporting period for a payment adjustment year is any continuous 90-day period in CY 2017 and applies for purposes of the payment adjustments in FY 2017.

We will also adopt a final policy beginning in 2018 to require CAH (new participants and returning participants) that attest to meaningful use under Medicare to complete a full CY EHR reporting period that is the payment adjustment year. We are adopting a limited exception of a 90-day EHR reporting period within the calendar year that is the payment adjustment year for Medicaid CAH participants demonstrating meaningful use for the first time that previously demonstrated AIU prior to 2017 to allow these providers to earn an incentive payment in the Medicaid program for 2018 without receiving an penalty in the Medicare program.

After consideration of the public comments, we are finalizing the following changes to

the EHR reporting period for a payment adjustment year for CAHs as proposed, with a modification for the EHR reporting period in 2017. For the reasons stated in section II.E.2.a. of this final rule with comment period for Medicaid EPs for Stage 3 in 2017, we are finalizing a similar policy for CAHs to establish a 90-day EHR reporting for Stage 3 participants in 2017 for the purposes of avoiding the payment adjustment for FY 2017. For further discussion of the policy related to the EHR reporting period in 2017 we direct readers to section II.B.1.b.(3).iii. of this final rule with comment period.

In CY 2015, the EHR reporting period for a payment adjustment year for CAHs that have not successfully demonstrated meaningful use in a prior year (new participants) is any continuous 90-day period beginning on October 1, 2014 and ending on December 31, 2015. A CAH that successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in FY 2015 if the CAH successfully attests by February 29, 2016.

In CY 2015, the EHR reporting period for a payment adjustment year for CAHs that have successfully demonstrated meaningful use in a prior year (returning participants) is any continuous 90-day period beginning on October 1, 2014 and ending on December 31, 2015. A CAH that successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in FY 2015 if the CAH successfully attests by February 29, 2016.

In CY 2016, the EHR reporting period for a payment adjustment year for CAHs that are new participants is any continuous 90-day period in CY 2016. A CAH that successfully demonstrates meaningful use for this period and satisfies all other program requirements will

avoid the payment adjustment in FY 2016 if the CAH successfully attests by February 28, 2017.

In CY 2016, the EHR reporting period for a payment adjustment year for CAHs that are returning participants is the full CY 2016. A CAH that successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in FY 2016 if the CAH successfully attests by February 28, 2017.

In CY 2017, the EHR reporting period for a payment adjustment year for CAHs that are new participants is any continuous 90-day period in CY 2017. A CAH that successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in FY 2017 if the CAH successfully attests by February 28, 2018.

In CY 2017, the EHR reporting period for a payment adjustment year for CAHs that are demonstrating Stage 3 is any continuous 90-day period in CY 2017. A CAH that successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in FY 2017 if the CAH successfully attests by February 28, 2018.

In CY 2017, the EHR reporting period for a payment adjustment year for CAHs that are returning participants and are not demonstrating Stage 3, is the full CY 2017. A CAH that successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in FY 2017 if the CAH successfully attests by February 28, 2018.

Beginning in CY 2018, the EHR reporting period for a payment adjustment year for CAHs is the calendar year that begins on the first day of the second quarter 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 2018, the CAH must demonstrate it is a meaningful EHR user for an EHR reporting period of the full CY 2018. The exception to this general rule is for CAHs that successfully demonstrated AIU under the Medicaid EHR Incentive Program for a payment year prior to 2017 and are demonstrating meaningful use for the first time under the Medicaid EHR Incentive Program in the calendar year that begins on the first day of the second quarter of the federal fiscal year that is the payment adjustment year. For those CAHs, the same 90-day EHR reporting period used for the Medicaid incentive payment will also apply for purposes of the Medicare payment adjustment year. For example, if a CAH has never successfully demonstrated meaningful use in a prior year and demonstrates under the Medicaid EHR Incentive Program that it is a meaningful EHR user for the first time in CY 2018, the EHR reporting period for the Medicaid incentive payment is any continuous 90-day period within CY 2018, and the same 90-day period also serves as the EHR reporting period for the FY 2018 payment adjustment year under Medicare. A CAH that successfully demonstrates meaningful use for the relevant period and satisfies all other program requirements will avoid the payment adjustment in the relevant year if the CAH successfully attests by the date specified by CMS.

We have revised the definition of “EHR reporting period for a payment adjustment year” under § 495.4 to reflect these final policies. Table 20 contains a summary of the final policies, although it does not include years beyond 2018.

TABLE 20 - EHR REPORTING PERIODS AND RELATED PAYMENT ADJUSTMENT YEARS FOR CAHs

2015		
	EHR reporting period for a payment adjustment year	Applies to avoid a payment adjustment in FY 2015
CAHs that have not successfully demonstrated meaningful use in a prior year (new participants)	Any continuous 90-day period from October 1, 2014 through December 31, 2015	Yes, if CAH successfully attests by February 29, 2016
CAHs that have successfully demonstrated meaningful use in a prior year (returning participants)	Any continuous 90-day period from October 1, 2014 through December 31, 2015	
2016		
	EHR reporting period for a payment adjustment year	Applies to avoid a payment adjustment in FY 2016
CAH new participants	Any continuous 90-day period in CY 2016	Yes, if CAH successfully attests by February 28, 2017
CAH returning participants	CY 2016	
2017		
	EHR reporting period for a payment adjustment year	Applies to avoid a payment adjustment in FY 2017
CAH new participants	Any continuous 90-day period in CY 2017	Yes, if CAH successfully attests by February 28, 2018
CAH Stage 3 participants	Any continuous 90-day period in CY 2017	
CAH returning participants	CY 2017	

2018		
	EHR reporting period for a payment adjustment year	Applies to avoid a payment adjustment in FY 2018
CAH new participants	Any continuous 90-day period in CY 2018	Yes, if CAH successfully attests by February 28, 2018
CAH returning participants	CY 2018	

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 the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20381), we proposed no changes to the types of hardship exceptions available to EPs, eligible hospitals, and CAHs. Further, we proposed no changes to the existing hardship exception process and timelines under our regulations.

In the Stage 3 proposed rule we proposed no changes to the types of exceptions previously finalized for EPs, eligible hospitals or CAHs (80 FR 16775, 80 FR 16777 and 80 FR 16779), nor did we propose any new types of exceptions for 2017 and subsequent years. Accordingly, we proposed that the exceptions continue as previously finalized. As follows is a

summary of the comments received for hardship exceptions:

Comment: We received a number of comments requesting an extension of the hardship exception application deadline from July 1 to December 31 of the year proceeding the payment adjustment year. A commenter noted that CMS allowed for providers to apply for a hardship exception in November of the year proceeding the payment adjustment year in 2014 and that such a provision should be possible in every year.

Response: We thank the commenters for their suggestions but disagree with their assessment. The extension of the hardship exception application deadline to later in the year is both unnecessary and a significant burden for the program and for those providers whose claims may need to be reprocessed. We note that the expedited processing and reprocessing of claims represents a significant cost which should be avoided where feasible. Furthermore, if the applicable EHR reporting period for a payment adjustment year occurs 2 years before the payment adjustment year, providers that fail to demonstrate meaningful use for that period will be aware of their status well in advance of the deadline for applying for a hardship exception, and thus no such extension is necessary. New participants in the program who are uncertain of their ability to meet the requirements of the program in a given year may apply for a hardship exception even if they later find they are able to successfully attest in the program. The provider is not required to withdraw the hardship exception application, and the application does not affect their subsequent attestation for meaningful use. Therefore, we do not believe a general extension of the hardship exception application deadline is necessary, although we may consider extensions in exceptional circumstances.

Comment: A large number of commenters requested that CMS add new hardship

exception categories for the EHR Incentive Programs. Commenters believed that there should be additional exception categories, especially for providers experiencing issues with certified EHR technology and EHR vendors; providers who are unable to achieve meaningful use due to the all-or-nothing approach; providers practicing in multiple locations or who have transitioned between locations; providers who are beyond retirement age; specialty providers; providers who are new to the EHR Incentive Program and have not yet achieved meaningful use; providers who see observation patients; and fellows. Commenters believe providers who fall into any of these categories have significant reasons to be included in the list of those who qualify for hardship exceptions and should not receive payment adjustments.

Response: We note that providers may already apply for a hardship exception under the extreme and uncontrollable circumstances category if they experience issues with a vendor product including issues related to upgrades and transitions from one product to another. In addition, we note that new participants have the same ability to apply for a hardship exception as any other provider. We also established hardship exception categories for newly practicing EPs, new eligible hospitals, and new CAHs. We do not believe there are acceptable standards to establish a category based on age or potential retirement status given the wide variation among providers and potential influencing factors. Finally, we believe that the existing categories are broad and comprehensive enough to cover many different circumstances where meeting the program requirements would be a significant hardship due to circumstances outside the control of the provider and related to their particular practice or organization.

Comment: Some commenters requested clarification around whether the 5-year limitation for hardship exceptions will be applicable to providers with PECOS specialties of

diagnostic radiology (30), nuclear medicine (36), interventional radiology (94), anesthesiology (05), and pathology (22). Commenters believed these providers might retain the same PECOS specialty code for more than 5 years.

Response: Under section 1848(a)(7)(B) of the Act, the Secretary has discretion, on a case-by-case basis, to exempt an EP from the Medicare payment adjustment if the Secretary determines, subject to annual renewal, that requiring the EP to be a meaningful EHR user would result in a significant hardship. Such exemptions are not granted once and applicable for a full five-year period. Under 495.102(d)(4)(iv)(C), an EP may receive a hardship exception if he or she has a primary specialty listed in PECOS as anesthesiology, radiology or pathology 6 months prior to the first day of the payment adjustments that would otherwise apply. The following five specialty codes correspond to those primary specialties in PECOS: Diagnostic Radiology (30), Nuclear Medicine (36), Interventional, Radiology (94), Anesthesiology (05), or Pathology (22).

Comment: A commenter expressed concern regarding the requirement that the hardship exception is subject to annual renewal, but in no case may an EP be granted an exception for more than 5 years. Specifically, the commenter stated that a large percentage of these EPs practice in areas that do not have availability of CEHRT for demonstration of meaningful use. Because these providers lack control over availability of CEHRT for more than 50 percent of patient encounters, they cannot demonstrate meaningful use. The commenter anticipates these providers to continue practicing at multiple locations beyond the 5 years allowed for hardship exceptions. Some commenters suggested a hardship exemption should be available for EPs working in long term post-acute care (LTPAC) which should continue beyond the 5-year time limit; while other commenters questioned what if there is not sufficient broadband access in the

region and 5 years may not be enough time for some remote areas to be “connected”. A commenter recommended simply eliminating the 5-year maximum for providers claiming this hardship exception.

Response: We are sympathetic to the challenges identified by the commenters and believe that barriers to achieving meaningful use should be minimized over time. As noted earlier, the 5-year limitation on hardship exceptions is a statutory requirement under section 1848(a)(7)(B) of the Act, and we do not have discretion to alter this requirement.

Comment: We received a suggestion from a commenter for an indication in the registration system that would identify the new EPs, which may be helpful to assist with program management. The commenter indicated for a large group practice, it is very difficult to determine if an EP is considered “new” by CMS standards and therefore may qualify for a hardship exception for newly practicing EPs. Some EPs have moonlighted during residency or fellowship and may be considered eligible for this hardship exception.

Response: We appreciate the commenter’s suggestion about an indicator to identify a newly practicing EP in the registration system and will consider analysis to determine feasibility.

Comment: Commenters supported the existing hardship exception structure and categories for the Medicare payment adjustment in the EHR Incentive Programs. Some commenters requested a change the hardship exception application date for eligible hospitals to reflect the realignment to the calendar year.

Response: We appreciate the support expressed by commenters of our current process for hardship exceptions for eligible hospitals. We agree with the recommendation to modify the hardship exception application deadline for eligible hospitals to allow for adequate time between

the close of the calendar year and the submission requirements for hardship applications. We will align the eligible hospital deadline with the EP deadline so that applications will be due on July 1 of the year preceding the payment adjustment year.

We are finalizing no changes to the types of hardship exceptions already available to EPs, eligible hospitals, and CAHs, nor do we finalize any new types of hardship exceptions. We are finalizing one procedural change to the hardship exception application deadline for eligible hospitals to July 1 of the year preceding the payment adjustment year to align the application period with EPs in light of the change to align hospitals with the calendar year for the EHR reporting period for a payment adjustment year and the changed attestation deadlines as finalized in section II.E.2.b and II.D of this final rule with comment period. This change is reflected in § 412.64(d)(4).

4. Administrative Review Process of Certain Electronic Health Record Incentive Program Determinations

In the Stage 2 final rule (77 FR 54112 through 54113), we discussed an administrative appeals process for both Stages 1 and 2 of meaningful use. We believe this appeals process is primarily procedural and does not need to be specified in regulation. We developed guidance on the appeals process, which is available on our website at www.cms.gov/EHRIncentivePrograms. We proposed no changes to this process and intend to continue to specify the appeals process in guidance available on our website.

Comments: We received a number of comments with references to specific instances of audits or appeals submitted. In addition, we received a wide range of recommendations for changes the auditors should make and for the requirements for the audit program. Finally, we

received a number of comments expressing frustration with failed audits due to lack of response from the provider or the provider not receiving notification.

Response: We thank the commenters for sharing their experiences and insight with us. While we will not respond to each individual circumstance in this final rule with comment period, as this is not the appropriate vehicle to address these individual concerns, we note that providers may contact us directly and we will work with them to understand their audit or appeal status, review any determinations and provide information related to the programs. We also appreciate those who provided suggestions for additional guidance which might assist the auditors to make determinations on certain requirements for the program. We have reviewed this information and will update our guidance in response to recommendations received. Finally, we note that it is incumbent on providers to maintain the appropriate contact information in the system of record and regularly verify that their contact information is correct. It is this contact information provided by the EP, eligible hospital, or CAH which we use to notify the provider of any status update or audit request for the EHR Incentive Programs. Once notification has been sent, it is also this contact information which is used by the auditors to communicate with the provider on status, documentation requests, and any other necessary items in order to expedite the audit process and ensure the use of verified and authorized contact information for the EP, eligible hospital or CAH.

We are finalizing our proposal to maintain this policy as previously adopted.

F. Medicare Advantage Organization Incentive Payments

We did not propose any changes to the existing policies and regulations for MA organizations. Our existing policies and regulations include provisions concerning the EHR incentive payments to qualifying MA organizations and the payment adjustments for 2015 and subsequent MA payment adjustment years. (For more information on MA organization incentive payments, we refer readers to the final rules for Stages 1 and 2 (75 FR 44468 through 44482 and 77 FR 54113 through 54119).)

Comment: A commenter requested clarification that CMS is not changing the quality reporting requirements for MA organizations in this proposed rule so that MA providers may still meet the quality reporting requirements by way of their Healthcare Effectiveness Data and Information Set (HEDIS) submission. Another commenter requested that hardship exceptions be granted to MA providers under the same provisions available for non-MA providers.

Response: We are confirming that we will continue to allow MA organizations to report HEDIS measures in lieu of CQMs for purposes of meaningful use for qualifying MA-EPs and MA-affiliated eligible hospitals.

We did not propose any changes to the hardship exemption policy for MA providers in the proposed regulation. Therefore, the comment is outside the scope of the proposed rule and is not addressed in this final rule with comment period.

G. The Medicaid EHR Incentive Program

1. State Flexibility for Meaningful Use

Consistent with our approach under both Stage 1 and 2, for Stage 3 we proposed to continue to offer states flexibility under the Medicaid EHR Incentive Program in Stage 3 by adding a new provision at § 495.316(d)(2)(iii) subject to the same conditions and standards as the Stage 2 flexibility policy. We proposed at that under Stage 3 (80 FR 16779), state flexibility would apply only with respect to the public health and clinical data registry reporting objective. We proposed that states could continue to specify the means of transmission of data and otherwise change the public health agency reporting objective as long as the state does not require functionality greater than what is required for Stage 3 and included in the 2015 Edition proposed rule.

Similarly, in the preamble to the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20349), we proposed to continue to offer states flexibility for the public health reporting objective as modified under Stage 2 for 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 that supersedes that which is included in the certification requirements specified under the 2014 Edition certification criteria.

Comment: Commenters requested clarification on the state flexibility that would be permitted. One commenter requested clarification on whether immunization registries would be included, whether states could continue to specify transport options, and whether states could decide not to declare readiness to accept submissions to clinical data registries for meaningful

use purposes.

Response: We note that the state flexibility to propose a revised definition of meaningful use with respect to particular public health measures continues as allowed in Stage 1 and Stage 2 at § 495.316(d)(2) and § 495.332(f)(2). We note that the final rule has altered the structure of meaningful use under Stage 2 with respect to the public health and clinical data registry reporting measures, such that there is a single objective with a list of measures that providers may choose from. However, we would still permit states to exercise flexibility with respect to each of the Stage 2 items listed at § 495.316(d)(2)(ii) that still apply in 2015 through 2017 under this final rule. We will also take the following considerations into account when, as part of our review and approval of the state's Medicaid HIT plan, we review state requests for flexibility with respect to the public health reporting objective (Objective 8) for Stage 3 (see section II.B.2.b.(viii). of this final rule with comment period. We want to balance states' flexibility to customize the public health and clinical data registry requirements for meaningful use against ensuring providers have options to submit to registries that are most relevant to their practices. Therefore, we expect that for Stage 3 we would be more likely to approve requests under which a state would require an EPs, eligible hospitals and CAHs to submit to a specific registry meeting the specification of measures 1 through 4 or 6 rather than establishing specific requirements for measure 5.

The flexibility to specify transmission standards remains unchanged from the Stage 2 Rule. In the Stage 2 final rule (77 FR 53979), we explained that a state could not require a different standard than the one included in 2014 ONC EHR certification criteria, but in cases where the 2014 ONC EHR certification criteria are silent, such as the means of transmission for

a given public health objective, the state may propose changes to public health measures. We maintain this distinction for Stage 3 in relation to the 2015 ONC certification criteria for health IT.

Comment: Most commenters supported the new provision to provide states with flexibility regarding the Stage 3 public health and clinical data registry reporting objective. One commenter questioned whether a state could opt to not declare readiness to accept clinical data registries for meaningful use purposes, expressing concern that providers may prioritize reporting to federal clinical data registries over the public health reporting objectives. Another commenter expressed concern that that this flexibility would lead to differing objectives and measures among the states instead of a consistent, standard approach.

Response: We proposed to continue to offer states flexibility under the Medicaid EHR Incentive Program in Stage 3, but subject to the same considerations discussed previously in Stage 2 (77 FR 53979). For Stage 3 of meaningful use, we would continue to allow states to specify the means of transmission of the data and otherwise change the public health agency reporting objective as long as they do not require functionality greater than what is required for Stage 3 and included in the 2015 Edition final rule. States may change the definition of meaningful use with respect to the public health registry and clinical data registry reporting objective as discussed in our earlier response. While this policy may lead to variations in the definition of meaningful use with respect to this objective among the states, we believe that it is important to allow states to better shape their public health policies and encourage providers to submit data to particular public health registries.

States generally do not have discretion to categorically deny providers from using clinical data registries to meet the public health and clinical data registry reporting objective, so long as the clinical data repositories fall within federal rules and guidance. To address concerns that providers may be discouraged from attesting to public health registries, we reiterate that states can submit for CMS approval revisions to their SMHPs that would require that providers meet certain measures.

We are finalizing the Stage 3 state flexibility provision generally as proposed, with only a minor change to update a cross-reference to the public health and clinical data registry objective.

2. EHR Reporting Period and EHR Reporting Period for a Payment Adjustment Year for First Time Meaningful EHR Users in Medicaid

In the Stage 3 proposed rule (80 FR 16779), we proposed several amendments to the definitions of "EHR Reporting Period" and "EHR reporting period for a payment adjustment year" in § 495.4 that would apply to providers attesting in the Medicaid EHR Incentive Program. While many of the proposed amendments would apply to providers attesting in either the Medicare or Medicaid EHR Incentive Program, we also proposed a limited exception for new meaningful EHR users in the Medicaid program beginning in 2017.

In the EHR Incentive Programs in 2015 through 2017 proposed rule (80 FR 20353 and 20354), we proposed that 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 fulfill the requirements of the EHR Incentive Programs beginning in calendar year 2015 (except for eligible hospitals and CAHs in 2015, which may begin an EHR reporting period as early as October 1, 2014 and must end by December 31, 2015). We also proposed 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; eligible hospitals and CAHs may select an EHR reporting period of any continuous 90-day period from October 1, 2014 through December 31, 2015. These proposed amendments and the final policies adopted are discussed in sections II.B.1.b.(3).(i). and (ii). of this final rule with comment period.

In the Stage 3 proposed rule (80 FR 16739), we proposed that beginning in 2017 and for all EPs, eligible hospitals, and CAHs, the EHR reporting period would be one full calendar year. This proposed amendment is discussed in section II.B.1.b.(3).(iii). of this final rule with comment period, and is finalized with a modification to begin for all providers in 2018 and multiple modifications to the EHR reporting period in 2017. For EPs, eligible hospitals, and CAHs that choose to meet Stage 3 in 2017, the EHR reporting period is any continuous 90-day period within CY 2017. For new participants, the EHR reporting period is any continuous 90-day reporting period within CY 2017. These modifications regarding providers attesting to Stage 3 of meaningful use in 2017 applies to providers attesting to the Medicaid EHR Incentive Program as well.

In the Stage 3 proposed rule (80 FR 16739), we also proposed a limited exception for Medicaid providers demonstrating meaningful use for the first time in 2017 and subsequent years. For that exception, we proposed to maintain the 90-day EHR reporting period for a provider's first payment year based on meaningful use for EPs and eligible hospitals participating in the Medicaid EHR Incentive Program. We proposed that this exception would apply both for purposes of receiving an incentive payment in the Medicaid program and for purposes of avoiding the payment adjustment under the Medicare program for the payment adjustment year

that is two years after the calendar year in which the provider first demonstrates meaningful use for an EHR reporting period. As the last year that an eligible professional can begin participation in the Medicaid EHR Incentive Program is 2016, this limited exception would apply only to providers who received an incentive payment for adopt, implement, or upgrade of CEHRT in 2011 through 2016, but did not receive an incentive payment for demonstration of meaningful use until 2017 or after. In this section, we address comments received on this limited exception for new meaningful EHR users in the Medicaid program.

Comment: Several commenters supported the proposal to allow Medicaid providers to have a 90-day EHR reporting period for their first year of demonstrating meaningful use under the Medicaid EHR Incentive Program.

Response: We refer readers to sections II.B.1.b.(3). and II.E.2. of this final rule with comment period with comment period for a discussion of our final policies for Medicaid providers for the EHR reporting period and the EHR reporting period for a payment adjustment year.

We believe that these changes will allow flexibility for providers who have not demonstrated meaningful use in a previous year and will encourage providers to participate in the program.

Comment: Some commenters opposed the proposed 90-day EHR reporting period for certain Medicaid providers because they believed it would cause confusion as it conflicts with the proposed Medicare policy. In addition, these commenters were concerned that providers attesting to the 90-day EHR reporting period for Medicaid would still be subject to the Medicare payment adjustment.

Response: We recognize the possibility of provider confusion regarding EHR reporting periods between the Medicare and Medicaid EHR Incentive Programs under the final rule, but we believe that there are benefits that outweigh this potential concern. A 90-day EHR reporting period would allow Medicaid providers additional time and flexibility within their first year of demonstrating meaningful use to implement certified EHR technology and otherwise integrate the meaningful use objectives into their practices. We believe that this will encourage participation in the program and move a greater number of providers towards meaningful use. It also would reduce the burden on states to implement significant policy and system changes in preparation for Stage 3, as the 90-day period for the first year of meaningful use is consistent with our previous policies and meaningful use timelines. With regard to the question raised by commenters if providers attesting to the 90-day EHR reporting period for Medicaid may still be subject to the Medicare payment adjustment, we refer to our discussion of the EHR reporting period for the payment adjustment year in section II.E.2. of this final rule with comment period.

Comment: Some commenters requested that CMS allow states to give providers the option to attest to "at least 90 days or 3 calendar months," rather than 90 days within the calendar year, because it is more convenient for providers to run reports out of their CEHRT by month.

Response: We believe that it is important to maintain a consistent EHR reporting period for providers in their first year of meaningful use and changing the EHR period at this point also risks provider confusion. Allowing 3 calendar months would open the possibility of a reporting period that is shorter than 90 days, and we believe that 90 days is already a short period as compared to the entire year. Furthermore, a 90-day period need not be tied to the beginning or end of a month and permits flexibility for providers.

Comment: A commenter requested that CMS provide outreach and education to assure understanding of the 90-day EHR reporting period for Medicaid providers demonstrating meaningful use for the first time.

Response: We will provide outreach and education around this policy. Because the exception for new meaningful EHR users in the Medicaid program who had successfully attested to AIU prior to 2016 to allow a 90-day EHR reporting period in 2018 and subsequent years is consistent with existing policy with respect to Medicaid provider EHR reporting periods, we do not anticipate significant additional confusion.

3. Reporting Requirements

a. State Reporting on Program Activities

In the Stage 3 proposed rule (80 FR 16779), we also proposed to amend § 495.316(c), as well as add a new paragraph § 495.316(f), to formalize the process of how states report to us annually on the providers that have attested to adopt, implement, or upgrade (AIU), or that have attested to meaningful use. Under this proposal, states would follow a structured submission process, in the manner prescribed by CMS, which would include a new annual reporting deadline. We proposed to require states to submit annual reports to CMS within 45 days of the end of the second quarter of each federal fiscal year.

We proposed to regularize the timing of the annual reporting process described in § 495.316 to ensure more timely annual reports and allow for clearer communication to states on when the reports should be submitted to CMS. In addition, CMS and states would be able to more effectively track the progress of states' incentive program implementation and oversight as well as provider progress in achieving meaningful use. Predictable deadlines for annual

reporting would permit CMS and the states to more quickly compare and assess overall program impact each year.

In the Stage 3 proposed rule (80 FR 16779), we also noted our intent to consider changes to the data that the annual reporting requirements outlined in § 495.316(d) require states to include in their annual reports. Specifically, we explained we were considering whether to remove the requirement that states report information about practice location for providers that qualify for incentive payments on the basis of having adopted, implemented, or upgraded CEHRT or on the basis of demonstrating they are meaningful users of CEHRT. We stated our belief that this data is useful to both CMS and the states for program implementation purposes, but that the benefits of including it in state reports might be outweighed by the burdens to states of reporting it and requested more information on state burdens and costs associated with complying with this requirement. We solicited comments both on the burdens associated with the requirement to report practice location information for providers that receive incentive payments through the Medicaid EHR Incentive Program, and on the benefits of including this information in state reports.

We proposed to amend § 495.352 to formalize the process of how states submit quarterly progress reports on implementation and oversight activities and to specify the elements that should be included in the quarterly reports. Under this proposal, states would follow a structured submission process, in the manner prescribed by CMS. We proposed that states would report on the following activities: state system implementation dates; provider outreach; auditing; state-specific SMHP tasks; state staffing levels and changes; the number and type of providers that qualified for an incentive payment on the basis of demonstrating that they are meaningful

EHR users of CEHRT and the amounts of incentive payments; and the number and type of providers that qualified for an incentive payment on the basis of having adopted, implemented, or upgraded CEHRT and the amounts of incentive payments.

We proposed these changes to the quarterly reporting process described in § 495.352 so that CMS and states can better track state implementation and oversight activity progress in a way that would permit CMS and the states to compare overall programmatic and provider progress. We also expect that streamlined and enhanced quarterly progress reporting would lead to an improvement in overall data quality that would help inform future meaningful use activity across states.

Finally, we proposed to include a deadline for states' quarterly reporting under the proposed amendments to § 495.352, and requested public comment on a deadline of 30 days after the end of each federal fiscal year quarter.

Comment: Commenters supported formalizing the process of how states report annually on the providers that have attested to AIU, or that have attested to meaningful use, but requested to submit annual reports within 60 days of the end of the second quarter of each federal fiscal year rather than the 45 days proposed in the rule. A commenter stated that this will alleviate systems and programming changes typically faced by states at the end of the calendar year, while another commenter expressed that states would need more time to produce current program year data to be included in the annual report.

Response: We agree with the commenter's statements regarding the implications of year-end program changes and the need for additional time to produce related data. Therefore, we are finalizing these provisions to require that annual reports be submitted to CMS within 60 days of

the end of the second quarter of each federal fiscal year rather than 45 days, as was proposed. States should have ample time to prepare to submit the annual reports to CMS, and we are not adding additional data elements for states to report; therefore, the first report under this amendment will be due within 60 days of the end of the second quarter of the federal fiscal year in which the final rule takes effect.

Comment: Commenters supported our proposal to remove practice location from the annual report. A commenter noted that their state already reports practice location, but does not find this data point to be beneficial and is in favor of removing this requirement. Another commenter finds this requirement to be burdensome because it requires manual review of attestations in order to identify accurate data on practice locations, and fears this will lead to inaccurate data.

Response: We appreciate the commenters' feedback on this topic. While we believe that there is a benefit to having states report this information in the annual reports, we believe that this benefit is outweighed by the burden of states having to collect and report this information on providers. Moreover, there is also a risk that inaccurate practice location data may be reported due to manual data collection processes. We believe that we can effectively oversee the program without states reporting this particular information. Therefore, we intend to remove the requirement at §495.316(d)(1)(i) and (iii) that states report information about practice location for providers that qualify for incentive payments on the basis of having adopted, implemented, or upgraded CEHRT or on the basis of demonstrating they are meaningful users of CEHRT. We encourage states to collect and use practice location information, as it could prove useful and

may differ from the business address information that is used for program administration purposes.

Comment: Commenters supported the proposed requirement for states to submit quarterly progress reports to CMS within 30 days after the end of each federal fiscal year quarter and do not anticipate that this requirement would create any burden.

Response: Based on the positive feedback we are finalizing the proposal with a modification to require the deadline of 30 days after the end of each federal fiscal year quarter that was discussed in the proposed rule. In order to give states sufficient time to prepare to submit the quarterly reports, the first report under the amendments to §495.352 will be due in the second quarter following the one in which the final rule takes effect.

Comment: A commenter recommended that all public health measures collected or tracked through the state reporting activities be reported to the public health agency.

Response: We support the notion of sharing public health measures collected through state reporting activities with the designated public health agency, but also recognize that the mechanism and interface between the reporting organization and the public health agency must be live, operational, and capable of interfacing with all parties involved. Additionally, our state reporting provisions are meant to cover reporting from state Medicaid agencies to CMS. We decline to add a requirement that state Medicaid agencies report this data to other entities, including public health agencies.

b. State Reporting on Meaningful EHR Users

In the Stage 3 proposed rule at (80 FR 16780), we noted that CMS must have accurate and timely data from states regarding both EPs and eligible hospitals that have successfully

demonstrated meaningful use for each payment year to ensure that meaningful EHR users in the Medicaid EHR Incentive Program are appropriately exempted from the Medicare payment adjustment for the applicable payment adjustment year. Accordingly, we proposed to add new paragraphs (g) and (h) to § 495.316 to require that states submit reports on a quarterly basis that identify certain providers that attested to meaningful use through the Medicaid EHR Incentive Program for each payment year. Under this proposal, states would submit quarterly reports, in the manner prescribed by CMS, for Medicaid EPs and eligible hospitals that successfully attest to meaningful use for each payment year.

We proposed that states would report quarterly information on each provider that successfully attests to meaningful use, regardless of whether the provider has been paid yet. The report would be required to specify the Medicaid state and payment year. For each EP or eligible hospital listed in the report, the state would also specify the payment year number, the NPI for EPs and the CCN for eligible hospitals, the attestation submission date, the state qualification (as either meaningful use or blank), and the state qualification date (the beginning date of the reporting period in which successful meaningful use attestation was achieved by the EP or eligible hospital). The EP's or eligible hospital's "payment year number" refers to the number of years that the provider has been paid in the EHR Incentive Program; so, for example, this would be "2" for the 2014 payment year if the provider received payments for 2013 and 2014. States would have this data, even for providers that have previously received an incentive payment through the Medicare EHR Incentive Program. If the state is reporting a disqualification, then the state would leave the state qualification field blank. If applicable, in the cases of EPs or eligible hospitals previously identified as meaningful EHR users, the state would be required to

specify the state disqualification and state disqualification date (that is, the beginning date of the EHR reporting period during which an EP or eligible hospital was found not to meet the definition of a meaningful EHR user).

We also proposed that states would submit this information beginning with payment year 2013 data. The reports would cover back to the 2013 payment year because that would be the EHR reporting period for the 2015 Medicare payment adjustment year under § 495.4. Providers that successfully attested to meaningful use for 2013 would be exempt from the Medicare payment adjustment in 2015.

We also proposed that states would not be required to report on those EPs who are eligible for the Medicaid EHR Incentive Program on the basis of being a nurse practitioner, certified nurse-midwife, or physician assistant.

Comment: Most comments favored and expressed no concern with the associated requirements, nor anticipated burden. A commenter shared that he or she found the state reporting on Meaningful EHR Users to be time consuming and suggested that we use the National Level Repository (NLR) transactions to determine meaningful users and remove this burden from the states. In this commenter's view, the payment adjustment is a Medicare function; therefore states should be removed from the process. Another commenter requested that we further clarify who is exempt from the state reporting.

Response: We intend to finalize these provisions as proposed for the reasons provided in the preamble to the Stage 3 proposed rule. As outlined in the Stage 3 proposed rule (80 FR 16780), we must have accurate and timely data from states regarding both EPs and eligible hospitals to ensure that meaningful users in the Medicaid EHR Incentive Program are

appropriately exempted from the Medicare payment adjustment for the applicable payment adjustment year. This additional reporting is necessary because the electronic data currently contained in the NLR are insufficient to determine which Medicaid providers should be exempted from the Medicare payment adjustments in an accurate and timely manner. Regarding the exemption with respect to reports on certain providers, we are not requiring states to report on nurse practitioners, certified nurse-midwives, or physician assistants because these provider types are not subject to the Medicare payment adjustments. The first report under this requirement will be due in the quarter following the one in which the rule takes effect.

4. Clinical Quality Measurement for the Medicaid Program

In the Stage 3 proposed rule (80 FR 16780), we noted that states are responsible for determining whether and how electronic reporting of CQMs would occur, or whether they wish to allow reporting through attestation. If a state does require electronic reporting, the state is responsible for sharing the details on the process with its provider community. States that wish to establish the method and requirements for electronically reporting would continue to be required to do so through the SMHP submission, subject to our prior approval.

To further our goals of alignment and avoiding duplicative reporting across quality reporting programs, we would recommend that states include a narrative in their SMHP for CY 2017 describing how their proposed meaningful use CQM data submission strategy aligns with their State Medicaid Quality Strategy and report which CEHRT requirements they mandate for eCQM reporting.

For more information on requirements around the State Medicaid Quality Strategy, see <http://medicaid.gov/Federal-Policy-Guidance/Downloads/SHO-13-007.pdf>.

Comment: A commenter supported the proposal to continue allowing states to be responsible for determining how providers will report CQMs because not all states are at the same readiness level to accept eCQMs, and states must implement system changes to accommodate policy change.

Response: We appreciate this comment, and we are finalizing this policy as proposed.

Comment: A number of commenters provided feedback regarding Medicaid quality improvement initiatives and recommendations on how to best conduct outreach and engagement to providers and patients in various clinical settings. Commenters also recommended ways to publicize EP accomplishments in providing essential health services to patients benefiting from the Medicaid EHR Incentive Program. In addition, commenters encouraged CMS to continue its conversations with state Medicaid agencies and health groups in an effort to explore the issues faced by eligible providers attempting to meaningfully use EHR in areas with large numbers of uninsured populations. They also recommended that CMS continue to encourage state Medicaid programs to collaborate with public health agencies, and to assist in reducing barriers to the use of Federal funding to build public health information infrastructure. A commenter recommended changes to the Medicaid patient-volume rules.

Response: We will consider these recommendations as we develop future planning for long-term delivery system reform and related policies. We note that some of these comments were outside of the scope of the proposed rules.

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 the proposed regulations that we believed were subject to PRA and collection of information requirements (ICRs) as a result of this final rule with comment period. This analysis finalizes our projections which were proposed in the March 30, 2015 **Federal Register** (80 FR 16781 through 16787) and the April 15, 2015 **Federal Register** (80 FR 20381 through 20386). The projected numbers of EPs, eligible hospitals, CAHs, MA organizations, MA EPs, and MA-affiliated hospitals were based on the numbers used in the impact analysis assumptions, as well as estimated federal costs and savings in the sections of the proposed rules. The actual burden would remain constant for all of Stage 3 as EPs, eligible hospitals, and CAHs would only need to attest that they have

successfully demonstrated meaningful use in 2017 and annually thereafter. The actual burden would remain constant for 2015 through 2017 as EPs, eligible hospitals, and CAHs would only need to attest that they have successfully demonstrated meaningful use in 2015 through 2017. The only variable from year to year will be the number of respondents, as noted in the impact analysis assumptions.

We solicited 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 (§ 495.24)

This final rule with comment period specifies applicable criteria for demonstrating meaningful use of CEHRT for EHR reporting periods in 2015 through 2017 and for Stage 3 in 2017 and subsequent years. The applicable criteria for demonstrating meaningful use for an EHR reporting period in 2015 through 2017 are based on modifications to the criteria previously set out in Stage 1 and 2 of the EHR Incentive Programs. These changes in the overall burden for providers reporting in 2015 through 2017 are discussed in further detail in the ICR analysis for 2015 through 2017 outlined in section III.B of this final rule with comment period. The ICRs in this section (that is, section III.A. of this final rule with comment period) reflect the provider burden associated with complying with and reporting of Stage 3 requirements beginning in 2017 and each subsequent year.

In § 495.24 (redesignated from § 495.7) we proposed that to successfully demonstrate meaningful use of CEHRT for Stage 3, 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:

- The provider used CEHRT and specified the technology was used.
- The provider satisfied each of the applicable objectives and associated measures in § 495.26.

In § 495.40 (redesignated from § 495.8), we stipulated that providers must also successfully report the clinical quality measures selected by CMS to CMS or the states, as applicable. We estimated that the CEHRT 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 noted that we also expect that the provider would enable the functionality required to complete the objectives and associated measures that require the provider to attest that they have done so.

We proposed that there would be five objectives and ten measures that would require an EP to enter numerators and denominators during attestation. Eligible hospitals and CAHs would have to attest they have met five objectives and ten measures that would require numerators and denominators. For objectives and associated measures requiring a numerator and denominator in the proposed rule, we limited our estimates to actions taken in the presence of certified EHR technology. We did not anticipate a provider would maintain two recordkeeping systems when CEHRT is present. Therefore, we assumed that all patient records that would be counted in the denominator would be kept using certified EHR technology. We expected 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. The security risk assessment and its associated measure would not require a numerator and denominator and we would expect it would take an individual provider or designee

approximately 6 hours to complete. The clinical decision support and active engagement with a public health agency measures would take an eligible professional, eligible hospital or critical access hospital 1 minute each to report each CDS intervention or registry.

We proposed that EPs would be required to report on a total of 8 objectives and 16 associated measures. For the purpose of the proposed collection of information, we assumed that all eligible providers would comply with the requirements of meaningful use Stage 3. We proposed that eligible hospitals and CAHs would be required to report on a total of 8 objectives and 17 associated measures. We estimated the total annual cost burden for all eligible hospitals and CAHs to attest to EHR technology, meaningful use objectives and associated measures, and electronically submit the clinical quality measures would be \$2,135,204 (4,900 eligible hospitals and CAHs \times 6 hours 52 minutes \times \$63.46²¹). We estimated the total annual cost burden for all EPs to attest to EHR technology, meaningful use objectives and associated measures, and electronically submit the clinical quality measures would be \$385,834,395 (609,100 EPs \times 6 hours 52 minutes \times \$92.25 (mean hourly rate for physicians based on May 2013 BLS) data).

Comment: One commenter noted that the time to attest is likely accurate; however, they stated that the estimate does not reflect the dollars and resources spent on software upgrades, implementation costs, continuous auditing, and the gathering of data for calculation.

Response: We appreciate the public comments on this burden analysis. However, this analysis specifically reflects the amount of time we estimate providers will take to prepare and report their meaningful use data through the Medicare and Medicaid EHR Incentive Programs Registration and Attestation System. We cannot account for other costs related to participation

²¹ Mean hourly rate for lawyers based on May 2013 Business and Labor Statistics (BLS) data.

in these programs or for variation in how an individual provider may collect, calculate or document actions related to their unique business practices and systems workflows.

After consideration of the public comments received, we are finalizing these burden estimates as proposed but have updated them to reflect policy changes implemented through this final rule with comment period.

In this final rule with comment period, there were five objectives that will require an EP to enter numerators and denominators during attestation. Eligible hospitals and CAHs will have to attest that they have met five 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 will maintain two recordkeeping systems when CEHRT is present. Therefore, we assume that all patient records that will be counted in the denominator will be kept using certified EHR technology. We expect it will 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 each CQM for providers attesting in their first year of the program.

Additionally, providers will be required to report they have completed objectives and associated measures that require a "yes" or "no" response during attestation. For EPs, there are three objectives that require a "yes" or "no" response during attestation. As discussed previously, the associated measures are that EPs are required to conduct a security risk analysis, report to three registries to fulfill the public health objective, and must implement at least five clinical decision support interventions. For eligible hospitals and CAHs, there are

three objectives that require a "yes" or "no" response during attestation. The associated measures for eligible hospitals and CAHs require the provider to conduct a security risk analysis, report to four registries to fulfill the public health objective and must implement at least five clinical decision support interventions. We estimate each of these measures would take 1 minute to report.

Providers will also be required to attest that they are protecting electronic health information. We estimate completion of the analysis required to meet successfully the associated measure for this objective will 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 do not account for the additional burden associated with the conduct or review of such analyses.

Table 21 lists the Stage 3 objectives and associated measures for EPs and eligible hospitals and CAHs. We estimate the objectives and associated measures will take an EP 6 hours 52 minutes to complete, and will take an eligible hospital or CAH 6 hours 52 minutes to complete.

We believe that EPs, eligible hospitals, and CAHs have virtually identical burdens. Eligible hospitals and CAHs are required to report to one additional registry than EPs are required to report. Consequently, we did not prepare lowest and highest burdens. Rather, we computed a burden for EPs and a burden for eligible hospitals and CAHs.

TABLE 21: BURDEN ESTIMATES Stage 3 - § 495.24

Objectives - Eligible Professionals	Objectives - Eligible Hospitals/CAHs	Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative and physical safeguards.	Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative and physical safeguards	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 created or maintained by CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process.	6 hours	6 hours
Generate and transmit permissible prescriptions electronically (eRx.)	Generate and transmit permissible discharge prescriptions electronically (eRx).	<p>1. EP Measure: More than 60% of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT.</p> <p>2. Eligible Hospital/CAH Measure: More than 25% of hospital discharge medication orders for permissible prescriptions (for new and changed prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.</p>	10 minutes	10 minutes
Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.	Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.	Measure 1. The EP, eligible hospital and CAH must implement five clinical decision support interventions related to four or more CQMs at a relevant point in patient care for the entire	1 minute	1 minute

Objectives - Eligible Professionals	Objectives - Eligible Hospitals/CAHs	Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
		<p>EHR reporting period. Absent four CQMs 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.</p> <p>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.</p>		
<p>Use CPOE for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.</p>	<p>Use CPOE for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.</p>	<p>Measure 1. More than 60 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</p> <p>Measure 2: More than 60 percent of laboratory 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</p> <p>Measure 3: More than 60 percent of diagnostic imaging orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or</p>	<p>10 minutes</p>	<p>10 minutes</p>

Objectives - Eligible Professionals	Objectives - Eligible Hospitals/CAHs	Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
		emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE		
The EP provides patients or their authorized representatives electronic access to their health information and patient-specific education	The eligible hospital or CAH provides patients or their authorized representatives electronic access to their health information and patient-specific education	<p>Measure 1:For more than 80 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):</p> <p>(1) The patient (or the patient-authorized representative) is provided access to view online, download, and transmit his or her health information; and</p> <p>(2) The provider ensures the patient’s health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the provider’s CEHRT.</p> <p>Measure 2:The EP, eligible hospital or CAH must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting</p>	10 minutes	10 minutes

Objectives - Eligible Professionals	Objectives - Eligible Hospitals/CAHs	Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
<p>Use CEHRT to engage with patients or their authorized representatives about the patient's care.</p>	<p>Use CEHRT to engage with patients or their authorized representatives about the patient's care.</p>	<p>period.</p> <p>Measure 1: During the EHR reporting period, more than 10 percent of all unique patients (or their authorized representatives) seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) actively engage with the EHR made accessible by the provider and either: (1) view, download or transmit to a third party their health information; or (2) access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's CEHRT; or (3) a combination of (1) and (2).</p> <p>Measure 2: For more than 25 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative)..</p>	<p>10 minutes</p>	<p>10 minutes</p>

Objectives - Eligible Professionals	Objectives - Eligible Hospitals/CAHs	Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
		<p>Measure 3: Patient-generated health data or data from a non-clinical setting is incorporated into the CEHRT for more than 5 percent of all unique patients seen by the EP or discharged by the eligible hospital or CAH (POS 21 or 23) during the EHR reporting period.</p>		
<p>The EP provides a summary of care record when transitioning or referring their patient to another setting of care, retrieves a summary of care record upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of CEHRT.</p>	<p>The eligible hospital or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, retrieves a summary of care record upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of CEHRT..</p>	<p>Measure 1: For more than 50 percent of transitions of care and referrals, the EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care—(1) creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.</p> <p>Measure 2: For more than 40 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP, eligible hospital or CAH incorporates into the patient's record an electronic summary of care document from a source other than the provider's EHR system.</p> <p>Measure 3: For more than 80 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the</p>	<p>10 minutes</p>	<p>10 minutes</p>

Objectives - Eligible Professionals	Objectives - Eligible Hospitals/CAHs	Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
		<p>patient, the EP, eligible hospital, or CAH performs a clinical information reconciliation. The provider must implement clinical information reconciliation for the following three clinical information sets:</p> <p><u>Medication</u>. Review of the patient's medication, including the name, dosage, frequency, and route of each medication.</p> <p><u>Medication allergy</u>. Review of the patient's known medication allergies.</p> <p><u>Current Problem list</u>. Review of the patient's current and active diagnoses.</p>		
<p>The EP is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.</p>		<p>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).</p> <p>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 an urgent care setting (urgent care ambulatory for EP,</p>	<p>1 minute</p>	<p>1 minute</p>

Objectives - Eligible Professionals	Objectives - Eligible Hospitals/CAHs	Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
		<p>emergency or urgent care department for eligible hospitals and CAHs).</p> <p>Measure 3 - Electronic Case Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions.</p> <p>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.</p> <p>Measure 5 – Clinical Data Registry Reporting: The EP, eligible hospital, or CAH is in active engagement to submit data to a clinical data registry.</p> <p>EPs must meet 2 measures and may choose to report to more than one public health registry or clinical data registry to meet the objective.</p>		
	<p>The eligible hospital or CAH is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.</p>	<p>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</p>	<p>1 minute</p>	<p>1 minute</p>

Objectives - Eligible Professionals	Objectives - Eligible Hospitals/CAHs	Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
		<p>information system (IIS).</p> <p>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 an urgent care setting (urgent care ambulatory for EP, emergency or urgent care department for eligible hospitals and CAHs).</p> <p>Measure 3 - Electronic Case Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions.</p> <p>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.</p> <p>Measure 5 – Clinical Data Registry Reporting: The EP, eligible hospital, or CAH is in active engagement to submit data to a clinical data registry.</p> <p>Measure 6 – Electronic Reportable Laboratory Result Reporting: The eligible hospital or CAH is in active engagement with a public health agency to</p>		

Objectives - Eligible Professionals	Objectives - Eligible Hospitals/CAHs	Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
		submit ELR results. Eligible Hospitals and CAHs must meet 4 measures and may choose to report to more than one public health registry and/or clinical data registry to meet the objective.		
Criteria Burden			6 hours 52 minutes	6 hours 52 minutes
Time to Attest and Report Clinical Quality Measures				
Total - Criteria Burden			6 hours 52 minutes	6 hours 52 minutes

In this final rule with comment period, we estimate that it will take no longer than 6 hours and 52 minutes for an EP to report on each of the applicable objectives and associated measures. The total burden hours for an EP to attest to the criteria previously specified will be 6 hours 52 minutes. We estimate that there could be approximately 609,100 non-hospital-based Medicare and Medicaid EPs in 2017.

We estimate the burden for the approximately 13,635 MA EPs in the MAO burden section. We estimate the total burden associated with these requirements for an EP will be 6 hours 52 minutes. The total estimate annual cost burden for all EPs to attest to EHR technology and meaningful use objectives will be \$385,834,395 (506,400 x 6 hours 52 minutes x \$92.25 (mean hourly rate for physicians based on May 2013 BLS data)).

Similarly, eligible hospitals and CAHs will attest that they have met the core meaningful use objectives and associated measures, and will electronically submit the clinical quality measures. We estimate that it will take no longer, than 6 hours and 52 minutes to attest that during the EHR reporting period, they used the certified EHR technology, specified the EHR technology used, and satisfied each of the applicable objectives and associated measures. We estimate that there are about 4,900 eligible hospitals and CAHs (3,397 acute care hospitals, 1,395 CAHs, 97 children's hospitals, and 11 cancer hospitals) that may attest to the aforementioned criteria in FY 2017. We estimate the total burden associated with these requirements for an eligible hospital and CAH would be 6 hours 52 minutes. The total estimated annual cost burden for all eligible hospitals and CAHs to attest to EHR technology, meaningful use core set and menu set criteria, and electronically submit the clinical quality measures will be \$2,135,204 (4,908 eligible hospitals and CAHs x \$63.46 (6 hours 52 minutes x \$63.46 (mean hourly rate for lawyers based on May 2013 BLS) data)).

B. ICR Regarding Demonstration of Meaningful Use Criteria (§ 495.20 through § 495.60)

In § 495.40 we proposed that to successfully demonstrate meaningful use of CEHRT 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 CEHRT 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 stipulated that providers must also successfully report the clinical quality measures selected by CMS to CMS or the states, as applicable. We estimated that the CEHRT 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 expected that the provider would enable the functionality required to complete the objectives and associated measures for which they are required to attest.

We proposed that EPs would be required to report on a total of ten objectives and associated measures and eligible hospitals and CAHs would report on a total of nine objectives and associated measures. There are six objectives that will require an EP to enter numerators and denominators during attestation. Eligible hospitals and CAHs will have to attest that they have met six 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 two recordkeeping systems when CEHRT is present. Therefore, we assumed that all patient records that would be counted in the denominator would be kept using certified EHR technology. We expect it will 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 three 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.

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.

Comment: Some stated that CMS should account for the amount of time required to prepare for attestation. They also stated that CMS should more carefully consider the multiple factors that contribute to the burden of physician reporting.

Response: We appreciate the public comments on this burden analysis. However, this analysis specifically reflects the amount of time we estimate providers will take to prepare and report their meaningful use data through the Medicare and Medicaid EHR Incentive Programs Registration and Attestation System.

After consideration of the public comments received, we are finalizing these burden estimates as proposed but have updated them to reflect policy changes implemented through this final rule with comment period. In this final rule with comment period, there are 10 objectives for EPs and 9 objectives for eligible hospitals and CAHs.

Table 22 lists those objectives and associated measures for EPs and eligible hospitals and CAHs. 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 22: BURDEN ESTIMATES - § 495.22

Eligible Professionals	Eligible Hospitals and CAHs	Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
Objectives and Measures				
Protect ePHI created or maintained by the CEHRT through the implementation of appropriate technical capabilities.	Protect ePHI created or maintained by the CEHRT through the implementation of appropriate technical capabilities.	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	6 hours
Use clinical decision support to improve performance on high-priority health conditions.	Use clinical decision support to improve performance on high-priority health conditions.	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.	1 minute	1 minute

Eligible Professionals	Eligible Hospitals and CAHs	Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
		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.		
Use 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 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
Generate and transmit permissible prescriptions electronically (eRx).		More than 50% of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT.	10 minutes	
	Generate and transmit permissible discharge prescriptions electronically (eRx).	More than 10% of hospital discharge medication orders for permissible prescriptions (for new or changed prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.		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 (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.	10 minutes	10 minutes

Eligible Professionals	Eligible Hospitals and CAHs	Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
Use clinically relevant information from CEHRT to identify patient-specific education resources and provide those resources to the patient.		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.	10 minutes	
	Use clinically relevant information from CEHRT to identify patient-specific education resources and provide those resources to the patient.	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.		10 minutes
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
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.		1. More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely online access to view online, download, and transmit to a third party their health information subject to the EP's discretion to withhold certain information.	10 minutes	

Eligible Professionals	Eligible Hospitals and CAHs	Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
		2. For 2015 and 2016: At least 1 patient seen by the EP during the EHR reporting period (or his or her authorized representative) views, downloads or transmits his or her health information to a third party during the EHR reporting period. For 2017: More than 5 percent of unique patients seen by the EP during the EHR reporting period (or their authorized representatives) views, downloads or transmits their health information to a third party during the EHR reporting period		

Eligible Professionals	Eligible Hospitals and CAHs	Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
	<p>Provide patients the ability to view online, download, and transmit their health information within 36 hours of hospital discharge.</p>	<p>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 are provided timely access to view online, download and transmit their health information to a third party their health information.</p> <p>2. For 2015 and 2016: 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 health information during the EHR reporting period For 2017: More than 5 percent of unique patients discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH (or his or her authorized representative) view, download, or transmit to a third party their health information during the EHR reporting period</p>		<p>10 minutes</p>

Eligible Professionals	Eligible Hospitals and CAHs	Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
<p>Use secure electronic messaging to communicate with patients on relevant health information.</p>		<p>For 2015: For an EHR reporting period in 2015, the capability for patients to send and receive a secure electronic message with the EP was fully enabled.</p> <p>For 2016: For at least 1 patient seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative) during the EHR reporting period.</p> <p>For 2017: For more than 5 percent of unique patients seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative) during the EHR reporting period.</p>	<p>10 minutes</p>	

Eligible Professionals	Eligible Hospitals and CAHs	Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
<p>The EP is in active engagement with a public health agency to submit electronic public health data from CEHRT except where prohibited and in accordance with applicable law and practice.</p>		<p>Stage 1 EPs in 2015 must meet at least 1 measure in 2015, Stage 2 EPs must meet at least 2 measures in 2015, and all EPs must meet at least 2 measures in 2016 and 2017.</p> <p><u>Measure 1 – Immunization Registry Reporting:</u> The EP is in active engagement with a public health agency to submit immunization data.</p> <p><u>Measure 2 – Syndromic Surveillance Reporting:</u> The EP is in active engagement with a public health agency to submit syndromic surveillance data.</p> <p><u>Measure 3 – Specialized Registry Reporting</u> – The EP is in active engagement with a public health agency to submit data to a specialized registry.</p>		

Eligible Professionals	Eligible Hospitals and CAHs	Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
	<p>The eligible hospital or CAH is in active engagement with a public health agency to submit electronic public health data from CEHRT except where prohibited and in accordance with applicable law and practice.</p>	<p>Stage 1 eligible hospitals and CAHs must meet at least 2 measures in 2015, Stage 2 eligible hospitals and CAHs must meet at least 3 measures in 2015, all eligible hospitals and CAHs must meet at least 3 measures in 2016 and 2017.</p> <ul style="list-style-type: none"> ● <u>Measure 1 – Immunization Registry Reporting</u>: The eligible hospital or CAH is in active engagement with a public health agency to submit immunization data. ● <u>Measure 2 – Syndromic Surveillance Reporting</u>: The eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data. ● <u>Measure 3 –Specialized Registry Reporting</u>: The eligible hospital or CAH is in active engagement with a public health agency to submit data to a specialized registry. ● <u>Measure4 – Electronic Reportable Laboratory Result Reporting</u>: The eligible hospital or CAH is in active engagement with a public health agency to submit ELR results. 	1 minute	1 minute
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

We estimate that it will 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 will be 8 hours 19 minutes. We estimate that there could be approximately 595,100 non-hospital-based Medicare EPs in 2015. 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 x 8 hours 19 minutes x \$92.25 (mean hourly rate for physicians based on May 2013 BLS data)). Similarly, eligible hospitals and CAHs will attest that they have met the meaningful use objectives and associated measures, and would submit the clinical quality measures. We estimate that it will 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, will 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 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 x \$63.46 (8 hours 18 minutes x \$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 for modifications for 2015 through 2017 are shown in Table 23.

For the purpose of this collection of information, we assumed that all eligible providers will comply with the requirements of Meaningful Use as previously defined if the policies proposed in this rule were not finalized. Therefore, we estimate that the policies contained herein will 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 23.

TABLE 23: 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 Core Set (including CQMs) + Least Burdensome Menu Set Criteria	9 hours 46 minutes	NA
Total Under Current Stage 2 Requirements at 42 CFR 495.6 Core Set (including CQMs) + Most Burdensome Menu Set Criteria	10 hours 13 minutes	10 hours 55 minutes
Total Under Proposed Modifications at 495.22 All Objectives and Measures + CQMs	8 hours 19 minutes	8 hours 18 minutes
Reduction from Least Burdensome Estimate	1 hour 27 minutes	NA
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 24.

TABLE 24: 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

C. ICRs Regarding Qualifying MA Organizations (§ 495.210)

We estimate that the burden will 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 CEHRT is in place and the qualifying MA organization requires its qualifying MA EPs to use the technology, qualifying MA organizations will be able to determine at a faster rate than individual FFS EPs, that its qualifying MA EPs meaningfully used CEHRT. In other words, qualifying MA organizations can make the determination in masse if the CEHRT 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 modifications in this rule will be negligible. We estimate that, on average, it will 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 will 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 will cost the participating qualifying MA organizations approximately \$426,050 annually to collect the required information and make the attestations ($[10,226 \text{ hours} \times \$25.00] + [3,408 \text{ hours} \times \$50.00]$).

D. ICR Regarding State Reporting Requirements (§ 495.316 and § 495.352)

We are revising 42 CFR 495 regarding state reporting requirements to CMS. With respect to the annual reporting requirements in § 495.316 and the quarterly reporting requirements in § 495.352, we do not believe that the amendments to these reporting requirements will increase the burden on states beyond what was previously finalized under OMB control number 0938-1158 following the Stage 2 final rule. The deadlines will be consistent with our past practice, and the changes to the data elements to be reported on are either reduced or similar in burden. Similarly, we do not expect that the amendments regarding the 90-day EHR reporting period for first time meaningful users will impose a burden on states because those amendments would generally maintain the current policy.

However, we are also amending § 495.316 to include a new quarterly reporting requirement. States will report quarterly to CMS regarding the EPs and Medicaid eligible hospitals that have successfully demonstrated meaningful use for each payment year. We need this information to ensure that those EPs who are meaningful EHR users in the Medicaid EHR Incentive Program are appropriately exempted from the Medicare payment adjustment. We cannot accurately exempt these providers using the current data received from states. We expect that it will take a state 20 hours each year to submit this report on a quarterly basis. We believe

that the state employee reporting the information could be equivalent to a GS 12, step 1 (2015 unadjusted for locality rate), with an hourly rate of approximately \$30.00/hour. This amount is then reduced by the 90 percent federal contribution for administrative services for Medicaid under the EHR Incentive Programs; this equates to approximately \$3.00/hour. Therefore, for all state Medicaid agencies to report 4 times per year at 20 hours per report the estimated cost is \$13,460 (4560 hours x \$3.00/hour).

TABLE 25: ESTIMATED ANNUAL INFORMATION COLLECTION BURDEN

Reg 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.x - Objectives/Measures (EPs)	0938-1158	609,100	609,100	6.86	4,178,426	92.25	385,834,395
§495.6 Objectives/Measures (hospitals/CAHs)	0938-1158	4,900	4,900	6.86	33,614	63.46	2,135,204
§495.210 - Gather information for attestation (MA EPs)	0938-1158	13,635	13,635	0.75	10,226	25.00	255,650
§495.210 –Attestation on behalf of MA EPs	0938-1158	13,635	13,635	0.25	3408.75	50.00	170,400
§495.316 – Quarterly Reporting	0938-1158	56	224	20	4480	3.00	13,440
Totals		627,635	627,635		4,225,674		388,408,189

Notes: 1. All non-whole numbers in this table are rounded to 2 decimal places.

2. There are no capital/maintenance costs associated with the information collection requirements contained in this rule. Therefore, we removed the associated column from Table 22.

V. Regulatory Impact Analysis

A. Statement of Need

This final rule with comment period will implement the provisions of the American Recovery and Reinvestment Act (ARRA) of 2009 that provide incentive payments to EPs, eligible hospitals, and CAHs participating in Medicare and Medicaid programs that adopt and meaningfully use CEHRT. This final rule with comment period specifies applicable criteria for demonstrating the Stage 3 requirements for the EHR Incentive Programs. This final rule with comment period also specifies the applicable criteria for an EHR reporting period in 2015 through 2017.

B. Overall Impact

We have examined the impacts of this final rule with comment period 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). This final rule with comment period is anticipated to have an annual effect on the

economy of \$100 million or more, making it an economically significant rule under the Executive Order and a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis (RIA) that presents the estimated costs and benefits of this final rule with comment period.

The portion of the final rule related to Stage 3 is one of two coordinated rules related to the EHR Incentive Programs. The other is ONC's 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications. Thus, there is an analysis that focuses on the impact associated with Stage 3 requirements for the EHR Incentive Program, the changes in quality measures that would take effect beginning in 2017, and other changes being for the Medicare and Medicaid EHR Incentive Programs.

As we discussed in the Stage 2 final rule (77 FR 54163 through 54291), a number of factors would affect the adoption of EHR systems and demonstration of meaningful use. In this final rule with comment period, we continue to believe that a number of factors would affect the adoption of EHR systems and demonstration of meaningful use. Readers should understand that these forecasts are also subject to substantial uncertainty since meeting the requirements of the program will depend not only on the standards and requirements for 2017 and for eligible hospitals and EPs, but on future rules issued by the Department of Health and Human Services (DHHS).

Based on the Stage 2 final rule, we expect spending under the EHR Incentive Programs for transfer payments to Medicare and Medicaid providers between 2015 and 2017 to be \$14.2 billion. However, the policies in this final rule with comment period which are applicable for the EHR Incentive Programs in 2015 through 2017 do not change these estimates over the

current period as the proposals in the EHR Incentive Programs in 2015 through 2017 proposed rule applied no changes to the payment of incentives or the application of payment adjustments for 2015 through 2017.

Our analysis of impacts for the policies in this final rule with comment period relate to the reduction in cost associated with provider reporting burden estimates for 2015 through 2017 as affected by the adopted changes to the current program and to the transfer payments for incentives for Medicaid providers and reductions in payments for Medicare providers through payment adjustments for 2018 and subsequent years. In the Stage 3 proposed rule, we noted our expectation that spending under the EHR Incentive Program for transfer payments to Medicare and Medicaid providers between 2017 and 2020 to be \$3.7 billion (this estimate includes net payment adjustments for Medicare providers who do not achieve meaningful use in the amount of \$0.8 billion).

We stated in the Stage 2 final rule (77 FR 54135 through 54136) that the statute provides Medicare and Medicaid incentive payments for the meaningful use of CEHRT. Additionally, the Medicaid program also provides incentives for the adoption, implementation, and upgrade of certified EHR technology. Beginning in 2015, payment adjustments are incorporated into the Medicare EHR Incentive Program for providers unable to demonstrate meaningful use. The absolute and relative strength of these is unclear. For example, a provider with relatively small Medicare billings will be less affected by payment adjustments than one with relatively large Medicare billings. Another uncertainty arises because there are likely to be "bandwagon" effects as the number of providers using EHRs rises, thereby inducing more participation in the program, as well as greater adoption by entities (for example, clinical laboratories) that are not eligible for incentives or subject to payment adjustments, but do business with EHR adopters. It

is impossible to predict exactly if and when such effects may take hold.

All of these factors taken together make it impossible in this final rule with comment period to predict with precision the timing or rates of adoption and successful participation in the program. However, new data is currently available regarding rates of adoption or costs of implementation since the publication of our Stage 1 and Stage 2 final rules. We have included the new data in our estimates, although even these forecasts are still uncertain.

We have also estimated "per entity" costs for EPs, eligible hospitals, and CAHs for implementation/maintenance and reporting requirement costs, not all costs. We believe many adopting entities may achieve dollar savings at least equal to their total costs, and that there may be additional benefits to society. We also believe that implementation costs are significant for each participating entity because providers who were likely to qualify as meaningful users of EHRs were likely to purchase CEHRT. However, we believe that providers who have already purchased CEHRT and participated in Stage 1 or Stage 2 of the EHR Incentive Program will experience significantly lower costs for participation in the program. We continue to believe that the short-term costs of the program may be outweighed by the long-term benefits, including practice efficiencies and improvements in medical outcomes. Although both cost and benefit estimates are highly uncertain, the RIA that we have prepared presents the estimated costs and benefits of this final rule with comment period.

In addition, we include the impact of the EHR Incentive Programs in 2015 through 2017. In relation to the existing program requirements outlined in the Stage 2 final rule (77 FR 53967 through 54162), we do not expect this final rule with comment period 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 implemented by this rule, which,

while they reduce the reporting burden on providers, do not affect the clinical processes and IT functions required to meet the objectives and measures of the EHR Incentive Programs. The provisions of the modifications portion in this final rule with comment period do not fundamentally change the technology required to support participation in the Medicare and Medicaid EHR Incentive Programs. Under the current program, the requirement to report data on the measures and objectives which have now been identified as redundant to other more advanced measures being retained, or are duplicative of other measures using the same CEHRT 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 provisions in this final rule with comment period, 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 the EHR Incentive Programs 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 provisions 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 EHR reporting period in 2015 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 EHR reporting period is for 2015 only and not for 2016 or 2017.
- Historical data on attestations shows no strong correlation between a shorter EHR

reporting period and the ability of providers to attest for a second year, 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 EHR reporting period.²²

- Performance data shows statistically negligible disparity among providers attesting for a 90-day EHR reporting period and those attesting for a full year EHR reporting period on the measures which have been identified as redundant, duplicative, and topped out.²³

For these reasons, we do not believe the modification provisions in this final rule with comment period will impact the overall estimates for incentive payments, payment adjustments, and the net transfer costs associated with the program. However, these provisions do affect the costs associated with the reporting burden on providers. The impacts directly attributable with the provisions in this final rule with comment period relate to both an hourly reduction per response and an overall reduction in the cost associated with provider reporting. The burden analysis for modifications in this final rule with comment period, 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 the modifications portion of this final rule with comment period will have additional impacts—most notably, cost savings for hospitals and providers that would have additional time to meet the requirements of the program—which cannot be adequately estimated because of the wide

²²CMS 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>

²³CMS 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>

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 implemented by the modifications of this final rule with comment period are outlined further in section III. of this final rule with comment period.

C. Anticipated Effects

The objective of the remainder of this final RIA is to summarize the costs and benefits of the HITECH Act incentive program for the Medicare FFS, Medicaid, and MA programs. We also provide assumptions and a narrative addressing the potential costs to the health care industry for implementation of this technology.

1. Overall Effects

a. EHR Technology Development and Certification Costs—Stage 3

We note that the costs incurred by IT developers for EHR technology development and certification to the 2015 Edition certification criteria for health IT are also in part attributable to the requirements for the use of CEHRT established in this final rule with comment period for Stage 3 of the EHR Incentive Programs. Therefore, to the extent that providers' implementation and adoption costs are attributable to this final rule with comment period, health IT developers' preparation and development costs would also be attributable as these categories of activities may be directly or indirectly incentivized by the requirements to participate in the EHR Incentive Programs. However, other CMS programs (for example PQRS and IQR) do require or promote certification to ONC's criteria—or a professional organization or other such entity could require or

promote certification to ONC's criteria.²⁴ As noted previously, this analysis focuses on the impact associated with Stage 3 requirements for providers, while the development and certification costs are addressed in the 2015 Edition final rule.

b. 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 final rule on small entities unless the Secretary can certify that the regulation 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 \$7.5 to \$38.5 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 would be economically significant. Accordingly, this RIA section, in conjunction with the remainder of the preamble, constitutes the required Final Regulatory Flexibility Analysis (IFRFA). We believe that the adoption and meaningful use of EHRs will have an impact on virtually every EP and eligible hospital, as well as CAHs and some EPs and hospitals affiliated with MA organizations. While the program is voluntary, in the first 5 years it carries substantial positive incentives that make it attractive to virtually all eligible entities. Furthermore, entities that do not

²⁴In this case, the provider implementation and adoption costs discussed in this CMS RIA would instead be attributable to ONC's rulemaking.

demonstrate meaningful use of EHR technology for an applicable EHR reporting period will be subject to significant Medicare payment reductions beginning in 2015. These Medicare payment adjustments are expected to motivate EPs, eligible hospitals, and CAHs to adopt and meaningfully use certified EHR technology.

For some EPs, CAHs, and eligible hospitals, the EHR technology currently implemented could be upgraded to meet the criteria for CEHRT as defined for this program. These costs may be minimal, involving no more than a software upgrade. "Home-grown" EHR systems that might exist may also require an upgrade to meet the certification requirements. We believe many currently used non-certified EHR systems will require significant changes to achieve certification and that EPs, CAHs, and eligible hospitals will have to make process changes to achieve meaningful use.

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 10 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 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 EPs used any type of EHR systems, up from 18 percent in 2001. The majority of EPs have already purchased CEHRT, 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 costs for implementation and complying with the criteria of EHR Incentive Programs could lead to higher operational expenses. However, we believe that the combination

of payment incentives and long-term overall gains in efficiency may compensate for some of the initial expenditures. Furthermore, the cost reductions provided by the EHR Incentive Programs in 2015 through 2017 offer a benefit to these providers.

(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, the CBO 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) will demonstrate the actual costs incurred by providers participating in the EHR Incentive Programs. The potential costs savings in modifications to the EHR Incentive Programs portion of this final rule with comment period will 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. We believe that the net effect on some individual providers may be positive. Furthermore, we believe that the provisions in this EHR Incentive Programs in 2015 through 2017 portion of this final rule with comment period 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 final rule with comment period.

c. Small Rural Hospitals--Modifications

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 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds.

The Stage 3 portion of this final rule with comment period will affect the operations of a substantial number of small rural hospitals because they may be subject to adjusted Medicare payments in 2015 if they fail to adopt CEHRT by the applicable EHR reporting period. As stated previously, we have determined that this final rule with comment period will create a significant impact on a substantial number of small entities, and have prepared a Regulatory Flexibility Analysis as required by the RFA and, for small rural hospitals, section 1102(b) of the Act. Furthermore, any impacts that would arise from the implementation of CEHRT in a rural eligible hospital would be positive, with respect to the streamlining of care and the ease of sharing information with other EPs to avoid delays, duplication, or errors. However, the

Secretary retains the discretionary statutory authority to make case-by-case exceptions for significant hardships, and has already established certain categories where case-by-case applications may be made such as barriers to internet connectivity that impact health information exchange.

There is no identifiable disparity among this group and the overall success rates for eligible hospitals and CAHs in meeting the requirements of the program; furthermore, 95 percent of eligible hospitals and CAHs have successfully participated 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 the modifications portion of this final rule with comment period will have a significant impact on a substantial number of small entities.

d. 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 2014, 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 final rule with comment period 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 EHR 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 the modifications portion of this final rule with comment period have very little impact on any state functions.

The investments needed to meet the requirements of the program and obtain incentive funding are voluntary, and hence not "mandates" within the meaning of the statute. However, the potential reductions in Medicare reimbursement beginning with FY 2015 would have a negative impact on providers that fail to meaningfully use CEHRT for the applicable EHR reporting period. We note that we have no discretion as to the amount of those potential payment reductions. Private sector EPs that voluntarily choose not to participate in the program may anticipate potential costs in the aggregate that may exceed \$141 million. However, because EPs may choose for various reasons not to participate in the program, we do not have firm data for the percentage of participation within the private sector. This RIA, taken together with the remainder of the preamble, constitutes the analysis required by UMRA.

e. 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 final rule with comment period will not have a substantial direct effect on state or local governments, preempt state law, or otherwise have a federalism implication. Importantly, state Medicaid agencies are

receiving 100 percent match from the federal government for incentives paid and a 90 percent match for expenses associated with administering the program. As previously stated, we believe that state administrative costs are minimal.

We note that the Stage 3 portion of this final rule with comment period does add a new business requirement for states, because of the existing systems that would need to be modified to track and report on the new requirements of the program for provider attestations. We are providing 90 percent Federal Financial Participation (FFP) to states for modifying their existing EHR Incentive Program systems. We believe the federal share of the 90 percent match will protect the states from burdensome financial outlays and, as noted previously, states offer the Medicaid EHR incentive program at their option.

The modifications portion of this final rule with comment period will 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

Based on the actual count of provider's 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

(1) EHR Incentive Programs in 2015 through 2017

There are no new costs associated with the modifications portion of this final rule with comment period. 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 meet the requirements of the program for the applicable EHR reporting period.

- The potential reduction in burden for EPs relate to assumptions of what options for meeting the requirements of the program they would otherwise attest to should the policies in this final rule with comment period 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 EHR attestations.

(2) Stage 3

The principal costs of the Stage 3 portion of final rule are the additional expenditures that will be undertaken by eligible entities in order to obtain the Medicaid incentive payments to

adopt, implement or upgrade and demonstrate (or both) meaningful use of certified EHR technology, and to avoid the Medicare payment adjustments that will ensue if they fail to do so. The estimates for the provisions affecting Medicare and Medicaid EPs, eligible hospitals, and CAHs are uncertain for the following reasons:

- The program is voluntary although payment adjustments will be imposed on Medicare providers beginning in 2015 if they are unable to demonstrate meaningful use for the applicable EHR reporting period.
- The criteria for the demonstration of meaningful use of CEHRT has been finalized for Stage 1 and Stage 2 and is being finalized for Stage 3, but may change over time.
- The impact of the financial incentives and payment adjustments on the rate of adoption of CEHRT by EPs, eligible hospitals, and CAHs is difficult to predict based on the information we have currently collected.

b. Industry Costs and Adoption Rates

(1) Modifications

In the EHR Incentive Programs in 2015 through 2017 proposed rule, we proposed no new policies which would require changes to the development, certification, and implementation of CEHRT or to adoption rates as compared to the policies in the existing program outlined in the Stage 2 final rule (77 FR 54136 through 54146).

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 final rule with comment period when compared to the previous requirements for 2015. Our estimates of the reduction in burden cost savings are presented in Table 27. They reflect our assumptions about the proportion of EPs who will demonstrate meaningful use of CEHRT outlined in Table 26 based on historical data.

TABLE 26: MEDICARE EPs DEMONSTRATING MEANINGFUL USE OF CEHRT

	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
Meaningful Users (in thousands)	357.1	391.4	426.4

TABLE 27: 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 will result from the policies in this final rule with comment period when compared to the previous requirements for 2015. Our estimates

of the reduction in burden cost savings are presented in Table 29. They reflect our assumptions about the proportion of eligible hospitals and CAHs that will demonstrate meaningful use of CEHRT outlined in Table 28 based on historical data.

TABLE 28: MEDICARE ELIGIBLE HOSPITALS AND CAHs DEMONSTRATING MEANINGFUL USE OF CEHRT

	Calendar Year		
	2015	2016	2017
Eligible Hospitals	3397	3397	3397
CAHs	1395	1395	1395
Percent Demonstrating Meaningful Use	95	97	99
Meaningful Users	4552	4648	4744

TABLE 29: ESTIMATED COST REDUCTION FOR MEDICARE ELIGIBLE HOSPITALS AND CAHs

	Calendar Year		
	2015	2016	2017
Meaningful Users	4552	4648	4744
Estimated Cost Savings	\$756,861.04	\$772,822.96	\$788,784.88

(c) 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 final rule with comment period when compared to the previous requirements for 2015. Our estimates of the reduction in burden cost savings are presented in Table 31. They reflect our assumptions about the proportion of Medicaid only EPs who will demonstrate meaningful use of CEHRT outlined in Table 30 based on historical data.

TABLE 30: 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 31: 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 meaningful use or because he or she has adopted, implemented, or upgraded CEHRT, 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.

(d) 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 final rule with comment period when compared to the previous requirements for 2015. Our estimates of the reduction in burden cost savings are presented in Table 33. They reflect our assumptions about the proportion of Medicaid only eligible hospitals that will demonstrate meaningful use of CEHRT outlined in Table 32 based on historical data.

TABLE 32: MEDICAID ONLY ELIGIBLE HOSPITALS DEMONSTRATING MEANINGFUL USE OF CEHRT

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

TABLE 33: ESTIMATED COST REDUCTION FOR MEDICARE ELIGIBLE HOSPITALS AND CAHs

	Calendar Year		
	2015	2016	2017
Meaningful Users	4552	4648	4744
Estimated Cost Savings	\$17,125.81	\$17,458.35	\$17,790.89

(2) Stage 3

In the Stage 2 final rule (77 FR 54136 through 54146), we estimated the impact on healthcare providers using information from four studies. In the absence of any more recent estimates that we are aware of, in this final rule with comment period, we continue to use the same estimates cited in the Stage 2 final rule. We continue to believe that these estimates are

reasonably reflective of EHR costs. However, we note, we are unable to delineate all costs due to the great variability in characteristics among the entities that are affected by the final rule; the variability includes, but is not limited to, the size of the practice, extent of use of electronic systems, type of system used, number of staff using the EHR system and the cost for maintaining and upgrading systems or both. Based on these studies and current average costs for available CEHRT products, we continue to estimate for EPs that the average adopt/implement/upgrade cost is \$54,000 per physician FTE, while annual maintenance costs average \$10,000 per physician FTE.

For all eligible hospitals, we continue to estimate the range is from \$1 million to \$100 million. Although reports vary widely, we continue to anticipate that the average will be \$5 million to achieve meaningful use, because providers who will likely qualify as meaningful users of EHRs will need to purchase certified EHRs. We further acknowledge "certified EHRs" may differ in many important respects from the EHRs currently in use and may differ in the functionalities they contain. We continue to estimate \$1 million for maintenance, upgrades, and training each year. Both of these estimates are based on average figures provided in the 2008 CBO report. However, as noted previously, we are unable to delineate all costs due to the great variability in characteristics among the entities that are affected by the final rule; the variability includes, but is not limited to, the size of the hospital, extent of use of electronic systems, type of system used, number of staff using the EHR system and the cost for maintaining and upgrading systems or both.

Industry costs are important, in part, because EHR adoption rates will be a function of these industry costs and the extent to which the costs of "certified EHRs" are higher than the total value of EHR incentive payments available to EPs and eligible hospitals (as well as

adjustments, in the case of the Medicare EHR incentive program) and any perceived benefits including societal benefits. Because of the uncertainties surrounding industry cost estimates, we have made various assumptions about adoption rates in the following analysis in order to estimate the budgetary impact on the Medicare and Medicaid programs.

c. Costs of EHR Adoption for EPs

Since the publication of the Stage 1 final rule, there has been little data published regarding the cost of EHR adoption and implementation. A 2011 study (<http://content.healthaffairs.org/content/30/3/481.abstract>) estimated costs of implementation for a five-physician practice to be \$162,000, with \$85,500 in maintenance expenses in the first year. In the absence of additional data regarding the cost of adoption and implementation costs for certified EHR technology, we proposed to continue to estimate for EPs that the average adopt/implement/upgrade cost is \$54,000 per physician FTE, while annual maintenance costs average \$10,000 per physician FTE, based on the cost estimate of the Stage 1 final rule. However, as noted previously, we are unable to delineate all costs due to the great variability that are affected by but not limited to the size of the practice, extent of use of electronic systems, type of system used, number of staff using the EHR system, and the cost for maintaining and upgrading systems or both.

d. Costs of EHR Adoption for Eligible Hospitals

According to the American Hospital Association 2008 Survey, the range in yearly information technology spending among hospitals ranged from \$36,000 to over \$32 million. EHR system costs specifically were reported by other experts to run as high as \$20 million to \$100 million (77 FR 54139). We note that recently about 96 percent of eligible hospitals have received at least one incentive payment under either the Medicare or Medicaid programs.

However, as noted previously, we are unable to delineate all costs due to the great variability that are affected by but not limited to the size of the eligible hospital, extent of use of electronic systems, type of system used, number of staff using the EHR system, and the cost for maintaining and upgrading systems or both.

3. Medicare and Medicaid Incentive Program Costs for Stage 3

Based on input from a number of internal and external sources, we estimated the numbers of EPs and eligible hospitals, including CAHs under Medicare, Medicaid, and MA expected to be eligible for the program in 2017 and used these estimates for the following analysis of Stage 3 program costs.

- About 675,500 Medicare FFS EPs in 2017 (some of whom will also be Medicaid EPs).
- About 60,600 non-Medicare eligible EPs (such as dentists, pediatricians, and eligible non-physicians such as certified nurse-midwives, nurse practitioners, and physician assistants) could be eligible to receive the Medicaid incentive payments in 2017.

- 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)

- All eligible hospitals, except for children's and cancer hospitals, may qualify and apply for both Medicare and Medicaid incentive payments.

- About 16 MA organizations

a. Medicare Program Costs for Stage 3

The estimates for the HITECH Act provisions are based on the economic assumptions

underlying the President's FY 2016 Budget. Under the statute, Medicare incentive payments for CEHRT are excluded from the determination of MA capitation benchmarks. We continue to expect a negligible impact on benefit payments to hospitals and EPs from Medicare and Medicaid because of the implementation of EHR technology.

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

(1) Medicare Eligible Professionals (EPs)

We began making EHR Incentive payments in 2011. Medicare payments are to be paid for the successful demonstration on meaningful use through CY 2016. Due to the payment lag, some payments may be issued in CY 2017. To avoid the Medicare payment adjustment beginning in 2015, EPs need to successfully demonstrate meaningful use regardless of whether they earn an incentive payment. We estimated the percentage of the remaining EPs who would be meaningful users each calendar year. Table 34 shows the results of these calculations.

TABLE 34: MEDICARE EPs DEMONSTRATING MEANINGFUL USE OF CEHRT

	Calendar year			
	2017	2018	2019	2020
Medicare EPs who have claims with Medicare (thousands)	675.5	683.3	691.1	698.8
Non-Hospital-based Medicare EPs (thousands)	609.1	616.1	623.1	630.1
Percent of EPs who are Meaningful Users	70	73	75	78
Meaningful Users (thousands)	426.4	446.7	467.3	488.3

Our estimates of the incentive payment costs and payment adjustment savings are presented in Table 35. They reflect actual historical data and our assumptions about the proportion of EPs who will demonstrate meaningful use of CEHRT. Estimated costs are expected to decrease in 2017 through 2020 due to a smaller number of new EPs that would

achieve meaningful use and the cessation of the incentive payment program. Payment adjustment receipts represent the estimated amount of money collected due to the payment adjustments for those not achieving meaningful use. Estimated net costs for the Medicare EP portion of the HITECH Act are also shown in Table 35.

TABLE 35: ESTIMATED COSTS (+) AND SAVINGS (–) FOR MEDICARE EPs DEMONSTRATING MEANINGFUL USE OF CEHRT (IN BILLIONS)

Fiscal Year	Incentive Payments	Payment Adjustment Receipts	Benefit Payments	Net Total
2017	\$0.6	–\$0.2	—	\$0.3
2018	—	–\$0.2	—	–\$0.2
2019	—	–\$0.2	—	–\$0.2
2020	—	–\$0.1	—	–\$0.1

(2). Medicare Eligible Hospitals and CAHs

In brief, the estimates of hospital adoption were developed by calculating projected incentive payments and then making assumptions about how rapidly hospitals would adopt meaningful use.

Specifically, the first step in preparing estimates of Medicare program costs for eligible hospitals was to determine how many eligible hospitals already received payments under the EHR Incentive program and for what years those payments were received. In order to do this, we used the most recent available data that listed the recipients of incentive payments, and the year and payment amount. This information pertained to eligible hospitals receiving payments through September 2014.

We assume that all eligible hospitals that receive a payment in the first year will receive payments in future years. We also assume the eligible hospitals that have not yet received any incentive payments will eventually achieve meaningful use (either to receive incentive payments or to avoid payment adjustments). We assume that all eligible hospitals would achieve

meaningful use by 2018. No new incentive payments would be paid after 2016. However, some incentive payments originating in 2016 would be paid in 2017.

The average incentive payment for each eligible hospital was \$1.5 million in the first year. In later years, the amount of the incentive payments drops according to the schedule allowed in law. The average incentive payment for CAHs received in the first year was about \$950,000. The average incentive payment received in the second year was about \$332,500. The average incentive payment received in the third year was about \$475,000. These average amounts were used for these incentive payments in the future. The third year average was also used for the fourth year. These assumptions about the number of hospitals achieving meaningful use in a particular year and the average amount of an incentive payment allows us to calculate the total amount of incentive payments to be made and the amount of payment adjustments for those hospitals who have not achieved meaningful use. The payment incentives available to hospitals under the Medicare and Medicaid EHR Incentive Programs are included in our regulations at 42 CFR part 495. We further estimate that there are 16 MA organizations that might be eligible to participate in the incentive program. Those plans have 32 eligible hospitals. The costs for the MA program have been included in the overall Medicare estimates.

The estimated payments to eligible hospitals were calculated based on the hospitals' qualifying status and individual incentive amounts under the statutory formula. Similarly, the estimated payment adjustments for non-qualifying hospitals were based on the market basket reductions and Medicare revenues. The estimated savings in Medicare eligible hospital benefit expenditures resulting from the use of hospital certified EHR systems were discussed earlier in this section. We assumed no future growth in the total number of hospitals in the U.S. because growth in acute care hospitals has been minimal in recent years. The results are shown in

Table 36.

TABLE 36: ESTIMATED COSTS (+) AND SAVINGS (-) FOR MEDICARE ELIGIBLE HOSPITALS DEMONSTRATING MEANINGFUL USE OF CEHRT
(in billions)

Fiscal Year	Incentive payments	Payment adjustment receipts	Benefit payments	Net Total
2017	\$1.6	(¹)	(¹)	\$1.6
2018	0.0	(¹)	(¹)	(¹)
2019	0.0	0.0	(¹)	(¹)
2020	0.0	0.0	(¹)	(¹)

¹Savings of less than \$50 million. All numbers are projections.

b. Medicaid Incentive Program Costs for Stage 3

Under section, 4201 of the HITECH Act, states and territories can voluntarily participate in the Medicaid EHR Incentive Program. However, as of the writing of this rule, all states already participate. The payment incentives available to EPs and eligible hospitals under the Medicaid EHR Incentive Program are included in our regulations at 42 CFR part 495. The federal costs for Medicaid incentive payments to providers who can demonstrate meaningful use of EHR technology were estimated similarly to the estimates for Medicare eligible hospitals and EPs. Table 37 shows our estimates for the net Medicaid costs for eligible hospitals and EPs.

TABLE 37: ESTIMATED FEDERAL COSTS (+) AND SAVINGS (-) UNDER MEDICAID, (In \$Billions)

Fiscal Year	Incentive Payments		Benefit Payments	Net Total
	Hospitals	Eligible Professionals		
2017	0.4	0.8	(¹)	1.2
2018	0.1	0.5	(¹)	0.6
2019	0	0.3	(¹)	0.3
2020	0.0	0.2	(¹)	0.2

¹ Savings of less than \$50 million.

(1) Medicaid EPs

TABLE 38: ASSUMED NUMBER OF NONHOSPITAL BASED MEDICAID EPs WHO WOULD BE MEANINGFUL USERS OF CEHRT (Population Figures in Thousands)

		Calendar Year			
		2017	2018	2019	2020
A	EPs who meet the Medicaid patient volume threshold	101.3	102.3	103.3	104.4
B	Medicaid only Eps	60.6	61.7	62.9	64.0
	Total Medicaid EPs (A + B)	161.8	164.0	166.2	168.4
	Percent of EPs receiving incentive payment during year	44.7%	30.9%	20.7%	14.3%
	Number of EPs receiving incentive payment during year	72.4	50.7	34.5	24.0
	Percent of EPs who have ever received incentive payment	67.9%	74.7%	78.0%	81.1%
	Number of EPs who have ever received incentive payment	109.9	122.5	129.6	136.6

It should be noted that since the Medicaid EHR Incentive Program provides that a Medicaid EP can receive an incentive payment in his or her first year because he or she has demonstrated a meaningful use or because he or she has adopted, implemented, or upgraded CEHRT, these participation rates include not only meaningful users but eligible providers implementing CEHRT as well.

(2) Medicaid Hospitals

Medicaid incentive payments to most eligible hospitals were estimated using the same methodology as described previously for Medicare eligible hospitals and shown in Table 39. Many eligible hospitals may qualify to receive both the Medicare and Medicaid incentive payment. We assume that all eligible hospitals would achieve meaningful use by 2016. However, many of these eligible hospitals would have already received the maximum amount of incentive payments. Table 40 shows our assumptions about the remaining incentive payments to be paid.

TABLE 39: ESTIMATED PERCENTAGE OF HOSPITALS THAT COULD BE PAID FOR MEANINGFUL USE AND ESTIMATED PERCENTAGE PAYABLE BY FISCAL YEAR

Fiscal Year	Percent of Hospitals Who are Meaningful Users	Percent of Hospitals being Paid
-------------	---	---------------------------------

2017	100.0	13.5
2018	100.0	5.2
2019	100.0	1.5
2020	100.0	0.0

As stated previously, the estimated eligible hospital incentive payments were calculated based on the eligible hospitals' qualifying status and individual incentive amounts payable under the statutory formula. The average Medicaid incentive payment in the first year was \$1 million. The estimated savings in Medicaid benefit expenditures resulting from the use of CEHRT are discussed in section V.C.4 of this final rule with comment period. Since we use Medicare data and little data existed for children's hospitals, we estimated the Medicaid incentives payable to children's hospitals as an add-on to the base estimate, using data on the number of children's hospitals compared to non-children's hospitals.

4. Benefits for all EPs and all Eligible Hospitals

In this final rule with comment period, we did not quantify 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, CEHRT) has not yet been collected, and although some studies question the benefits of health information technology, a 2011 study completed by ONC²⁵ 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. 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

²⁵Buntin et al. 2011 "The Benefits of Health Information Technology: A Review of the Recent Literature Shows Predominantly Positive Results" Health Affairs.

for hospitals with less advanced health IT. A subsequent 2013 study completed by the RAND Corporation for ONC²⁶ 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. 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 return on investment within 16 months and annual savings thereafter.²⁷ 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 adoption²⁸. As participation and adoption increases, there will be more opportunities to capture and report on cost savings and benefits.

5. Benefits to Society

According to a CBO study, when used effectively, EHRs can enable providers to deliver health care more efficiently²⁹. 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

²⁶Shekelle et al. 2013 "Health Information Technology: An Updated Systemic Review with a Focus on Meaningful Use Functionalities

²⁷Greiger 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>.

²⁸DeLeon et al. 2010, "The business end of health information technology".

²⁹ Congressional Budget Office: "Evidence on the Costs and Benefits of Health Information Technology"
<http://www.cbo.gov/ftpdocs/91xx/doc9168/05-20-HealthIT.pdf>

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 final rule with comment period are even harder to quantify because they represent, in many cases, adding functionality to existing systems and reaping the network externalities created by larger numbers of providers participating in information exchange. In many cases, they represent the reduction in the time spent per each individual respondent to attest to the EHR Incentive Program 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 at 77 FR 54144, we discussed research documenting the

association of EHRs with improved outcomes among diabetics³⁰ and trauma patients³¹, enhanced efficiencies in ambulatory care settings³², and improved outcomes and lower costs in hospitals³³. 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, health IT and safety 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. However, data relating specifically to the EHR Incentive Programs is limited at this time.

6. Summary

In this final rule with comment period, the 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 for an EHR reporting period on an annual basis for 2015 through 2017. For further information on prior estimates of program costs we direct readers to the Stage 2 final rule (77 FR 54145).

The total cost to the Medicare and Medicaid programs between 2017 and 2020 is estimated to be \$3.7 billion in transfers.

³⁰(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)

³¹Deckelbaum, 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

³²Chen, C et al. (2009) "The Kaiser Permanente Electronic Health Record: Transforming and Streamlining Modalities Of Care." *Health Affairs*" 28(2):323-333

³³Amarasingham, R. et al. (2009) "Clinical information technologies and inpatient outcomes: a multiple hospital study" *Archives of Internal Medicine* 169(2):108-14

TABLE 40: ESTIMATED EHR INCENTIVE PAYMENTS AND BENEFITS IMPACTS ON THE MEDICARE AND MEDICAID PROGRAMS OF THE HITECH EHR INCENTIVE PROGRAM (FISCAL YEAR)
(in billions)

Fiscal Year	Medicare Eligible		Medicaid Eligible		Total
	Hospitals	Professionals	Hospitals	Professionals	
2017	\$1.6	\$0.3	\$0.4	\$0.8	\$3.1
2018	\$0.0	-\$0.2	\$0.1	\$0.5	\$0.4
2019	\$0.0	-\$0.2	\$0.0	\$0.3	\$0.1
2020	\$0.0	-\$0.1	\$0.0	\$0.2	\$0.1
Total	\$1.6	-\$0.2	\$0.5	\$1.8	\$3.7

D. Alternatives Considered for Stage 3

As stated in the Stage 1 final rule (75 FR 44546), HHS has no discretion to change the incentive payments or payment adjustment reductions specified in the statute for providers that adopt or fail to adopt CEHRT and demonstrate meaningful use of CEHRT. However, we have discretion around how best to meet the HITECH Act requirements for meaningful use for FY 2017 and subsequent years, which we have exercised in this final rule with comment period. Additionally, we have used our discretion to propose the timing of registration, attestation, and payment requirements to allow EPs and eligible organizations as much time as possible in coordination with the anticipated certification of EHR technology to obtain and meaningfully use CEHRT. We recognize that there may be additional costs that result from various discretionary policy choices by providers. However, those costs cannot be estimated as the potential for variance by provider type, organization size, place of service, geographic location, patient population, and the impact of state and local laws is extensive and such variations are not captured in this analysis.

E. Accounting Statement and Table

When 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 final rule with comment period. Monetary annualized benefits and non-budgetary costs are presented as discounted flows using 3 percent and 7 percent factors in the following tables. We are not able to explicitly define the universe of those additional costs, nor specify what the high or low range might be to implement EHR technology in this final rule with comment period. We note that federal annualized monetized transfers represent the net total of annual incentive payments in the Medicare and Medicaid EHR Incentive programs less the reductions in Medicare payments to providers failing to demonstrate meaningful use as a result of the related Medicare payment adjustments.

(1) EHR Incentive Programs in 2015 through 2017

**TABLE 41: ACCOUNTING STATEMENT FOR MODIFICATIONS:
CLASSIFICATION OF ESTIMATED COST REDUCTIONS AND BENEFITS CYs 2015
THROUGH 2017 (in millions)**

CATEGORY					
BENEFITS					
Annualized Monetized Cost Reductions to Private Industry Associated with Reporting Requirements		Low Estimate	High Estimate		
	2015	\$52.8	\$68.9	7%	CYs 2015-2017
	\$52.8	\$68.9	3%		
Qualitative --Other private industry and societal benefits associated with the reduction in provider reporting burden and with having additional time to meet the requirements of the program.					

In this final rule with comment period, there is no estimated increase in costs associated with incentive payments or payment adjustments for the Medicare and Medicaid EHR Programs attributable to the modifications to the program proposed in the EHR Incentive Programs in 2015 through 2017 proposed rule.

(2) Stage 3

Expected qualitative benefits include improved quality of care, better health outcomes, reduced errors and the like. Private industry costs would include the impact of EHR activities

such as temporary reduced staff productivity related to learning how to use the EHR, the need for additional staff to work with HIT issues, and administrative costs related to reporting. Transfers related to the payment of EHR Incentive Payments for 2017 through 2020 based on the policies in this final rule with comment period and the estimated reduction in Medicare payments through the application of payment adjustments for the same period. We note that this estimate relates only to the policies in this final rule with comment period and does not address subsequent changes pertaining to the MIPS program as established by MACRA which will be further defined in future rulemaking.

**TABLE 42: STAGE 3 - ACCOUNTING STATEMENT:
CLASSIFICATION OF ESTIMATED EXPENDITURES CYs 2017 THROUGH 2020
(in millions)**

CATEGORY				
	BENEFITS			
Qualitative	Expected qualitative benefits include improved quality of care, better health outcomes, reduced errors and the like.			
	COSTS			
	Year Dollar	Estimates (in millions)	Unit Discount Rate	Period Covered
		Primary Estimate		
Annualized Monetized Costs to Private Industry Associated with Reporting Requirements	2017	\$478.1	7%	CY 2017
		\$478.4	3%	
Qualitative--Other private industry costs associated with the adoption of EHR technology.	These costs would include the impact of EHR activities such as reduced staff productivity related to learning how to use the EHR technology, the need for additional staff to work with HIT issues, and administrative costs related to reporting.			
	TRANSFERS			
	Year Dollar	Estimates (in millions)	Unit Discount Rate	Period Covered
Federal Annualized Monetized	2017	\$1,000.4	7%	CYs 2017-2020
		\$954.8	3%	
From Whom To Whom?	Federal Government to Medicare- and Medicaid-eligible professionals and hospitals			

VI. 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 final rule with comment period, and, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

List of Subjects**42 CFR Part 412**

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

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 stated in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV as set forth below:

PART 412--PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

1. The authority citation for Part 412 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), sec. 124 of Pub. L. 106-113 (113 Stat. 1501A-332), sec. 1206 of Pub. L. 113-67, and sec. 112 of Pub. L. 113-93.

§412.64 [Amended]

2. Section 412.64 is amended by--

A. In paragraph (d)(4)(ii)(A) by removing the phrase "April 1" wherever it appears and adding the phrase "July 1" in its place.

B. In paragraph (d)(4)(ii)(B)(1) by removing the phrase "April 1" and adding the phrase "July 1" in its place.

C. In paragraph (d)(4)(ii)(B)(2) by removing the phrase "April 1" and adding the phrase "July 1" in its place.

PART 495--STANDARDS FOR THE ELECTRONIC HEALTH RECORD**TECHNOLOGY INCENTIVE PROGRAM**

3. 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).

4. Section 495.4 is amended as follows:

A. Adding the definition of "API" in alphabetical order.

B. Revising the definition of "Certified electronic health record technology".

C. Amending the definition of "EHR reporting period" by--

i. Redesignating paragraphs (1)(i), (1)(ii), (1)(iii) introductory text, (1)(iii)(A), (1)(iii)(B), (1)(iii)(C), (1)(iii)(D), and (1)(iv) as paragraphs (1)(i)(A), (1)(i)(B), (1)(i)(C) introductory text, (1)(i)(C)(1), (1)(i)(C)(2), (1)(i)(C)(3), (1)(i)(C)(4), and (1)(i)(D), respectively.

ii. Adding new paragraph (1)(i) introductory text.

iii. Adding new paragraphs (1)(ii) and (iii).

iv. Redesignating paragraphs (2)(i), (2)(ii), (2)(iii) introductory text, (2)(iii)(A),

(2)(iii)(B), (2)(iii)(C), and (2)(iii)(D), as paragraphs (2)(i)(A), (2)(i)(B), (2)(i)(C) introductory text and (2)(i)(C)(1), (2)(i)(C)(2), (2)(i)(C)(3), and (2)(i)(C)(4), respectively.

v. Adding new paragraphs (2)(i) introductory text.

vi. Adding new paragraphs (2)(ii) and (iii).

D. Amending the definition of "EHR reporting period for a payment adjustment year"

by:

i. Redesignating paragraphs (1)(i)(A), (1)(i)(B), (1)(ii), (1)(iii)(A), and (1)(iii)(B) as paragraphs (1)(i)(A)(1), (1)(i)(A)(2), (1)(i)(B), (1)(i)(C)(1) and (1)(i)(C)(2), respectively.

ii. In newly redesignated paragraph (1)(i)(A)(1), by removing the cross-reference "paragraphs (1)(i)(B), (ii), and (iii)" and adding in its place the cross-reference "paragraphs (1)(i)(A)(2), (1)(i)(B), and (1)(i)(C)".

iii. In newly redesignated paragraph (1)(i)(A)(2), by removing the cross-reference "paragraphs (1)(iii) or (1)(iv)" and adding in its place the cross-reference "paragraph (1)(i)(C)".

iv. Adding new paragraph (1)(i) introductory text.

v. Adding new paragraph. (1)(ii).

vi. Redesignating paragraphs (2)(i)(A), (2)(i)(B), (2)(ii), (2)(iii)(A), and (2)(iii)(B) as paragraphs (2)(i)(A)(1), (2)(i)(A)(2), (2)(i)(B), (2)(i)(C)(1), and (2)(i)(C)(2), respectively.

vii. In newly redesignated paragraph (2)(i)(A)(1), by removing the cross-reference "paragraphs (2)(i)(B), (ii), and (iii)" and adding in its place the cross-reference "paragraphs (2)(i)(A)(2), (2)(i)(B), and (2)(i)(C)".

viii. In newly redesignated paragraph (2)(i)(A)(2), by removing the cross-reference "paragraph (2)(iii)" and adding in its place the cross-reference "paragraph (2)(i)(C)".

ix. Adding new paragraph (2)(i) introductory text.

- x. Adding new paragraphs (2)(ii) and (iii).
- xi. Redesignating paragraphs (3)(i) and (3)(ii) as paragraphs (3)(i)(A) and (3)(i)(B).
- xii. In newly redesignated paragraph (3)(i)(A), by removing the cross-reference "paragraph (3)(ii)" and adding in its place the cross-reference "paragraph (3)(i)(B)".
- xiii. Adding new paragraph (3)(i) introductory text.
- xiv. Adding new paragraphs (3)(ii) and (iii).
- e. 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 "under §495.6 " and adding in its place the reference "under §§495.20, 495.22, and 495.24".

The additions and revision read as follows:

§495.4 Definitions.

* * * * *

API stands for application programming interface.

Certified electronic health record technology (CEHRT) means the following:

(1) For any Federal fiscal year or calendar year before 2018, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets one of the following:

- (i) The 2014 Edition Base EHR definition (as defined at 45 CFR 170.102) and has been certified to the certification criteria that are necessary to be a Meaningful EHR User (as defined in this section), including the applicable measure calculation certification criterion at 45 CFR 170.314(g)(1) or (2) for all certification criteria that support a

meaningful use objective with a percentage-based measure.

(ii) Certification to--

(A) The following certification criteria:

(1) CPOE at--

(i) 45 CFR 170.314(a)(1), (18), (19) or (20); or

(ii) 45 CFR 170.315(a)(1), (2) or (3).

(2)(i) Record demographics at 45 CFR 170.314(a)(3); or

(ii) 45 CFR 170.315(a)(5).

(3)(i) Problem list at 45 CFR 170.314(a)(5); or

(ii) 45 CFR 170.315(a)(6).

(4)(i) Medication list at 45 CFR 170.314(a)(6); or

(ii) 45 CFR 170.315(a)(7).

(5)(i) Medication allergy list 45 CFR 170.314(a)(7); or

(ii) 45 CFR 170.315(a)(8).

(6)(i) Clinical decision support at 45 CFR 170.314(a)(8); or

(ii) 45 CFR 170.315(a)(9).

(7) Health information exchange at transitions of care at one of the following:

(i) 45 CFR 170.314(b)(1) and (2).

(ii) 45 CFR 170.314(b)(1), (b)(2), and (h)(1).

(iii) 45 CFR 170.314(b)(1), (b)(2), and (b)(8).

(iv) 45 CFR 170.314(b)(1), (b)(2), (b)(8), and (h)(1).

(v) 45 CFR 170.314(b)(8) and (h)(1).

(vi) 45 CFR 170.314(b)(1), (b)(2), and 170.315(h)(2).

- (vii) 45 CFR 170.314(b)(1), (b)(2), (h)(1), and 170.315(h)(2).
 - (viii) 45 CFR 170.314(b)(1), (b)(2), (b)(8), and 170.315(h)(2).
 - (ix) 45 CFR 170.314(b)(1), (b)(2), (b)(8), (h)(1), and 170.315(h)(2).
 - (x) 45 CFR 170.314(b)(8), (h)(1), and 170.315(h)(2).
 - (xi) 45 CFR 170.314(b)(1), (b)(2), and 170.315(b)(1).
 - (xii) 45 CFR 170.314(b)(1), (b)(2), (h)(1), and 170.315(b)(1).
 - (xiii) 45 CFR 170.314(b)(1), (b)(2), (b)(8), and 170.315(b)(1).
 - (xiv) 45 CFR 170.314(b)(1), (b)(2), (b)(8), (h)(1), and 170.315(b)(1).
 - (xv) 45 CFR 170.314(b)(8), (h)(1), and 170.315(b)(1).
 - (xvi) 45 CFR 170.314(b)(1), (b)(2), (b)(8), (h)(1), 170.315(b)(1), and 170.315(h)(1).
 - (xvii) 45 CFR 170.314(b)(1), (b)(2), (b)(8), (h)(1), 170.315(b)(1), and 170.315(h)(2).
 - (xviii) 45 CFR 170.314(h)(1) and 170.315(b)(1).
 - (xix) 45 CFR 170.315(b)(1) and (h)(1).
 - (xx) 45 CFR 170.315(b)(1) and (h)(2).
 - (xxi) 45 CFR 170.315(b)(1), (h)(1), and (h)(2); and
- (B) Clinical quality measures at --
- (1) 45 CFR 170.314(c)(1) or 170.315(c)(1);
 - (2) 45 CFR 170.314(c)(2) or 170.315(c)(2);
 - (3) 45 CFR 170.314(c)(3) or 170.315(c)(3); and
- (C) Privacy and security at --
- (1) 45 CFR 170.314(d)(1) or 170.315(d)(1);
 - (2) 45 CFR 170.314(d)(2) or 170.315(d)(2);
 - (3) 45 CFR 170.314(d)(3) or 170.315(d)(3);

- (4) 45 CFR 170.314(d)(4) or 170.315(d)(4);
- (5) 45 CFR 170.314(d)(5) or 170.315(d)(5);
- (6) 45 CFR 170.314(d)(6) or 170.315(d)(6);
- (7) 45 CFR 170.314(d)(7) or 170.315(d)(7);
- (8) 45 CFR 170.314(d)(8) or 170.315(d)(8); and

(D) The certification criteria that are necessary to be a Meaningful EHR User (as defined in this section), including the applicable measure calculation certification criterion at 45 CFR 170.314(g)(1) or (2) or 45 CFR 170.315(g)(1) or (2) for all certification criteria that support a meaningful use objective with a percentage-based measure.

(iii) The definition for 2018 subsequent years specified in paragraph (2) of this definition.

(2) For 2018 and subsequent years, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition (as defined at 45 CFR 170.102) and has been certified to the 2015 Edition health IT certification criteria--

(i) At 45 CFR 170.315(a)(12) (family health history) and 45 CFR 170.315(e)(3) (patient health information capture); and

(ii) Necessary to be a Meaningful EHR User (as defined in this section), including the following:

(A) The applicable measure calculation certification criterion at 45 CFR 170.315(g)(1) or (2) for all certification criteria that support a meaningful use objective with a percentage-based measure.

(B) Clinical quality measure certification criteria that support the calculation and

reporting of clinical quality measures at 45 CFR 170.315(c)(2) and (3).

* * * * *

EHR reporting period.* * *

(1) * * *

(i) The following are applicable before 2015:

* * * * *

(ii) The following are applicable for 2015, 2016, and 2017:

(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.

(C) For the CY 2017 payment year under the Medicaid EHR Incentive Program:

(1) For the EP first demonstrating he or she is a meaningful EHR user, any continuous 90-day period within CY 2017.

(2) For the EP who has successfully demonstrated he or she is a meaningful EHR user in any prior year, the CY 2017.

(3) For the EP demonstrating the Stage 3 objectives and measures at § 495.24, any continuous 90-day period within CY 2017.

(iii) The following are applicable beginning with the CY 2018 payment year under the Medicaid EHR Incentive Program:

(A) For the payment year in which the EP is first demonstrating he or she is a

meaningful EHR user, any continuous 90-day period within the calendar year.

(B) For the subsequent payment years following the payment year in which the EP first successfully demonstrates he or she is a meaningful EHR user, the calendar year.

(2) * * *

(i) The following are applicable before 2015:

* * * * *

(ii) The following are applicable for 2015, 2016, and 2017:

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

(B) For the FY 2016 payment year as follows:

(1) For the eligible hospital or CAH first demonstrating it is a meaningful EHR user, any continuous 90-day period within CY 2016.

(2) For the eligible hospital or CAH that has successfully demonstrated it is a meaningful EHR user in any prior year, the CY 2016.

(C) For the FY 2017 payment year under the Medicaid EHR Incentive Program:

(1) For the eligible hospital or CAH first demonstrating it is a meaningful EHR user, any continuous 90-day period within CY 2017.

(2) For the eligible hospital or CAH that has successfully demonstrated it is a meaningful EHR user in any prior year, the CY 2017.

(3) For the eligible hospital or CAH demonstrating the Stage 3 objectives and measures at § 495.24, any continuous 90-day period within CY 2017.

(iii) The following are applicable beginning with the FY 2018 payment year under the Medicaid EHR Incentive Program:

(A) For the payment year in which the eligible hospital or CAH is first demonstrating it is a meaningful EHR user, any continuous 90-day period within the calendar year.

(B) For the subsequent payment years following the payment year in which the eligible hospital or CAH first successfully demonstrates it is a meaningful EHR user, the calendar year.

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

(1) * * *

(i) The following are applicable before 2015:

* * * * *

(ii) The following are applicable for 2015, 2016, and 2017:

(A) In 2015 as follows:

(1) If an EP has not successfully demonstrated he or she is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within CY 2015 and applies for the CY 2016 and 2017 payment adjustment years.

(2) If in a prior year an EP has successfully demonstrated he or she is a meaningful EHR user, the EHR reporting period is any continuous 90-day period within CY 2015 and applies for the CY 2017 payment adjustment year.

(B) In 2016 as follows:

(1) If an EP has not successfully demonstrated he or she is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within CY 2016 and applies for the CY 2017 and 2018 payment adjustment years. For the CY 2017 payment adjustment year, the EHR reporting period must end before and the EP must successfully register for and attest to meaningful use no later than October 1, 2016.

(2) If in a prior year an EP has successfully demonstrated he or she is a meaningful EHR

user, the EHR reporting period is CY 2016 and applies for the CY 2018 payment adjustment year.

(C) In 2017 as follows:

(1) If an EP has not successfully demonstrated he or she is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within CY 2017 and applies for the CY 2018 payment adjustment year. For the CY 2018 payment adjustment year, the EHR reporting period must end before and the EP must successfully register for and attest to meaningful use no later than October 1, 2017.

(2) If an EP is demonstrating Stage 3 of meaningful use in 2017 under § 495.24 in the Medicaid program, the EHR reporting period is any continuous 90-day period within CY 2017 and applies for the FY 2019 payment adjustment year.

(2) * * *

(i) The following are applicable before 2015:

* * * * *

(ii) The following are applicable for 2015, 2016, and 2017:

(A) In 2015 as follows:

(1) If an eligible hospital has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within the period beginning on October 1, 2014 and ending on December 31, 2015 and applies for the FY 2016 and 2017 payment adjustment years.

(2) If in a prior year an eligible hospital has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is any continuous 90-day period within the period beginning on October 1, 2014 and ending on December 31, 2015 and applies for the FY 2017

payment adjustment year.

(B) In 2016 as follows:

(1) If an eligible hospital has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within CY 2016 and 2017 applies for the FY 2017 and 2018 payment adjustment years. For the FY 2017 payment adjustment year, the EHR reporting period must end before and the eligible hospital must successfully register for and attest to meaningful use no later than October 1, 2016.

(2) If in a prior year an eligible hospital has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is CY 2016 and applies for the FY 2018 payment adjustment year.

(C) In 2017 as follows:

(1) If an eligible hospital has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within CY 2017 and applies for the FY 2018 and 2019 payment adjustment years. For the FY 2018 payment adjustment year, the EHR reporting period must end before and the eligible hospital must successfully register for and attest to meaningful use no later than October 1, 2017.

(2) If an eligible hospital is demonstrating Stage 3 of meaningful use under § 495.24, the EHR reporting period is any continuous 90-day period within CY 2017 and applies for the FY 2019 payment adjustment year.

(3) If in a prior year an eligible hospital has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is CY 2017 and applies for the FY 2019 payment adjustment year.

(iii) The following are applicable beginning in 2018:

(A) Except as provided in paragraph (2)(iii)(B) of this definition, the EHR reporting period is the calendar year that is 2 years before the payment adjustment year.

(B) If an eligible hospital is demonstrating under the Medicaid EHR Incentive Program that it is a meaningful EHR user for the first time in the calendar year that is 2 years before the payment adjustment year, the EHR reporting period for that payment adjustment year is the same continuous 90-day period that is the EHR reporting period for the Medicaid incentive payment within the calendar year that is 2 years before that payment adjustment year.

(3) * * *

(i) The following are applicable before 2015:

* * * * *

(ii) The following are applicable for 2015, 2016, and 2017:

(A) In 2015 as follows:

(1) The EHR reporting period is any continuous 90-day period within the period beginning on October 1, 2014 and ending on December 31, 2015 and applies for the FY 2015 payment adjustment year.

(B) In 2016 as follows:

(1) If a CAH has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within CY 2016 and applies for the FY 2016 payment adjustment year.

(2) If in a prior year a CAH has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is CY 2016 and applies for the FY 2016 payment adjustment year.

(C) In 2017 as follows:

(1) If the CAH has not successfully demonstrated meaningful EHR use in a prior year

the EHR reporting period is any continuous 90-day period within CY 2017 and applies for the FY 2017 payment adjustment year.

(2) If a CAH is demonstrating Stage 3 of meaningful use under § 495.24, the EHR reporting period is any continuous 90-day period within CY 2017 and applies for that begins on the first day of second quarter of the FY 2017 payment adjustment year.

(3) If in a prior year a CAH has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is CY 2017 and applies for the FY 2017 payment adjustment year.

(iii) The following are applicable beginning in 2018:

(A) Except as provided in paragraph (3)(iii)(B) of this definition, the EHR reporting period is the calendar year that begins on the first day of second quarter of the Federal fiscal year that is the payment adjustment year.

(B) If a CAH is demonstrating under the Medicaid EHR Incentive Program that it is a meaningful EHR user for the first time in the calendar year that begins on the first day of the second quarter of the Federal fiscal year that is the payment adjustment year, then any continuous 90-day period within such calendar year. The EHR reporting period for that payment adjustment year is the same continuous 90-day period that is the EHR reporting period for the Medicaid incentive payment within the calendar year that that begins on the first day of the second quarter of the Federal fiscal year that is the payment adjustment year.

* * * * *

§495.6 [Redesignated as §495.20]

5. Redesignate § 495.6 as §495.20.

§495.8 [Redesignated as §495.40]

6. Redesignate § 495.8 as §495.40.

§495.10 [Redesignated as §495.60]

7. Redesignate § 495.10 as §495.60.

8. 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:

* * * * *

9. Section §495.22 is added 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 non-applicable 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 to the exclusion.

(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 non-applicable 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 to the exclusion.

(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 CEHRT. A patient's record is maintained using CEHRT if sufficient data was entered in the CEHRT 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 CEHRT.

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

(1) 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.

(2) 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. 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 for an EHR reporting period in 2015.

(1) Alternate objective. Implement one clinical decision support rule relevant to a high priority hospital condition along with the ability to track compliance with that rule.

(2) Alternate 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. An EP previously scheduled to be in Stage 1 in 2015 may meet an alternate measure (e)(3)(ii)(C)(1) 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 for an EHR reporting period in 2015. An EP previously scheduled to be in Stage 1 in 2016 may exclude the measures outlined under paragraphs (e)(3)(ii)(A)(2) and (3) of this section for an EHR reporting period in 2016.

(1) Alternate measure 1 in 2015. 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.

(2) Alternate exclusions in 2015. An EP scheduled to be in Stage 1 in 2015 may exclude the measures specified in paragraphs (e)(3)(ii)(A)(2) and (e)(3)(ii)(A)(3) of this section in 2015.

(3) Alternate exclusions in 2016. An EP scheduled to be in Stage 1 in 2016 may exclude the measure specified in paragraph (e)(3)(ii)(A)(3) of this section in 2016.

(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. (1) An eligible hospital or CAH previously scheduled to be in Stage 1 in 2015 may 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 may exclude the measures outlined under paragraphs (e)(3)(iii)(A)(2) and (e)(3)(iii)(A)(3) of this section for an EHR reporting period in 2015. An eligible hospital or CAH previously scheduled to be in Stage 1 in 2016 may exclude the measures outlined under paragraphs (e)(3)(iii)(A)(2) and (3) of this section for an EHR reporting period in 2016.

(2) Alternate measure 1 in 2015. 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 in 2015 and 2016. An eligible hospital or CAH scheduled to be in Stage 1 in 2015 may exclude the following measures in 2015 and eligible hospital or CAH scheduled to be in Stage 1 in 2016 may exclude the following measures in 2016:

(i) The measure specified in paragraph (e)(3)(iii)(A)(2) of this section.

(ii) The measure specified in paragraph (e)(3)(iii)(A)(3) of this section.

(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 written by the EP are queried for a drug formulary and transmitted electronically using CEHRT.

(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 specification. In 2015 an EP--

(1) 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; and

(2) Subject to paragraph (d) of this section, more than 40 percent of all permissible prescriptions written by the EP are transmitted electronically using CEHRT.

(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 are queried for a drug formulary and transmitted electronically using CEHRT.

(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. (1) An eligible hospital or CAH previously scheduled to be in --

(i) 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

(ii) 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.

(2) An eligible hospital or CAH previously scheduled to be in ---

(i) Stage 1 in 2016, may exclude the measure specified in paragraph (e)(4)(iii)(A) of this section for an EHR reporting period in 2016; or

(ii) Stage 2 in 2016, may exclude the measure specified in paragraph (e)(4)(iii)(A) of this section for an EHR reporting period in 2016.

(5) Health Information Exchange— (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 exclusion. 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 exclusion. 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

CEHRT to identify patient-specific education resources and provide those resources to the patient.

(ii) EP measure. (A) Measure. Patient-specific education resources identified by CEHRT 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 exclusion. 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.

(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 CEHRT.

(B) Alternate exclusion. 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.

(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 performs 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 exclusion. 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.

(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 exclusion. 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.

(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) Measure 1: More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely access to view online, download and transmit to a third party their health information subject to the EP's discretion to withhold certain information.

(2) Measure 2: For an EHR reporting period --

(i) In 2015 and 2016, at least 1 patient seen by the EP during the EHR reporting period (or patient-authorized representative) views, downloads or transmits his or her health information

to a third party during the EHR reporting period.

(ii) In 2017, more than 5 percent of unique patients seen by the EP during the EHR reporting period (or their authorized representatives) views, downloads or transmits their health information to a third party during the EHR reporting period.

(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 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 exclusion. 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) Measure 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 timely

access to view online, download and transmit to a third party their health information.

(2) Measure 2. For an EHR reporting period--

(i) In 2015 or 2016, at least 1 patient(or patient-authorized representative) who is discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH during the EHR reporting period views, downloads or transmits to a third party his or her information during the EHR reporting period; and

(ii) In 2017, more than 5 percent of unique patients (or patient-authorized representatives) discharged from the inpatient or emergency department (POS 21 or POS 23) of an eligible hospital or CAH during the EHR reporting period view, download or transmit to a third party their health information during the EHR reporting period.

(B) Exclusion applicable under paragraph (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 exclusion. 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. For an EHR reporting period --

(1) In 2015, the capability for patients to send and receive a secure electronic message with the EP was fully enabled during the EHR reporting period;

(2) In 2016, for at least 1 patient seen by the EP during the EHR reporting period, a

secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative) during the EHR reporting period; and

(3) In 2017, for more than 5 percent of unique patients seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative) 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 specification. 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 Reporting— (i) EP Public Health Reporting—(A) Objective. The EP is in active engagement with a public health agency to submit electronic public health data from CEHRT, 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 3 (as specified in paragraphs (e)(10)(i)(B)(1) through (3) of this section) and must successfully attest to any combination of

two measures. The EP may attest to measure 3(as specified in paragraph (e)(10)(i)(B)(3) of this section more than one time. These measures may be met by any combination 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.

(2) Syndromic surveillance reporting. The EP is in active engagement with a public health agency to submit syndromic surveillance data.

(3) Specialized registry reporting. The EP is in active engagement to submit data to specialized 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 in which 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) Is not in a category of providers from which ambulatory syndromic surveillance data is collected by their jurisdiction's syndromic surveillance system;

(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) Any EP who meets one or more of the following criteria may be excluded from the specialized registry reporting measure described in paragraph(e)(10)(i)(B)(3) of this section if the EP:

(i) Does not diagnose or treat any disease or condition associated with or collect relevant data that is required by a specialized registry in their jurisdiction during the EHR reporting period;

(ii) Operates in a jurisdiction for which no specialized 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

(iii) Operates in a jurisdiction where no specialized registry for which the EP is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period.

(D) Alternate specifications. An EP previously scheduled to be in Stage 1 in 2015 may choose from measures 1 through 3 (as specified in paragraphs (e)(10)(i)(B)(1) through (3) 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.

(ii) 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 to submit electronic public health data from CEHRT, 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 4 (as described in paragraphs (e)(10)(ii)(B)(1) through (4) of this section) and must successfully attest to any combination of three measures. These measures may be met by any combination, including meeting the measure specified in paragraph (e)(10)(ii)(B)(3) 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.

(2) Syndromic surveillance reporting. The eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data

(3) Specialized registry reporting. The eligible hospital or CAH is in active engagement to submit data to a specialized registry.

(4) 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) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the specialized registry reporting measure described in paragraph(e)(10)(i)(B)(3) of this section if the EP:

(i) Does not diagnose or directly treat any disease associated with or collect relevant data

is required by a specialized registry for which the eligible hospital or CAH is eligible in their jurisdiction.

(ii) Operates in a jurisdiction for which no specialized 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

(iii) Operates in a jurisdiction where no specialized 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.

(4) 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)(4) 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 specification. An eligible hospital or CAH previously scheduled to be in Stage 1 in 2015 may choose from measures 1 through 4 (as specified in paragraphs

(e)(10)(ii)(B)(1) through (4) 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)(3) of this section multiple times, in accordance with applicable law and practice.

10. Section 495.24 is added to read as follows:

§ 495.24 Stage 3 meaningful use objectives and measures for EPs, eligible hospitals, and CAHs for 2018 and subsequent years.

The following criteria are optional for EPs, eligible hospitals, and CAHs in 2017 as outlined at § 495.40(a)(2)(i)(E)(3) and (b)(2)(E)(3) and applicable for all EPs, eligible hospitals, and CAHs for 2018 and subsequent years:

(a) Stage 3 criteria for EPs—(1) General rule regarding Stage 3 criteria for meaningful use for EPs. Except as specified in paragraphs (a)(2) through (a)(3) of this section, EPs must meet all objectives and associated measures of the Stage 3 criteria specified in paragraph (d) of this section to meet the definition of a meaningful EHR user.

(2) Selection of measures for specified objectives in paragraph (d) of this section. An EP may meet the criteria for 2 out of the 3 measures associated with an objective, rather than meeting the criteria for all 3 of the measures, if the EP meets all of the following requirements:

(i) Must ensure that the objective in paragraph (d) of this section includes an option to meet 2 out of the 3 associated measures.

(ii) Meets the threshold for 2 out of the 3 measures for that objective.

(iii) Attests to all 3 of the measures for that objective

(3) Exclusion for non-applicable objectives and measures. (i) An EP may exclude a particular objective that includes an option for exclusion contained in paragraph (d) of this section, if the EP meets all of the following requirements:

(A) Meets the criteria in the applicable objective that would permit the exclusion.

(B) Attests to the exclusion.

(ii) An EP may exclude a measure within an objective which allows for a provider to meet the threshold for 2 of the 3 measures, as outlined in paragraph (a)(2) of this section, in the following manner:

(A)(1) Meets the criteria in the applicable measure or measures that would permit the exclusion; and

(2) Attests to the exclusion or exclusions.

(B)(1) Meets the threshold; and

(2) Attests to any remaining measure or measures.

(4) Exception for Medicaid EPs who adopt, implement or upgrade in their first payment year. For Medicaid EPs who adopt, implement or upgrade its CEHRT in their first payment year, the meaningful use objectives and associated measures of the Stage 3 criteria specified in paragraph (d) of this section apply beginning with the second payment year, and do not apply to the first payment year.

(b) Stage 3 criteria for eligible hospitals and CAHs—(1) General rule regarding Stage 3 criteria for meaningful use for eligible hospitals or CAHs. Except as specified in paragraphs (b)(2) and (3) of this section, eligible hospitals and CAHs must meet all objectives and associated measures of the Stage 3 criteria specified in paragraph (d) of this section to meet the definition of a meaningful EHR user.

(2) Selection of measures for specified objectives in paragraph (d) of this section. An eligible hospital or CAH may meet the criteria for 2 out of the 3 measures associated with an objective, rather than meeting the criteria for all 3 of the measures, if the eligible hospital or CAH meets all of the following requirements:

(i) Must ensure that the objective in paragraph (d) of this section includes an option to meet 2 out of the 3 associated measures.

(ii) Meets the threshold for 2 out of the 3 measures for that objective.

(iii) Attests to all 3 of the measures for that objective.

(3) Exclusion for non-applicable objectives and measures. (i) An eligible hospital or CAH may exclude a particular objective that includes an option for exclusion contained in paragraph (d) of this section, if the eligible hospital or CAH meets all of the following requirements:

(A) Meets the criteria in the applicable objective that would permit the exclusion.

(B) Attests to the exclusion.

(ii) An eligible hospital or CAH may exclude a measure within an objective which allows for a provider to meet the threshold for 2 of the 3 measures, as outlined in paragraph (b)(2) of this section, in the following manner:

(A)(1) Meets the criteria in the applicable measure or measures that would permit the exclusion; and

(2) Attests to the exclusion or exclusions.

(B)(1) Meets the threshold; and

(2) Attests to any remaining measure or measures.

(4) Exception for Medicaid eligible hospitals or CAHs that adopt, implement or upgrade in their first payment year. For Medicaid eligible hospitals or CAHs who adopt, implement or upgrade CEHRT in their first payment year, the meaningful use objectives and associated measures of the Stage 3 criteria specified in paragraph (d) of this section apply beginning with the second payment year, and do not apply to the first payment year.

(c) Objectives and associated measures in paragraph (d) of this section that rely on measures that count unique patients or actions. (1) If a measure (or associated objective) in paragraph (d) of this section references paragraph (c) of this section, then the measure may be calculated by reviewing only the actions for patients whose records are maintained using CEHRT. A patient's record is maintained using CEHRT if sufficient data was entered in the CEHRT 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 (c) of this section, then the measure must be calculated by reviewing all patient records, not just those maintained using CEHRT.

(d) Stage 3 objectives and measures for EPs, eligible hospitals, and CAHs—(1) Protect patient health information— (i) EP protect patient health information. (A) Objective. Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards.

(B) Measure. Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (including encryption) of data created or maintained by CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process.

(ii) Eligible hospital/CAH protect patient health information— (A) Objective. Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards.

(B) Measure. Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (including

encryption) of data created or maintained by CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process.

(2) Electronic prescribing— (i) EP electronic prescribing— (A) Objective. Generate and transmit permissible prescriptions electronically (eRx).

(B) Measure. Subject to paragraph (c) of this section, more than 60 percent of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT.

(C) Exclusions in accordance with paragraph (a)(3) of this section. (1) Any EP who writes fewer than 100 permissible prescriptions during the EHR reporting period; or

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

(ii) Eligible hospital/CAH electronic prescribing— (A) Objective. Generate and transmit permissible discharge prescriptions electronically (eRx).

(B) Measure. Subject to paragraph (c) of this section, more than 25 percent of hospital discharge medication orders for permissible prescriptions (for new and changed prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.

(C) Exclusions in accordance with paragraph (b)(3) of this section. Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions and there are no pharmacies that accept electronic prescriptions within 10 miles at the start of the eligible hospital or CAH's EHR reporting period.

(3) Clinical decision support— (i) EP clinical decision support— (A) Objective.

Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.

(B) 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; and

(2) The EP has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

(C) Exclusion in accordance with paragraph (a)(3) of this section for paragraph (d)(3)(i)(B)(2) of this section. An EP who writes fewer than 100 medication orders during the EHR reporting period.

(ii) Eligible hospital/CAH clinical decision support— (A) Objective. Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.

(B) 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 patient population, the clinical decision support interventions must be related to high-priority health conditions; and

(2) The eligible hospital or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

(4) Computerized provider order entry (CPOE)— (i) EP CPOE—(A) Objective. Use

computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant, who can enter orders into the medical record per state, local, and professional guidelines.

(B) Measures. Subject to paragraph (c) 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 60 percent of laboratory orders created by the EP during the EHR reporting period are recorded using computerized provider order entry; and

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

(C) Exclusions in accordance with paragraph (a)(3) of this section. (1) For the measure specified in paragraph (d)(4)(i)(B)(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 (d)(4)(i)(B)(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 (d)(4)(i)(B)(3) of this section, any EP who writes fewer than 100 diagnostic imaging orders during the EHR reporting period.

(ii) Eligible hospital and CAH CPOE— (A) Objective. Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can

enter orders into the medical record per state, local, and professional guidelines.

(B) Measures. Subject to paragraph (c) 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 60 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; and

(3) More than 60 percent of diagnostic imaging 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.

(5) Patient electronic access to health information— (i) EP patient electronic access to health information— (A) Objective. The EP provides patients (or patient-authorized representative) with timely electronic access to their health information and patient-specific education.

(B) Measures. EPs must meet the following two measures:

(1) For more than 80 percent of all unique patients seen by the EP--

(i) The patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and

(ii) The provider ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the provider's CEHRT.

(2) The EP must use clinically relevant information from CEHRT to identify

patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients seen by the EP during the EHR reporting period.

(C) Exclusions in accordance with paragraph (a)(3) of this section. (1) Any EP who has no office visits during the reporting period may exclude from the measures specified in paragraphs (d)(5)(i)(B)(1) and (B)(2) of this section.

(2) Any EP that 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 may exclude from the measures specified in paragraphs (d)(5)(i)(B)(1) and (2) of this section.

(ii) Eligible hospital and CAH patient electronic access to health information— (A) Objective. The eligible hospital or CAH provides patients (or patient-authorized representative) with timely electronic access to their health information and patient-specific education.

(B) Measures. Eligible hospitals and CAHs must meet the following two measures:

(1) For more than 80 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):

(i) The patient (or patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and

(ii) The provider ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the provider's CEHRT.

(2) The eligible hospital or CAH must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials

to more than 35 percent of unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

(C) Exclusion in accordance with paragraph (b)(3) 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 the measures specified in paragraphs (d)(5)(ii)(B)(1) and (2) of this section.

(6) Coordination of care through patient engagement— (i) EP coordination of care through patient engagement— (A) Objective. Use CEHRT to engage with patients or their authorized representatives about the patient's care.

(B) Measures. In accordance with paragraph (a)(2) of this section, an EP must satisfy 2 out of the 3 following measures in paragraphs (d)(6)(i)(B)(1), (2), and (3) of this section except those measures for which an EP qualifies for an exclusion under paragraph (a)(3) of this section.

(1) During the EHR reporting period, more than 10 percent of all unique patients (or their authorized representatives) seen by the EP actively engage with the electronic health record made accessible by the provider and either of the following:

- (i) View, download or transmit to a third party their health information;
- (ii) Access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's CEHRT; or
- (iii) A combination of paragraphs (d)(6)(i)(B)(1)(i) and (ii).

(iv) For an EHR reporting period in 2017 only, an EP may meet a threshold of 5 percent instead of 10 percent for the measure at paragraph (d)(6)(i)(B)(1) of this section.

(2) During the EHR reporting period--

(i) For an EHR reporting period in 2017 only, for more than 5 percent of all unique patients seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or their authorized representatives), or in response to a secure message sent by the patient; or

(ii) For an EHR reporting period other than 2017, for more than 25 percent of all unique patients seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or their authorized representatives), or in response to a secure message sent by the patient.

(3) Patient generated health data or data from a nonclinical setting is incorporated into the CEHRT for more than 5 percent of all unique patients seen by the EP during the EHR reporting period.

(C) Exclusions in accordance with paragraph (a)(3) of this section. (1) Any EP who has no office visits during the reporting period may exclude from the measures specified in paragraphs (d)(6)(i)(B)(1), (2), and (3) of this section.

(2) Any EP that 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 may exclude from the measures specified in paragraphs (d)(6)(i)(B)(1), (2), and (3) of this section.

(ii) Eligible hospital and CAH coordination of care through patient engagement— (A) Objective. Use CEHRT to engage with patients or their authorized representatives about the patient's care.

(B) Measures. In accordance with paragraph (b)(2) of this section, an eligible hospital or

CAH must satisfy 2 of the 3 following measures in paragraph (d)(6)(ii)(B)(1), (2), and (3) of this section, except those measures for which an eligible hospital or CAH qualifies for an exclusion under paragraph (b)(3) of this section.

(1) During the EHR reporting period, more than 10 percent of all unique patients (or their authorized representatives) discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) actively engage with the electronic health record made accessible by the provider and one of the following:

(i) View, download or transmit to a third party their health information.

(ii) Access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's CEHRT.

(iii) A combination of paragraphs (d)(6)(ii)(B)(1)(i) and (ii).

(iv) For an EHR reporting period in 2017, an eligible hospital or CAH may meet a threshold of 5 percent instead of 10 percent for the measure at paragraph (d)(6)(ii)(B)(1) of this section.

(2) During the EHR reporting period--

(i) For an EHR reporting period in 2017 only, for more than 5 percent of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or their authorized representatives), or in response to a secure message sent by the patient (or their authorized representatives).

(ii) For an EHR reporting period other than 2017, for more than 25 percent of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic

messaging function of CEHRT to the patient (or their authorized representatives), or in response to a secure message sent by the patient (or their authorized representatives).

(3) Patient generated health data or data from a non-clinical setting is incorporated into the CEHRT for more than 5 percent of unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

(C) Exclusions under paragraph (b)(3) of this section. Any eligible hospital or CAH operating in a location 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 may exclude from the measures specified in paragraphs (d)(6)(ii)(B)(1), (B)(2), and (B)(3) of this section.

(7) Health information exchange— (i) EP health information exchange— (A) Objective. The EP provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of CEHRT.

(B) Measures. In accordance with paragraph (a)(2) of this section, an EP must attest to all 3 measures, but must meet the threshold for 2 of the 3 measures in paragraph (d)(7)(i)(B)(1), (2), and (3), in order to meet the objective. Subject to paragraph (c) of this section--

(1) Measure 1. For more than 50 percent of transitions of care and referrals, the EP that transitions or refers their patient to another setting of care or provider of care--

- (i) Creates a summary of care record using CEHRT; and
- (ii) Electronically exchanges the summary of care record.

(2) Measure 2. For more than 40 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP incorporates into the patient's EHR an electronic summary of care document.

(3) Measure 3. For more than 80 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP performs clinical information reconciliation. The EP must implement clinical information reconciliation for two of the following three clinical information sets:

(i) Medication. Review of the patient's medication, including the name, dosage, frequency, and route of each medication.

(ii) Medication allergy. Review of the patient's known allergic medications.

(iii) Current problem list. Review of the patient's current and active diagnoses.

(C) Exclusions in accordance with paragraph (a)(3) of this section. An EP must be excluded when any of the following occur:

(1) 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 must be excluded from paragraph (d)(7)(i)(B)(1) of this section.

(2) Any EP for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period may be excluded from paragraphs (d)(7)(i)(B)(2) and (d)(7)(i)(B)(3) of this section.

(3) Any EP that 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 may exclude from the measures specified in paragraphs (d)(7)(i)(B)(1) and (2) of this section.

(ii) Eligible hospitals and CAHs health information exchange— (A) Objective. The eligible hospital or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of CEHRT.

(B) Measures. In accordance with paragraph (b)(2) of this section, an eligible hospital or CAH must attest to all three measures, but must meet the threshold for 2 of the 3 measures in paragraph (d)(7)(ii)(B)(1), (2), and (3). Subject to paragraph (c) of this section--

(1) Measure 1. For more than 50 percent of transitions of care and referrals, the eligible hospital or CAH that transitions or refers its patient to another setting of care or provider of care-

-

(i) Creates a summary of care record using CEHRT; and

(ii) Electronically exchanges the summary of care record.

(2) Measure 2. For more than 40 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH incorporates into the patient's EHR an electronic summary of care document from a source other than the provider's EHR system.

(3) Measure 3. For more than 80 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH performs a clinical information reconciliation. The provider must implement clinical

information reconciliation for two of the following three clinical information sets:

(i) Medication. Review of the patient's medication, including the name, dosage, frequency, and route of each medication.

(ii) Medication allergy. Review of the patient's known allergic medications.

(iii) Current problem list. Review of the patient's current and active diagnoses.

(C) Exclusions in accordance with paragraph (b)(3) of this section. (1) Any eligible hospital or CAH for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period may be excluded from paragraphs (d)(7)(i)(B)(2) and (3) of this section.

(2) Any eligible hospital or CAH operating in a location 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 may exclude from the measures specified in paragraphs (d)(7)(ii)(B)(1), and (2) of this section.

(8) Public Health and Clinical Data Registry Reporting— (i) EP Public Health and Clinical Data Registry: Reporting objective— (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 CEHRT, except where prohibited, and in accordance with applicable law and practice.

(B) Measures. In order to meet the objective under paragraph (d)(8)(i)(A) of this section, an EP must choose from measures 1 through 5 (paragraphs (d)(8)(i)(B)(1) through (d)(8)(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 measure specified in paragraph (d)(8)(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 an urgent care setting

(3) Electronic 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 (a)(3) 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 (d)(8)(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 their 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 its EHR reporting period.

(iii) Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to

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 (d)(8)(i)(B)(2) of the section if the EP:

(i) Is not in a category of providers from which ambulatory syndromic surveillance data is collected by their jurisdiction's syndromic surveillance system.

(ii) Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance 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 syndromic surveillance data from EPs as of 6 months prior to the start of the EHR reporting period.

(3) Any EP meeting one or more of the following criteria may be excluded from the case reporting measure at paragraph (d)(8)(i)(B)(3) of this section if the EP:

(i) 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.

(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 as of 6 months prior to 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 (d)(8)(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 the EP's 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, eligible hospital, or CAH is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to 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 (d)(8)(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 their 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, eligible hospital, or CAH is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the EHR reporting period.

(ii) 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 (PHA) or clinical data registry (CDR) to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.

(B) Measures. In order to meet the objective under paragraph (d)(8)(ii)(A) of this section, an eligible hospital or CAH must choose from measures 1 through 6 (as described in paragraphs (d)(8)(ii)(B)(1) through (6) of this section) and must successfully attest to any combination of four measures. These measures may be met by any combination, including meeting the measure specified in paragraph (d)(8)(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 urgent care setting.

(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 (b)(3) of this section. (1) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from to the immunization registry reporting measure specified in paragraph (d)(8)(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 as of 6 months prior to 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 (d)(8)(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 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 as of 6 months prior to the

start of the EHR reporting period.

(3) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the case reporting measure specified in paragraph (d)(8)(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 their 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 their EHR reporting period.

(iii) Operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data as of 6 months prior to 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 (d)(8)(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 its 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, eligible hospital, or CAH is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to 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 (d)(8)(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 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, eligible hospital, or CAH is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start 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)(8)(ii)(B)(6) of this section if the eligible hospital or CAH:

(i) Does not perform or order laboratory tests that are reportable in its 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 an eligible hospital or CAH as of 6 months prior to the start of the EHR reporting period.

11. Newly redesignated § 495.40 is amended by:

- a. In paragraph (a) introductory text, by removing the cross-reference "under §495.6 of this subpart" 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(d) and §495.6(e) of this subpart" 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 and §495.8 of this subpart" 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. Adding paragraphs (a)(2)(i)(E) and (F).
- g. In paragraph (a)(2)(iv), by removing the cross-reference "in §495.6 and §495.8 of this subpart" and adding in its place the cross-reference "in §495.20 or §495.24 and §495.40".
- h. In paragraph (b)(1)(i)(B), by removing the cross-reference " under §495.6(f) and §495.6(g)" and adding in its place the cross-reference "under §495.20 or §495.24".
- i. Redesignating paragraph (b)(1)(iv) as paragraph (b)(1)(iii).
- j. In newly redesignated paragraph (b)(1)(iii), by removing the cross-reference "in §495.6 and §495.8 of this subpart" and adding in its place the cross-reference "in §495.20 or §495.24 and §495.40".
- k. Revising paragraph (b)(2)(i)(B).
- l. 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)".
- m. Adding paragraphs (b)(2)(i)(E), (F), and (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); or

(2) Objectives and measures specified in § 495.24 (d).

* * * * *

(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(d) for meaningful use.

* * * * *

§495.310 [Amended]

12. Section 495.310(d) is amended by removing the reference "§495.10 of this part" and adding in its place the reference "§495.60".

13. Section 495.316 is amended by:

a. Revising paragraph (c) introductory text.

b. In paragraphs (d)(1)(i) and (iii) removing the phrase "The number, type, and practice location(s) of providers" and adding in its place "The number and type of providers".

c. Adding paragraphs (d)(2)(iii), (f), (g), and (h) to read as follows:

§495.316 State monitoring and reporting regarding activities required to receive an incentive payment.

* * * * *

(c) Subject to § 495.332 and § 495.352, the State is required to submit to CMS annual reports, in the manner prescribed by CMS, on the following:

* * * * *

(d) * * *

(2) * * *

(iii) Subject to § 495.332, the State may propose a revised definition for Stage 3 of

meaningful use of CEHRT, subject to CMS prior approval, but only with respect to the public health and clinical data registry reporting objective described in § 495.24(d)(8).

* * * * *

(f) Each State must submit to CMS the annual report described in paragraph (c) of this section within 60 days of the end of the second quarter of the Federal fiscal year.

(g) The State must, on a quarterly basis and in the manner prescribed by CMS, submit a report(s) on the following:

(1) The State and payment year to which the quarterly report pertains.

(2) Subject to paragraph (h)(2) of this section, provider-level attestation data for each EP and eligible hospital that attests to demonstrating meaningful use for each payment year beginning with 2013.

(h)(1) Subject to paragraph (h)(2) of this section, the quarterly report described in paragraph (g) of this section must include the following for each EP and eligible hospital:

(i) The payment year number.

(ii) The provider's National Provider Identifier or CCN, as appropriate.

(iii) Attestation submission date.

(iv) The state qualification.

(v) The state qualification date, which is the beginning date of the provider's EHR reporting period for which it demonstrated meaningful use.

(vi) The State disqualification, if applicable.

(vii) The State disqualification date, which is the beginning date of the provider's EHR reporting period to which the provider attested but for which it did not demonstrate meaningful use, if applicable.

(2) The quarterly report described in paragraph (g) of this section is not required to include information on EPs who are eligible for the Medicaid EHR incentive program on the basis of being a nurse practitioner, certified nurse-midwife or physician assistant.

14. Section 495.352 is revised to read as follows:

§ 495.352 Reporting requirements.

(a) Beginning with the first quarter of calendar year 2016, each State must submit to HHS on a quarterly basis a progress report, in the manner prescribed by HHS, documenting specific implementation and oversight activities performed during the quarter, including progress in implementing the State's approved Medicaid HIT plan.

(b) The quarterly progress reports must include, but need not be limited to providing, updates on the following:

- (1) State system implementation dates.
- (2) Provider outreach.
- (3) Auditing.
- (4) State-specific State Medicaid HIT Plan tasks.
- (5) State staffing levels and changes.

(6) The number and type of providers that qualified for an incentive payment on the basis of having adopted, implemented or upgraded CEHRT and the amounts of incentive payments.

(7) The number and type of providers that qualified for an incentive payment on the basis of having demonstrated that they are meaningful users of CEHRT and the amounts of incentive payments.

(c) States must submit the quarterly progress reports described in this section within 30

days after the end of each federal fiscal year quarter.

CMS-3310- & 3311-FC

Dated: September 23, 2015.

Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare & Medicaid Services.

Dated: September 25, 2015.

Sylvia M. Burwell,

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