This document is scheduled to be published in the
Federal Register on 09/04/2012 and available online at
http://federalregister.gov/a/2012-21050, and on **FDsys.gov**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, and 495

[CMS-0044-F]

RIN 0938-AQ84

Medicare and Medicaid Programs; Electronic Health Record Incentive Program--Stage 2

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

ACTION: Final rule.

SUMMARY: This final rule specifies the Stage 2 criteria that eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) must meet in order to qualify for Medicare and/or Medicaid electronic health record (EHR) incentive payments. In addition, it specifies payment adjustments under Medicare for covered professional services and hospital services provided by EPs, eligible hospitals, and CAHs failing to demonstrate meaningful use of certified EHR technology (CEHRT) and other program participation requirements. This final rule revises certain Stage 1 criteria, as finalized in the July 28, 2010 final rule, as well as criteria that apply regardless of Stage.

DATES: Effective dates: This final rule is effective on [insert date 60 days after the date of publication in the **Federal Register**], with the exception of the definition of "meaningful EHR user" in §495.4 and the provisions in §495.6(f), §495.6(g), §495.8, §495.102(c), and part 495 subpart D, which are effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Applicability dates: Sections 495.302, 495.304, and 495.306 are applicable beginning payment year 2013.

FOR FURTHER INFORMATION CONTACT:

Elizabeth Holland, (410) 786-1309, or Robert Anthony, (410) 786-6183, EHR Incentive Program issues or Administrative appeals process issues.

David Koppel, (410) 786-3255, for Medicaid Incentive Program issues.

Frank Szeflinski, (303) 844-7119, for Medicare Advantage issues.

Travis Broome, (214) 767-4450, Medicare payment adjustment issues.

Douglas Brown, (410) 786-0028, or Maria Michaels, (410) 786-2809 for Clinical quality measures issues.

SUPPLEMENTARY INFORMATION:

Acronyms

ARRA	American Recovery and Reinvestment Act of 2009
AAC	Average Allowable Cost (of CEHRT)
ACO	Accountable Care Organization
AIU	Adopt, Implement, Upgrade (CEHRT)
CAH	Critical Access Hospital
CAHPS	Consumer Assessment of Healthcare Providers and Systems
CCN	CMS Certification Number
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

CPOE	Computerized Provider Order Entry
CQM	Clinical Quality Measure
CY	Calendar Year
EHR	Electronic Health Record
EP	Eligible Professional
EPO	Exclusive Provider Organization
FACA	Federal Advisory Committee Act
FFP	Federal Financial Participation
FFY	Federal Fiscal Year
FFS	Fee-For-Service
FQHC	Federally Qualified Health Center
FTE	Full-Time Equivalent
FY	Fiscal Year
HEDIS	Healthcare Effectiveness Data and Information Set
HHS	Department of Health and Human Services
HIE	Health Information Exchange
HIT	Health Information Technology
HITPC	Health Information Technology Policy Committee
HIPAA	Health Insurance Portability and Accountability Act of 1996
HITECH	Health Information Technology for Economic and Clinical Health Act
HMO	Health Maintenance Organization
HOS	Health Outcomes Survey
HPSA	Health Professional Shortage Area

HRSA	Health Resource and Services Administration
IAPD	Implementation Advance Planning Document
ICR	Information Collection Requirement
IHS	Indian Health Service
IPA	Independent Practice Association
IT	Information Technology
LOINC	Logical Observation Identifiers and Codes System
MA	Medicare Advantage
MAC	Medicare Administrative Contractor
MAO	Medicare Advantage Organization
MCO	Managed Care Organization
MITA	Medicaid Information Technology Architecture
MMIS	Medicaid Management Information Systems
MSA	Medical Savings Account
NAAC	Net Average Allowable Cost (of CEHRT)
NCQA	National Committee for Quality Assurance
NCVHS	National Committee on Vital and Health Statistics
NPI	National Provider Identifier
NPRM	Notice of Proposed Rulemaking
ONC	Office of the National Coordinator for Health Information Technology
PAHP	Prepaid Ambulatory Health Plan
PAPD	Planning Advance Planning Document
PCP	Primary Care Provider

PECOS	Provider Enrollment, Chain, and Ownership System
PFFS	Private Fee-For-Service
PHO	Physician Hospital Organization
PHR	Personal Health Record
PHS	Public Health Service
PHSA	Public Health Service Act
PIHP	Prepaid Inpatient Health Plan
POS	Place of Service
PPO	Preferred Provider Organization
PQRS	Physician Quality Reporting System
PSO	Provider Sponsored Organization
RHC	Rural Health Clinic
RPPO	Regional Preferred Provider Organization
SAMHSA	Substance Abuse and Mental Health Services Administration
SMHP	State Medicaid Health Information Technology Plan
TIN	Tax Identification Number

Table of Contents

I. Executive Summary and Overview

A. Executive Summary

1. Purpose of Regulatory Action

a. Need for the Regulatory Action

b. Legal Authority for the Regulatory Action

2. Summary of Major Provisions

a. Stage 2 Meaningful Use Objectives and Measures

b. Reporting on Clinical Quality Measures (CQMs)

c. Payment Adjustments and Exceptions

d. Modifications to Medicaid EHR Incentive Program

e. Stage 2 Timeline Delay

3. Summary of Costs and Benefits

B. Overview of the HITECH Programs Created by the American Recovery and Reinvestment Act of 2009

II. Provisions of the Proposed Regulations and Analysis of and Responses to Public Comments

A. Definitions Across the Medicare FFS, Medicare Advantage, and Medicaid Programs

1. Uniform Definitions

2. Meaningful EHR User

3. Definition of Meaningful Use

a. Considerations in Defining Meaningful Use

b. Changes to Stage 1 Criteria for Meaningful Use

c. State Flexibility for Stage 2 of Meaningful Use

d. Stage 2 Criteria for Meaningful Use (Core Set and Menu Set)

(1) Discussion of Whether Certain EPs, Eligible Hospitals or CAHs can meet all Stage 2 Meaningful Use Objectives Given Established Scopes of Practice

(2) EPs Practicing in Multiple Practices/Locations

(3) Discussion of the Reporting Requirements of the Measures Associated with the Stage 2 Meaningful Use Objectives

B. Reporting on Clinical Quality Measures Using Certified EHRs Technology by

Eligible Professionals, Eligible Hospitals, and Critical Access Hospitals

1. Time Periods for Reporting Clinical Quality Measures

2. Certification Requirements for Clinical Quality Measures

3. Criteria for Selecting Clinical Quality Measures

4. Clinical Quality Measures for Eligible Professionals

a. Statutory and Other Considerations

b. Clinical Quality Measures for Eligible Professionals for CY 2013

c. Clinical Quality Measures for Eligible Professionals Beginning with CY 2014

5 Reporting Methods for Clinical Quality Measures for Eligible Professionals

a. Reporting Methods for Medicaid EPs

b. Reporting Methods for Medicare EPs in CY 2013

c. Reporting Methods for Medicare EPs Beginning with CY 2014

d. Group Reporting Option for Medicare and Medicaid Eligible Professionals Beginning with CY 2014

6. Clinical Quality Measures for Eligible Hospitals and Critical Access Hospitals

a. Statutory and Other Considerations

b. Clinical Quality Measures for Eligible Hospitals and CAHs for FY 2013

7. Reporting Methods for Eligible Hospitals and Critical Access Hospitals

a. Reporting Methods in FY 2013

b. Reporting Methods Beginning with FY 2014

c. Electronic Reporting of Clinical Quality Measures for Medicaid Eligible Hospitals

C. Demonstration of Meaningful Use and Other Issues

1. Demonstration of Meaningful Use

a. Common Methods of Demonstration in Medicare and Medicaid

b. Methods for Demonstration of the Stage 2 Criteria of Meaningful Use

c. Group Reporting Option of Meaningful Use Core and Menu Objectives and Associated Measures for Medicare and Medicaid EPs Beginning with CY 2014

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

3. Hospital-Based Eligible Professionals

4. Interaction with Other Programs

D. Medicare Fee-for-Service

1. General Background and Statutory Basis

2. Payment Adjustment Effective in CY 2015 and Subsequent Years for EPs who are not Meaningful Users of CEHRT for an Applicable Reporting Period

a. Applicable Payment Adjustments in CY 2015 and Subsequent Calendar Years for EPs who are not Meaningful Users of CEHRT

b. EHR Reporting Period for Determining Whether an EP is Subject to the Payment Adjustment for CY 2015 and Subsequent Calendar Years

c. Exception to the Application of the Payment Adjustment to EPs in CY 2015 and Subsequent Calendar Years

d. HPSA Bonus Technical Change

e. Payment Adjustment Not Applicable To Hospital-Based EPs

3. Incentive Market Basket Adjustment Effective in FY 2015 and Subsequent Years for Eligible Hospitals that are not Meaningful EHR Users for an Applicable Reporting Period

a. Applicable Market Basket Adjustment for Eligible Hospitals who are not Meaningful

EHR Users for FY 2015 and Subsequent FYs

b. EHR Reporting Period for Determining Whether a Hospital is Subject to the Market Basket Adjustment for FY 2015 and Subsequent FYs

c. Exception to the Application of the Market Adjustment to Hospitals in FY 2015 and Subsequent FYs

d. Application of Market Basket Adjustment in FY 2015 and Subsequent FYs to a State Operating Under a Payment Waiver Provided by Section 1814(B)(3) of the Act

4. Reduction of Reasonable Cost Reimbursement in FY 2015 and Subsequent Years for CAHs that are not Meaningful EHR Users

a. Applicable Reduction of Reasonable Cost Payment Reduction in FY 2015 and Subsequent Years for CAHs that are not Meaningful EHR Users

b. EHR Reporting Period for Determining Whether a CAH is Subject to the Applicable Reduction of Reasonable Cost Payment in FY 2015 and Subsequent Years

c. Exception to the Application of Reasonable Cost Payment Reductions to CAHs in FY 2015 and Subsequent FYs

5. Administrative Review Process of Certain Electronic Health Record Incentive Program Determinations

E. Medicare Advantage Organization Incentive Payments

1. Definition (§495.200)

2. Identification of Qualifying MA Organizations, MA-EPs and MA-affiliated Eligible Hospitals (§495.202)

3. Incentive Payments to Qualifying MA Organizations for Qualifying MA EPs and Qualifying MA-Affiliated Eligible Hospitals (§495.204)

a. Amount Payable to a Qualifying MA Organization for its Qualifying MA EPs

b. Increase in Incentive Payment for MA EPs Who Predominantly Furnish Services in a Geographic Health Professional Shortage Area (HPSA)

4. Avoiding Duplicate Payments

5. Payment Adjustments Effective in 2015 and Subsequent MA Payment Adjustment Years (§495.211).

6. Reconsideration Process for MA Organizations

F. Revisions and Clarifications to the Medicaid EHR Incentive Program

1. Net Average Allowable Costs

2. Eligibility Requirements for Children's Hospitals

3. Medicaid Professionals Program Eligibility

a. Calculating Patient Volume Requirements

b. Practices Predominately

4. Medicaid Hospital Incentive Payment Calculation

a. Discharge Related Amount

b. Acute Care Inpatient Bed Days and Discharges for the Medicaid Share and Discharge-Related Amount

c. Hospitals Switching States

5. Hospital Demonstrations of Meaningful Use - Auditing and Appeals

6. State Flexibility for Stage 2 of Meaningful Use

7. State Medicaid Health Information Technology Plan (SMHP) and Implementation Advance Planning Document (IAPD)

a. Frequency of Health Information Technology (HIT) Implementation Advanced Planning Document (IAPD) Updates

b. Requirements of States Transitioning from HIT Planning Advanced Planning Documents (P-APDs) to HIT IAPDs

III. Waiver of Delay in Effective Date

IV. Collection of Information Requirements

A. ICR Regarding Demonstration of Meaningful Use Criteria (§495.6 and §495.8)

B. ICRs Regarding Qualifying MA Organizations (§495.210)

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

V. Regulatory Impact Analysis

A. Statement of Need

B. Overall Impact

C. Anticipated Effects

1. Overall Effects

a. Regulatory Flexibility Analysis and Small Entities

(1) Number of Small Entities

(2) Conclusion

b. Small Rural Hospitals

c. Unfunded Mandates Reform Act

d. Federalism

2. Effects on Eligible Professionals, Eligible Hospitals, and CAHs

a. Background and Assumptions

b. Industry Costs and Adoption Rates

c. Costs of EHR Adoption for EPs

d. Costs of EHR Adoption for Eligible Hospitals

3. Medicare Incentive Program Costs

a. Medicare Eligible Professionals (EPs)

b. Medicare Eligible Hospitals and CAHs

c. Critical Access Hospitals (CAHs)

4. Medicaid Incentive Program Costs

a. Medicaid EPs

b. Medicaid Hospitals

5. Benefits for all EPs and all Eligible Hospitals

6. Benefits to Society

7. General Considerations

8. Summary

9. Explanation of Benefits and Savings Calculations

D. Accounting Statement

E. Conclusion

Regulations Text

I. Executive Summary and Overview

A. Executive Summary

1. Purpose of Regulatory Action

a. Rationale for the Regulatory Action

In this final rule the Secretary of the Department of Health and Human Services (the

Secretary) will specify Stage 2 criteria beginning in 2014 that eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) must meet in order to qualify for an incentive payment, as well as introduce changes to the program timeline and detail Medicare payment adjustments. Recommendations on Stage 2 criteria from the Health IT Policy Committee (HITPC), a Federal Advisory Committee that coordinates industry and provider input regarding the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs were substantially adopted, with consideration of current program data for the Medicare and Medicaid EHR Incentive Programs. Our current program data is derived from two sources. First, data elements from the registration and attestation process of those providers who have already registered and attested to Stage 1 of meaningful use. This includes demographic information about the provider, the Certified EHR Technology (CEHRT) used by the provider and their performance on the meaningful use objectives and measures. Second, we have information from thousands of questions providers submitted about the EHR Incentive Programs. These questions provide insights into the difficulties faced by providers and also into the areas of the EHR Incentive Programs that warrant additional clarification.

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, and 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, Medicare Advantage (MA) organizations (for certain qualifying EPs and

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

Sections 1903(a)(3)(F) and 1903(t) of the Act provide the statutory basis for Medicaid incentive payments. (There are no payment adjustments under Medicaid). For a more detailed explanation of the statutory basis for the EHR incentive payments, see the Stage 1 final rule (75 FR 44316 through 44317).

2. Summary of Major Provisions

a. Stage 2 Meaningful Use Objectives and Measures

In the Stage 1 final rule we outlined Stage 1 meaningful use criteria, we finalized a separate set of core objectives and menu objectives for EPs, eligible hospitals and CAHs. EPs and hospitals must meet the measure or qualify for an exclusion to all 15 core objectives and 5 out of the 10 menu objectives in order to qualify for an EHR incentive payment. In this final rule, we maintain the same core-menu structure for the program for Stage 2. We are finalizing that EPs must meet the measure or qualify for an exclusion to 17 core objectives and 3 of 6 menu objectives. We are finalizing that eligible hospitals and CAHs must meet the measure or qualify for an exclusion to 16 core objectives and 3 of 6 menu objectives. Nearly all of the Stage 1 core and menu objectives are retained for Stage 2. The "exchange of key clinical information" core objective from Stage 1 was re-evaluated in favor of a more robust "transitions of care" core objective in Stage 2, and the "Provide patients with an electronic copy of their health information" objective was removed because it was replaced by a "view online, download, and

transmit" core objective. There are also multiple Stage 1 objectives that were combined into more unified Stage 2 objectives, with a subsequent rise in the measure threshold that providers must achieve for each objective that has been retained from Stage 1.

b. Reporting on Clinical Quality Measures (CQMs)

EPs, eligible hospitals, and CAHs are required to report on specified clinical quality measures in order to qualify for incentive payments under the Medicare and Medicaid EHR Incentive Programs. This final rule outlines a process by which EPs, eligible hospitals, and CAHs will submit CQM data electronically, reducing the associated burden of reporting on quality measures for providers. EPs will submit 9 CQMs from at least 3 of the National Quality Strategy domains out of a potential list of 64 CQMs across 6 domains. We are recommending a core set of 9 CQMs focusing on adult populations with a particular focus on controlling blood pressure. We are also recommending a core set of 9 CQMs for pediatric populations. EPs should report on these recommended CQMs if they are representative of their clinical practice and patient population. Eligible hospitals and CAHs will submit 16 CQMs from at least 3 of the National Quality Strategy domains out of a potential list of 29 CQMs across 6 domains. For the Medicare EHR Incentive Program, EPs, eligible hospitals, and CAHs in their first year of demonstrating meaningful use must submit their CQM data via attestation, and those beyond their first year must submit their CQM data electronically via a CMS-designated transmission method. For EPs, this includes an aggregate electronic submission or a patient-level electronic submission through the method specified by the Physician Quality Reporting System (PQRS) that would provide one submission for credit in both the PQRS and Medicare EHR Incentive Program. For eligible hospitals and CAHs, this includes an aggregate electronic submission or a patient-level data submission through the method similar to the Medicare EHR Incentive

Program Electronic Reporting Pilot, which is proposed for extension in the CY 2013 Hospital Outpatient Prospective Payment System (OPPS) proposed rule (July 30, 2012, 77 FR 45188). For electronic submissions, patient-level data must be submitted using the Quality Reporting Data Architecture (QRDA) Category I format, and aggregate-level data must be submitted using the QRDA Category III format.

c. Payment Adjustments and Exceptions

Medicare payment adjustments are required by statute to take effect in 2015. We are finalizing a process by which payment adjustments will be determined by a prior reporting period. Therefore, we specify that EPs and eligible hospitals that are meaningful EHR users in 2013 will avoid payment adjustment in 2015. Also, if such providers first meet meaningful use in 2014, they will avoid the 2015 payment adjustment, if they are able to demonstrate meaningful use at least 3 months prior to the end of the calendar (for EPs) or fiscal year (for eligible hospitals) and meet the registration and attestation requirement by July 1, 2014 (for eligible hospitals) or October 1, 2014 (for EPs).

We also are finalizing exceptions to these payment adjustments. This final rule outlines four categories of exceptions based on (1) the lack of availability of internet access or barriers to obtaining IT infrastructure; (2) a time-limited exception for newly practicing EPs or new hospitals that will not otherwise be able to avoid payment adjustments; (3) unforeseen circumstances such as natural disasters that will be handled on a case-by-case basis; and (4) (EP only) exceptions due to a combination of clinical features limiting a provider's interaction with patients or, if the EP practices at multiple locations, lack of control over the availability of CEHRT at practice locations constituting 50 percent or more of their encounters.

d. Modifications to Medicaid EHR Incentive Program

We are expanding the definition of what constitutes a Medicaid patient encounter, which is a required eligibility threshold for the Medicaid EHR Incentive Programs. We include encounters for individuals enrolled in a Medicaid program, including Title XXI-funded Medicaid expansion encounters (but not separate Children's Health Insurance Programs (CHIPs)). We also specify flexibility in the lookback period for patient volume to be over the 12 months preceding attestation, not tied to the prior calendar year.

We are also making eligible approximately 12 additional children's hospitals that have not been able to participate to date, despite meeting all other eligibility criteria, because they do not have a CMS Certification Number since they do not bill Medicare.

These changes would take effect beginning with payment year 2013.

e. Stage 2 Timeline Delay

Lastly, we are finalizing a delay in the implementation of the onset of Stage 2 criteria. In the Stage 1 final rule, we established that any provider who first attested to Stage 1 criteria in 2011 would begin using Stage 2 criteria in 2013. This final rule delays the onset of those Stage 2 criteria until 2014, which we believe provides the needed time for vendors to develop CEHRT. We are also introducing a special 3-month EHR reporting period, rather than a full year of reporting, for providers attesting to either Stage 1 or Stage 2 in 2014 in order to allow time for providers to implement newly certified CEHRT. In future years, providers who are not in their initial year of demonstrating meaningful use must meet criteria for 12-month reporting periods. The 3-month reporting period allows providers flexibility in their first year of meeting Stage-2 without warranting any delay for Stage-3. This policy is consistent with CMS's commitment to ensure that Stage 3 occurs on schedule (implemented by 2016).

3. Summary of Costs and Benefits

This final rule 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 that to the best of our ability presents the costs and benefits of the final rule. The total Federal cost of the Medicare and Medicaid EHR Incentive Programs between 2014 and 2019 is estimated to be $15.4 billion (these estimates include net payment adjustments for Medicare providers who do not achieve meaningful use in 2015 and subsequent years in the amount of $2.1 billion). In this final rule we have not quantified the overall benefits to the industry, nor to EPs, eligible hospitals, or CAHs participating in the Medicare and Medicaid EHR Incentive Programs. Information on the costs and benefits of adopting systems specifically meeting the requirements for the EHR Incentive Programs has not yet been collected and information on costs and benefits overall is limited. Nonetheless, we believe there are substantial benefits that can be obtained by eligible hospitals and EPs, including reductions in medical recordkeeping costs, reductions in repeat tests, decreases in length of stay, increased patient safety, and reduced medical errors. There is evidence to support the cost-saving benefits anticipated from wider adoption of EHRs.

TABLE 1: 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	
2014	$2.1	$1.9	$0.6	$0.5	$5.10
2015	$1.8	$1.9	$0.4	$0.8	$4.90
2016	$1.2	$0.6	$0.5	$0.8	$3.10
2017	$0.2	$0.1	$0.5	$0.7	$1.50
2018	-$0.1	–$0.2	$0.1	$0.7	$0.50
2019	$0.0	–$0.2	$0.0	$0.5	$0.30

B. Overview of the HITECH Programs Created by the American Recovery and Reinvestment Act of 2009

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, and CAHs, and Medicare Advantage (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 entitled "Medicare and Medicaid Programs; Electronic Health Record Incentive Program," that specified the Stage 1 criteria that 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 (hereinafter referred to as the Stage 1 final rule). (For a full explanation of the amendments made by ARRA, see the Stage 1 final rule (75 FR 44316).) In that final rule, we also detailed that the Medicare and Medicaid EHR Incentive Programs will consist of 3 different stages of meaningful use requirements.

For Stage 1, CMS and the Office of the National Coordinator for Health Information Technology (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 part 170.

For Stage 2, CMS and ONC again worked together to align our regulations.

In the March 7, 2012 **Federal Register** (77 FR 13698), we published a proposed rule that specified the potential Stage 2 criteria that EPs, eligible hospitals, and CAHs would have to meet in order to qualify for Medicare and/or Medicaid EHR incentive payments (hereinafter referred

to as the Stage 2 proposed rule). In addition, the proposed rule --(1) proposed payment adjustments under Medicare for covered professional services and hospital services provided by EPs, eligible hospitals, and CAHs failing to demonstrate meaningful use of CEHRT and other program participation requirements; and (2) proposed the revision of certain Stage 1 criteria, as well as criteria that apply regardless of stage.

In the April 18, 2012 **Federal Register** (77 FR 23193), we published a document that corrected typographical and technical errors in the March 7, 2012 Stage 2 proposed rule.

Simultaneously in the March 7, 2012 **Federal Register** (77 FR 13832), ONC published its notice of proposed rulemaking titled Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology. The notice of proposed rulemaking proposed revisions to the initial set of standards, implementation specifications, and certification criteria in ONC's July 28, 2010 final rule as well as the adoption of new standards, implementation specifications, and certification criteria.

We urge those interested in this final rule to also review the ONC final rule on standards and implementation specifications for CEHRT. Readers may also visit http://www.cms.hhs.gov/EHRincentiveprograms and http://healthit.hhs.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

We received approximately 6,100 items of timely correspondence in response to our Stage 2 proposed rule published in the March 7, 2012 **Federal Register**. We received some comments that were outside the scope of the proposed rule and therefore are not addressed in this final rule. Summaries of the timely public comments that are within the scope of the Stage 2 proposed rule and our responses to those comments are set forth in the various sections of this final rule under the appropriate headings. We have generally organized those sections by stating our proposals, summarizing and responding to the timely public comments received, and describing our final policy.

A. Definitions Across the Medicare FFS, Medicare Advantage, and Medicaid Programs

1. Uniform Definitions

As discussed in the proposed rule, in the Stage 1 final rule, we finalized many uniform definitions for the Medicare FFS, Medicare Advantage (MA), and Medicaid EHR incentive programs. These definitions are set forth in part 495 subpart A of the regulations, and we proposed to maintain most of these definitions, including, for example, "Certified EHR Technology (CEHRT)," "Qualified EHR," "Payment Year," and "First, Second, Third, Fourth, Fifth, and Sixth Payment Year." We noted in the Stage 2 proposed rule that our definitions of "CEHRT" and "Qualified EHR" incorporate the definitions adopted by ONC, and to the extent that ONC's definitions are revised, our definitions would also incorporate those changes. For these definitions, we refer readers to ONC's standards and certification criteria final rule that is published elsewhere in this issue of the **Federal Register**.

We did not receive any comments on our proposal and will continue to use the existing

definitions in part 495 subpart A, except where stated otherwise in this final rule.

We stated that we would revise the descriptions of the EHR reporting period to clarify that providers who are demonstrating meaningful use for the first time would have an EHR reporting period of 90 days regardless of payment year. We proposed to add definitions for the applicable EHR reporting period that would be used in determining the payment adjustments, as well as a definition of a payment adjustment year.

A summary of the comments pertaining to the EHR reporting period, the applicable EHR reporting period for determining the payment adjustments, and the definition of a payment adjustment year, as well as our responses to those comments, can be found in sections II.A.3.a and II.D.2 of this final rule.

2. Meaningful EHR User

We proposed to include clinical quality measure reporting as part of the definition of "meaningful EHR user" under §495.4 instead of as a separate meaningful use objective under §495.6.

Comment: A few commenters suggested that this change would create confusion, but the majority supported this change to alleviate confusion caused by the current situation. Many comments discussed the specifics of clinical quality measures.

Response: We appreciate the support expressed for the proposal. We continue to believe that separating clinical quality measures from the meaningful use objectives and measures in §495.6 will reduce confusion and finalize the change as proposed. We address comments on the specifics of clinical quality measures in section II.B of this final rule. While clinical quality measure reporting will no longer be listed as a separate objective and measure in §495.6, as it is now incorporated in the definition of meaningful EHR user in §495.4, it remains a condition for

demonstrating meaningful use.

We proposed to revise the third paragraph of the definition of meaningful EHR user at §495.4 to refer specifically to the payment adjustments and read as follows: "(3) To be considered a meaningful EHR user, at least 50 percent of an EP's patient encounters during an EHR reporting period for a payment year (or during an applicable EHR reporting period for a payment adjustment year) must occur at a practice/location or practices/locations equipped with CEHRT." We did not receive any comments on this revision and we are finalizing it as proposed.

3. Definition of Meaningful Use

a. Considerations in Defining Meaningful Use

In sections 1848(o)(2)(A) and 1886(n)(3)(A) of the Act, the Congress identified the broad goal of expanding the use of EHRs through the concept of meaningful use. Section1903(t)(6)(C) of the Act also requires that Medicaid providers adopt, implement, upgrade or meaningfully use CEHRT if they are to receive incentives under Title XIX. CEHRT used in a meaningful way is one piece of the broader HIT infrastructure needed to reform the health care system and improve health care quality, efficiency, and patient safety. This vision of reforming the health care system and improving health care quality, efficiency, and patient safety should inform the definition of meaningful use.

As we explained in our Stage 1 meaningful use rule and again in our Stage 2 proposed rule, we seek to balance the sometimes competing considerations of health system advancement (for example, improving health care quality, encouraging widespread EHR adoption, promoting innovation) and minimizing burdens on health care providers given the short timeframe available under the HITECH Act.

Based on public and stakeholder input received during our Stage 1 rule, we laid out a phased approach to meaningful use. Such a phased approach encompasses reasonable criteria for meaningful use based on currently available technology capabilities and provider practice experience, and builds up to a more robust definition of meaningful use as technology and capabilities evolve. The HITECH Act acknowledges the need for this balance by granting the Secretary the discretion to require more stringent measures of meaningful use over time. Ultimately, consistent with other provisions of law, meaningful use of CEHRT should result in health care that is patient centered, evidence-based, prevention-oriented, efficient, and equitable.

Under this phased approach to meaningful use, we update the criteria of meaningful use through staggered rulemaking. We published the Stage 1 final rule (75 FR 44314) on July 28, 2010, and this rule finalizes the criteria and other requirements for Stage 2. We currently are planning at least one additional update, and anticipate finalizing the Stage 3 criteria through additional rulemaking in early 2014 with Stage 3 starting in 2016. The stages represent an initial graduated approach to arriving at the ultimate goal.

- The Stage 1 meaningful use criteria, consistent with other provisions of Medicare and Medicaid law, focused on electronically capturing health information in a structured format; using that information to track key clinical conditions and communicating that information for care coordination purposes (whether that information is structured or unstructured, but in structured format whenever feasible); implementing clinical decision support tools to facilitate disease and medication management; using EHRs to engage patients and families and reporting clinical quality measures and public health information. Stage 1 focused heavily on establishing the functionalities in CEHRT that will allow for continuous quality improvement and ease of information exchange. By having these functionalities in CEHRT at the onset of the program

and requiring that the EP, eligible hospital or CAH become familiar with them through the varying levels of engagement required by Stage 1, we believe we created a strong foundation to build on in later years. Though some functionalities were optional in Stage 1, all of the functionalities are considered crucial to maximize the value to the health care system provided by CEHRT. We encouraged all EPs, eligible hospitals and CAHs to be proactive in implementing all of the functionalities of Stage 1 in order to prepare for later stages of meaningful use, particularly functionalities that improve patient care, the efficiency of the health care system and public and population health. The specific criteria for Stage 1 of meaningful use are discussed in the Stage 1 final rule, published on July 28, 2010 (75 FR 44314 through 44588). We are finalizing certain changes to the Stage 1 criteria in section II.A.3.b. of this final rule.

- Stage 2: We stated in the Stage 2 proposed rule that our Stage 2 goals, consistent with other provisions of Medicare and Medicaid law, would expand upon the Stage 1 criteria with a focus on ensuring that the meaningful use of EHRs supports the aims and priorities of the National Quality Strategy. Specifically, Stage 2 meaningful use criteria would encourage the use of health IT for continuous quality improvement at the point of care and the exchange of information in the most structured format possible. Our proposed Stage 2 meaningful use requirements included rigorous expectations for health information exchange including: more demanding requirements for e-prescribing; incorporating structured laboratory results; and the expectation that providers will electronically transmit patient care summaries with each other and with the patient to support transitions in care. Increasingly robust expectations for health information exchange in Stage 2 and Stage 3 would support the goal that information follows the patient. In addition, as we forecasted in the Stage 1 final rule, we proposed that nearly every objective that was optional for Stage 1 would be part of the core for Stage 2

- Stage 3: We anticipate that Stage 3 meaningful use criteria will focus on: promoting improvements in quality, safety and efficiency leading to improved health outcomes; focusing on decision support for national high priority conditions; patient access to self-management tools; access to comprehensive patient data through robust, secure, patient-centered health information exchange; and improving population health. For Stage 3, we currently intend to propose higher standards for meeting meaningful use. For example, we intend to propose that every objective in the menu set for Stage 2 be included in Stage 3 as part of the core set. While the use of a menu set allows providers flexibility in setting priorities for EHR implementation and takes into account their unique circumstances, we maintain that all of the objectives are crucial to building a strong foundation for health IT and to meeting the objectives of the HITECH Act. In addition, as the capabilities of HIT infrastructure increase, we may raise the thresholds for these objectives in both Stage 2 and Stage 3.

In the Stage 1 final rule (75 FR 44323), we published the following Table 2 with our expected timeline for the stages of meaningful use.

TABLE 2: STAGE OF MEANINGFUL USE CRITERIA BY PAYMENT YEAR AS FINALIZED IN 2010

First Payment Year	**Payment Year**				
	2011	**2012**	**2013**	**2014**	**2015**
2011	Stage 1	Stage 1	Stage 2	Stage 2	TBD
2012		Stage 1	Stage 1	Stage 2	TBD
2013			Stage 1	Stage 1	TBD
2014				Stage 1	TBD

We proposed changes to this timeline as well as its extension beyond 2014. As we explained in the Stage 2 proposed rule, under the timeline used in Table 2, an EP, eligible hospital, or CAH that became a meaningful EHR user for the first time in 2011 would need to begin their EHR reporting period for Stage 2 on January 1, 2013 (EP) or October 1, 2012

(eligible hospital or CAH). The HITPC recommended we delay by 1 year the start of Stage 2 for providers who became meaningful EHR users in 2011. We stated in the proposed rule that Stage 2 of meaningful use would require changes to both technology and workflow that cannot reasonably be expected to be completed in the time between the publication of the final rule and the start of the EHR reporting periods as listed in Table 2. We noted the similar concerns we have heard from other stakeholders and agreed that, based on our proposed definition of meaningful use for Stage 2, providers could have difficulty implementing these changes in time. Therefore, we proposed a 1-year extension of Stage 1 of meaningful use for providers who successfully demonstrated meaningful use for 2011. Our proposed timeline through 2021, which we finalize in this rule with a notation of the special EHR reporting period in 2014, is displayed in Table 3. We refer readers to section II.D.2 of this final rule for a discussion of the applicable EHR reporting period that will be used to determine whether providers are subject to payment adjustments.

TABLE 3: STAGE OF MEANINGFUL USE CRITERIA BY FIRST PAYMENT YEAR

First Payment Year	Stage of Meaningful Use										
	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
2011	1	1	1	2*	2	3	3	TBD	TBD	TBD	TBD
2012		1	1	2*	2	3	3	TBD	TBD	TBD	TBD
2013			1	1*	2	2	3	3	TBD	TBD	TBD
2014				1*	1	2	2	3	3	TBD	TBD
2015					1	1	2	2	3	3	TBD
2016						1	1	2	2	3	3
2017							1	1	2	2	3

*3-month quarter EHR reporting period for Medicare and continuous 90-day EHR reporting period (or 3 months at state option) for Medicaid EPs. All providers in their first year in 2014 use any continuous 90-day EHR reporting period.

We explained in the proposed rule that the Medicare EHR incentive program and the Medicaid EHR incentive program have different rules regarding the number of payment years

available, the last year for which incentives may be received, and the last payment year for initiating the program. The last year for which an EP and an eligible hospital or CAH can begin receiving Medicare incentive payments is 2014 and 2015 respectively. These providers would begin in Stage 1 of meaningful use. Medicaid EPs and eligible hospitals can receive a Medicaid EHR incentive payment for "adopting, implementing, and upgrading" (AIU) to CEHRT for their first payment year, which is not reflected in Table 3. For example, a Medicaid EP who earns an incentive payment for AIU in 2013 would have to meet Stage 1 of meaningful use in his or her next 2 payment years (2014 and 2015). The applicable payment years and the incentive payments available for each program are discussed in the Stage 1 final rule.

If we anticipate future criteria beyond Stage 3 of meaningful use, we expect to update Table 3 in the rulemaking for Stage 3, which remains on schedule for implementation in 2016.

Comment: We received numerous comments, which represented a significant majority of all comments received, on the timing of the stages of meaningful use. Commenters asserted that the timeline is too aggressive and will result in many providers being unable to meet Stage 2 of meaningful use, particularly those who first attested in 2011 and 2012. The most common justification for this claim was the lack of sufficient time between the publication of this final rule and the time when a provider who first attested to meaningful use in 2011 or 2012 would have to begin Stage 2 of meaningful use. Some commenters suggested that the time was insufficient regardless of resource constraints, while others suggested that currently vendors of CEHRT lack the necessary capacity to make the necessary upgrades to their CEHRT products and implement them for their customers in time. Commenters also pointed to competing priorities and demands on provider time and resources, such as the transition to ICD-10, the various programs and policies under the Affordable Care Act and other priorities that diminish

the time and resources that can be devoted to reaching Stage 2 of meaningful use. Commenters offered several suggestions on how to increase the time available between publication of this final rule and the EHR reporting periods in 2014. The suggestions included using a shorter than full year EHR reporting period in 2014, delaying the start of Stage 2 until 2015 and using a shorter than full year EHR reporting period in 2015, and delaying the start of Stage 2 until 2015 with a full year EHR reporting period. Several commenters suggested a minimum of 18 months is needed, while others suggested longer periods.

Response: While our proposal would provide more than a year between the publication of this final rule and the first day any provider would start their EHR reporting period in 2014 for any stage of meaningful use, we agree that additional time to demonstrate meaningful use in 2014 would be helpful to providers, many of whom will need to upgrade to new technology as well as ensure they are able to meet all of the objectives and measures for Stage 2. In considering what would be an appropriate length of time between publication of this final rule and the start of the EHR reporting periods for providers in 2014 for either Stage 2 or Stage 1, we weighed two primary factors against the comments calling for a delay. The first is that by delaying Stage 2 until 2015, the movement towards improved outcomes that is the main goal of meaningful use would be put off by a full year. This full-year delay would have a ripple effect through the timeline of the stages as providers move along their own timelines across the stages of meaningful use. For this reason, we will not delay Stage 2 until 2015, but instead we are using a 3-month EHR reporting period in 2014 as the first year any provider would attest to Stage2. The second consideration is the data integrity of meaningful use attestations and clinical quality measure submissions, especially as it relates to our efforts towards alignment with other programs such as PQRS, Medicare Shared Savings Program (SSP), and potentially others. The

more robust data set provided by a full year reporting period offers more opportunity for alignment than the data set provided by a shorter reporting period, especially compared across years. By altering the reporting period from year to year the data is less comparable from year to year. However, we agree with commenters that the use of a shorter EHR reporting period in 2014 is necessary to allow sufficient time for vendors to upgrade their CEHRT and for providers to implement it. In an effort to preserve some data validity with similar Medicare quality measurement programs, we are finalizing 3-month quarter EHR reporting periods in 2014 for certain providers that are beyond their first year of meaningful use, rather than any continuous 90-day period within the year as for first-time meaningful users. For more information on alignment with other programs, we refer readers to our discussion on clinical quality measures (see section II.B.1. of this final rule).

While commenters generally suggested a shorter EHR reporting period for the start of Stage 2 in any year rather than just Stage 2 in 2014, we believe that most of the reasons for a shorter period are due to the time constraints for vendor certification, upgrades and provider implementation between publication of this final rule and the beginning of Stage 2 in 2014. Any provider starting Stage 2 after 2014 will have more time and therefore most of the constraints are lifted. We acknowledge that not all constraints go away, but we believe that the balance is sufficiently shifted such that the concerns of data validity and program alignment outweigh the few remaining concerns with a full year EHR reporting period for the provider's first year of Stage 2 if it is after 2014. In addition, since ONC's 2014 Edition certification is for all EHR systems, regardless of the stage of meaningful use the provider using that system is in, there are far fewer implementation concerns after 2014. For example, if a provider begins Stage 2 in 2015, that provider would have been required to use CEHRT (that was certified to the 2014

Edition EHR certification criteria) for the previous year (2014) for Stage 1.

Finally, we considered that for the Medicaid EHR incentive program, EPs work exclusively with the states as they must choose between either the Medicare or Medicaid EHR incentive program. We do not know whether shifting from an EHR reporting period of any continuous 90-days to a 3-month quarter will provide any alignment benefits for Medicaid EPs, and it could introduce system complexity for Medicaid agencies. Therefore, we are maintaining flexibility for states to allow Medicaid EPs to select any continuous 90-day EHR reporting period during 2014 as defined by the state Medicaid program, or, if the state so chooses, any 3-month calendar quarter in 2014. As nearly all hospitals participate in both Medicare and Medicaid, we are using the 3-month quarter EHR reporting period for all hospitals to align both programs.

After consideration of the public comments received, we are modifying our proposal with regard to the EHR reporting periods for EPs, eligible hospitals and CAHs that attest to meaningful use for 2014 for their first year of Stage 2 or their second year of Stage 1. Our final policy is as follows: For 2014, Medicare EPs will attest using an EHR reporting period of January 1, 2014 through March 31, 2014; April 1, 2014 through June 30, 2014; July 1, 2014 through September 30, 2014; or October 1, 2014 through December 31, 2014. For 2014, Medicare and Medicaid eligible hospitals and CAHs will attest using an EHR reporting period of October 1, 2013 through December 31, 2013; January 1, 2014 through March 31 2014; April 1, 2014 through June 30, 2014; or July 1, 2014 through September 30, 2014. Medicaid EPs will attest using an EHR reporting period of any continuous 90-day period between January 1, 2014 and December 1, 2014 as defined by the state Medicaid program, or, if the state so chooses, any 3-month calendar quarter in 2014.

b. Changes to Stage 1 Criteria for Meaningful Use

We proposed the following changes to the objectives and associated measures for Stage 1:

● Computerized Provider Order Entry (CPOE) -- In 2013 (CY for EPs, FY for eligible hospitals/CAHs), we proposed that providers in Stage 1 could use the alternative denominator of the number of medication orders created by the EP or in the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period (for further explanation of this alternative denominator, see the discussion of the CPOE objective in the Stage 2 criteria section at II.A.3.d. of this final rule).

A provider seeking to meet Stage 1 in 2013 can use either the denominator defined in the Stage 1 final rule or the alternative denominator to calculate the percentage for the CPOE measure. We also proposed to require the alternative denominator for Stage 1 beginning in 2014.

Comment: Commenters both supported and opposed the new denominator for CPOE. Those supporting the proposed denominator did so for its simplicity and greater accuracy for measuring actual CPOE usage. Those opposing the proposed denominator did so either because they were concerned with the burden associated with counting paper or other orders that are never entered into the EHR or because of the potential higher performance required by the proposed denominator.

Response: We proposed the alternative denominator to alleviate the burden associated with measurement, not to create a higher performance threshold. As we stated in the proposed rule, feedback from many providers indicated that the alternative denominator was more easily measurable. In response to concerns from commenters, we are finalizing the alternative

denominator for this measure and specify that providers at any year in Stage 1 may elect to use either the denominator defined in the Stage 1 final rule or the alternative denominator to calculate the percentage for the CPOE measure. In response to comments, we are not requiring that the alternative denominator be used beginning in 2014, which will give providers who may find it difficult to measure the flexibility to continue to use the denominator defined in the Stage 1 final rule.

- Vital Signs--For the objective of record and chart changes in vital signs, the proposed Stage 2 measure would allow an EP to split the exclusion and exclude blood pressure only or height/weight only (for more detail, see the discussion of this objective in the Stage 2 criteria section at II.A.3.d. of the final rule). We proposed an identical change to the Stage 1 exclusion as well, starting in CY 2013. We also proposed changing the age limitations on vital signs for Stage 2 (for more detail, see the discussion of this objective in the Stage 2 criteria section). We proposed an identical change to the age limitations on vital signs for Stage 1, starting in 2013 (CY for EPs, FY for eligible hospitals/CAHs). These changes to the exclusion and age limitations were proposed as an alternative in 2013 to the current Stage 1 requirements but required for Stage 1 beginning in 2014.

Comment: While some commenters suggested that these changes would be confusing, most commenters supported the changes and indicated that they would provide added flexibility for providers who seek to incorporate the recording of this data into their clinical workflow. These commenters also noted that the age change reflects best clinical practices. Some commenters suggested removing BMI and growth charts from the measure since there are no best practices on BMI for patients under 3 years of age and since providers who would not record height and weight would not be able to provide BMI or growth charts.

Response: We appreciate the support for these changes and finalize them as proposed. We also note that BMI and growth charts are not required to meet this measure but are instead a capability provided by CEHRT. Providers who claim the exclusion for height and weight will not have data for CEHRT to create either BMI or growth charts and this will not affect their ability to meet the measure of this objective.

Comment: Some commenters requested clarification on whether providers who provide ancillary services and do not normally record any of these elements as part of their regular scope of practice can claim the exclusion.

Response: If a provider believes that height and weight and/or blood pressure are relevant to their scope of practice, they must record those data elements and cannot qualify for the exclusion. We believe that most providers who provide ancillary services can meet the measure of this objective by obtaining this information from a referring provider and recording the necessary data in their CEHRT.

Comment: Some providers asked for clarification on whether providers who only occasionally record height and weight and/or blood pressure are still permitted to claim the exclusions for this measure.

Response: We recognize that there are situations in which certain providers may only record height and weight and/or blood pressure for a very limited number of patients (for example, high-risk surgical patients or patients on certain types of medication) but do not normally regard these data as relevant to their scope of practice. When a provider does not believe that height and weight and/or blood pressure are typically relevant to their scope of practice but still records these vital signs only in exceptional circumstances, the provider is permitted to claim the exclusions for this measure.

After consideration of the public comments received, we are finalizing the changes to vital signs as proposed. We are making technical corrections to the regulation text at §495.6(d)(8) and §495.6(f)(7) to clarify these are alternatives in 2013 and required beginning in 2014.

- Exchange Key Clinical Information --As noted in the proposed rule, the objective of "capability to exchange key clinical information" has been surprisingly difficult for providers to understand, which has made the objective difficult for most providers to achieve. We solicited comment on several options for this objective that we believed would reduce or eliminate the burden associated with this objective or increase the value of the objective. The first option we considered was removal of this objective. The second option was to require that the test be successful. The third option was to eliminate the objective, but require that providers select either the Stage 1 medication reconciliation objective or the Stage 1 summary of care at transitions of care and referrals objective from the menu set. The fourth option was to move from a test to one case of actual electronic transmission of a summary of care document for a real patient either to another provider of care at a transition or referral or to a patient authorized entity. We proposed the first option to remove this objective and measure from the Stage 1 core set beginning in 2013 (CY for EPs, FY for eligible hospitals/CAHs), but we also stated we would evaluate all four options in light of the public comments we received.

Comment: While we received feedback and support from commenters on all of the proposed options, the majority of commenters supported the elimination of this objective for Stage 1. Some commenters instead supported a more exact definition of data exchange for this measure, and other commenters supported additional elements or additional requirements for exchange to be included as part of the measure. Other proposals included implementing a

system that would allow case-by-case reporting of data exchange that would allow CMS to measure successes and failures by provider, vendor, and other elements.

Response: We appreciate the many suggestions from commenters on clarifying data exchange and/or adding requirements to the measure. We also appreciate the suggestion of a case-by-case reporting system for data exchange. However, we are concerned that all of these options would not alleviate but actually increase the burden of this measure for providers by requiring them to document and submit substantially greater information than is currently required by attestation. While such a burden may be justified, we do not believe it is in this case because the Stage 2 requirements for actual electronic exchange of summary of care records create sufficient incentive to begin testing in Stage 1 without there being an explicit meaningful use requirement to do so. Because of these concerns and in reaction to the opinion of most commenters, we are finalizing the removal of this objective and measure for Stage 1 beginning in 2013. Although some commenters suggested removing this objective earlier, we do not believe the timing of publication of this final rule would allow us to implement such a change and allow consistent reporting for all providers in 2012. Therefore, this objective and measure will be removed from the Stage 1 criteria beginning in 2013 (CY for EPs, FY for eligible hospitals and CAHs).

- View Online, Download, and Transmit -- We proposed for Stage 2 a new method for making patient information available electronically, which would enable patients to view online, download, and transmit their health information and hospital admission information. We discuss in the Stage 2 criteria section at II.A.3.d the "view online, download, and transmit" objectives for EPs and hospitals. We noted in the proposed rule that starting in 2014, CEHRT would no longer be certified to the Stage 1 EP and hospital core objectives of providing patients with electronic

copies of their health information (§495.6(d)(12) and (f)(11)) or the Stage 1 hospital core objective of providing patients with electronic copies of their discharge instructions upon request (§495.6(f)(12)), nor would it support the Stage 1 EP menu objective of providing patients with timely electronic access to their health information (§495.6(e)(5)). Therefore starting in 2014, for Stage 1, we proposed to replace these objectives with the new "view online, download and transmit" objectives.

Comment: There were a number of commenters who asked for clarifications regarding the requirements of these objectives. Other commenters raised concerns regarding the implementation of these objectives in both Stage 1 and Stage 2.

Response: We discuss the clarifications and concerns raised by commenters in our Stage 2 criteria at II.A.3.d regarding these objectives. Please refer to those discussions for additional information.

Comment: Some commenters supported this change while other commenters disagreed with it. Those who disagreed with the proposed change indicated that providers would not be ready to implement online access to health information in Stage 1, and that it was unlikely that providers could convince more than 50 percent of patients to sign up for online access within the Stage 1 reporting period. These commenters suggested eliminating all of the Stage 1 objectives for providing electronic copies of health information or discharge summaries and not replacing these objectives with the "view, download, and transmit" objectives.

Response: We disagree that the Stage 1 objectives for providing patients with electronic copies of their health information and discharge instructions should be eliminated without replacing these objectives with the "view online, download, and transmit" objectives. We believe patient access to their health information is an important aspect of patient care and

engagement, and we further believe that the capabilities of CEHRT in 2014 and beyond will enable providers to make this information available online in a way that does not impose a significant burden on providers.

We note that only the first measure of the "view online, download, and transmit" objectives would be required for Stage 1. This means that providers would only have to make information available online to view online, download, and transmit for more than 50 percent of all unique patients during the EHR reporting period in order to meet the measure. We further clarify that providers are only required to make this information available online to view online, download, and transmit and that patients who do not access the information or would not affect whether or not the provider is able to meet the measure. For Stage 1, providers are not required to meet the second measure of more than 5 percent of patients view online, download, or transmit to a third party their health or hospital admission information. Providers are only required to meet the second measure of the objectives in Stage 2. However, the exclusions for these objectives are available for providers in Stage 1. Therefore, we are finalizing our proposal to replace the existing Stage 1 EP and hospital objectives listed above with the "view online, download, and transmit" objectives beginning in 2014 for Stage 1. We are making a technical correction to the regulations text to clarify that the existing Stage 1 objective at §495.6(f)(11) is being replaced. We clarify in Table 4 the four existing Stage 1 objectives that are being replaced. We are also making a technical correction to the regulation text to remove the existing exclusion for the objective at §495.6(f)(12)(iii) beginning in 2014 because the objective that this exclusion applies to is being replaced.

- Removing CQM Reporting from Stage 1 Objectives -- We proposed a revised definition of a meaningful EHR user at §495.4 which would incorporate the requirement to

submit clinical quality measures, as discussed in section II.A.2 of this final rule. We also proposed to remove the objective to submit clinical quality measures from §495.6 beginning in 2013 for Stage 1 to conform with this change in the definition of a meaningful EHR user.

Comment: While some commenters indicated that this change would be confusing, most commenters supported this change.

Response: We appreciate the support of commenters and believe that removing the objective will actually alleviate confusion. Therefore, as discussed earlier in II.A.2. of this final rule, we are finalizing as proposed, the revised definition of a meaningful EHR user at §495.4 to include clinical quality measure submission, as well as the removal of this objective from §495.6 beginning in 2013.

- Public Health Objectives - For the Stage 1 public health objectives, beginning in 2013, we proposed to add "except where prohibited" to the regulation text in order to encourage all EPs, eligible hospitals, and CAHs to submit electronic immunization data, even when not required by state/local law. Therefore, if they are authorized to submit the data, they should do so even if it is not required by either law or practice. There are a few instances where some EPs, eligible hospitals, and CAHs are prohibited from submitting to a state/local immunization registry. For example, in sovereign tribal areas that do not permit transmission to an immunization registry or when the immunization registry only accepts data from certain age groups (for example, adults).

Comment: Some commenters supported this change while others disagreed with it. A number of commenters interpreted the proposed addition of language as a change to either the measure of the objectives or the exclusions that are currently in place.

Response: As noted in the proposed rule, the addition of this language was intended to

ensure that providers who are not required by law or practice to submit data would do so and to make it clear that EPs, eligible hospitals, and CAHs that are prohibited from submitting data would not be required to submit such data. Immunizations was used as a descriptive example in the proposed rule, but this change applies to all Stage 1 public health objectives. The exclusions provided for these objectives in Stage 1 are not affected by the addition of this language and remain in place for all providers. Therefore, we are finalizing the addition of this language as proposed.

- Menu Set Exclusions Policy – We proposed to change the policy on menu set exclusions for Stage 1 beginning in 2014. Please see section II.A.3.d. of this final rule for a discussion of the proposal and our final policy.

- Electronic Prescribing

Comment: We received comments pointing out that we proposed a new exclusion for electronic prescribing objective for Stage 2 regarding the availability of pharmacies that can accept electronic prescriptions. These commenters noted that if this exclusion was not also made available for Stage 1 then it would create a strange scenario where an EP might have to electronically prescribe during their 2 years of Stage 1 and then meet an exclusion in Stage 2.

Response: We agree that it makes no sense to apply this exclusion to e-prescribing in Stage 2, but not in Stage 1. We consider it an oversight of our proposed rule that we did not include that exclusion in our proposed changes to the Stage 1 criteria. We are finalizing an exclusion for the e-prescribing objective in Stage 2 for any EP who 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/her EHR reporting period. We are also finalizing the addition of this exclusion to Stage 1 starting in CY 2013.

TABLE 4: STAGE 1 CHANGES

Stage 1 Objective	Final Changes	Effective Year (CY/FY)
Use CPOE for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines	Change: Addition of an alternative measure More than 30 percent of medication orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE	2013 - Onward (Optional)
Generate and transmit permissible prescriptions electronically (eRx)	Change: Addition of an additional exclusion Any EP who: 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/her EHR reporting period.	2013 – Onward (Required)
Record and chart changes in vital signs	Change: Addition of alternative age limitations More than 50 percent of all unique patients 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 blood pressure (for patients age 3 and over only) and height and weight (for all ages) recorded as structured data	2013 Only (Optional)
Record and chart changes in vital signs	Change: Addition of alternative exclusions Any EP who (1) Sees no patients 3 years or older is excluded from recording blood pressure; (2) Believes that all three vital signs of height, weight, and blood pressure have no relevance to their scope of practice is excluded from recording them; (3) Believes that height and weight are relevant to their scope of practice, but blood pressure is not, is excluded from recording blood pressure; or (4) Believes that blood pressure is relevant to their scope of practice, but height and weight are not, is excluded from recording height and weight.	2013 Only (Optional)

Stage 1 Objective	Final Changes	Effective Year (CY/FY)
Record and chart changes in vital signs	Change: Age limitations on height, weight and blood pressure More than50 percent of all unique patients 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 blood pressure (for patients age 3 and over only) and height and weight (for all ages) recorded as structured data.	2014 – Onward (Required)
Record and chart changes in vital signs	Change: Changing the age and splitting the EP exclusion Any EP who (1) Sees no patients 3 years or older is excluded from recording blood pressure; (2) Believes that all three vital signs of height, weight, and blood pressure have no relevance to their scope of practice is excluded from recording them; (3) Believes that height and weight are relevant to their scope of practice, but blood pressure is not, is excluded from recording blood pressure; or (4) Believes that blood pressure is relevant to their scope of practice, but height and weight are not, is excluded from recording height and weight.	2014 – Onward (Required)
Capability to exchange key clinical information (for example, problem list, medication list, medication allergies, and diagnostic test results), among providers of care and patient authorized entities electronically	Change: Objective is no longer required.	2013 – Onward (Required)
Report ambulatory (hospital) clinical quality measures to CMS or the states	Change: Objective is incorporated directly into the definition of a meaningful EHR user and eliminated as an objective under §495.6	2013 – Onward (Required)

Stage 1 Objective	Final Changes	Effective Year (CY/FY)
EP and Hospital Objectives: Provide patients with an electronic copy of their health information (including diagnostics test results, problem list, medication lists, medication allergies, discharge summary, procedures) upon request. Hospital Objective: Provide patients with an electronic copy of their discharge instructions at time of discharge, upon request. EP Objective: Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, and allergies) within 4business days of the information being available to the EP.	Change: Replace these four objectives with the Stage 2 objective and one of the two Stage 2 measures. 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: 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. Hospital Objective: Provide patients the ability to view online, download, and transmit information about a hospital admission. Hospital Measure: 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.	2014 – Onward (Required)
Public Health Objectives:	Change: Addition of "except where prohibited" to the objective regulation text for the public health objectives under §495.6	2013 – Onward (Required)
Stage 1 Policy Changes		
Meeting an exclusion for a menu set objective counts towards the number of menu set objectives that must be satisfied to meet meaningful use	Meeting an exclusion for a menu set objective does not count towards the number of menu set objectives that must be satisfied to meet meaningful use.	2014 – Onward (Required)

c. State Flexibility for Stage 2 of Meaningful Use

We proposed to offer states flexibility under the Medicaid incentive program with the public health measures in Stage 2, similar to that of Stage 1, subject to the same conditions and standards as the Stage 1 flexibility policy. This applies to the public health measures as well as

the measure to generate lists of specific conditions to use for quality improvement, reduction of disparities, research or outreach. We clarify that our proposal included the existing public health measures from Stage 1 as well as the new public health measures proposed for Stage 2.

In addition, we stated that whether a state moved an objective to the core or left it in the menu, states may also 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 2014 ONC EHR certification criteria.

We solicited comments on extending state flexibility as described for Stage 2 of meaningful use and whether this remains a useful tool for state Medicaid agencies.

Comment: Commenters requested clarification of the requirement that states cannot require EHR functionality above and beyond that which is included in the 2014 ONC EHR certification criteria. These commenters point out that the Stage 2 public health measures require capabilities beyond that which is included in the 2014 ONC EHR certification criteria already.

Response: We assume commenters are referring to transmission methods which are not included in 2014 Edition EHR certification criteria adopted by ONC for public health objectives (immunizations, electronically reportable lab results, syndromic surveillance, cancer registries and specialized registries). This limitation applies only to those capabilities and standards included in 2014 ONC EHR certification criteria for a given public health objective. For example, a state could not require a different standard than the one included in 2014 ONC EHR certification criteria. 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.

Comment: Several commenters supported extending state flexibility with meaningful use

for Stage 2, but requested that CMS provide a clearer definition of state flexibility. Commenters suggested that it would be helpful to EPs and eligible hospitals if states follow a common timeline for establishing state-specific requirements.

Response*:* We appreciate these comments and would like to clarify that the state flexibility for Stage 2 remains defined the same way as it is defined in Stage 1 at §495.316 (d)(2) and §495.322 (f)(2)**.** Given that states are launching their programs at different times and are therefore at different stages in the program lifecycle and process, at this time we do not support the development of a common timeline for establishing state-specific requirements. The parameters remain the same as for Stage 1 and providers are subject to the requirements found in §495.332. CMS approval of states' requests will include a review of the outlined elements.

After consideration of the public comments received, we are finalizing these provisions as proposed.

d. Stage 2 Criteria for Meaningful Use (Core Set and Menu Set)

We proposed to continue the Stage 1 concept of a core set of objectives and a menu set of objectives for Stage 2. In the Stage 1 final rule (75 FR 44322), we indicated that for Stage 2, we expected to include the Stage 1 menu set objectives in the core set. We proposed to follow that approach for our Stage 2 core set with two exceptions. We proposed to keep the objective of "capability to submit electronic syndromic surveillance data to public health agencies" in the menu set for EPs. Our experience with Stage 1 is that very few public health agencies have the ability to accept non-emergency or non urgent care ambulatory syndromic surveillance data electronically and those that do are less likely to support EPs than hospitals; therefore we do not believe that current infrastructure supports moving this objective to the core set for EPs. We also proposed to keep the objective of "record advance directives" in the menu set for eligible

hospitals and CAHs. As we stated in our Stage 1 final rule (75 FR 44345), we have continuing concerns that there are potential conflicts between storing advance directives and existing state laws.

We proposed new objectives for Stage 2, some of which would be part of the Stage 2 core set and others would make up the Stage 2 menu set, as discussed below with each objective. We proposed to eliminate certain Stage 1 objectives for Stage 2, such as the objective for testing the capability to exchange key clinical information. We proposed to combine some of the Stage 1 objectives for Stage 2. For example, the objectives of maintaining an up-to-date problem list, active medication list, and active medication allergy list would not be separate objectives for Stage 2. Instead, we proposed to combine these objectives with the objective of providing a summary of care record for each transition of care or referral by including them as required fields in the summary of care.

We proposed a total of 17 core objectives and 5 menu objectives for EPs. We proposed that an EP must meet the criteria or an exclusion for all of the core objectives and the criteria for 3 of the 5 menu objectives. This is a change from our current Stage 1 policy where an EP could reduce the number of menu set objectives that the EP would otherwise need to meet by the number of menu set objectives that the EP could exclude. We noted the feedback we received on Stage 1 from providers and health care associations leads us to believe that most EPs had difficulty understanding the concept of deferral of a menu objective in Stage 1. Therefore, we proposed this change for Stage 2, as well as for Stage 1 beginning in 2014, to make the selection of menu objectives easier for EPs. We also proposed this change because we are concerned that under the current Stage 1 requirements some EPs could select and exclude menu objectives when there are other menu objectives they can legitimately meet, thereby making it easier for them to

demonstrate meaningful use than EPs who attempt to legitimately meet the full complement of menu objectives. Although we provided the ability to do this in the selection of Stage 1 menu objectives through 2013, we stated that EPs participating in Stage 1 and Stage 2 starting in 2014 should focus solely on those objectives they can meet rather than those for which they have an exclusion. In addition, we noted the exclusions for the Stage 2 menu objectives that we believe would accommodate EPs who are unable to meet certain objectives because of scope of practice. However, just as we signaled in our Stage 1 regulation, we stated our intent to propose in our next rulemaking that every objective in the menu set for Stage 2 (as described later in this section) be included in Stage 3 as part of the core set.

We explained that in the case where an EP meets the criteria for the exclusions for 3 or more of the Stage 2 menu objectives, the EP would have more exclusions than the allowed deferrals. EPs in this situation would attest to an exclusion for 1 or more menu objectives in his or her attestation to meaningful use. In doing so, the EP would be attesting that he or she also meets the exclusion criteria for all of the menu objectives that he or she did not choose. We stated that the same policy would also apply for the Stage 1 menu objectives for EPs beginning in 2014.

We proposed a total of 16 core objectives and 4 menu objectives for eligible hospitals and CAHs for Stage 2. We proposed that an eligible hospital or CAH must meet the criteria or an exclusion for all of the core objectives and the criteria for 2 of the 4 menu objectives. We proposed that the policy for exclusions for EPs discussed in the preceding paragraph would also apply to eligible hospitals and CAHs for Stage 1 beginning in 2014 and for Stage 2.

We received many comments on the appropriateness of individual objectives placement in the core or menu set. We discuss these comments below for each individual objective.

Comment: Commenters expressed concern over the small number of objectives in the menu set. They were concerned that the small number of objectives limited the usefulness of the menu set to providers.

Response: Stage 2 does contain a more specialized and smaller menu set than Stage 1. We see this as a natural result of moving up the staged path towards improved outcomes and adding fewer new objectives. We also see specialization as necessary for meaningful use to be applicable to all EPs. Due to comments received we are adding two objectives for hospitals and one for EPs which will be in the menu, as further explained later in this section.

After consideration of the public comments received, we finalize the concept of a core and menu set for Stage 2.

We finalize a total of 17 core objectives and 6 menu objectives for EPs for Stage 2. We finalize that an EP must meet the criteria or an exclusion for all of the core objectives and the criteria for 3 of the 6 menu objectives unless an exclusion can be claimed for more than 3 of the menu objectives in which case the criteria for the remaining non-excluded objectives must be met.

We finalize a total of 16 core objectives and 6 menu objectives for eligible hospitals and CAHs for Stage 2. We finalize that an eligible hospital or CAH must meet the criteria or an exclusion for all of the core objectives and the criteria for 3 of the 6 menu objectives.

We also finalize our proposal to change the menu set exclusions policy for Stage 1. Beginning in 2014, qualifying for an exclusion from a menu set objective will no longer reduce the number of menu set objectives that an EP or hospital must otherwise satisfy to demonstrate meaningful use for Stage 1. There is an exception for EPs who meet the criteria to exclude five or more of the menu set objectives, in which case the EP must meet the criteria for all of the

remaining non-excluded menu set objectives. This exception would not be applicable to hospitals due to the number of hospital menu set objectives that include exclusions.

(1) Discussion of Whether Certain EPs, Eligible Hospitals or CAHs can meet all Stage 2 Meaningful Use Objectives Given Established Scopes of Practice

We noted in the proposed rule that we do not believe that any of the proposed new objectives for Stage 2 make it impossible for any EP, eligible hospital or CAH to meet meaningful use. Where scope of practice may prevent an EP, eligible hospital or CAH from meeting the measure associated with an objective, we discussed the barriers and included exclusions in our descriptions of the individual objectives. We proposed to include new exclusion criteria when necessary for new objectives, continue the Stage 1 exclusions for Stage 2, and continue the option for EPs and hospitals to defer some of the objectives in the menu set unless they meet the exclusion criteria for more objectives than they can defer as explained previously.

We recognized in the proposed rule that at the time of publication, our data (derived internally from attestations) only reflected the meaningful use attestations from Medicare providers. There have been no significant changes in the data derived from meaningful use attestations since the publication of the proposed rule.

We did not receive any comments on this provision.

(2) EPs Practicing in Multiple Practices/Locations

We proposed for Stage 2 to continue our policy that 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. 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. We gave the following in the proposed rule example: if the EP practices at a federally qualified health center (FQHC) and within his or her individual practice at 2 different locations, we would include in our review all 3 of these locations, and CEHRT would have to be available at one location or a combination of locations where the EP has 50 percent or more of his or her patient encounters. If CEHRT is only available at one location, then only encounters at this location would be included in meaningful use assuming this one location represents 50 percent or more of the EP's patient encounters. If CEHRT is available at multiple locations that collectively represent 50 percent or more of the EP's patient encounters, then all encounters from those locations would be included in meaningful use.

In the proposed rule we stated that we have received many inquiries on this requirement since the publication of the Stage 1 final rule. We define patient encounter as any encounter where a medical treatment is provided and/or evaluation and management services are provided. This includes both individually billed events and events that are globally billed, but are separate encounters under our definition. We define 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. This can be accomplished in 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, or the EP could access CEHRT remotely using computing devices at the practice/location. Although it is currently allowed under Stage1 for an EP to create a record of the encounter without using CEHRT at the practice/location and then later input that information into CEHRT that exists at a different practice/location, we do not believe this process takes advantage of the value CEHRT offers. We proposed not to allow this practice beginning in

2013. We have also received inquiries whether the practice locations have to be in the same state, to which we clarify that they do not. Finally, we received inquiries regarding the interaction with hospital-based EP determination. The determination of whether an EP is hospital-based or not occurs prior to the application of this policy, so only nonhospital-based eligible professionals are included. Furthermore, this policy, like all meaningful use policies for EPs, only applies to outpatient settings (all settings except the inpatient and emergency department of a hospital).

Comment: Some commenters suggested that for EPs practicing in multiple locations that meaningful use attestations should be limited to just reporting on meaningful use for the most prevalent location due to the difficulty in aggregating data across locations.

Response: We continue to believe that for the core measures, aggregating data is not overly burdensome. We allow the numerators and denominators calculated by CEHRT to be summed across an EP's various practice locations.

Comment: We received request for clarification on what to do when an EP is practicing in multiple locations that select different menu objectives to pursue, and the EP does not control this selection.

Response: An EP who does not have the same menu objectives implemented across each of their practice locations equipped with CEHRT would attest to the three menu objectives that represent the greatest number of their patient encounters. For example, if six menu objectives are implemented between two locations, an EP would attest to the three menu objectives implemented at the location where they have the greatest number of encounters during the EHR reporting period. For measures that utilize a percentage threshold, they can limit the denominator to the location or locations that pursued that menu objective.

After consideration of the public comments received, we are finalizing the proposed provisions with the modifications previously discussed.

(3) Discussion of the Reporting Requirements of the Measures Associated with the Stage 2 Meaningful Use Objectives

In our experience with Stage 1, we found the distinction between limiting the denominators of certain measures to only those patients whose records are maintained using CEHRT, but including all patients in the denominators of other measures, to be complicated for providers to implement. We proposed to remove this distinction for Stage 2 and instead include all patients in the denominators of all of the measures associated with the meaningful use objectives for Stage 2. We believe that by the time an EP, eligible hospital, or CAH has reached Stage 2 of meaningful use all or nearly all of their patient population should be included in their CEHRT, making this distinction no longer relevant.

Comment: We received comments that maintain that this distinction is still necessary for Stage 2 because there are situations where significant patient records may still be maintained outside of CEHRT. Examples provided by commenters include worker's compensation or other special contracts for certain patients, specialized departments or units in a hospital for which CEHRT is not tailored and patient requests to keep their records on paper.

Response: We continue to believe that nearly all patient records will be stored in CEHRT by the time a provider reaches Stage 2. However, we acknowledge that if this assertion is correct then there is no practical consequence of maintaining the distinction, while if it is not, removing the distinction could have adverse impacts on providers.

After consideration of the comments, we are not finalizing our proposed change. Instead, 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 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's or CAH's inpatient or emergency department during the EHR reporting period.

Comment: Some commenters suggested that the denominators should be limited to either just Medicare-covered patients for those participating in the Medicare EHR Incentive Program or just Medicaid-covered patients for those participating in the Medicaid EHR Incentive Program. Commenters presented two arguments in favor of this suggestion. First, that requiring a provider to include all patients was more burdensome than including just Medicare-covered or Medicaid-covered patients and that this burden was not offset by the incentive payments that are based (for Medicare only) on charges submitted to Medicare. Second, that if identifiable patient data was included in Medicare or Medicaid meaningful use reporting for patient not covered by Medicare or Medicaid this would raise serious privacy concerns and possibly require patient consent. Other commenters were supportive of current denominators that does not account for payers.

Response: We discussed the burden differences between all patients versus patients differentiated by payer in our Stage 1 final rule (75 FR44332). We continue to believe that it is highly unlikely that providers will use different record keeping systems based on payer. Where there are differences in patient populations such as age we account for them directly in the measure not indirectly with payer as a generalized proxy. The burden of breaking out the patients by payer for purposes of meaningful use measurement would have only increased from the publication of the Stage 1 final rule as measurement tools have been designed and

implemented to measure patients regardless of payer. If at a future date, the demonstration of meaningful use includes the submission of identifiable patient data we will certainly address the privacy implications of that requirement. However, the Stage 1 objectives and measures and Stage 2 objectives and measures included in this final rule do not require the submission of identifiable patient information. We are not making any changes to this policy in this final rule.

We proposed new objectives that could increase reporting burden. To minimize the burden, we proposed to create a uniform set of denominators that would be used for all of the Stage 2 meaningful use objectives, as discussed later.

Many of our meaningful use objectives use percentage-based measures if appropriate. To provide a check on the burden of reporting of meaningful use, we proposed for Stage 2 to use 1 of 4 denominators for each of the measures associated with the meaningful use objectives. We focused on denominators because the action that moves something from the denominator to the numerator usually requires the use of CEHRT by the provider. These actions are easily tracked by the technology.

The four proposed denominators for EPs are--

- Unique patients seen by the EP during the EHR reporting period (stratified by age or previous office visit);
- Number of orders (medication, labs, radiology);
- Office visits, and
- Transitions of care/referrals.

Comment: We received many comments supporting our efforts to minimize the variety of denominators. Some commenters argued that any variation (such as by age or orders of different types) should be considered separate denominators.

Response: We appreciate the support for our proposal to minimize the variety of denominators. Our base of four denominators are only modified by information that must be entered into CEHRT in order to meet meaningful use; therefore, we believe that such modifications represent a small burden and are in keeping with our overall goal in minimizing the variety of denominators.

In the proposed rule, we stated that the term "unique patient" means that if a patient is seen or admitted more than once during the EHR reporting period, the patient only counts once in the denominator. Patients seen or admitted only once during the EHR reporting period will count once in the denominator. A patient is seen by the EP when the EP has an actual physical encounter with the patient in which they render any service to the patient. A patient seen through telemedicine will also still count as a patient "seen by the EP." In cases where the EP and the patient do not have an actual physical or telemedicine encounter, but the EP renders a minimal consultative service for the patient (like reading an EKG), the EP may choose whether to include the patient in the denominator as "seen by the EP" provided the choice is consistent for the entire EHR reporting period and for all relevant meaningful use measures. For example, a cardiologist may choose to exclude patients for whom they provide a one-time reading of an EKG sent to them from another provider, but include more involved consultative services as long as the policy is consistent for the entire EHR reporting period and for all meaningful use measures that include patients "seen by the EP." EPs who never have a physical or telemedicine interaction with patients must adopt a policy that classifies at least some of the services they render for patients as "seen by the EP," and this policy must be consistent for the entire EHR reporting period and across meaningful use measures that involve patients "seen by the EP" -- otherwise, these EPs will not be able to satisfy meaningful use, as they will have denominators of zero for

some measures. In cases where the patient is seen by a member of the EP's clinical staff the EP can include or not include those patients in their denominator at their discretion as long as the decision applies universally to all patients for the entire EHR reporting period and the EP is consistent across meaningful use measures. In cases where a member of the EP's clinical staff is eligible for the Medicaid EHR incentive in their own right (for example, nurse practitioners (NPs) and certain physician assistants (PA)), patients seen by NPs or PAs under the EP's supervision can be counted by both the NP or PA and the supervising EP as long as the policy is consistent for the entire EHR reporting period.

Comment: While generally supporting the concept of a unique patient as a good tool to address the fact that not all meaningful use objectives need be addressed at every patient encounter or rendering of medical service, some commenters expressed concern about the ability to identify unique patients across CEHRTs in situations where an EP practices at multiple locations or in situations where an EP might switch CEHRT during an EHR reporting period.

Response: We agree that determining unique patients across CEHRTs is difficult. When aggregating performance on meaningful use measures across multiple practice locations using different CEHRTs we do not require that it be determined that a patient seen at one location was not also seen at another location. While this could result in the same patient appearing more than once in the denominator of unique patients seen, we believe that the burden of seeking out these patients is greater than any gain in measurement accuracy. Furthermore, it is not possible for a provider to increase only the numerator with this policy as any increase in the numerator would also increase the denominator. Accordingly, we are adopting a final policy that will give EPs who practice at multiple locations or switch CEHRT during the EHR reporting period some flexibility as to the method for counting unique patients in the denominators. We leave it up to

the EP to decide for the EHR reporting period whether to count a unique patient across all locations equipped with different CEHRT (for example, 1 patient seen at 3 locations with different CEHRT counts once) or at each location equipped with CEHRT (for example, 1 patient seen at 3 locations with different CEHRT counts thrice). In cases where a provider switches CEHRT products at a single location during the EHR reporting period, they also have the flexibility to count a patient as unique on each side of the switch and not across it (for example, 1 patient seen before the switch and after the switch could be counted once or twice). EPs in these scenarios must choose one of these methods for counting unique patients and apply it consistently throughout the entire EHR reporting period.

With the flexibility for EPs practicing in multiple locations using different CEHRT or switching CEHRT during the EHR reporting period, we otherwise finalize our description of "unique patient" as proposed.

We proposed that an office visit is defined as any billable visit that includes: (1) concurrent care or transfer of care visits; (2) consultant visits; or (3) prolonged physician service without direct, face-to-face patient contact (for example, telehealth). A consultant visit occurs when a provider is asked to render an expert opinion/service for a specific condition or problem by a referring provider. The visit does not have to be individually billable in instances where multiple visits occur under one global fee.

Comment: We received comments requesting that we establish a list of billing codes that constitute an office visit for purposes of clarity.

Response: We continue to believe that the use of a list of billing codes would inappropriately limit the discretion of EPs that we have built into this measure. We finalize as proposed our description of an office visit and emphasize that there is room for EP discretion in

this definition and that the most important consideration in utilizing that discretion is that the policy apply for the entire EHR reporting period and across all patients.

We proposed to describe 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. Currently, the meaningful use measures that use transitions of care require there to be a receiving provider of care to accept the information. Therefore, a transition home without any expectation of follow-up care related to the care given in the prior setting by another provider is not a transition of care for purpose of Stage 2 meaningful use measures as there is no provider recipient. A transition within one setting of care does not qualify as a transition of care. Referrals are cases where one provider refers a patient to another, but the referring provider maintains their care of the patient as well. Please note that a "referral" as defined here and elsewhere in this final rule is only intended to apply to the EHR Incentive Programs and is not applicable to other Federal regulations.

Comment: We have received many comments that determining when a transition of care occurs is very difficult under our current Stage 1 rule, particularly when the provider is on the receiving end of the transition of care. Commenters suggest that the only reliable way to know if a patient saw another provider is to ask the patient at each encounter and even then this is not guaranteed. Several suggestions were presented to make the definition more precise on both the receiving and transitioning side. They were as follows:--

- Discharges for eligible hospitals/CAHs and referrals to other providers who do not share the same CEHRT as the EP are very clearly identified and should be the focus of the numerator/denominator.

- A transition within one setting of care does not qualify as a transition of care. Referral

is defined as care "where one provider refers a patient to another, but the referring provider maintains their care of the patient as well."

- A patient is referred to another provider (for EPs) or a patient is discharged (for eligible hospitals).

- Sharing data with health plans.

Response: In reviewing the comments, we agree that a refinement of our transitions of care definition is needed. We also agree with the suggestions to point to specific events that identify a transition of care has occurred without relying entirely on asking the patient. Therefore, we revise our description of transitions of care for the purpose of defining the denominator. For an EP who is on the receiving end of a transition of care or referral, (currently used for the medication reconciliation objective and measure), 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. The summary of care record can be provided either by the patient or by the referring/transiting provider or institution. We believe that both of these situations would create information in the CEHRT that can be automatically recorded. For an EP who is initiating a patient transfer to another setting and/or referring a patient to another provider, (currently used for providing summary of care documents at transitions of care), the initiating/referring EP would count the transitions and/or referrals that were ordered by the EP in the measure denominator. If another provider also sees the same patient, only the EP who orders the transition/referral would need to account for this transition for the purpose of this measure. EPs are not responsible for including patient-initiated transitions and referrals that were not ordered by the EP. For example, if the EP creates an order for admission to a nursing home, this transition of care would be counted in the EP's measure

denominator. If one of the EP's patients is admitted to a nursing home by another provider, this transition would only have to be counted by the EP who creates the order and not necessarily by other EPs who care for the patient. We want to emphasize that these transitions of care/referral descriptions have been developed for purposes of reducing the provider measurement burden for the EHR Incentive Program and do not necessarily apply to other programs or regulations. We also clarify that these descriptions are minimum requirements. An EP can include in the denominator transitions of care and referrals that fit the broader descriptions of these terms, but are not one of the specific events described previously.

The four proposed denominators for eligible hospitals and CAHs are--

- Unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department during the EHR reporting period (stratified by age);
- Number of orders (medication, labs, radiology);
- Inpatient bed days; and
- Transitions of care.

We noted in the proposed rule that our explanation of "unique patients" and "transitions of care" for EPs would also apply for eligible hospitals and CAHs.

Comment: Commenters suggested a problem with unique patients could arise if a hospital switched CEHRT during the EHR reporting period.

Response: Our final policy on EPs who switch CEHRT during the EHR reporting period counting unique patients in the denominator would also apply for hospitals in the same situation.

Comment: We have received many comments that determining when a transition of care occurs is very difficult under our Stage 1 regulations, particularly when the provider is on the receiving end of the transition of care. Commenters suggest that the only reliable way to know if

a patient saw another provider is to ask the patient at each encounter and even then this is not guaranteed. Several suggestions were presented to make the definition more precise on both the receiving and transitioning side, which we summarized previously in the discussion of the proposed denominators for EPs.

Response: For the same reasons as discussed for EPs, we agree that pointing to specific occurrences is needed to accurately measure this denominator. For transitions of care when the hospital is on the receiving end, (currently used for the medication reconciliation objective and measure), we include all admissions to the inpatient and emergency departments. For transitions of care when the hospital is transitioning the patient, (currently used for providing summary of care documents at transitions of care), we include all discharges from the inpatient department and after admissions to the emergency department when follow-up care is ordered by an authorized provider of the hospital. As with EPs, these are the minimum events that must be included in the denominator for the transitions of care measure. Hospitals can include additional transitions of care that match the full description of transitions of care, but are not one of these specific events.

We proposed that admissions to the eligible hospital or CAH can be calculated using one of two methods currently available under Stage 1 of meaningful use. The observation services method includes all patients admitted to the inpatient department (POS 21) either directly or through the emergency department and patients who initially present to the emergency department (POS 23) and receive observation services. Details on observation services can be found in the Medicare Benefit Policy Manual, Chapter 6, Section 20.6. Patients who receive observation services under both the outpatient department (POS 22) and emergency department (POS 23) should be included in the denominator under this method. The all emergency

department method includes all patients admitted to the inpatient department (POS 21) either directly or through the emergency department and all patients receiving services in the emergency department (POS 23).

Comment: Commenters expressed near universal support for the continuance of the two options in defining an admission to the emergency department.

Response: We continue to believe that not all information required by meaningful use may be relevant to all encounters in the emergency department and that this decision is best left to the hospital; therefore, we are finalizing this as proposed.

We proposed that inpatient bed days are the admission day and each of the following full 24-hour periods during which the patient is in the inpatient department (POS 21) of the hospital. For example, a patient admitted to the inpatient department at noon on June 5th and discharged at 2 p.m. on June 7th will be admitted for 2-patient days: the admission day (June 5th) and the 24 hour period from 12:00 a.m. on June 6th to 11:59 p.m. on June 6th.

We did not receive comments on this proposal. This denominator is not used by the proposed meaningful use objectives and measures nor the finalized objectives and measures.

As discussed later in this section, we are including the menu objective for hospitals of "Provide structured electronic lab results to ambulatory providers". The measure associated with the objective uses a denominator that was not included in our proposal. The denominator is the number of electronic lab orders received by the hospital from ambulatory providers. For this objective, we use the same description of "laboratory services" as for our Stage 2 CPOE objective: any service provided by a laboratory that could not be provided by a nonlaboratory. We also use the definition of "laboratory" at §493.2 as for the Stage 2 CPOE objective. Any order for a laboratory service will be considered a lab order. For the order to be considered

received electronically, it must be received by the hospital utilizing an electronic transmission method and not through methods such as physical electronic media, electronic fax, paper document or telephone call.

After consideration of public comments, we are finalizing the following denominators for EPs:

- Unique patients seen by the EP during the EHR reporting period (stratified by age or previous office visit);
- Number of orders (medication, labs, radiology);
- Office visits; and
- Transitions of care/referrals including at a minimum one of the following:

++ 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.

We are finalizing the following denominators for eligible hospitals and CAHs:

- Unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department during the EHR reporting period (stratified by age);
- Number of orders (medication, labs, radiology);
- Transitions of care including at a minimum one of the following:

++ When the hospital is the recipient of the 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; and

- Electronic lab orders received by the hospital from ambulatory providers.

(4) Discussion of the Relationship of Meaningful Use to CEHRT

We proposed to continue our policy of linking each meaningful use objective to certification criteria for CEHRT. As with Stage 1, EPs, eligible hospitals, and CAHs must use the capabilities and standards that are certified to meet the objectives and associated measures for Stage 2 of meaningful use. In meeting any objective of meaningful use, an EP, eligible hospital or CAH must use the capabilities and standards that are included in certification. We noted that in some instances, meaningful use objectives and measures require use that is not directly enabled by certified capabilities and/or standards. In these cases, the EP, eligible hospital and CAH is responsible for meeting the objectives and measures of meaningful use, but the way they do so is not constrained by the capabilities and standards of CEHRT. In the proposed rule we gave the following example: in e-Rx and public health reporting, CEHRT applies standards to the message being sent and enables certain capabilities for transmission in 2014; however, to actually engage in e-Rx or public health reporting many steps must be taken outside of these standards and capabilities such as contacting both parties and troubleshooting issues that may arise through the normal course of business.

Comment: We received many comments that expressed confusion of when the capabilities and standards included in certification must be used and when they do not.

Response: Nearly all of these comments were objective-specific, so we address them at the referenced objective. With each measure we include a universal statement on the applicability of the specific standards and capabilities included in the 2014 edition of

certification criteria for EHR technologies and, if applicable, specific allowances for that measure.

After consideration of the public comments received, we are finalizing these provisions as proposed.

(5) Discussion of the Relationship between a Stage 2 Meaningful Use Objective and its Associated Measure

We proposed to continue our Stage 1 policy that regardless of any actual or perceived gaps between the measure of an objective and full compliance with the objective (such as a measure threshold of less than 100 percent or a measure designed to account for circumstances where 100 percent compliance in not the intention of the objective), meeting the criteria of the measure means that the provider has met the objective for Stage 2.

We did not receive any comments and we are finalizing these provisions as proposed.

(6) Objectives and Their Associated Measures

(a) Objectives and Measures Carried Over (Modified or Unmodified) from Stage 1 Core Set to Stage 2 Core Set

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

In the proposed rule, we outlined the following benefits of CPOE. 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.

Consistent with the recommendations of the HIT Policy Committee, we proposed to expand the orders included in the objective to medication (which was included in Stage 1), laboratory, and radiology. We believe that the expansion to laboratory and radiology furthers the goals of the CPOE objective, that such orders are commonly included in CPOE roll outs and that inclusion of the entry of these orders using CPOE is a logical step in the progression of meaningful use. We note that this does not require the electronic transmission of the order.

We proposed to continue to define CPOE as the provider's use of computer assistance to directly enter medical orders (for example, medications, consultations with other providers, laboratory services, imaging studies, and other auxiliary services) from a computer or mobile device. The order is then documented or captured in a digital, structured, and computable format for use in improving safety and efficiency of the ordering process. We further proposed that the CPOE function of CEHRT must be used by the ordering provider or licensed healthcare professionals under his or her direction to create the first record of that order, or it would not count as CPOE. As this proposed objective limits the use of CPOE to the creation of the first record of the order (a more restrictive standard than in Stage 1), we invited public comment on whether the stipulation that the CPOE function be used only by licensed healthcare professionals remains necessary or if CPOE can be expanded to include non-licensed healthcare professionals such as scribes.

Comment: Commenters focused primarily on CPOE's value as the trigger for clinical decision support interventions. It was suggested the term be revised from computerized provider order entry to computerized order evaluation. This focus led to the suggestion by several commenters that as long as the ordering providers "signs" or otherwise authorizes the order before it is carried out this should count for CPOE. These commenters maintain that meaningful

use should not dictate any of the processes that lead up to this authorization including who enters the order into CEHRT nor what types of record of the order may exist prior to entry into CEHRT.

Response: We agree that CPOE as the trigger for CDS interventions is the primary value creating function of CPOE. However, we disagree that it is the only one. We believe automating aspects of and/or eliminating steps in the ordering process prior to final authorization of the order does reduce communication and other errors. Furthermore, it is our understanding from both commenters and our own experiences with CEHRT that many EHRs use the entry of the order as the trigger for CDS interventions and either display them again at authorization or do not display them at all at authorization. For these reasons, we continue to focus the definition and measurement of CPOE on when and by whom the order is entered into CEHRT and not on when it is authorized by the ordering provider in CEHRT.

Comment: Commenters stated that the authentication of verbal orders is already covered by the conditions of participation for hospitals at 42 CFR482.24(c)(1)(iii) which states that "[a]ll verbal orders must be authenticated based upon Federal and state law. If there is no state law that designates a specific timeframe for the authentication of verbal orders, verbal orders must be authenticated within 48 hours." Meaningful use should adopt this same standard.

Response: We are not adopting this standard for two reasons. First, as this is in an incentive program, we do not believe it is logical to base a requirement for meaningful use solely on a condition of participation. Hospitals already must comply with the conditions of participation, so we believe as an incentive program meaningful use should be incentivizing behavior beyond the conditions of participation. Second, as discussed later, we are not limiting the communication of orders prior to CPOE to verbal orders so there is not a direct corollary

between this condition of participation and our description of CPOE. Section 482.23(c)(2) also speaks to verbal orders. First, it states, "If verbal orders are used, they are to be used infrequently. Second, it states, "When verbal orders are used, they must only be accepted by persons who are authorized to do so by hospital policy and procedures consistent with Federal and state law." We discuss who may enter the order later in comment and response, but reiterate our position that meaningful use should incentivize behavior that benefits patients beyond that required by the conditions of participation.

Comment: Commenters objected to our proposal to change our policy regarding CPOE from "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" to "the order created using the EHR must be the first record of that order or it would not count as CPOE". The commenters stressed that if they used a process that created a record of the order that was not part of the patient's medical record, then the proposed policy requiring this record not be retained is not advisable. The commenters asserted that even if it was not part of the patient's medical record the initial record of the order could be used for quality control purposes.

Response: Our proposed policy change was intended as an evolution from the Stage 1 requirements for CPOE. However, after reviewing the comments received, we agree that requiring an electronic or written order that is not created using the CPOE function of CEHRT to not be retained in order for it to count as CPOE could have unforeseen and possibly detrimental consequences for quality control. We continue to believe that our original proposal would have increased CPOE's ability to improve safety and efficiency and encourage all providers to streamline the ordering process to minimize the number of steps involved. However, we do not have sufficient information to determine whether the gains of the proposal are greater than or

less than the potential cost of not retaining written or electronic orders issued before the use of the CPOE function. Therefore, we are not finalizing the proposed revised description of when the CPOE function must be utilized during the ordering process and instead finalize our existing Stage 1 description 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. Based on the questions we have received on CPOE to date, the limiting criterion is the first time the order becomes part of the patient's medical record rather than the limitation of before any action can be taken on the order. The provider must make the determination as to what constitutes the patient's medical record and what does not based on their existing policies and applicable state and Federal law. Our only requirements in this regard are that the determination be made by the provider prior to the start of the EHR reporting period and be uniformly applied.

Comment: We have received many comments on who can enter the order into CEHRT for it to count as CPOE. Four possibilities received comment support. First, only the ordering provider be able to enter the order into CEHRT. Second, any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines can enter the order into CEHRT. This is the current policy which was proposed to continue. Third, an expansion to any licensed, certified or appropriately credentialed healthcare professional (some commenters replaced medical assistant with healthcare professional) who can enter orders into the medical record per state, local and professional guidelines. Fourth, an expansion to allow anyone, including those commonly referred to as scribes, enter the orders into the medical record per state, local and professional guidelines. We also note that there was some confusion among commenters as to our current limitation and proposal of any licensed healthcare professional using CPOE to create the first entry of the order into the patient's medical record as we received

many comments suggesting that nurses should be able to enter the orders. We clarify that nurses who are licensed and can enter orders into the medical record per state, local and professional guidelines may enter the order into CEHRT and have it count as CPOE.

Response: As we did not revise our description of when in the ordering process the CPOE function must be used, we are inclined to not revise our description of who may enter it into CEHRT. However, we are particularly concerned with CPOE usage by EPs in this regard. Many EPs practice without the assistance of other licensed healthcare professionals. These EPs in their comments urged the expansion indicated in the third possibility of credentialed healthcare professionals/medical assistants. We believe that this expansion is warranted and protects the concept that the CDS interventions will be presented to someone with medical knowledge as opposed to a layperson. The concept of credentialed healthcare professionals is over broad and could include an untold number of people with varying qualifications. Therefore, we finalize the more limited description of including credentialed medical assistants. The credentialing would have to be obtained from an organization other than the employing organization. Our responses to earlier comments factored into this decision as well. Based on the public comments received, questions submitted by the public on Stage 1 and demonstrations of CEHRT we have participated in, 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 could be required to enter the order correctly, evaluate CDS 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 CDS intervention or bypass the intervention. We do not believe that a layperson is qualified to do this, and as there is no

licensing or credentialing of scribes, there is no guarantee of their qualifications.

Comment: We received comments on a particular category of orders referred to as "protocol" or "standing" orders. The defining characteristic of these orders is that they are not created due to a specific clinical determination by the ordering provider for a given patient, but rather are pre-determined for patients with a given set of characteristics (for example, administer medication X and order lab Y for all patients undergoing a certain procedure or refills for given medication). Commenters maintain that these orders require special treatment in regards to when they are entered into CEHRT and who enters them. Commenters indicate that administrative staff should be allowed to enter them, but not override any CDS interventions that may appear.

Response: 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. We therefore 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. We foresee two circumstances where a provider would not want to exclude this category of orders. The first is that they disagree that these type of orders warrant different considerations and therefore enter them according to our description of CPOE. The second is providers who are unable to separate them from other orders in their calculation of the denominator and numerator.

Comment: Commenters mostly support the expansion to the laboratory and radiology orders. Three concerns were raised. First, commenters believed that as laboratory and radiology orders were new additions they should have a lower threshold than medication orders. Second, commenters desired a more descriptive definition on what constitutes a laboratory and

particularly a radiology order. Third, commenters suggested that laboratory and radiology orders should be delayed for EPs until more laboratory and radiology providers could receive the order electronically.

Response: We discuss the measure separately later in this section and address the comments on the threshold there. We describe laboratory services as any service provided by a laboratory that could not be provided by a non-laboratory. Laboratory is defined at 42 CFR 493.2 as: "a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories." We describe radiologic services as any imaging service that uses electronic product radiation. Electronic product radiation is defined at 21 CFR 1000.3 as: "any ionizing or nonionizing electromagnetic or particulate radiation, or [a]ny sonic, infrasonic, or ultrasonic wave that is emitted from an electronic product as the result of the operation of an electronic circuit in such product." If the provider desires to include other types of imaging services that do not rely on electronic product radiation they may do so as long as the policy is consistent across all patients and for the entire EHR reporting period. Finally, as we discuss in the next comment and response, electronic transmission of the order is not a requirement for CPOE.

Comment: Some commenters stated that while CPOE is a commonly understood

function in the hospital setting, in the ambulatory setting its use is more ambiguous. For medication orders, the difference between CPOE for the medication and e-prescribing the medication is more subtle. The expansion to laboratory and radiology further complicates this in the ambulatory setting as most laboratory and radiology orders are sent to a third party which may or may not be able to receive such orders electronically.

Response: While we agree that the concept of CPOE is a more definitive action in the ordering process in the hospital setting, we believe that it is still integral to the ambulatory setting and serves the same purposes in both settings as a trigger for CDS interventions and as a way to increase the efficiency and safety of the ordering process. CPOE is the entry of the order into the patient's EHR that uses a specific function of CEHRT. It is not how that order is filled or otherwise carried out. For medications, on the ambulatory side CPOE feeds into e-prescribing, and on the hospital side electronic medication administration record may be used, but neither of these are requirements for CPOE. For example, a medication could be entered into CEHRT using CPOE and then be electronically transmitted to a pharmacy. This would be both CPOE and e-prescribing. However, a medication could be entered into CEHRT using CPOE and then a printed copy of the prescription could be generated by CEHRT and given to the patient. This would still be CPOE, but not e-prescribing. Similarly, whether the ordering of laboratory or radiology services using CPOE in fact results in the order being transmitted electronically to the laboratory or radiology provider does not dictate whether CPOE was met. 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.

After consideration of the public comments received, we are modifying this objective for EPs as §495.6(j)(1)(i) and for eligible hospitals and CAHs at §495.6(l)(1)(i) to use the same

language as Stage 1 (with the addition of laboratory and radiology orders), as we did not finalize our proposed changes to when the order must be entered: "Use computerized provider order entry (CPOE) for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local, and professional guidelines."

Proposed Measure: More than 60 percent of medication, laboratory, and 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.

In Stage 1 of meaningful use, we adopted a measure of 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. In the Stage 1 final rule, we adopted a threshold of 60 percent for this measure for Stage 2.

In our proposed rule, we discussed how our experience with Stage 1 has shown that the denominator of all orders created by the EP or in the hospital would not be unduly burdensome for providers and creates a better measurement for CPOE usage, particularly for EPs who infrequently order medications. We explained that the denominator recommended by the HITPC of "patients with at least one type of order" is a proxy measure for the number of orders issued. We asked for comments on whether the barriers to collecting information for our proposed denominator would be greater in a hospital or ambulatory setting. We also requested that commenters suggest different denominators or measures and encouraged any commenter proposing an alternative denominator to discuss whether the proposed threshold or an alternative

threshold should be used for this measure and to include any exclusions they believe are necessary based on their alternative denominator.

We also stated in our proposed rule that we believed providers do not roll out CPOE for only one order type, but rather for a package of order types. The HITPC had recommended a percentage threshold for laboratory orders, but a yes/no attestation of one order for radiology (not for both laboratory and radiology, as we mistakenly stated in the proposed rule). We also expressed concerns in the 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 proposed a percentage threshold for all three types of orders: medication, laboratory, and radiology.

Comment: Commenters both supported and opposed the new denominator for CPOE. Those supporting the proposed denominator did so for its simplicity and greater accuracy for measuring actual CPOE usage. Commenters that opposed the proposed denominator did so for one of two reasons. Either they were concerned with the burden associated with counting paper or other orders that are never entered into CEHRT or they were concerned that the proposed denominator requires much higher performance of CPOE usage. For example, in the hospital setting an inpatient might have 20 orders during a stay. Under the proposed denominator, 13 of those orders would have to be entered using CPOE, while under the current denominator only one order would have to be entered using CPOE. A few commenters opposed the new denominator for both reasons.

Response: In regards to the perceived higher performance of CPOE usage required by switching from the Stage 1 denominator to the Stage 2 proposed denominator, the sole purpose of the proxy measure for CPOE used in Stage 1 was to alleviate the measurement burden, not

create a lower level of CPOE usage than implied by the percentage threshold. Therefore, as a more accurate measure is possible, it should reflect the percentage of CPOE use indicated by the established thresholds. In regards to the burden of the measure, we had stated in our proposed rule that the reason we believed we could move to the proposed denominator was feedback from many providers indicating that they could in fact measure the proposed denominator. In addition due to problems associated with the proxy for EPs who have comprehensive medication lists for their patients, but were not the ordering provider for many of those medications some EPs were having to use an alternative measure issued through guidance (https://questions.cms.gov/faq.php?id=5005&faqId=3257) that allowed them to only include patients with medications the EP had ordered. We assume in determining the measures of meaningful use that the patient's medical record conforms to existing Federal and state laws, which we believe would generally require that all orders issued by a provider for a patient become part of the patient's medical record (for example, 42 CFR 482.24(c)(2)(vi)). Therefore, the concept that some orders do not become part of the CEHRT means that the provider is maintaining patient medical records both electronically in CEHRT and outside of CEHRT using either paper charts or another electronic system. When a provider starts their first Stage 2 EHR reporting period, they will have been using CEHRT for at least 15 months. In our proposed rule, we have stated our belief that most providers would have fully transitioned patients' medical records to CEHRT by the time they start Stage 2. However, as discussed previously, we are leaving open the option for limiting certain measures to only those records maintained in CEHRT. As this is one of those measures, there is no reason to change the measure to accommodate patient records not maintained in CEHRT as provider can choose to not include records not maintained in CEHRT in the denominator. Thus, we finalize the denominator as

proposed.

Comment: Commenters requested clarification on whether the measure puts all medication, laboratory and radiology orders in the same denominator and therefore it was potentially possible to meet the 60 percent threshold without CPOE being used 60 percent of the time for one or more order type, up to and including the possibility that CPOE may never be used for one or more order type. Many commenters suggested that if all orders were in the same denominator this was not a good measure of the expansion of CPOE to laboratory and radiology and that the orders should be broken out separately. Only a few commenters suggested that the denominator should be the aggregate of all three types of orders.

Response: We agree with the commenters that an aggregate denominator does not best reflect our expansion to laboratory and radiology and therefore create a separate denominator for each order type. This is consistent with the suggestions of the majority of commenters and most accurately reflects the use of CPOE. While CPOE does not require the electronic transmission of the order, many CEHRT will be linked to the technology systems that manage medication, as well as those for laboratories and radiology departments. These systems may be different thereby presenting unique challenges for each order type that could result in differing roll out times and utilization rates. In addition, a provider with a high number of one order type compared to others may even be able to reach a combined threshold without implementing CPOE for one or more of the order types. This would negate the benefits of expanding CPOE to these order types. We have 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: We received several suggestions on the percentage threshold for medication orders to reduce it below 60 percent. The suggestions ranged from 50 percent to 30 percent.

Two reasons were given. First, that 60 percent was simply too high. Second, that the proposed denominator made 30 percent a much higher bar than it was when the proxy was in place and the threshold should not be raised until we have data based on the proposed denominator.

Response: As we stated previously, the purpose of the proxy denominator was not to create a lower bar than CPOE usage at 30 percent, but to address measurement burden. While we agree that the information generated using the proxy denominator for CPOE is different from the finalized denominator, this is only true in a limited set of circumstances, especially for EPs. For it to be different at all, a provider must have ordered more than one medication for a patient during the EHR reporting period. Furthermore, this is most likely limited to providers who see a patient on more than one occasion. We believe it would be highly unlikely that a provider would use CPOE to order one medication and then not use it to order another during the same encounter or admission. For these reasons, we believe that while not a perfect correlation the information gained through Stage 1 attestations. The Stage 1 attestations provide a reasonable basis on which to set the Stage 2 thresholds. We believe it is reasonable to expect the actual use of CPOE to increase from 30 percent in Stage 1 to 60 percent in Stage 2 and consist with the expectations that were finalized in the Stage 1 regulations. Therefore, for medication orders, we finalize the threshold at 60 percent.

Comment: Some commenters maintain that the addition of laboratory and radiology orders to CPOE is a new function and should not be introduced at the same threshold.

Response: Based on the same logic supporting the 60 percent threshold for medication orders (that is, 30 percent is reasonable when CPOE is first introduced for an order type, and 60 percent in the next stage following CPOE introduction), we agree with the commenters that the thresholds should be different. We finalize a threshold of 30 percent for each laboratory and

radiology orders.

After consideration of the public comments received, we are splitting the proposed measure into three measures and changing the threshold for radiology and laboratory orders at §495.6(j)(1)(ii) for EPs and §495.6(l)(1)(ii) for eligible hospitals and CAHs.

- 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.

- More than 30 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 CPOE.

- More than 30 percent 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.

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 CEHRT at 45 CFR 170.314(a)(1).

As discussed in the comment and response section, an EP, eligible hospital or CAH can limit the denominators to only include medication, laboratory and radiology orders for patients whose records are maintained using CEHRT.

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

- 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.

- 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.

- 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.

An EP through a combination of meeting the thresholds and/or exclusions must satisfy all three measures for this objective.

A hospital must meet the thresholds for all three measures.

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

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

We proposed to continue to define prescription as the authorization by an EP to dispense a drug that will not be dispensed without such authorization. This includes authorization for refills of previously authorized drugs. We proposed to define a permissible prescription as all drugs meeting the definition of prescription not listed as a controlled substance in Schedules II – V http://www.deadiversion.usdoj.gov/schedules/index.html. Although the Drug Enforcement Administration's (DEA) interim final rule on electronic prescriptions for controlled substances (75 FR 16236) removed the Federal prohibition to electronic prescribing of controlled substances, some challenges remain including more restrictive state law and widespread

availability of products both for providers and pharmacies that include the functionalities required by the DEA's regulations. We asked for public comments as to whether over the counter (OTC) medicines will be routinely electronically prescribed and proposed to continue to exclude them from the definition of a prescription.

In our proposed rule we discussed several different workflow scenarios are possible when an EP prescribes a drug for a patient. First, the EP could prescribe the drug and provide it to the patient at the same time, and sometimes the EP might also provide a prescription for doses beyond those provided concurrently. Second, the EP could prescribe the drug, transmit it to a pharmacy within the same organization, and the patient would obtain the drug from that pharmacy. Third, the EP could prescribe the drug, transmit it to a pharmacy independent of the EP's organization, and the patient would obtain the drug from that pharmacy. Although each of these scenarios would result in the generation of a prescription, the transmission of the prescription would vary. In the first situation, there is no transmission. In the second situation, the transmission may be the viewing of the generation of the prescription by another person using the same CEHRT as the EP, or it could be the transmission of the prescription from the Certified EHR Technology used by the EP to another system used by the same organization in the pharmacy. In the third situation, the EP's Certified EHR Technology transmits the prescription outside of their organization either through a third party or directly to the external pharmacy. These differences in transmissions create differences in the need for standards. We proposed that only the third situation would require standards to ensure that the transmission meets the goals of electronic prescribing. In the first two scenarios one organization has control over the whole process. In the third scenario, the process is divided between organizations. In that situation, standards can ensure that despite the lack of control the whole process functions

reliably. To have successfully e-prescribed, we proposed that the EP needs to use CEHRT as the sole means of creating the prescription, and when transmitting to an external pharmacy that is independent of the EP's organization such transmission must use standards adopted for EHR technology certification.

We did not receive any public comments on this objective, therefore, we are finalizing this objective at §495.6(j)(2)(i) as proposed.

Proposed EP Measure: More than 65 percent of all permissible prescriptions written by the EP are compared to at least one drug formulary and transmitted electronically using CEHRT.

We proposed a new exclusion for Stage 2 that would allow EPs to exclude this objective if no pharmacies within 25 miles of an EP's practice location at the start of his/her EHR reporting period accept electronic prescriptions. This is 25 miles in any straight line from the practice location independent of the travel route from the practice location to the pharmacy. We stated that EP's practicing at multiple locations would be eligible for the exclusion if any of their practice locations that are equipped with CEHRT meet this criteria. An EP would not be eligible for this exclusion if he or she is part of an organization that owns or operates its own pharmacy within the 25-mile radius regardless of whether that pharmacy can accept electronic prescriptions from EPs outside of the organization. We also proposed an exclusion for EPs who write fewer than 100 prescriptions during the EHR reporting period.

Comment: Most commenters agreed with the exclusion of controlled substances in the denominator. They were concerned about industry readiness as well as potentially conflicting state regulations. Other commenters expressed concerns that specialists (that is, surgeons, psychiatrists) who write prescriptions that are not permissible (that is, controlled substances) would not be able to meet the measure.

Response: We agree with the commenters and will continue to exclude controlled substances from the denominator. However, we are also adding an alternative denominator to provide additional flexibility for EPs who are able to electronically prescribe controlled substances and want to count these prescriptions in the measure.

Comment: Most commenters did not support the inclusion of OTC medicines in this objective, as OTC medicines are not usually intended for the pharmacy to fill. Those commenters who did support it noted that OTC medicines are prescribed often times because it allows patients to use their health care spending accounts to pay for the cost.

Response: After consideration of public comments, we agree with the majority of commenters in that OTC medicines should not be included as a part of this objective. While some OTC medicines are ordered by the EP, the low prevalence of such occurrences means the costs of including them in both measurement and actual e-prescribing outweighs any benefit of inclusion.

Comment: Most commenters thought the proposed threshold was too high or just right. Those who thought it was too high expressed concerns about the abilities of mail-order pharmacies to accept electronic subscriptions. Some commenters suggested lowering the threshold to 50 percent. Other commenters expressed concerns that patients may prefer a paper prescription and suggested excluding those patients from the denominator. The commenters who thought the proposed threshold was "just right" noted that most EPs who successfully demonstrated meaningful use for Stage 1 far exceeded the Stage 1 threshold of 40 percent.

Response: Preliminary analysis of Stage 1 meaningful use attestation data shows that those EPs who successfully attested for this measure exceeded the 40 percent threshold – many reporting thresholds of 80-100 percent. However, the Surescripts Q4 2011 Report suggests that

close to 40 percent of physicians who began e-prescribing in 2008 meet the 65 percent threshold. This report only represents the earliest adopters. Based on public comments, we believe the 65 percent threshold we proposed may be unattainable for many EPs and question whether any real difference in provider behavior is achieved with a 65 percent threshold versus a 50 percent threshold. This lower threshold also accounts for patients who may prefer a paper prescription, rather than having their prescription sent to a pharmacy electronically. After consideration of public comments, we are finalizing the threshold for this measure at 50 percent.

Comment: Most commenters supported comparing prescriptions written by the EP to a drug formulary, but not without concern. Many noted that drug formularies are not always readily available, are linked to specific payers, or may not otherwise be readily available.

Response: After review of the public comments, we realize this measure needs to be further clarified. We recognize that not every patient will have a formulary that is relevant for him or her. Therefore, we require not that the CEHRT check each prescription against a formulary relevant for a given patient, but rather that the CEHRT check each prescription for the existence of a relevant formulary. If a relevant formulary is available, then the information can be provided. We believe that this initial check is essentially an on or off function for the CEHRT and should not add to the measurement burden. Therefore, with this clarification of the check we are referring to, we are finalizing the drug formulary check as a component of this measure. We look forward to the day when a relevant formulary is available for every patient. We also modified the measure to use the word "query" instead of "compare" because it better explains the process in which the EP uses the CEHRT to consult the information provided in the formulary.

Comment: Many commenters expressed concerns about patients who request paper copies of their prescriptions and how they would be accounted for in this measure. Commenters

also expressed concerns about patients who prefer to use mail-order pharmacies that do not accept eRx.

Response: We have accounted for patient preferences by lowering the threshold for this measure from 65 percent to 50 percent.

Comment: Many commenters expressed concerns that the word "permissible" was omitted from the proposed exclusion for EPs who write fewer than 100 prescriptions during the EHR reporting period.

Response: We agree with commenters in that we inadvertently omitted the word "permissible" from this exclusion. After consideration of public comments, we are finalizing this exclusion as "EPs who write fewer than 100 permissible prescriptions during the EHR reporting period."

Comment: Many commenters supported this exclusion but expressed concerns about how it was proposed and would be implemented. Some commenters suggested reducing the radius to 10 miles or less in urban areas and leaving it at 25 miles in rural areas. Other commenters suggested revising this exclusion for EPs where less than 20 percent of pharmacies e-prescribe within a 25-mile radius of their office. Other commenters expressed concerns that there may only be a limited number of pharmacies in their geographic area that can accept prescriptions electronically. Yet others suggested including a grace period for EPs in areas where no pharmacies e-prescribe at the beginning of their EHR reporting period, but later begin accepting eRx.

Response: We appreciate the commenters' concerns about this exclusion. We agree with commenters in that a 25-mile radius may be too large. We believe the 10-mile radius is more reasonable as it takes the country's geographic diversity (urban, suburban, rural areas) into

account. We are therefore finalizing that if no pharmacies within a 10-mile radius of an EP's practice location at the start of the EHR reporting period accept electronic prescriptions, the EP would qualify for this exclusion, unless the EP is part of an organization that owns or operates a pharmacy within the 10-mile radius. As for patient preference, we agree with commenters that not all patients will want to go to a particular pharmacy just because they accept electronic prescriptions. However, we believe we accounted for patient preference by lowering the threshold for the measure to 50 percent.

After consideration of public comments, we are revising the measure at §495.6(j)(2)(ii) to read: "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 further specify that in order to meet this objective and measure, an EP must use the capabilities and standards of CEHRT at 45 CFR 170.314(b)(3) and 45 CFR 170.314(a)(10).

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: (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/her EHR reporting period.

Consolidated Objective: Maintain an up-to-date problem list of current and active diagnoses.

Consolidated Objective: Maintain active medication list.

Consolidated Objective: Maintain active medication allergy list.

For Stage 2, we proposed to consolidate the objectives for maintaining an up-to-date problem list, active medication list, and active medication allergy list with the Stage 2 objective for providing a summary of care for each transition of care or referral. We stated that we continue to believe that an up-to-date problem list, active medication list, and active medication allergy list are important elements to be maintained in CEHRT. However, the continued demonstration of their meaningful use in Stage 2 would be required by other objectives focused on the transitioning of care of patients removing the necessity of measuring them separately. Providing this information is critical to continuity of care, so we proposed to add these as required fields in the summary of care for the following Stage 2 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 should provide summary care record for each transition of care or referral." We stated that EPs and hospitals would have to ensure the accuracy of these fields when providing the summary of care, which we believe would ensure a high level of compliance in maintaining an up-to-date problem list, active medication list, and active medication allergy list for patients. The required standards for these fields are discussed in the ONC standards and certification final rule published elsewhere in this issue of the **Federal**

Register.

Comment: Overall, we received very few comments on our proposal to consolidate the up-to-date problem list, active medication list, and active medication allergy list objectives. Some commenters opposed our proposal as they believe it would detract from the importance of these items. However, the vast majority of those who commented on this proposal supported the consolidation of these objectives.

Response: After consideration of public comments, we are finalizing the consolidation of these objectives as proposed for the reasons discussed in the proposed rule. The objectives of maintaining an up-to-date problem list, active medication list, and active medication allergy list will be consolidated with the Stage 2 objective for providing a summary of care for each transition of care or referral.

Proposed EP Objective: Record the following demographics: preferred language, gender, race and ethnicity, and date of birth.

Proposed Eligible Hospital/CAH Objective. Record the following demographics: preferred language, gender, race and ethnicity, date of birth, and date and preliminary cause of death in the event of mortality in the eligible hospital or CAH.

We proposed to continue the policy that EPs, eligible hospitals and CAHs collect baseline demographic data for all unique patients in the EHR using OMB standards for race and ethnicity. The proposed rule outlines some of the numerous benefits from recording basic patient demographic information in the EHR, including improved patient-centered care and management of the health of populations. In response to multiple comments from the Stage 1 final rule regarding the preliminary cause of death data element required for eligible hospitals and CAHs, we clarified the following; this element is the preliminary cause of death recorded by the hospital

and is not required to be amended when additional information becomes available, there is no specified timeframe for recording this element, and we invited additional public comment regarding these clarifications in the proposed rule. We also asked for public comment on the burden and ability to include additional measures of disability status, gender identity and/or sexual orientation.

Comment: We received many comments suggesting CMS differentiate between the terms sex and gender. One commenter provided the definition that the term sex is used in recording vital health statistics that describe the physiological characteristics at time of birth. The term gender incorporates behaviors, roles, and expectations corresponding to an individual's sex and is generally self reported.

Response: We appreciate this clarification and will incorporate the change in terminology for the final rule using the term sex instead of gender in EP, eligible hospital and CAH objectives for recording demographics. This change in terminology aligns with vital statistic reporting and the HHS final demographic data collection standards published October 31, 2011.

Comment: Several commenters indicated that the collection of race and ethnicity demographic information can be sensitive and patients may be unwilling or uncomfortable reporting this information to the individual collecting demographic data. Other comments supported CMS clarification in the Stage 1 final rule that providers can be allowed to account for patients who decline to provide elements of demographic information. Additional comments suggested that a single system parameter be developed to identify states that prohibit data reporting should be available to the EHR.

Response: If a patient declines to provide information of ethnicity or race or if capturing

a patient's ethnicity or race is prohibited by state law, this should be duly noted as structured data in the EHR and this would still count as an entry for the purpose of meeting this measure. A study by the Agency for Healthcare Research and Quality (AHRQ) states that current state prohibitions on the collection of ethnicity and race apply to health plans collection of data at the time of enrollment. Title VI of the Civil Rights Act of 1964 permits health care organizations to collect race, ethnicity, and preferred language patient data for the purpose of quality improvement.

Comment: Several commenters suggested that CMS use the same definition for race and ethnicity as the Centers for Disease Control and Prevention (CDC) and the United States Census Bureau. Other commenters were concerned about the need to collect data granular enough to identify differences between subpopulations and aligned across government programs.

Response: We recognize that the CDC has developed codes that allow for the mapping of more detailed race and ethnicity categories such as those maintained by the U.S. Bureau of the Census to the less detailed OMB standard. We appreciate that providers may need to collect more granular demographic data to manage their patient populations. For purposes of achieving Stage 2 of meaningful use, we will continue to rely on the OMB standard as a minimum standard for the collection of race and ethnicity data. EPs, eligible hospitals, and CAHs who wish to collect more granular level data on patient race and ethnicity may do so as long as they can map the data to 1 of the 5 races included in the existing OMB standards. The standards associated with the meaningful use objectives and measures are discussed further in the ONC standards and certification criteria final rule and we refer readers to that regulation published elsewhere in this issue of the **Federal Register**.

Comment: Many commenters agreed with the need to incorporate disability status in

EHR technology. However, it was also clear that several of these commenters varied in their definition of disability with interpretations that ranged from physical, mental, occupational, and economic disability status. Commenters also differed regarding the most appropriate location for the capture and storage of disability status data elements within the EHR. Suggestions for where to incorporate disability status data varied (for example; from the demographic objective, to physician notes, and/or the problem list component of the summary of care document). Another commenter suggested that the demographic objective should be limited to collecting data with static values and the active problem list, electronic notes and/or care summary documents that are continually updated would be more appropriate for recording changes in patient disability status.

Response: We wish to clarify that the term disability status used in the proposed rule was meant to be all-encompassing by incorporating both the concepts of physical and cognitive disabilities as well as the concept of functional status limitations that impact an individual's capability to perform activities in different environments. This latter concept incorporates metrics useful for planning and coordination across care settings. Commenters varied in their responses regarding the level of consensus on measurement standards for each of these health status measures. Since publishing the proposed rule we have learned that significant progress has been made regarding the capture of functional status into the consolidated clinical document architecture (C-CDA) standard for summary of care records. The C-CDA Implementation Guide provides the following examples that may be incorporated under functional status; assessments of a patient's language, vision, hearing, activities of daily living, behavior, general function, mobility, self-care status, physical state and cognitive function.[1] The C-CDA standards support

[1]Implementation Guide for CDA Release 2.0 (US REALM) July 2012, © 2012 Health Level Seven, Inc. Ann Arbor, MI

the exchange of clinical documents between those involved in the care of a patient and allow for the re-use of clinical data for clinical care giving, public health reporting, quality monitoring, patient safety and clinical trials. This inclusion is addressed more fully under the discussion of the transition of care objective in this final rule.

We strongly support the adoption, implementation and meaningful use of CEHRT for all individuals and the reduction of barriers for persons with disabilities. In finalizing this rule, we also considered the operational challenges that could result from the lack of consensus noted by many commenters to incorporate a physical disability standard measure in the demographic section of CEHRT at this time. As a result, we will not require the collection of disability status data under the demographic objective for Stage 2 of meaningful use. However, we suggest that providers examine the questions developed by the HHS as required by section 4302 of the Affordable Care Act. The questions resulted from an interagency process and are closely aligned to the Census Bureau's American Community Survey and the International Classification of Disability. These questions may be found on the HHS website at http://minorityhealth.hhs.gov/templates/content.aspx?ID=9232#1. The answers to these questions could be incorporated as functional status or other data elements in the C-CDA summary of care document mentioned above and discussed more fully in the transition of care objective later in this rule.

We will continue to work with ONC, other federal agencies and seek the advice of the HIT Policy Committee to explore further how disability status could be included in meaningful use Stage 3.

Comments: Many commenters supported the proposed inclusion of recording gender identity and/or sexual orientation as part of the demographic objective. Other commenters

suggested that the collection of this information is extremely sensitive and could be considered offensive for some patients especially when collected by administrative staff. Still other commenters did not see the clinical significance of collecting and recording this information in the demographic section of the EHR. Others commenters were against recording gender identity and/or sexual orientation because they did not consider this would provide additional clinical benefit. Still others suggested that the reporting of gender identity or sexual orientation be optional and up to individual clinician judgment whether or not it is appropriate to collect this information.

Similar to the comments for the proposed inclusion of disability status, commenters noted both the data collection challenges and data reporting burden. Many commenters were opposed to the mandatory collection of all three additional measures for Stage 2 of meaningful use and suggested that reporting could be optional.

Response: Considering the lack of consensus for the definition of the concept of gender identity and/or sexual orientation as well as for a standard measure of the concept and where it would be most appropriate to store the data within the EHR, we will await further development of a consensus for the goal and standard of measurement for gender identity and/or sexual orientation. Additionally, we note that many commenters raised concerns as to whether such data collection is necessary for all EPs, eligible hospital, and CAH regardless of specialty.

Comments: Several additional measures were suggested under the demographic objective including; measuring the level of access to and use of the internet, measuring computer literacy, and measuring standardized occupation using established industry codes.

Response: We appreciate the numerous comments suggesting additional demographic information that will allow providers to improve the quality of individual patient centered care as

well as population health. We may consider these suggestions further in the development of Stage 3 of meaningful use.

Comment: A minority of commenters recommended removing the preliminary cause of death element altogether from the eligible hospital/CAH objective. Others suggested that the eligible hospital /CAH measure for preliminary cause of death be modified to simply capture whether or not the patient had a cause of death recorded, regardless of when that information was entered into the EHR, because the preliminary cause of death may often be inaccurate since by law the coroner or medical examiner makes the final determination for the patient's death certificate.

Response: We appreciate the suggestion for measure simplification. However, for this measure we want to respect the existing hospital workflow where a clinician evaluates the patient to pronounce the death. This preliminary cause of death is documented by the clinician in the patient's chart. We recognize that these workflows may change as EHR technology develops and becomes more widely adopted and the exchange of health information is able to link to vital statistic reporting. However, for the time being the measure of preliminary cause of death under the demographic objective will remain unchanged.

After consideration of the public comments received, we are modifying the meaningful use objective at §495.6(j) (3) (i) of our regulations as follows: EPs "Record all of the following demographics: preferred language, sex, race, ethnicity, and date of birth."

After consideration of the public comments received, we are modifying the meaningful use objective at §495.6(l)(2)(i) of our regulations as follows: Eligible hospitals and CAHs "Record all of the following demographics: Preferred language, sex, race, ethnicity, date of birth, date and preliminary cause of death in the event of mortality in the eligible hospital or

CAH."

Proposed Measure: More than 80 percent of all unique patients 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 demographics recorded as structured data.

Comment: Most commenters were supportive of the increased threshold for this measure.

Response: Our analysis of the meaningful use data for Stage 1 found that over 90 percent of EPs, eligible hospitals and CAHs were able to successfully report the demographic measure. Therefore, based on comments and actual performance data we do not foresee a burden in increasing the measure threshold from more than 50 percent in Stage 1 to greater than 80 percent in Stage 2.

After consideration of public comments, we are finalizing this measure for EPs at §495.6(j)(3)(ii) and for eligible hospitals and CAHs at §495.6(l)(2)(ii) as proposed.

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 CEHRT at 45 CFR 170.314(a)(3).

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

● Denominator: Number of unique patients seen by the EP or admitted to 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 have all the elements of demographics (or a specific notation if the patient declined to provide one or more elements or if recording an element is contrary to state law) recorded as structured data.

● Threshold: The resulting percentage must be more than 80 percent in order for an EP, eligible hospital or CAH to meet this measure.

If a patient declines to provide one or more demographic elements this can be noted in the CEHRT and the EP or hospital may still count the patient in the numerator for this measure. The required elements and standards for recording demographics and noting omissions because of state law restrictions or patients declining to provide information will be discussed in the ONC standards and certification rule, published elsewhere in this issue of the **Federal Register**.

Proposed Objective: Record and chart changes in the following vital signs: height/length and weight (no age limit); blood pressure (ages 3 and over); calculate and display body mass index (BMI); and plot and display growth charts for patients 0-20 years, including BMI.

We proposed to continue our policy objective from Stage 1 to collect and record basic vital sign data for patients across health care settings. In the proposed rule, we outlined the benefits of documenting basic vital signs including that the data provides important clinical information on both the patient's current condition as well as the ability to track changes in patient status over time. For Stage 2, we proposed to remove the age restrictions on recording height/length and weight, and also proposed to remove the age restrictions on calculating and displaying BMI and growth charts. In addition, we proposed to modify the Stage 1 blood pressure guideline to align with the American Academy of Pediatrics guideline recommendations to measure blood pressure for children 3 years of age and older. We also proposed to continue our exclusions policy from Stage 1 (with modifications, as discussed below) for EPs who believe that recording and charting vital signs is outside the scope of their practice.

Comment: Several commenters questioned why all providers need to collect vital sign data when this information should be available from a robust health information exchange across providers.

Response: We will continue the Stage 1 meaningful use policy that any method of obtaining height, weight and blood pressure is acceptable for the purpose of this objective as long as the information is recorded as structured data in the CEHRT. As stated in the proposed rule, the vital sign information can be entered into the patient's medical record in a number of ways including: direct entry by the EP, eligible hospital, or CAH; entry by a designated individual from the EP, eligible hospital, or CAH's staff; data transfer from another provider electronically, through an HIE or through other methods; or data entered directly by the patient through a portal or other means. Some of these methods are more accurate than others, and it is up to the EP or eligible hospital to determine the level of accuracy needed to care for their patient and how best to obtain this information. We also look forward to the time when a more robust health information exchange network will allow providers to share relevant data across settings and/or alert providers when additional data should be obtained.

Comment: We received comments requesting that CMS include a statement clarifying which specialties would be included or excluded from this objective.

Response: We appreciate commenter's efforts to clarify this objective. However, we will continue our more general policy from Stage 1 (with modifications, as explained later) of allowing EPs to exclude this objective if they believe recording and charting changes in vital signs is not relevant to their scope of practice. We cannot define the scope of practice and/or interventions necessary for each individual patient and will continue to rely on provider determinations based on individual patient circumstances. Consider a hypothetical example of

an elderly patient with multiple chronic conditions that includes depression. When the patient is seen by his behavioral healthcare provider to manage his depression, it is up to that provider to determine whether it would be medically necessary to record and chart the patient's weight in order to manage the patient's care.

After consideration of public comments, we are finalizing this objective for EPs at §495.6(j)(4)(i) and for eligible hospitals and CAHs at §495.6(l)(3)(i) as proposed.

Proposed Measure: More than 80 percent of all unique patients 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 blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data.

We proposed to split the exclusions from Stage 1 such that an EP could choose to record height/length and weight only and exclude blood pressure, or record blood pressure only and exclude height/length and weight. We encouraged comments on this split and whether it should go both ways. We proposed to increase the threshold from more than 50 percent to more than 80 percent for this measure.

Comment: Several commenters agreed with the policy that height/length, weight, and blood pressure do not each need to be updated by a provider neither at every patient encounter nor even once per patient seen during the EHR reporting period.

Response: We will maintain our policy from Stage 1 that it is up to the EP or hospital to determine whether height/length, weight, and blood pressure each need to be updated, the level of accuracy needed to care for their patient, and how best to obtain the vital sign information that will allow for the right care for each patient.

Comment: Another commenter suggested that CMS clarify that the growth charts and

BMI are not part of the actual measure for this objective.

Response: We clarify that to satisfy the measure of this objective, the CEHRT must have the capability to calculate BMI and produce growth charts for patients as appropriate. Since BMI and growth charts are only produced when height/length and weight vital sign data are captured in the CEHRT, the measure is limited to these data elements.

Overall commenters supported the added flexibility of our proposal to split the exclusion and allow EPs to record blood pressure only or height/length and weight only. Our analysis of the meaningful use data for Stage 1 found that over 90 percent of EPs, eligible hospitals and CAHs were able to successfully report the vital signs measure. We did not propose additional measure elements that could increase the reporting burden at this time.

After consideration of the public comments received, we are finalizing this measure as proposed for EPs at §495.6 (j)(4)(ii) and for eligible hospitals and CAHs at §495.6(l)(3)(ii).

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 CEHRT at 45 CFR 170.314(a)(4). The ability to calculate the measure is included in CEHRT.

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

- Denominator: Number of unique patients seen by the EP or admitted to an eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period

- Numerator: Number of patients in the denominator who have at least one entry of their height/length and weight (all ages) and/or blood pressure (ages 3 and over) recorded as structured data.

- Threshold: The resulting percentage must be more than 80 percent in order for an EP, eligible hospital, or CAH to meet this measure.

- Exclusions: Any EP who sees no patients 3 years or older is excluded from recording blood pressure. Any EP who believes that all 3 vital signs of height/length, weight, and blood pressure have no relevance to their scope of practice is excluded from recording them. Any EP who believes that height/length and weight are relevant to their scope of practice, but blood pressure is not, is excluded from recording blood pressure. Any EP who believes that blood pressure is relevant to their scope of practice, but height/length and weight are not, is excluded from recording height/length and weight.

Proposed Objective: Record smoking status for patients 13 years old or older.

We stated in the proposed rule that accurate information on smoking status provides context to a high number and wide variety of clinical decisions, such as immediate needs for smoking cessation or long-term outcomes for chronic obstructive pulmonary disease. Cigarette smoking is a key component to the current Million Hearts Initiative (http://millionhearts.hhs.gov). We did not propose rules on who may record smoking status or how often the record should be updated. In addition, we proposed to continue the age limitation at 13 years old. We also requested comments specifically on the possible inclusion of other forms of tobacco use and second hand smoke.

Comment: We have received comments that assert that the objective is not relevant to a significant number of EPs due to their scope of practice and that it is redundant to the clinical quality measure "National Quality Forum (NQF) 28: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention". Some of the comments suggest that it should be eliminated and those EPs for whom it is relevant select the CQM.

Response: We disagree that the proposed objective and the clinical quality measure identified by commenters serve the same purpose and therefore only one should be included. The objective seeks to ensure that information on smoking status is included in the patient's record. Furthermore, that the information is stored in a structured format so that it can automatically be identified by CEHRT as smoking status for possible reporting or exchanging. We also note that the clinical quality measure only focuses on patients 18 years or older, while the objective focuses on patients 13 years or older. In addition, many quality measures related to smoking are coupled with follow-up actions by the provider such as counseling. We consider those follow-up actions to be beyond the scope of what we hope to achieve for this objective and would move the objective beyond the scope of practice for many providers. We disagree that the objective is not relevant to EPs seeing patient 13 years old or older. We note that this is intended to inform the provider. The frequency of when the information is updated, detail beyond the standard included in certification of EHR technology and many other factors discussed later are all left up to the provider to decide and fit to their scope of practice and their patient population.

Comment: We received conflicting suggestions in comments regarding the age limitation. These comments can be divided into those suggesting a lower age (as low as 8 to 12), those supporting 13 years old and those who believe it should be raised to 18 to match the clinical quality measures associated with smoking.

Response: It is apparent from the comments that the appropriate age for smoking status is an elusive target highly dependent on the situation. For example, it was suggested in comments that the age be lowered for patients meeting certain characteristics such as parents who smoke or other risk factors, while remaining at 13 for other patients. In our review of the public comments, we do not believe a consensus has been reached on a different age limitation

than our Stage 1 age limitation of 13 years old and therefore finalize the age limitation as proposed. As with other meaningful use objectives and measures, this represents a minimum requirement. We encourage each and every provider to evaluate whether their scope of practice and/or patient population calls for collecting smoking status on patients younger than 13 or more detailed information than required by this objective.

Comment: There continues to be strong support for expanding smoking to other forms of tobacco use. Commenters note that other types of tobacco use are supported by the clinical quality measure "NQF 28: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention".

Response: We refer readers to ONC's standards and certification criteria final rule that is published elsewhere in this issue of the **Federal Register** for discussions on the adoption of a standard that would support other types of tobacco use. As ONC did not adopt a standard supporting other forms of tobacco use, we do not expand the objective.

Comment: Some commenters expressed strong support for the inclusion of second-hand smoke either as part of this objective or as a separate objective.

Response: We agree with the importance of collecting second-hand smoke information for many EPs and hospitals. However, as with other forms of tobacco use, there is not a standard on which to base the requirement of collection of this information as structured data.

After consideration of the public comments received, we are finalizing this objective as proposed for EPs as §495.6(j)(5)(i) and for eligible hospitals and CAHs at §495.6(l)(4)(i).

Proposed Measure: More than 80 percent of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) during the EHR reporting period have smoking status recorded as

structured data.

In our proposed rule, based on Stage 1 data showing performance on this measure far exceeded the measure threshold of more than 50 percent, we proposed a threshold of more than 80 percent for this measure for Stage 2 of meaningful use.

Comment: We received comments asking for clarification on what must be recorded in the EHR and how often for the numerator to be met.

Response: Information on smoking status must be present as structured data using the standard specified at 45 CFR 170.314(a)(11). There is no requirement that the smoking status be entered into the record by a specific person or category of persons, there is no requirement that smoking status be entered into the CEHRT already in the terminology of the standard and there is no requirement on how frequently this information be updated. A patient indicating how many packs he smokes a day on a new patient questionnaire which is then entered by an administrative person and mapped in the CEHRT to one of the responses in the standard is valid for this measure. A physician could also ask a patient detailed questions to determine if the patient is a current smoker, input the information into the CEHRT, and select one of the responses of the standard. ONC has provided a mapping of SNOMED CT® ID to the descriptions at 45 CFR 170.314(a)(11).

Comment: We received a few comments on the threshold. Most were supportive, while others believe it should remain at 50 percent.

Response: Due to our analysis of performance on this measure from Stage 1 and the support received from commenters, we are finalizing the threshold as proposed.

After consideration of public comments, we are finalizing this measure as proposed for EPs at §495.6(j)(5)(ii) and for eligible hospitals and CAHs at §495.6(l)(4)(ii).

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 CEHRT at 45 CFR 170.314(a)(11).

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

- Denominator: Number of unique patients age 13 or older seen by the EP or admitted to an eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) during the EHR reporting period.

- Numerator: The number of patients in the denominator with smoking status recorded as structured data.

- 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 that neither sees nor admits any patients 13 years old or older.

CQM Reporting as a Stage 2 Objective – We proposed to add CQM reporting to the definition of "meaningful EHR user" under §495.4 instead of including it as a separate objective under §495.6. Accordingly, we did not propose a CQM reporting objective for EPs and hospitals as part of the Stage 2 criteria under §495.6.

Comment: While some commenters indicated that this change would be confusing, most commenters supported this change.

Response: We appreciate the support of commenters and believe including CQM reporting in the definition of "meaningful EHR user" under §495.4 will actually alleviate confusion. Therefore, we are not finalizing an objective related to the reporting of CQMs in the Stage 2 criteria for meaningful use under §495.6. Although CQM reporting is not listed as a

separate objective and measure under §495.6, it remains a condition for demonstrating meaningful use..

Consolidated Objective: Implement drug-drug and drug-allergy interaction checks.

For Stage 2, we proposed to make the objective for "Implement drug-drug and drug-allergy checks" one of the measures of the core objective for "Use clinical decision support to improve performance on high-priority health conditions." 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 clinical decision support that focuses on patient health and safety, we proposed to include this functionality as part of the objective for using clinical decision support.

We discuss comments regarding this consolidation in the discussion of the clinical decision support objective.

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

We proposed to modify the clinical decision support (CDS) objective for Stage 2 such that CDS would be used to improve performance on high-priority health conditions. We stated it would be left to the provider's clinical discretion to select the most appropriate CDS interventions for their patient population. We also proposed that the CDS interventions selected must be related to five or more of the clinical quality measures (CQMs) on which providers would be expected to report. The goal of the proposed CDS objective is for providers to implement improvements in clinical performance for high-priority health conditions that will result in improved patient outcomes.

Comment: A few commenters voiced concern regarding the maturity of the development

of clinical decision support systems. Others voiced a misconception that not all CEHRT includes pre-built CDS interventions where both capabilities and content are vendor supplied. The commenter went on to clarify that the CDS interventions must be specific to each provider's requirements. Still others commented on the CMS change in terminology from CDS "rules" to CDS "interventions" increases the range of available interventions.

Response: We recognize commenters' concerns regarding the maturity of CDS systems. Closely linked to the development of EHRs, there are multiple factors impacting the evolution of CDS systems including; the increasing availability and sophistication of information technology in clinical settings, the increasing pace of publication of new evidence-based guidelines for clinical practice and the continual evaluation and improvements of CDS.[2] We clarify that all CEHRT includes CDS interventions. The companion ONC standards and certification criteria final rule published elsewhere in this issue of the **Federal Register** includes further information regarding the criteria necessary to implement CDS in CEHRT for Stage 2 of meaningful use**.** With each incremental phase of meaningful use, CDS systems progress in their level of sophistication and ability to support patient care. For Stage 2 of meaningful use, it is our expectation that at a minimum, providers will select clinical decision support 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, we will consider a broad range of CDS interventions that improve both clinical performance and the efficient use of healthcare resources

[2]Study Protocol for the Effects of computerized clinical decision support systems on practitioner performance and patient outcome: Methods of a decision-maker-researcher partnership systematic review. R Brian Haynes*, Nancy L Wilczynski and the Computerized Clinical Decision Support System (CCDSS) Systematic Review Team. IMPLEMENTATION SCIENCE 2010, 5:12

in measuring providers' ability to demonstrate the meaningful use of CEHRT for Stage 2.

After consideration of the public comments received, we are finalizing this objective as proposed for EPs at §495.6(j)(6)(i) and for eligible hospitals and CAHs at §495.6(l)(5)(i).

Proposed Measure: We proposed two measures for EPs, eligible hospitals and CAHs for this objective. Both of the measures must be met in order for the provider to satisfy this objective:

1. Implement five clinical decision support interventions related to five or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period; and

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.

We proposed to make the Stage 1 objective for "implement drug-drug and drug-allergy interaction checks" one of the measures of the CDS objective for Stage 2. Based on the HIT Policy Committee's recommendation, we proposed that each CDS intervention must enable providers to review all of the following attributes for the intervention: developer of the intervention, bibliographic citation, funding source of the intervention, and the release or revision date of each intervention. The ONC standards and certification criteria final rule published elsewhere in this issue of the **Federal Register** provides additional information regarding the incorporation of the CDS in CEHRT**.** We proposed that providers must implement the CDS intervention at a relevant point in patient care when the intervention can influence clinical decision making before an action is taken on behalf of the patient. We proposed that providers must implement five CDS interventions that they believe will result in improvement in performance for five or more of the clinical quality measures on which they report. If none of the clinical quality measures is applicable to an EP's scope of practice, the EP should implement

a CDS intervention that he or she believes will be effective in improving the quality, safety, or efficiency of patient care.

Comment: Many commenters noted that at least one of the CDS interventions implemented should be tied to efficiency goals (for example, reducing the overuse of high-cost procedures).

Response: While we believe that it is entirely possible for a CDS intervention to improve both the quality of care and improve healthcare efficiency, we agree with the suggestion that at least one intervention could be tied directly to improving the efficient use of healthcare resources. In considering whether a CDS intervention increases healthcare efficiency, providers can consider improvements in any healthcare process. Some examples, of CDS interventions that may lead to improvements in healthcare efficiency include, alerts when duplicate tests, procedures or treatments are ordered for the same patient, using clinical guidelines for direct patient care processes, documentation templates to reduce variability in recording and alerting when outside of specified parameters, and using evidence based pre-specified order sets for blood products. Therefore, we are modifying the proposed CDS measure such that four of the CDS interventions are related to four or more CQMs, and the fifth CDS intervention should be related to improving healthcare efficiency. We clarify that any of the five CDS interventions may be related to both CQMs and improving healthcare efficiency.

Comment: Various comments were received in response to the proposed number of CDS interventions that are related to five or more CQMs. One commenter noted the potential for improved provider reporting and user efficiencies due to the inherent measure associations. Several commenters welcomed this improved alignment of CQM measures and reporting between the EHR Incentive Program and other CMS quality programs. Other commenters

expressed the difficult burden for specialists and others who may not be able to identify sufficient CQMs related to their patient population. Still other comments suggested that providers could easily implement double the number of proposed CDS interventions.

Response: Overall comments were supportive of the proposed number of CDS interventions and of aligning these interventions with CQM reporting. If none of the clinical quality measures are applicable to an EP's scope of practice, the EP should implement a clinical decision support intervention that he or she believes will be effective in improving the quality, safety or efficiency of patient care. We believe that the proposed clinical quality measures for eligible hospitals and CAHs would provide ample opportunity for implementing clinical decision support interventions related to high-priority health conditions. Comment: Commenters also supported continuing the requirement for providers to enable and implement drug-drug and drug-allergy interaction checks for the entire reporting period under the new CDS measure. An AHA Survey indicated that 73 percent of hospitals could perform the drug/drug and drug/allergy check, as well as at least one additional clinical decision support function in the Fall of 2011.

Response: We appreciate the commenters' overall support for consolidating this Stage 1 objective into one of the required clinical decision support measures. We also agree that drug-drug and drug-allergy interaction checks are important CDS tools contributing to improvements in patient safety and the overall quality of patient care.

Comment: Additional comments addressed concerns regarding the point at which professionals will be able to exercise clinical judgment about the CDS intervention before action is taken on behalf of the patient. The specific concern is that some interventions are only triggered when an action is about to be taken, and proposed that CMS revise this criterion to "before or at the time an action is taken."

Response: We 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." We clarify that the CDS implementation criterion which allow for CDS implementation at a relevant point in patient care includes interventions that may occur before or at the time an action is taken in the care delivery process.

Comment: Several commenters expressed concern with "alert fatigue" associated with increased use of clinical decision support interventions. These commenters cited studies that suggest that multiple alerts may be disabled or ignored resulting in adverse effects in the quality of care and patient safety.

Response: We recognize that "alert fatigue" is a potential occurrence with the increased use of some types of clinical decision support interventions. However, meaningful use seeks to leverage the capabilities of CEHRT to improve patient care. The selection of CDS interventions should weigh both the potential for unintended consequences including alert fatigue against the benefits of each CDS intervention, and the appropriate selection of an intervention type that interferes minimally with the provider's clinical workflow and cognitive burden. We believe such determinations are best left to providers. CDS is included as a meaningful use objective because we believe that the overall benefit of CDS is to improve patient safety and the quality of care. Therefore, we will continue to require the implementation of clinical decision support interventions in order to achieve meaningful use. Finally, as defined in the ONC standards and certification criteria final rule published elsewhere in this issue of the **Federal Register**, CDS is "not simply an alert, notification, or explicit care suggestion." While some alerts may be helpful and necessary, we encourage EPs and hospitals to consider the selection of CDS interventions

that are not alerts in order to reduce the burden of alert fatigue. Examples of non-alert CDS may include patient or disease specific order sets, referential decision support (presentation or availability of clinical reference information such as diagnostic guidance, dosing guidelines, or lab value interpretation assistance, or patient or disease specific documentation forms/templates that remind the provider to capture essential historical or physical exam findings for a patient with a certain condition). A common example of a CDS form/template would be a documentation form that is presented for patients with diabetes that includes a required section for the diabetic foot exam, where the same form would be presented for patients without diabetes and with the diabetic foot exam section removed.

Comment: Several commenters requested the flexibility to be able to change CDS interventions at any point during the reporting period so that in effect they would not be implementing the CDS intervention during the entire reporting period. Commenters cited provider uncertainty at the beginning of a reporting period of which CQMs they will ultimately report during the attestation process (for example, due to low counts for the measures). Many commenters requested the additional flexibility for providers to be permitted to implement CDS interventions relevant to any of the finalized panel of clinical quality measures specific to the provider type, even if the provider ultimately chooses different clinical quality measures to report. Commenters requested the opportunity to change CDS interventions during the reporting period and not be penalized for the CDS measure that requires the intervention during the entire reporting period. Commenters also wanted clarification whether they have to align CDS interventions with the same CQM measures reported for meaningful use.

Response: We expect providers to align CDS interventions with CQMs to the extent possible, although we recognize that providers may not know at the beginning of a reporting

period which CQMs they will end up selecting to report. Based on the comments, we clarify that EPs and hospitals may implement CDS interventions that are related (as defined in the proposed rule) to any of the clinical quality measures for EPs and hospitals, respectively, and that are finalized for the EHR Incentive Program for the relevant year of reporting. In other words, providers are not required to implement CDS interventions that are related to the specific CQMs that they choose to report for that year. 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 improving the quality, safety or efficiency of patient care. We will require providers to implement a minimum of five CDS interventions for the entire EHR reporting period. The provider may switch between CDS interventions or modify them during the EHR reporting period as long as a minimum of five are implemented for the entire EHR reporting period. We expect that providers may choose to implement a greater number of interventions from which they can select five interventions that have been enabled for the entire EHR reporting period when they attest to meaningful use.

Comment: Several providers recommend to be allowed to use their clinical judgment regarding which clinical decision support interventions would best benefit patients within the scope of their practice.

Response: We thank providers for this comment and want to clarify that in Stage 1; CMS allowed providers significant leeway in determining the clinical support interventions most relevant to their scope of practice. In Stage 2, we will continue to provide the flexibility for providers to identify high-priority health conditions that are most appropriate for CDS. As we stated in the proposed rule, for Stage 2 we will not require the provider to demonstrate actual

improvements in performance on clinical quality measures for this objective. Because CQMs focus on high-priority health conditions by definition, to the extent possible, four of the five CDS interventions that are implemented must be related to CQMs. Providers are also reminded that the CDS interventions selected for Stage 2 represent only a floor. 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.

Comment: Several commenters voiced concern that CDS interventions must be predetermined at the beginning of an EHR reporting period but providers do not have to choose CQMs until the end of the attestation reporting period. There is concern that providers will be unable to change the CDS interventions if they decide to change the related CQMs in a reporting period.

Response: We proposed alignment with CQMs to facilitate provider reporting and measurement, but as we clarified earlier, 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. 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 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 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: Commenters supported the inclusion of drug-drug and drug-allergy checks

noting that they are critical to ensuring the safety of the medications prescribed for patients, and agree with the inclusion of this measure. Other commenters noted the lack of an for EPs who do not prescribe medications and thus would not be able to meet this core set objective.

Response: We received similar feedback after publication of the Stage 1 final rule and after careful consideration of the comments, we will allow an exclusion to this measure for EPs that write fewer than 100 medication orders during the EHR reporting period. We did not include this exclusion as a change to Stage 1 as this is primarily an implementation of a function of CEHRT and there is no requirement to update CEHRT in 2013. This exclusion aligns with the exclusion under the objective CPOE for medication orders discussed earlier in this rule.

Comment: There were several comments regarding the implementation of CDS and the attributes required for each intervention. Commenters did not believe that the information requested in order to support the inclusion of CDS attributes would be available to many providers, particularly for providers in a group practice. Commenters also requested clarification whether these attributes would be required for drug-drug and drug-allergy interactions. Other commenters requested additional clarification regarding the extent that CDS attributes are required when the interventions result from self-generated evidence. Other comments addressed provider concerns regarding the need to purchase additional expensive vendor products and upgrades to incorporate these requirements.

Response: We appreciate the many comments for the proposed CDS attributes. We clarify that the need for inclusion of attributes for each CDS intervention also applies to drug-drug and drug-allergy interventions as well as interventions based on self-generated evidence. The companion ONC standards and certification criteria final rule published elsewhere in this issue of the **Federal Register** further describes CEHRT requirements for these CDS attributes in

order to ensure that all users of CEHRT will have access to this new functionality. After consideration of the public comments and for the reasons discussed earlier, we are modifying the measures for EPs at §495.6(j)(6)(ii) and for eligible hospitals and CAHs at §495.6(l)(5)(ii) as follows:

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

- 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 further specify that in order to meet this objective and measure, an EP, eligible hospital, or CAH must use the capabilities and standards of CEHRT at 45 CFR 170.314(a)(8) and (a)(2).

Replaced Objective: Provide patients with an electronic copy of their health information.

Replaced Objective: Provide patients with an electronic copy of their discharge instructions.

For Stage 2, we did not propose the Stage 1 meaningful use objectives for EPs and hospitals to provide patients with an electronic copy of their health information and discharge

instructions upon request. As we stated in the proposed rule, the HIT Policy Committee recommended that these objectives be combined with the objectives for view online, download, and transmit. We agreed with the HIT Policy Committee and proposed to replace the Stage 1 objectives above with objectives and measures for Stage 2 that would enable patients to view online and download their health information and hospital admission information. We stated that continued online access to such information is more useful and provides greater accessibility over time and in different health care environments than a single electronic transmission or a one-time provision of an electronic copy, especially when that access is coupled with the ability to download a comprehensive point in time record.

We received no comments that supported the retention of these objectives for Stage 2. Therefore, we are finalizing the replacement of these objectives for EPs, eligible hospitals, and CAHs as proposed. Please refer to the discussions later in this rule regarding view online, download, and transmit objectives for both EPs and eligible hospitals and CAHs for more information about the Stage 2 objectives that replace these Stage 1 objectives.

Proposed EP Objective: Provide clinical summaries for patients for each office visit.

In the proposed rule, we outlined the following benefits of providing clinical summaries for patients for each office visit: A summary of an office visit provides patients and their families with a record of the visit. This record can prove to be a vital reference for the patient and their caregivers about their health and actions they should be taking to improve their health. Without this reference, the patient must either recall each detail of the visit, potentially missing vital information, or contact the provider after the visit. Certified EHR technology enables the provider to create a summary easily and in many cases instantly. This capability removes nearly all of the barriers that exist when using paper records.

As noted in the proposed rule, clinical summaries for each office visit are important because without this reference the patient must either recall each detail of the visit, potentially missing vital information, or contact the provider after the visit. We also noted that this is a meaningful use requirement, which does not override an individual's broader 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. However, none of the HIPAA access requirements preclude an EP from releasing electronic copies of clinical summaries to their patients as required by this meaningful use provision. For Stage 2, we proposed this as a core objective for EPs.

Comment: Some commenters believed that this objective should be eliminated because the same information would be made available through the objective to "Provide patients the ability to view online, download, and transmit their health information." Other commenters suggested combining these objectives with a concomitant rise in the measure threshold.

Response: While it is true that there may be overlap between the information in the clinical summary and the information made available through the objective to "Provide patients the ability to view online, download, and transmit their health information," we believe the clinical summary after an office visit serves a different purpose than online access to health information. A summary of an office visit provides patients and their families with a record of the visit and specific lab tests or specific follow-up actions and treatment related to the visit. While this information is certainly part of the patient's overall electronic health record, the clinical summary serves to highlight information that is relevant to the patient's care at that particular moment. Therefore, we decline to eliminate or combine the objective.

After consideration of the public comments, we are finalizing the meaningful use

objective for EPs at §495.6(j)(11)(i) as proposed.

Proposed EP Measure: Clinical summaries provided to patients within 24 hours for more than 50 percent of office visits.

In the proposed rule, we proposed to maintain several policies regarding this objective from Stage 1. As we stated, for purposes of meaningful use, an EP could withhold information from the clinical summary if they believe substantial harm may arise from its disclosure through an after-visit clinical summary. An EP could also choose whether to offer the summary electronically or on paper by default, but at the patient's request must make the other form available. The EP could select any modality (for example, online, CD, USB) as their electronic option and would not have to accommodate requests for different modalities. We also stated in the proposed rule that we do not believe it would be appropriate for an EP to charge the patient a fee for providing the summary. Finally, we stated that when a single consolidated summary is provided for an office visit that lasts for several consecutive days, or for an office visit where a patient is seen by multiple EPs, that office visit must be counted only once in both the numerator and denominator of the measure. We are finalizing all of these policies for Stage 2 as proposed.

Comment: Many commenters suggested that the measure should be changed from "24 hours" to "1 business day." Other commenters believed that this timeframe was too short, especially for specialty providers who might not come into the office every day, and suggested either changing the timeframe to 48 hours or reverting to the 72-hour measure of Stage 1. Another commenter noted that delays past 24 hours can sometimes occur outside of the provider's control—for example, in the case of new patients where the provider might not have access to adequate previous records.

Response: We believe that Certified EHR technology enables the provider to create a

summary with the required information easily and in most cases instantly. The feedback we have received on this objective in Stage 1 through discussions with providers indicates that most providers make this clinical summary available as patients leave the office visit, and we expect this workflow to continue for most providers. Therefore a longer timeframe of 48 or 72 hours should not be necessary for providing clinical summaries. We also note that the clinical summary contains information relevant to the patient's office visit and therefore the EP should not need to include information from previous records for most patients. However, we believe the threshold of more than 50 percent of office visits allows EPs to meet the measure of this objective despite these challenges for a small number of patients. We also agree that the measure should be changed from "24 hours" to "1 business day" since all providers may not have staff available to issue clinical summaries prior to the close of a work week or the beginning of a Federal holiday. Therefore, we are finalizing the change from "24 hours" to "1 business day."

Comment: A number of commenters raised questions regarding the provision of the clinical summary. They asked whether the summary should be given automatically to each patient or whether offering the summary at the end of an office visit was sufficient to meet the measure. Commenters also asked whether patients who refused a copy of the clinical summary should be counted in the numerator of the measure.

Response: It is the intention of this objective that clinical summaries be automatically given to patients within 1 business day of an office visit. However, we do recognize that some patients may decline a physical copy of their clinical summary. In the event that a clinical summary is offered to and subsequently declined by the patient, that patient may still be included in the numerator of the measure. We note that the clinical summary must be offered to the patient; a passive indication of the clinical summary's availability (for example, a sign at the

reception desk, a note in form, etc.) would not serve as offering the clinical summary and those patients could not be counted in the numerator of the measure. However, the clinical summary does not necessarily need to be printed before being offered to the patient.

Comment: Commenters asked whether making clinical summaries available on a patient portal or as part of the objective to "Provide patients the ability to view online, download, and transmit their health information" would meet the measure of this objective. Some commenters suggested that patients should be permitted to demand an electronic copy of clinical summaries where an EP has chosen to provide them in hard copy form.

Response: We are continuing our policy from Stage 1 that the clinical summary can be provided through a patient portal or through other electronic means to satisfy this measure. A clinical summary provided through the same means that the provider makes other patient information available to meet the objective to "Provide patients the ability to view online, download, and transmit their health information" would also meet the measure of this objective. As stated previously, an EP can choose whether to offer the summary electronically or on paper by default, but at the patient's request must make the other form available. The EP could select any modality (for example, online, CD, USB) as their electronic option and would not have to accommodate requests for different electronic modalities.

Comment: Some commenters suggested that this measure should be based on the number of unique patients seen by the EP instead of office visits. Other commenters suggested that the threshold for the measure should be reduced.

Response: We do not agree that the measure should be based on unique patients. The purpose of the clinical summary is to provide patients and their authorized representatives with a record of an office visit and specific lab tests or specific follow-up actions and treatment related

to that visit. Nor do we agree that the percentage threshold of this measure should be reduced. We note that the threshold for this measure in Stage 1 was also 50 percent; any reduction would constitute a step backward for the meaningful use of this capability.

Comment: Some commenters suggested that EPs should be permitted to charge a fee for provision of a clinical summary.

Response: Because the clinical summary is meant to summarize the office visit and any lab tests, follow-up actions, or treatments related to that visit, we do not believe it is appropriate for an EP to charge patients additional fees for its provision. Also, because this is a meaningful use requirement for the incentivized provider and not a response to a patient request, we do not believe it is appropriate for an incentivized provider to charge the patient. This is consistent with our position for this objective in Stage 1 (75 FR 44358).

Comment: Commenters suggested that clinical summaries provided to patient-authorized representatives should also be counted for this measure.

Response: We agree that the provision of a clinical summary to a patient-authorized representative should also be counted, and we have amended the measure accordingly.

Comment: Many commenters believed that the list of required elements to be included in the clinical summary was excessive and not useful to the patient. Commenters suggested that the list be shortened or left to the provider's discretion. Additionally, many commenters asked for clarification on whether certain fields could be left blank and still permit the EP to meet the measure of this objective. Finally, a number of commenters suggested that this objective should focus on whether the summary is provided and not on required information since CEHRT cannot distinguish between information not provided in a clinical summary because it is not relevant or because a provider has exercised discretion to withhold it.

Response: This measure is focused on the provision of the clinical summary. The clinical summary represents a patient's current care and health as a snapshot in time. When provided, we believe it can significantly improve a patient's overall awareness of the care they are receiving as well as any conditions they may need to manage between office visits. The required information listed at the end of this section are provided as a way to standardize and prioritize for the purposes of EHR technology certification the minimum amount of information that must be available to EPs to select. Further, we believe that the information in this minimum list is the most applicable and beneficial to improving patient care. This is a list of information, not a particular structure or format for the summary handed to the patient.

We have no requirements on the design of the summary just the information that must be present if it is in the CEHRT. The design of the summary should reflect the context of the visit. For example, the information of future appointments, referrals to other providers, future scheduled tests, and clinical instructions could all appear in a section of the summary called "Next steps". If all of these information areas were empty then "next steps" could just be none and all the feeding information elements would be covered. Alternatively, if the summary is provided on letterhead that includes the office location and the provider's name that information does not have to be repeated in the text of the summary. We cannot emphasize enough that this is required information for the summary not a particular required structure for the summary. We do not believe that the list of required information imposes an undue burden on providers because CEHRT will be able to automatically generate the clinical summary with at least all of the required information. In ONC's rule it has included in the certification criterion that correlates to this objective the capability for end-users to customize (for example, edit) the clinical summary to make it more relevant to the patient encounter.

In circumstances where there is no information available to populate one or more of the fields previously listed, either because the EP can be excluded from recording such information (for example, vital signs) or because there is no information to record (for example, no medication allergies or laboratory tests), an indication that the information is not available in the clinical summary would meet the measure of this objective. The feedback we have received on this objective in Stage 1 through discussions with providers indicates that the absence of information in the clinical summary sometimes offers an opportunity for reconciliation of misinformation; for example, if "no medication allergies" is listed but the patient has one, he or she may communicate that to the provider, thus improving the quality of the data in the EHR. We do note that the measure of this objective already focuses on provision of the clinical summary and is not specific to the information which is provided within the clinical summary; the list of required elements is meant to standardize the information given to patients, not to create an additional measure for the objective.

We also refer providers to our discussion of what constitutes an office visit. Many of the concerns we have heard regarding this summary are the result of misunderstandings about what constitutes an office visit. For example, in some cases removing sutures or giving allergy shots do not represent an office visit if that is the only service provided.

Comment: Commenters asked for clarification on "current problem list and any updates," "current medication list and any updates," and "current medication allergy list and any updates," since updates would be included in any current problem list. They suggested simplifying these requirements to "current problem list;" "current medication list;" and "current medication allergy list".

Response: We agree that including the language "and any updates" is redundant since a

current problem, medication, or medication allergy list would already include updated information. We are amending this language in the list of required elements below. However, the clinical summary should include both a current problem list and any diagnosis specifically related to the office visit as separate fields. The diagnosis related to the office visit should be expressed in the "Reason for the patient's visit" field, though it may also be included in the current problem list. We note that this is consistent documentation available in the Consolidated Clinical Document Architecture (CDA), which defines the "Reason for the patient's visit" field as the provider's description of the reason for visit and the "Chief complaint field" as the patient's own description.

Comment: Commenters asked for clarification on "vital signs and any updates" and suggested simplifying this requirement to "Vitals taken during visit".

Response: While we agree that vital signs taken during the visit would be most useful in the clinical summary, we also recognize that all vital signs may not be updated at each office visit. Therefore, we are amending this language to "Vital signs taken during the visit (or other recent vital signs)" in the list of required elements below.

Comment: Commenters asked us to clarify if the requirement relating to the inclusion of laboratory test results applies only to test results available at the time of the office visit or to test results that become available after the clinical summary is issued.

Response: By laboratory test results, we mean for the clinical summary to include results that are available at the time the clinical summary is issued to the patient. As we stated in the proposed rule, clinical summaries can quickly become out of date due to information not available to the EP at the end of the visit. The most common example of this is laboratory test results. We believe that EPs should make this information known to the patient when the results

are available, but do not require that a new clinical summary must be issued when information needs to be updated.

Comment: Commenters asked us to clarify if the list of diagnostic tests pending indicates diagnostic tests that have been scheduled or diagnostic tests for which results are not yet available.

Response: Diagnostic tests pending refers to diagnostic tests that have been performed but for which results are not yet available. Laboratory or diagnostic tests that have been scheduled but not yet performed should be recorded under "Future scheduled tests" in the list of required elements later in this section.

Comment: Some commenters asked us to define clinical instructions. Other commenters asked if the instructions included as part of the care plan were redundant with the "clinical instructions" element in the list of required information.

Response: By clinical instructions we mean care instructions for the patient that are specific to the office visit. Although we recognize that these clinical instructions at times may be identical to the instructions included as part of the care plan, we also believe that care plans may include additional instructions that are meant to address long-term or chronic care issues, whereas clinical instructions specific to the office visit may be related to acute patient care issues. Therefore, we maintain these as separate items in the list of required elements later.

Comment: A commenter noted that future appointments and future scheduled tests might be stored in a scheduling system that is separate from CEHRT and suggested that if the information is not available in CEHRT that the EP be excluded from having to provide it as part of the clinical summary.

Response: As noted previously, in circumstances where there is no information available

to populate one or more of the fields previously listed, either because the EP can be excluded from recording such information (for example, vital signs) or because there is no information to record (for example, no medication allergies or laboratory tests), an indication that the information is not available in the clinical summary would meet the measure of this objective. This would also be true if the information is not accessible through CEHRT.

Comment: Commenters asked for clarification regarding demographics "maintained by EP." Specifically, they asked whether the EP was required to enter demographics or whether these could be maintained by a member of his or her staff.

Response: By demographics we mean the demographics maintained within CEHRT. We do not intend to specify that only the EP can enter such information into the EHR; demographic information can be entered into CEHRT by any person or through any electronic interface with another system. Therefore, we are amending the language to "Demographic information maintained within CEHRT" in our list of required elements later in this section.

Comment: In regard to the inclusion of "care plan field" in the list of required information, some commenters believed that the wording was overly prescriptive since CEHRT could utilize multiple fields to structure care plans. Other commenters requested a more detailed definition of care plan.

Response: We agree that the language proposed could be viewed as prescriptive, and we do not intend to limit the inclusion of the care plan to a single field. Therefore, we are amending the language to "Care plan field(s), including goals and instructions" in our list of required elements below. However, we decline to provide an alternate definition that would limit the information in the care plan. We believe that the definition we proposed in the proposed rule is sufficient to allow for the inclusion of a variety of care plans in the clinical summary. For

purposes of the clinical summary, we define a care plan as the structure used to define the management actions for the various conditions, problems, or issues. A care plan must include at a minimum the following components: problem (the focus of the care plan), goal (the target outcome) and any instructions that the provider has given to the patient. A goal is a defined target or measure to be achieved in the process of patient care (an expected outcome).

Comment: Some commenters asked for clarification about what is meant by patient decision aids.

Response: By patient decision aids we mean any educational resource or tool that the provider believes can inform patient decisions about their own care. An example is an educational handout on the pros and cons of having surgery for a particular condition.

Comment: Some commenters noted that because EHRs capture medical data, they will produce clinical summaries with medical terminology, whereas patients should receive summaries with nonmedical terminology and descriptions of both medications and lab test results that are easy to read and contain actionable items.

Response: While we agree that clinical summaries with nonmedical terminology and extended descriptions would be most beneficial to patients, we also believe that the utility of this objective must be balanced against the potential burden it places on EPs. Since clinical summaries can be automatically generated from existing data in CEHRT, this removes significant workflow barriers to providing a summary for patients. We believe that requiring providers or their staff to render all information in the clinical summary into nonmedical terms at this time would impose a significant burden on providers and reduce the number of clinical summaries that providers make available to patients, thereby reducing the effectiveness of this objective. However, we note that most of the information that is required as part of the clinical

summary should be easily understandable by most patients. Also, there is nothing to prevent an EP from providing additional information if he or she believes it would be more effective for the overall quality of patient care. We further note that we anticipate that the capabilities of CEHRT may soon allow for the provision of non-medical terminology and extended descriptions and we are considering adding this requirement in future stages of meaningful use.

Comment: One commenter noted that the clinical summary contains a vast amount of protected health information (PHI) which could be compromised if patients discard the clinical summary insecurely. The commenter suggested requiring the clinical summary only for those patients who affirm they want it to eliminate any provider responsibility for security of the information.

Response: We do not believe that making protected health information available to patients in any way compromises either patients or providers. On the contrary, we believe that offering this information is critical to improving the overall quality of patient care by offering specific follow-up instructions, test results, and care plan information to patients so that they can actively participate in their own care. We believe that providers can take steps to inform patients about the need to securely dispose of PHI, and we further note that making clinical summaries available electronically through an online portal or other means can be used to keep such PHI secure. Therefore, we decline to change the measure for this objective.

After consideration of the public comments, we are finalizing the meaningful use measure for EPs as "Clinical summaries provided to patients or patient-authorized representatives within 1 business day for more than 50 percent of office visits" at §495.6(j)(11)(ii).

We further specify that in order to meet this objective and measure, an EP must use the

capabilities and standards of CEHRT at 45 CFR 170.314(e)(2).

We clarify that the following information (or an indication that there is no information available) is required to be part of the clinical summary for Stage 2:

- Patient name.
- Provider's name and office contact information.
- Date and location of the visit.
- Reason for the office visit.
- Current problem list.
- Current medication list.
- Current medication allergy list.
- Procedures performed during the visit.
- Immunizations or medications administered during the visit.
- Vital signs taken during the visit (or other recent vital signs).
- Laboratory test results.
- List of diagnostic tests pending.
- Clinical instructions.
- Future appointments.
- Referrals to other providers.
- Future scheduled tests.
- Demographic information maintained within CEHRT (sex, race, ethnicity, date of birth, preferred language).
- Smoking status
- Care plan field(s), including goals and instructions.

- Recommended patient decision aids (if applicable to the visit).

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

- Denominator: Number of office visits conducted by the EP during the EHR reporting period.

- Numerator: Number of office visits in the denominator where the patient or a patient-authorized representative is provided a clinical summary of their visit within 1 business day.

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

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

Removed Objective: Capability to exchange key clinical information.

In Stage 2, we proposed to move to actual use cases of electronic exchange of health information through the following 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 should provide summary care record for each transition of care or referral." We also proposed to remove this objective for Stage 1 as well, but requested comments on other options. Please refer to the section titled "Changes to Stage 1" at II.A.3.b. of this final rule for details of the options considered. We are finalizing the removal of this objective as proposed in favor of the more robust, actual use case of electronic exchange through a summary of care record following each transition of care or referral. We believe that this actual use case is not only easier for providers to understand but it is also more beneficial because it contributes directly to the care of the patient through enhanced coordination between providers. A prudent

provider will be preparing and testing to conduct actual exchange prior to the start of Stage 2 during their Stage 1 EHR reporting periods.

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

In the proposed rule, we outlined the following benefits of protecting health information: Protecting electronic health information is essential to all other aspects of meaningful use. Unintended and/or unlawful disclosures of personal health information could diminish consumers' confidence in EHRs and electronic health information exchange. Ensuring that health information is adequately protected and secured will assist in addressing the unique risks and challenges that may be presented by electronic health records.

Comment: A number of commenters supported the continued inclusion of this objective, yet several commenters requested the elimination of this objective as redundant to HIPAA regulations.

Response: We believe that it is crucial that EPs, eligible hospitals, and CAHs evaluate the privacy and security implications of CEHRT as part of the EHR Incentive Programs, particularly as they pertain to 45 CFR 164.308(a)(1) and the protection and safeguarding of personal health information in general. Therefore, we retain this objective and measure for meaningful use in the final rule.

After consideration of the public comments, we are finalizing the meaningful use objective for EPs at §495.6(j)(16)(i) and eligible hospitals and CAHs at §495.6(l)(15)(i) as proposed.

Proposed Measure: Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the encryption/security of data

at rest 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.

In the proposed rule, we explained that this measure is the same as in Stage 1 except that we specifically address the encryption/security of data is that is stored in CEHRT (data at rest). Due to the number of breaches reported to HHS involving lost or stolen devices, the HIT Policy Committee recommended specifically highlighting the importance of an entity's reviewing its encryption practices as part of its risk analysis. We agree that this is an area of security that appears to need specific focus. Recent HHS analysis of reported breaches indicates that almost 40 percent of large breaches involve lost or stolen devices. Had these devices been encrypted, their data would have been secured. It is for these reasons that we specifically call out this element of the requirements under 45 CFR 164.308(a)(1) for the meaningful use measure. We did not propose to change the HIPAA Security Rule requirements, or require any more than is required under HIPAA. We only emphasize the importance of an EP or hospital including in its security risk analysis an assessment of the reasonable and appropriateness of encrypting electronic protected health information as a means of securing it, and where it is not reasonable and appropriate, the adoption of an equivalent alternative measure.

We proposed this measure because the implementation of CEHRT has privacy and security implications under 45 CFR 164.308(a)(1). 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.

In the proposed rule, we emphasized that our discussion of this measure and

45 CFR 164.308(a)(1) is only relevant for purposes of the meaningful use requirements and is not intended to supersede what is separately required under HIPAA and other rulemaking. Compliance with the HIPAA requirements is outside of the scope of this rulemaking. Compliance with 42 CFR Part 2 and state mental health privacy and confidentiality laws is also outside the scope of this rulemaking. EPs, eligible hospitals or CAH affected by 42 CFR Part 2 should consult with the Substance Abuse and Mental Health Services Administration (SAMHSA) or state authorities.

Comment: Some commenters asked if the Stage 2 requirements for this objective contradict earlier Stage 1 requirements and HIPAA regulations. Specifically, the addition of addressing encryption/security of data at rest to the measure was raised as a concern.

Response: We do not believe that the Stage 2 measure of this objective contradicts either the Stage 1 measure or current HIPAA regulations. As noted in the proposed rule, this measure is the same as in Stage 1 except that we specifically highlight the encryption/security of data that is stored in CEHRT (data at rest). Recent HHS analysis of reported breaches indicates that almost 40 percent of large breaches (breaches affecting 500 or more individuals) involve lost or stolen devices. Had these devices been encrypted, their data would have been secured. It is for these reasons that we specifically call out this requirement under 45 CFR 164.308(a)(1). We did not propose to change the HIPAA Security Rule requirements, or require any more under this measure than is required under HIPAA. We only emphasize the importance of an EP or hospital including in its security risk analysis an assessment of the reasonable and appropriateness of encrypting electronic protected health information as a means of securing it, and where it is not reasonable and appropriate, the adoption of an equivalent alternative measure.

Comment: Several commenters asked for clarification of what constitutes an acceptable

security risk analysis. Commenters also asked if the security risk analysis required in the measure should apply to health data stored in data centers with physical security.

Response: We did not propose to change the HIPAA Security Rule requirements or impose additional requirements under this measure than those required under HIPAA. A review must be conducted for each EHR reporting period and any security updates and deficiencies that are identified should be included in the provider's risk management process and implemented or corrected as dictated by that process. We refer providers to the requirements under 45 CFR 164.308(a)(1), including addressing the encryption/security of data at rest in accordance with requirements under 45 CFR 164.312 (a)(2)(iv) and 45 CFR 164.306(d)(3), of the HIPAA Security Rule for compliance. The HHS Office for Civil Rights (OCR) has issued guidance on conducting a security risk assessment pursuant to the HIPAA Security Rule (http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/rafinalguidancepdf.pdf). The scope of the security risk analysis for purposes of this meaningful use measure applies only to data created or maintained by CEHRT. This measure does not apply to data centers that are not part of CEHRT. However, we note that such data centers may be subject to the security requirements under 45 CFR 164.308(a)(1) and refer providers to the HIPAA Security Rule for compliance information.

Comment: One commenter asked if the measure of the objective required hospitals to report on data encryption methods.

Response: No, eligible hospitals and CAHs are not required to report to CMS or the states on specific data encryption methods used. However, they are required to address the encryption/security of data at rest in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3).

Compliance with 42 CFR Part 2 and state mental health privacy and confidentiality laws is also outside the scope of this rulemaking. EPs, eligible hospitals or CAH affected by 42 CFR Part 2 should consult with the Substance Abuse and Mental Health Services Administration (SAMHSA) or state authorities.

We are making a change in this final rule to the language of "data at rest" to specify our intention of data that is stored in CEHRT. After consideration of the public comments, we are finalizing the meaningful use measure as "Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the encryption/security 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" for EPs "at §495.6(j)(16)(ii) and eligible hospitals and CAHs at §495.6(l)(15)(ii).

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 CEHRT at 45 CFR 170.314(d)(1) through 170.314(d)(8).

(b) Objectives and Measures Carried Over (Modified or Unmodified) from Stage 1 Menu Set to Stage 2 Core Set

We signaled our intent in the Stage 1 final rule to move the objectives from the Stage 1 menu set to the Stage 2 core set. The HIT Policy Committee also recommended that we move all of these objectives to the core set for Stage 2. We proposed to include in the Stage 2 core set all of the objectives and associated measures from the Stage 1 menu set, except for the objective "capability to submit electronic syndromic surveillance data to public health agencies" for EPs, which will remain in the menu set for Stage 2. As discussed later, we also proposed to modify

and combine some of these objectives and associated measures for Stage 2--

Consolidated Objective: Implement drug formulary checks.

For Stage 2, we proposed to include this objective within the core objective for EPs "Generate and transmit permissible prescriptions electronically (eRx)" and the menu objective for eligible hospitals and CAHs of "Generate and transmit permissible discharge prescriptions electronically (eRx)." We believe that drug formulary checks are most useful when performed in combination with e-prescribing, where such checks can allow the EP or hospital to increase the efficiency of care and benefit the patient financially. We address the comments related to these proposals and state our final policy in the discussions of the eRx objectives for EPs and hospitals.

Proposed Objective: Incorporate clinical lab test results into CEHRT as structured data.

We propose to continue the policy from Stage 1 to incorporate clinical lab test results into CEHRT as structured data. We believe this measure contributes to the exchange of health information between providers of care, facilitates the sharing of information with patients and their designated representatives, and may reduce order entry errors which will contribute to patient care improvements.

We did not receive any comments for this objective. We are finalizing the meaningful use objective for EPs at §495.6(j)(7)(i) and eligible hospitals and CAHs at §495.6(l)(6)(i) as proposed.

Proposed Measure: More than 55 percent of all clinical lab tests results ordered by the EP or by authorized providers of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period whose results are either in a positive/negative or numerical format are incorporated in CEHRT as

structured data.

We proposed to increase the measure threshold from more than 40 percent for Stage 1 to more than 55 percent for Stage 2. We also solicited public comment regarding the feasibility of continuing to account for individual lab tests separately from group and panel tests. In addition, we solicited comment on whether standards and other capabilities would allow for the expansion of this measure to include all quantitative lab results.

Comment: Many of the commenters voiced their concern that not all EHRs are capable of splitting out individual test results from panel tests and that it would not be feasible to require this for Stage 2 of meaningful use. Other commenters suggested modifying the current measure to use the number of laboratory test results in the EHR as the numerator and the total laboratory test results from the Lab Information System as the denominator. Others questioned the validity of the current measure that counts orders in the denominator and results in the numerator. Another comment is that not all providers have access to a lab interface system and not all lab interfaces are compatible

Response: We appreciate the many comments and suggestions submitted regarding this measure which were carefully considered as we developed the final regulation. Some commenters questioned the measure validity suggesting that the measure is imperfect since the numerator and denominator are incongruent. However, in considering the broader policy goal underlying this measure (to incorporate lab results into CEHRT in a standard format) the measure needs to be broad enough to allow providers to incorporate laboratory orders and results from multiple service providers. By incorporating all lab orders (whether panel or individual) in the denominator, and all lab test results in the numerator, providers will be able to capture structured lab data from a broad range of provider laboratory information systems into the

CEHRT. We understand that the most likely scenario is that the denominator of total lab orders (if panel orders are counted as one) will be less than the numerator of laboratory results because results are provided for each individual test rather than by panel. Therefore, it is highly unlikely that the measure would impact a provider's ability to meet the increased threshold in this scenario.

Providers will need to continue to report individual lab test results recorded as structured data in the numerator, and in the denominator report all individual lab-tests ordered whether or not they are ordered individually or as part of a panel or group lab order. For example, one panel order of ten individual lab tests could be counted as 1 or 10 lab tests ordered in the denominator depending on the system that is used to incorporate this data into the CEHRT. We will monitor provider experience with this measure as technological capacity for the reporting and exchange of lab data continues to evolve.

Comment: Other commenters mentioned uncertainty regarding the proper vocabulary to use for the incorporation of lab test results in a structured format. Several commenters went on to mention that there is not one current vocabulary that encompasses all types of tests. Another comment proposed that CMS work to amend the clinical laboratory improvement amendments (CLIA) to require hospital labs to report results in standard vocabulary such as the Logical Observation Identifiers Names and Codes System (LOINC) by the time Stage 2 is implemented in 2014.

Response: We refer readers to the ONC standards and certification criteria final rule published elsewhere in this issue of the **Federal Register** for vocabulary specifications.

Comment: Many commenters were confused by the clarification CMS provided in the proposed rule for expanding the measure to all quantitative results (all results that can be

compared on as a ratio or on a difference scale). Comments were mixed on whether this measure should include all types of lab tests that produce quantitative results. One commenter suggested CMS should allow ordinal responses for the measure since that is what LOINC uses as the response rather than counting test results with either a positive, negative or numeric response since operationally, counting tests based on whether or not they have two allowed answer choices is difficult, where counting tests based on whether the LOINC code for them had a Scale of QN or Ord would be quite simple. Another commenter suggested most people would assume that "numeric/quantitative tests" would include decimals and whole numbers as well as results reported in a range (for example, >7.4 or <150) and ratios such as also titer levels (for example, 1:128).

Response: We appreciate the number of comments regarding an expansion of the existing measure as well as further clarification. Based on both CMS and companion ONC comments received, we clarify that the measure incorporate all numeric/quantitative tests that report whole or decimal numbers. The structured data for the numeric/quantitative test results may include positive or negative affirmations and/or numerical format that would include a reference range of numeric results and/or ratios.

Comment: Most commenters agreed that the increase measure threshold is appropriate. One commenter referenced a recent AHA survey that found "60 percent of hospitals could perform this function in Fall 2011 at the raised threshold".

Response: Our analysis of the Stage 1 attestation data shows that 91.5 percent of EPs and 95 percent of eligible hospitals and CAHs were able to successfully demonstrate meaningful use for this measure. Therefore, combined with the AHA survey data results, we will adopt the proposed threshold of 55 percent or more for this measure.

After consideration of the public comments received, we modify the measure for EPs at §495.6(j)(7)(ii) and eligible hospitals and CAHs at §495.6(l)(6)(ii) to:

More than 55 percent of all clinical lab tests results ordered by the EP or by authorized providers of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period whose results are either in a positive/negative affirmation or numerical format are incorporated in CEHRT as structured data.

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 CEHRT at 45 CFR 170.314(b)(5).

- Denominator: Number of lab tests ordered during the EHR reporting period by the EP or by authorized providers of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) whose results are expressed in a positive or negative affirmation or as a number.

- Numerator: Number of lab test results which are expressed in a positive or negative affirmation or as a numeric result which are incorporated in CEHRT as structured data.

- Threshold: The resulting percentage must be more than 55 percent in order for an EP, eligible hospital, or CAH to meet this measure.

- Exclusion: Any EP who orders no lab tests where results are either in a positive/negative affirmation or numeric format during the EHR reporting period.

There is no exclusion available for eligible hospitals and CAHs because we do not believe any hospital will ever be in a situation where its authorized providers have not ordered any lab tests for admitted patients during an EHR reporting period.

Proposed Objective: Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach.

In the proposed rule, we outlined the following benefits of generating lists of patients by specific conditions: Generating patient lists is the first step in proactive management of populations with chronic conditions and is critical to providing accountable care. The ability to look at a provider's entire population or a subset of that population brings insight that is simply not available when looking at patients individually. Small variations that are unnoticeable or seem insignificant on an individual basis can be magnified when multiplied across a population. A number of studies have shown that significant improvements result merely due to provider awareness of population level information. We believe that many EPs and eligible hospitals will use these reports in combination with one of the selected quality measures and decision support interventions to improve quality for a high priority issue (for example, identify patients who are in the denominator for a measure, but not the numerator, and in need of an intervention). The capabilities and variables used to generate the lists are defined in the ONC standards and certification final rule published elsewhere in this issue of the **Federal Register**; not all capabilities and variables must be used for every list.

We have combined the comments and responses for this objective with the measure below. After consideration of the public comments, we are finalizing the meaningful use objective for EPs at §495.6(j)(8)(i) and eligible hospitals and CAHs at §495.6(l)(7)(i) as proposed.

Proposed Measure: Generate at least one report listing patients of the EP, eligible hospital, or CAH with a specific condition.

We proposed to continue our Stage 1 policies for this measure. The objective and measure do not dictate the specific report(s) that must be generated, as the EP, eligible hospital, or CAH is best positioned to determine which reports are most useful to their care efforts. The

report used to meet the measure can cover every patient or a subset of patients. We believe there is no EP, eligible hospital, or CAH that could not benefit their patient population or a subset of their patient population by using such a report to identify opportunities for quality improvement, reductions in disparities of patient care, or for purposes of research or patient outreach; therefore, we did not propose an exclusion for this measure. The report can be generated by anyone who is on the EP's or hospital's staff during the EHR reporting period. We also solicited comment on whether a measure that either increases the number and/or frequency of the patient lists will further the intent of this objective.

Comment: Most commenters voiced support for the objective and measure and wish it to remain unchanged in the final rule, although some commenters stated that the measure should only require demonstration that a list can be created and not require a certain number of patient lists until the needs to create certain patient lists are better ascertained.

Response: We appreciate the support for this objective, and we note that the measure of the objective remains unchanged from Stage 1. Demonstration only of the capability to generate lists of patients by specific conditions would represent a step backward from the Stage 1 measure, therefore we do not agree that this would be an appropriate measure for Stage 2. We also believe there is ample evidence to support the use of patient lists in a variety of quality improvement efforts.

Comment: Some commenters suggested that the measure requirements should be increased, either to require more than one report be generated during the EHR reporting period or to require that the report generated is linked to one of the EP's or eligible hospital's clinical decision support interventions. Another commenter suggested that the measure should indicate how the list should be used.

Response: We believe that moving the objective from the menu set to the core represents an adequate increase for Stage 2. We also continue to believe that an EP, eligible hospital, or CAH is best positioned to determine which reports are most useful to their care efforts. Therefore, we do not propose to direct certain reports be created or link reports to clinical decision support interventions at this time.

Comment: Some commenters suggested that lists should be generated according to specific clinical conditions or include specific elements, such as demographics, to aid analysis. One commenter wanted to know whether EPs retain flexibility in deciding the lists they generate, particularly in coordinating public health activities with state and local public health departments and Medicaid agencies. Another commenter suggested that the measure of the objective specify the continuous use of the report throughout the EHR reporting period.

Response: As noted previously, we are continuing our policy from Stage 1 that an EP, eligible hospital, or CAH is best positioned to determine which reports are most useful to their care efforts. Therefore, we do not propose to direct certain reports be created, nor do we require that specific conditions or elements be required for the reports. Also, we do not set requirements for the frequency of use of the report.

Comment: A commenter asked us to clarify whether the EP must generate the patient list or if the patient list could be generated by a member of the EP's staff in order to meet the measure.

Response: For this and most meaningful use objectives, we do not specify how information must be entered into CEHRT or who must complete the required action to meet the measure. Therefore an EP or a member of the EP's staff could generate the list and meet this measure. The exception to this rule is for computerized provider order entry (CPOE) of

medication, laboratory, and radiology orders, which must be entered by a licensed healthcare professional per state, local, and professional guidelines.

After consideration of the public comments, we are finalizing the meaningful use measure for EPs at §495.6(j)(8)(ii) and eligible hospitals and CAHs at §495.6(l)(7)(ii) as proposed.

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 CEHRT at 45 CFR 170.314(a)(14).

Proposed EP Objective: Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care.

In the proposed rule, we described the following benefits of this objective. By proactively reminding patients of preventive and follow-up care needs, EPs can increase compliance. These reminders are especially beneficial when long time lapses may occur as with some preventive care measures and when symptoms subside, but additional follow-up care is still required.

We also proposed to revise this objective for Stage 2 to "Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care" based on the HITPC recommendation. An EP should use clinically relevant information stored within the CEHRT to identify patients who should receive reminders. We believe that the EP is best positioned to decide which information is clinically relevant for this purpose.

Comment: A commenter stated that the language in the proposed objective is in conflict with the proposed measure. The proposed objective is to "Use clinically relevant information to identify patients who should receive reminders for preventive /follow-up," with no indication that the reminder be sent. However, the proposed measure refers to "patient who had an office

visit and were sent a reminder, per patient preference."

Response: We agree with the commenter that the objective as proposed only speaks to the identification of the need for the reminder and that the proposed measure requires that the reminder be sent. The value of this objective is created when the reminder is sent to the patient and therefore, we revise the objective accordingly.

Comment: Commenters requested request clarification of the operative definition of "reminder." Remembering to keep the appointment is an important first step to follow-up and preventive care and therefore should be counted.

Response: We believe that reminders should be limited to new actions that need to be taken not of actions that are already taken. For example, a reminder to schedule your next mammogram is a reminder to take action, while a reminder that your next mammogram is scheduled for next week is a reminder of action already taken. If we were to allow for reminders of existing scheduled appointments then every provider could meet this objective and measure without any patient ever learning new information. So we clarify that reminders for preventive/follow-up care should be for care that the patient is not already scheduled to receive. Reminders are not necessarily just to follow up with the reminding EP. Reminders for referrals or to engage in certain activities are also included in this objective and measure.

After consideration of the public comments received, we are modifying the objective at §495.6 (j)(9)(i) to "Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care and send these patients the reminders, per patient preference."

Proposed EP Measure: More than 10 percent of all unique patients who have had an office visit with the EP within the 24 months prior to the beginning of the EHR reporting period

were sent a reminder, per patient preference.

In Stage 1, the measure of this objective was limited to more than 20 percent of all patients 65 years old or older or 5 years old or younger. Rather than raise the threshold for this measure, the HIT Policy Committee recommended lowering the threshold but extending the measure to all active patients. We proposed to apply the measure of this objective to all unique patients who have had an office visit with the EP within the 24 months prior to the beginning of the EHR reporting period. We believe this not only identifies the population most likely to consist of active patients, but also allows the EP flexibility to identify patients within that population who can benefit most from reminders. We solicited comments on the appropriateness of this timeframe. We also recognize that some EPs may not conduct face-to-face encounters with patients but still provide treatment to patients. These EPs could be unintentionally prevented from meeting this core objective under the measure requirements, so we proposed an exclusion for EPs who have no office visits in order to accommodate such EPs. Patient preference refers to the method of providing the reminder.

Comment: Commenters expressed concern that even with the proposed revisions many patients in the denominator might not require a reminder. One example given was some colonoscopies are done on a schedule of once every ten years. Another example provided was specialists who see some patients only for one-time consults. Suggestions by commenters to deal with patients in the denominator who do not require reminders involve either much more precise measurement such as tracking and following up when CEHRT identifies the need for a patient reminder, to specific exclusions of certain visit types in the measure or to move the requirement to the menu set. Others suggested that providers who do not typically send reminders be sent granted exclusions.

Response: We agree that not every active patient will require a reminder during the EHR reporting period, which is why the threshold is far below 100 percent. We believe that a low threshold of 10 percent is the best way to account for the contextually specific reasons a patient might not be sent a reminder. We proposed an exclusion for EPs who would typically not send reminders, specifically those without office-based visits. This may not include all providers who do not typically send reminders, but as an exclusion must contain definitive criteria we believe it is a good exclusion. We did not receive in comments precise criteria for an alternative exclusion.

Comment: We received many comments as to what constitutes an active patient in a practice. Many voiced the opinion that given the 24 month look back period in a typical practice, many patients would have moved to another practice. One suggestion given for an alternate way to count patients was to change the definition of "active patients" to be either three or more visits in 24 months or two or more visits in 12 months. Other commenters recommended that the time limitation be removed.

Response: We proposed active patients as a method to limit the denominator to patients more likely to require a reminder. The goal is to limit the denominator as much as possible without excluding patients who should receive a reminder. After reviewing the comments, we change the look back to patients with at least two office visits in the last 24 months. We believe this better establishes a relationship between the provider and the EP. This would account for those specialists that do not have continuing relationships with their patients, but rather hand their care back to the referring provider.

Comment: Several commenters raised concerns with the requirement that it be per patient preference. They asked for clarification on the definition of "per patient preference". Specifically commenters asked if patient preference referred to whether the patient wanted

reminders or what method of communication they wanted to receive the reminders. Second, clarification is requested on how providers should document these preferences. Third, there is concern that an insufficient number of patients will have their preferences recorded at the start of the EHR reporting period and if so, any method of communication should suffice for those patients.

Response: We clarify that patient preference is the method of communication that patients prefer to receive their reminders such as (but not limited to) by mail, by phone or by secure messaging. Given the look back period associated with this measure, we agree that it is not feasible to have all patient preferences recorded prior to the start of the EHR reporting period. Therefore, we clarify that reminders must be sent using the preferred communication medium only when it is known by the provider. This is limited to the type of communication (phone, mail, secure messaging, etc.) and does not extend to other constraints like time of day. Patients may decline to provide their preferred communication medium in which case the provider may select the communication medium. A patient may also decline to receive reminders. We believe that this will be rare enough that combined with the 10 percent through, patients declining to receive reminders will not affect the ability of an EP to meet this measure. It is our expectation that providers will begin to collect this information and that in the future as the look back period catches up to the publication of this final rule it will become possible to require that all reminders be sent per patient preference. We do not specify how things are documented beyond the capabilities and standards included in CEHRT.

After consideration of the public comments received, we are modifying the measure at §495.6 (j)(9)(ii) to "More than 10 percent of all unique patients who have had 2 or more office visits with the EP within the 24 months before the beginning of the EHR reporting period were

sent a reminder, per patient preference when available."

We further specify that in order to meet this objective and measure, an EP must use the capabilities and standards of CEHRT at 45 CFR 170.314(a)(14).

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

● Denominator: Number of unique patients who have had two or more office visits with the EP in the 24 months prior to the beginning of the EHR reporting period.

● Numerator: Number of patients in the denominator who were sent a reminder per patient preference when available during the EHR reporting period.

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

● Exclusion: Any EP who has had no office visits in the 24 months before the EHR reporting period.

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.

In the 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. In addition, we noted that this objective aligns with the Fair Information Practice Principles (FIPPs),[3] in affording baseline privacy protections

[3] In 1973, the Department of Health, Education, and Welfare (HEW) released its report, *Records, Computers, and the Rights of Citizens*, which outlined a Code of Fair Information Practices that will create "safeguard requirements" for certain "automated personal data systems" maintained by the Federal Government. This Code of Fair Information Practices is now commonly referred to as fair information practice principles (FIPPs) and established

to individuals.[4] In particular, the principles include Individual Access (patients should be provided with a simple and timely means to access and obtain their individually identifiable information in a readable form and format). We indicated that this objective replaces the Stage 1 core objective for EPs of "Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, medication allergies) upon request" and the Stage 1 menu objective for EPs of "Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, and allergies) within 4 business days of the information being available to the EP." The HIT Policy Committee recommended making this a core objective for Stage 2 for EPs, and we agreed with their recommendation consistent with our policy of moving Stage 1 menu objectives to the core set for Stage 2. Consistent with the Stage 1 requirements, we noted that the patient must be able to access this information on demand, such as through a patient portal or personal health record (PHR). However, we noted that providers should be aware that while meaningful use is limited to the capabilities of CEHRT to provide online access there may be patients who cannot access their EHRs electronically because of their disability. Additionally, other health information may not be accessible. Finally, we noted that providers who are covered by civil rights laws must provide individuals with disabilities equal access to information and appropriate auxiliary aids and services as provided in the applicable statutes and regulations.

Comment: Some commenters suggested that this objective should be part of the menu set

---

the framework on which much privacy policy will be built. There are many versions of the FIPPs; the principles described here are discussed in more detail in *The Nationwide Privacy and Security Framework for Electronic Exchange of Individually Identifiable Health Information*, December 15, 2008. http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__privacy___security_framework/1173.

[4] The FIPPs, developed in the United States nearly 40 years ago, are well-established and have been incorporated into both the privacy laws of many states with regard to government-held records[4] and numerous international frameworks, including the development of the OECD's privacy guidelines, the European Union Data Protection Directive, and the Asia-Pacific Economic Cooperation (APEC) Privacy Framework.http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__privacy___security_framework/1173.

instead of a core objective for Stage 2. This would permit EPs who do not believe they can meet the measure at this time to select different objectives.

Response: We do not agree that this objective should be part of the menu set. We proposed this objective as part of the core for EPs because it is intended to replace the previous Stage 1 core objective of "Provide patients with an electronic copy of their health information upon request" and the Stage 1 menu objective of "Provide patients with timely electronic access to their health information." Although CEHRT will provide added capabilities for this objective, we do not believe the objective itself is sufficiently different from previous objectives to justify placing it in the menu set. Also, we believe that patient access to their electronic health information is a high priority for the EHR Incentive Programs and this objective best provides that access in a timely manner.

Comment: Some commenters expressed the opinion that this objective should not be included as part of meaningful use and was more appropriately regulated under HIPAA and through the Office for Civil Rights.

Response: We do not agree that this objective should not be included in meaningful use. Although we recognize that many issues concerning the privacy and security of electronic health information are subject to HIPAA requirements, we believe that establishing an objective to provide online access to health information is within the regulatory purview of the EHR Incentive Programs and consistent with the statutory requirements of meaningful use.

Comment: Some commenters suggested that this objective should be combined with the objective to "Provide clinical summaries for patients after each office visit" since much of the information provided in these objectives is identical.

Response: While it is true that there may be overlap between the information provided in

the clinical summary and the information made available through this objective, we believe the clinical summary after an office visit serves a different purpose than online access to health information. A summary of an office visit provides patients and their families with a record of the visit and specific lab tests or specific follow-up actions and treatment related to the visit. While this information is certainly part of the patient's overall electronic health record, the clinical summary serves to highlight information that is relevant to the patient's care at that particular moment. Therefore, we decline to combine the two objectives.

After consideration of the public comments, we are finalizing the meaningful use objective for EPs at §495.6(j)(10)(i) as proposed.

Proposed EP Measures: We proposed two measures for this objective, both of which must be satisfied in order to meet the objective:

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.

More than 10 percent of all unique patients seen by the EP during the EHR reporting period (or their authorized representatives) view, download or transmit to a third party their health information.

Exclusions: Any EP who neither orders nor creates any of the information listed for inclusion as part of this measure may exclude both measures. 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 only the second

measure.

As we stated in the proposed rule, transmission can be any means of electronic transmission according to any transport standard(s) (SMTP, FTP, REST, SOAP, etc.). However, the relocation of physical electronic media (for example, USB, CD) does not qualify as transmission although the movement of the information from online to the physical electronic media will be a download.

Comment: Some commenters suggested that the timeframe for the first measure should be expanded to 7 days, since the data required to be provided in order to meet the measure of this objective would sometimes be incomplete only 4 days after the patient's visit. Other commenters suggested the timeline for the first measure should be shortened to 2 business days or 24 hours.

Response: We do not agree that the timeframe for the measure should be lengthened. In the Stage 1 menu objective of "Provide patients with timely electronic access to their health information," we established the measure for providing access within 4 business days. Also, we believe that most of the information required by this measure, except for lab tests, will be readily available within the specified time period. However, we also believe that 24 hours or 2 business days would not provide adequate time to make all information available online. Therefore, we maintain the requirement of making information available within 4 business days.

Comment: Some commenters asked for clarification on whether online access had to be made available using CEHRT or if the information could be made available through other means (patient portal, PHR, etc.).

Response: Both of the measures for this objective must be met using CEHRT. Therefore, for the purposes of meeting this objective, the capabilities provided by a patient portal, PHR, or any other means of online access and that would permit a patient or authorized

representative to view, download, or transmit their personal health information would have to be certified in accordance with the certification requirements adopted by ONC. We refer readers to ONC's standards and certification criteria final rule that is published elsewhere in this issue of the **Federal Register**.

Comment: A commenter asked how long data should be made available online before it can be removed. In a related topic, another commenter asked which provider would be responsible for excluding data from sharing when multiple providers share CEHRT.

Response: It is the goal of this objective to make available to the patient both current and historical health information. Therefore, we would anticipate that the data should be available online on an ongoing basis. However, an EP may withhold or remove information from online access if they believe substantial harm may arise from its disclosure online. In regard to withholding data and which provider should be responsible for making the determination when multiple providers share CEHRT, we would expect that providers sharing the CEHRT would make a joint determination regarding the information to be withheld. Therefore, we leave this decision to the providers' discretion.

Comment: Some commenters asked for clarification on how access by the patient is defined.

Response: We define access as having been given when the patient possesses all of the necessary information needed to view, download, or transmit their information. This could include providing patients with instructions on how to access their health information, the website address they must visit for online access, a unique and registered username or password, instructions on how to create a login, or any other instructions, tools, or materials that patients need in order to view, download, or transmit their information.

Comment: Some commenters suggested that patients under the age of 18 should not have the same access to the same information to which adult patients have access and requested a separate list of required elements for patients under the age of 18.

Response: An EP may decide that online access is not the appropriate forum for certain health information for patients under the age of 18. Within the confines of the laws governing guardian access to medical records for patients under the age of 18, we would defer to the EP's judgment regarding which information should be withheld for such patients. In lieu of providing online access to patients under the age of 18, EPs could provide online access to guardians for patients under the age of 18, in accordance with state and local laws, in order to meet the measure of this objective. Providing online access to guardians in accordance to state and local laws would be treated the same as access for patients, and guardians could then be counted in the numerator of the measure. We recognize that state and local laws may restrict the information that can be made available to guardians, and in these cases such information can be withheld and the patient could still be counted in the numerator of the measure. No requirement of meaningful use supersedes any federal, state or local law regarding the privacy of a person's health information.

Comment: Some commenters suggested that specialists should transmit information to the patient's primary care provider rather than providing online access to information in order to reduce the number of portals a patient must visit, which could cause confusion.

Response: We believe that much of this information will be transmitted between providers as part of the summary of care record following a transition of care. However, we also believe there is value to the patient in having online access to this information for all providers they visit, including specialists. Therefore, we maintain this measure for all EPs.

Comment: Many commenters voiced objections to the second measure of this objective and the concept of providers being held accountable for patient actions. The commenters believed that while providers could be held accountable for making information available online to patients, providers could not control whether patients actually accessed their information. Many commenters also noted that the potential barriers of limited internet access, computer access, and patient engagement with health IT for certain populations (for example, rural, elderly, lower income, visually impaired, non-English-speaking, etc.) might make the measure impossible to meet for some providers. There were also a number of comments stating that metrics used to track views or downloads can be misleading and are not necessarily the most accurate measure of patient usage. Commenters suggested a number of possible solutions to allow providers to overcome these barriers, including eliminating the percentage threshold of the measure or requiring providers to offer and track patient access but not requiring them to meet a percentage measure in order to demonstrate meaningful use. However, some commenters believed that the measure was a reasonable and necessary step to ensure that providers had accountability for engagement of their patients in use of electronic health information and integration of it into clinical practice. In addition, commenters pointed to the unique role that providers can play in encouraging and facilitating their patients' and their families' use of online tools.

Response: While we recognize that EPs cannot directly control whether patients access their health information online, we continue to believe that EPs are in a unique position to strongly influence the technologies patients use to improve their own care, including viewing, downloading, and transmitting their health information online. We believe that EPs' ability to influence patients coupled with the low threshold of more than 10 percent of patients having

viewed online, downloaded, or transmitted to a third party the patient's health information make this measure achievable for all EPs.

We recognize that certain patient populations face greater challenges in online access to health information. We address the potential barrier of limited internet access in the comment regarding a broadband exclusion below. We address the potential barrier to individuals with disabilities through ONC's rules requiring that EHRs meet web content accessibility standards. While we agree that excluding certain patient populations from this requirement would make the measure easier for EPs to achieve, we do not know of any reliable method to quantify these populations for each EP in such a way that we could standardize exclusions for each population. We also decline to eliminate the percentage threshold of this measure because we do not believe that a simple yes/no attestation for this objective is adequate to encourage a minimum level of patient usage. However, in considering the potential barriers faced by these patient populations, we agree that it would be appropriate to lower the proposed threshold of this measure to more than 5 percent of unique patients who view online, download, or transmit to a third party the patient's health information. In addition, we are concerned that blanket exclusions for certain disadvantaged populations could serve to extend existing disparities in electronic access to health information and violate civil rights laws. All entities receiving funds under this program are subject to civil rights laws. For more information about these laws and their requirements (see http://www.hhs.gov/ocr/civilrights/index.html). We believe that this lower threshold, combined with the broadband exclusion detailed in the response that follow, will allow all EPs to meet the measure of this objective.

Comment: Some commenters suggested an alternate definition of the second measure based on the number of patients seen within the last 2 years that access their health information

online.

Response: We believe that the current numerator and denominator for this measure encourage the active online access by patients of their health information. We further believe that broadening the time period of this measure to patients seen within the last 2 years does not encourage both EPs and current patients to use online access to health information in the active management of their care, which is one of the goals of the EHR Incentive Programs. Therefore, we decline to adopt this suggested alternate definition.

Comment: Some commenters asked for clarification on how view is defined.

Response: We define view as the patient (or authorized representative) accessing their health information online.

Comment: Some commenters noted that the potential financial burden of implementing an online patient portal to provide patients online access to health information. These commenters noted the added time burden for staff in handling the additional patient use of online resources, which may increase costs through the hiring of additional staff, as well as the need to modify their existing workflow to accommodate additional online messages from patients. Some commenters also believed that there would be an additional cost for sharing content before standards exist for content types and formats.

Response: We do not believe that implementing online access for patients imposes a significant burden on providers. While we note that in some scenarios it may be possible for an EP to receive reimbursement from private insurance payers for online messaging, we acknowledge that EPs are generally not reimbursed for time spent responding to electronic messaging. However, it is also true that EPs are generally not reimbursed for other widely used methods of communication with patients (for example, telephone). As we noted in the proposed

rule, many providers have seen a reduction in time responding to inquires and less time spent on the phone through the use of health IT, including online messages from patients. We expect the same will be true for online access to health information by reducing continuous requests for health records, test results, and other pertinent patient information. Finally, we believe that the standards established for this objective by ONC will serve as a content standard that will allow this information to be more easily transmitted and uploaded to another certified EHR, thereby reducing additional costs.

Comment: Some commenters noted that patient engagement could occur effectively with or without online access, and patients should be encouraged to use any method (for example, telephone, internet, traditional mail) that suits them. These commenters noted that engagement offline reduces both the need and value for engagement online.

Response: We agree that patient engagement can occur effectively through a variety of media, and we also believe that electronic access to health information can be an important component of patient engagement. We do not believe that offline engagement reduces the need for online access, as patients may opt to access information in a variety of ways. Because of the variety of ways that patients/families may access information, we keep the threshold for this measure low. We also note that online access to health information can enhance offline engagement—for example, patients could download information from an office visit with their primary care provider to bring with them for a consult with a specialist—which is one of the primary goals of the EHR Incentive Programs.

Comment: Some commenters expressed concern that vendors would not be able to make these capabilities available as part of CEHRT in time for the beginning of Stage 2.

Response: Many CEHRT vendors already make patient portals available that would meet

the certification criteria and standards required for this measure. In fact, many vendors have already incorporated these capabilities into their CEHRT products in order to meet the measure of the Stage 1 objective to "Provide patients with timely electronic access to their health information." Although the Stage 2 measure requires some additional capabilities, we believe vendors will be able to make these capabilities available in time for the beginning of Stage 2.

Comment: Some commenters requested clarification on the exclusion regarding an EP "who neither orders nor creates any of the information listed for inclusion as part of this measure may exclude both measures." Because the list of required elements for this measure includes the patient's name, provider's name, and office contact information, these commenters suggested that no EP could qualify for this exclusion.

Response: We amend the wording of the exclusion to accommodate providers who do not order or create any of the information listed, except for patient name, provider name, and office contact information.

Comment: Some commenters suggested that basing an exclusion on the broadband data available from the FCC website (www.broadband.gov) was suspect since the data originates from vendors.

Response: The broadband data made available from the FCC was collected from over 3,400 broadband providers nationwide. This data was then subject to many different types of analysis and verification methods, from drive testing wireless broadband service across their highways to meeting with community leaders to receive feedback. Representatives met with broadband providers, large and small, to confirm data, or suggest changes to service areas, and also went into the field looking for infrastructure to validate service offerings in areas where more information was needed. Therefore, we believe the data is appropriate for the exclusion to

this measure. We note that since publication of our proposed rule the website has changed to www.broadbandmap.gov and the speed used has changed from 4Mbps to 3Mbps. We are updating our exclusion to reflect these changes.

Comment: Some commenters believe that broadband exclusions should be based on the patients' locations instead of the providers, since county-level data may not be granular enough to capture all areas of low broadband availability within a particular region.

Response: Although we agree that a broadband exclusion based primarily on the individual locations of each patient seen would be more accurate, we do not believe that there is any method of making this determination for every patient without placing an undue burden on the provider. We continue to believe that limited broadband availability in the EP's immediate practice area, coupled with the low threshold of this measure, adequately serves as an acceptable proxy for determining areas where online access can present a challenge for patients. Therefore, we retain the broadband exclusion as proposed.

Comment: Some commenters requested a clarification of the required element of "Any additional known care team members beyond the referring or transitioning provider and the receiving provider."

Response: With this element we mean for providers to indicate the names and contact information for any other health care professionals known to the EP. This could include referring providers, receiving providers, or any other provider inside or outside the EP's practice that provides care to the patient. We are amending the language for this required element to "Any known care team members."

Comment: Some commenters suggested that growth charts should not be included for either download or transmission, since these charts are simply visualizations of the height and

weight data elements.

Response: We believe that growth charts can be a useful tool for both patients and providers, especially in instances where a patient may elect to download or transmit their health information to another provider. Therefore, we require them to be included to meet the measure of this objective.

Comment: One commenter suggested that images should not be included in the list of required elements to be provided to patients online. They cited specific difficulties in image viewing online, as well as concerns over file size.

Response: We note the commenter's concerns and further note that images are not among the required elements to meet the measure of this objective.

After consideration of the public comments, we finalize the first meaningful use measure for EPs as proposed at §495.6(j)(10)(ii)(A). We finalize the second meaningful use measure for EPs as "More than 5 percent of all unique patients seen by the EP during the EHR reporting period (or their authorized representatives) view, download or transmit to a third party their health information" at §495.6(j)(10)(ii)(B). We finalize the following exclusions for EPs at §495.6(j)(10)(iii): "Any EP who neither orders nor creates any of the information listed for inclusion as part of both measures, except for "Patient name" and "Provider's name and office contact information," may exclude both measures;" "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 3Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude only the second measure".

We further specify that in order to meet this objective and measure, an EP must use the capabilities and standards of CEHRT at 45 CFR 170.314(e)(1).

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:

- 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.

For the second measure for reporting on the number of unique patients seen by the EP during the EHR reporting period (or their authorized representatives) who view, download or transmit health information, CMS and ONC have worked together to define the following for this objective:

- Denominator: Number of unique patients seen by the EP 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 5 percent in order for an EP to meet this measure.
- Exclusions: Any EP who neither orders nor creates any of the information listed for inclusion as part of both measures, except for "Patient name" and "Provider's name and office

contact information," may exclude both measures. 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 3Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude only the second measure.

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

As we stated in the proposed rule, this is not intended to limit the information made available by the EP. An EP can make available additional information and still align with the objective. In circumstances where there is no information available to populate one or more of the fields previously listed, either because the EP can be excluded from recording such information (for example, vital signs) or because there is no information to record (for example,

no medication allergies or laboratory tests), the EP may have an indication that the information is not available and still meet the objective and its associated measure. Please note that while some of the information made available through this measure is similar to the information made available in the summary of care document that must be provided following transitions of care or referrals, the list of information above is specific to the view online, download, and transmit objective. Patients and providers have different information needs and contexts, so CMS has established separate required fields for each of these objectives.

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

In the proposed rule, we explained that providing clinically relevant education resources to patients is a priority for the meaningful use of CEHRT. Based on our experience with this objective in Stage 1, we are clarifying that while CEHRT must be used to identify patient-specific education resources, these resources or materials do not have to be stored within or generated by the CEHRT. We are aware that there are many electronic resources available for patient education materials, such as through the National Library of Medicine, that can be queried via CEHRT (that is, specific patient characteristics are linked to specific consumer health content). The EP or hospital should utilize CEHRT in a manner where the technology suggests patient-specific educational resources based on the information stored in the CEHRT. Certified EHR technology is certified to use the patient's problem list, medication list, or laboratory test results to identify the patient-specific educational resources. The EP or hospital may use these elements or additional elements within CEHRT to identify educational resources specific to patients' needs. The EP or hospital can then provide these educational resources to patients in a

useful format for the patient (such as, electronic copy, printed copy, electronic link to source materials, through a patient portal or PHR).

In the Stage 1 final rule (75 FR 44359), we included the phrase "if appropriate" in the objective so that the EP or the authorized provider in the hospital could determine whether the education resource was useful and relevant to a specific patient. Consistent with the recommendations of the HIT Policy Committee, we proposed to remove the phrase "if appropriate" from the objective for Stage 2 because we do not believe that any EP or hospital will have difficulty identifying appropriate patient-specific education resources for the low percentage of patients required by the measure of this objective.

We also recognized that providing education materials at literacy levels and cultural competency levels appropriate to patients is an important part of providing patient-specific education. However, we continue to believe that there is not currently widespread availability of such materials and that such materials could be difficult for EPs and hospitals to identify for their patients.

Comment: Many commenters sought clarification on the meaning of the term "identified by CEHRT." They questioned how the CEHRT would identify resources and whether the education resources had to be stored in the CEHRT or if it could contain links to the materials.

Response: We clarified in the proposed rule (77 FR 13720) that while CEHRT must be used to identify patient-specific education resources, these resources or materials do not have to be stored within or generated by the Certified EHR Technology. We refer readers to ONC's standards and certification criteria final rule that is published elsewhere in this issue of the **Federal Register** which describes the capabilities and standards that CEHRT must include. For patient-specific education materials, this includes a general functional capability to identify

educational materials as well as a capability to do so using the HL7 Context-aware Information Retrieval "Infobutton" standard. This measure requires that an EP or hospital use the capabilities CEHRT includes to identify patient education materials. To clarify, although CEHRT will include the ability to identify education materials using the HL7 Infobutton standard, such capability alone does not need to be used in order to be counted in the numerator (that is, the general capability to identify education materials also counts towards the numerator).

After reviewing the public comments, we finalize the objective for EPs at §495.6(j)(12)(i) and for eligible hospitals and CAHs at §495.6(l)(9)(i) as proposed.

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

In the proposed rule, we noted that the Stage 1 measure for this objective for EPs was "More than 10 percent of all unique patients seen by the EP are provided patient-specific education resources." Because we proposed this as a core objective for Stage 2, we proposed to modify the measure for EPs to "Patient-specific education resources identified by CEHRT are provided to patients for more than 10 percent of all office visits by the EP." We recognized that some EPs may not conduct face-to-face encounters with patients but still provide treatment to patients. These EPs could be prevented from meeting this core objective under the previous measure requirements, so we proposed to alter the measure to account for office visits rather than unique patients seen by the EP. We also proposed an exclusion for EPs who have no office visits in order to accommodate such EPs.

The resources will have to be those identified by CEHRT. If resources are not identified by CEHRT and provided to the patient then it will not count in the numerator. We do not intend through this requirement to limit the education resources provided to patient to only those

identified by CEHRT. We proposed the threshold at only 10 percent for this reason. We believe that the 10 percent threshold both ensures that providers are using CEHRT to identify patient-specific education resources and is low enough to not infringe on the provider's freedom to choose education resources and to which patients these resources will be provided. The education resources will need to be provided prior to the calculation and subsequent attestation to meaningful use.

Comment: Many commenters expressed concerns about the availability of resources that would be available at the appropriate literacy level for their patient populations. Some stated that there is a dearth of low-literacy materials available as most education sites are geared toward college-educated patients; others stated that most materials are designed to be appropriate for a broad spectrum of literacy levels. Some commenters expressed concerns about the lack of resources available for non-English speaking patients. Yet other commenters were unclear as to what appropriate sources of patient-specific education would be. Some commenters expressed concerns that another alert within the system may create physician fatigue.

Response: We understand the commenters concerns that the educational materials identified by the CEHRT may not be appropriate for certain patients. To accommodate these concerns, we are maintaining the threshold for this measure at 10 percent. As we stated in our proposed rule and in the Stage 1 Final Rule, we account for these concerns by maintaining a low threshold for this objective.

Comment: Some commenters expressed concerns that the CEHRT, not the provider, would "choose" which educational resources would be provided to the patient.

Response: We cannot define the scope of practice and/or appropriate educational resources to be shared with each individual patient and will continue to rely on provider

determinations based on individual patient circumstances.

Comment: Many commenters were concerned that the denominator for the EP measure included the number of office visits by the EP during the EHR reporting period. Commenters agreed with the rationale that EPs might not have the opportunity to provide educational materials to a patient if the patient has not had an office visit with the EP, however, commenters also stated that if an EP has a series of office visits with a patient, it might not be appropriate to provide education at each visit (for example, a patient with heart disease or high blood pressure that would see the EP multiple times during the EHR reporting period). To avoid the potential for presenting redundant information to patients, commenters suggested that the denominator be based on unique patients with office visits. This is consistent with the denominator for eligible hospitals, as that denominator is based on unique patients admitted. Additionally, commenters noted that counting unique patients is more appropriate to account for patient-specific education resources that are not provided in the context of an office visit, such as reference materials available from a portal or PHR about a patient's medications, conditions, or lab results.

Response: We agree with commenters in that counting unique patients with office visits during the EHR reporting period for EPs, rather than office visits, is a more appropriate denominator for this measure. A patient with a chronic disease, such as diabetes or heart disease, may have multiple office visits with an EP during the EHR reporting period. While providing educational resources for these patients is important, presenting the same materials each office visit may prove to be redundant. We encourage EPs to refer educational resources to their patients with multiple visits during the EHR reporting period at their discretion.

Additionally, we do maintain that EPs with no office visits during the EHR reporting period can be excluded from this measure. Therefore, we are finalizing the denominator for this

measure as the "Number of unique patients with office visits seen by the EP during the EHR reporting period."

Comment: Most commenters agreed that 10 percent was a reasonable threshold for this measure as it was proposed.

Response: We agree with commenters and are finalizing 10 percent as the threshold for this measure. It will remain unchanged from Stage 1.

After reviewing the public comments, we are finalizing the measure for EPs at §495.6(j)(12)(ii) as "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 further specify that in order to meet this objective and measure, an EP must use the capabilities and standards of CEHRT at 45 CFR 170.314(a)(15).

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

- Denominator: Number of unique patients with office visits seen by the EP during the EHR reporting period.
- Numerator: Number of patients in the denominator who were provided patient-specific education resources identified by the Certified EHR Technology.
- Threshold: The resulting percentage must be more than 10 percent in order for an EP to meet this measure.
- Exclusion: Any EP who has no office visits during the EHR reporting period.

Proposed Eligible Hospital/CAH Measure: More than 10 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23)

are provided patient-specific education resources identified by Certified EHR Technology.

After consideration of public comments, we are finalizing the measure for eligible hospitals and CAHs at §495.6(l)(9)(ii) as proposed.

We further specify that in order to meet this objective and measure, an eligible hospital or CAH must use the capabilities and standards of CEHRT at 45 CFR 170.314(a)(15).

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's or CAH's 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 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 proposed rule we outlined the following benefits of this objective. 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 their direct patient care, it also improves the accuracy of information they provide to others through health information exchange.

In the proposed rule, we noted that that when conducting medication reconciliation during a transition of care, the EP, eligible hospital or CAH that receives the patient into their

care should conduct the medication reconciliation. We reiterated that the measure of this objective does not dictate what information must be included in medication reconciliation. Information included in the process of medication reconciliation is appropriately determined by the provider and patient. In the proposed rule 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. We proposed that the electronic exchange of information is not a requirement for medication reconciliation.

Comment: Commenters requested that the definition of medication reconciliation should specifically mention over-the-counter medications, vitamins, herbal or other alternative care medications in the definition.

Response: We believe our term medications is expansive and not limiting. We in no way limit what any provider chooses to include or not include in their conduct of a medication reconciliation. As we are focused on the use of CEHRT to assist in medication reconciliation it is not our intent to develop a definitive definition of what medication reconciliation is.

Comment: Commenters stated that the objective is so reliant on health information exchange that it should not be moved to core until health information exchange capability increases.

Response: Robust health information exchange is certainly of great assistance to medication reconciliation. However, it is not required for medication reconciliation. Nor is electronic health information exchange the only way EHRs can assist with medication reconciliation. So while we believe that medication reconciliation will become easier as health information exchange capability increases, it is not a prerequisite to performing medication

reconciliation.

After consideration of the comments received, we are finalizing this objective as proposed for EPs at §495.6 (j)(13)(i) and for eligible hospitals and CAHs at §495.6(l)(10)(i).

Proposed Measure: The EP, eligible hospital or CAH performs medication reconciliation for more than 65 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).

In the proposed rule, we stated that although the HITPC recommended maintaining this threshold at 50 percent we believed that due to this measure's role in information exchange that we seek to promote through meaningful use a higher measure was appropriate. Based on the performance of providers in Stage 1, we proposed to raise the measure to 65 percent.

Comment: If as stated in the proposed rule "the majority chose to defer this measure in Stage 1," commenters asserted that this is insufficient information to justify raising the threshold to 65 percent and move the objective to core. Other commenters assert that any measure that moves from menu to core should maintain its Stage 1 threshold regardless of the particular measure's rate of deferral.

Response: After considering the arguments for lowering the threshold to 50 percent and the lack of robust data in support of the proposed threshold, we do lower the threshold to 50 percent. For this measure in particular, we agree that since most providers chose to defer this measure in Stage 1 the information available on performance from Stage 1 meaningful EHR users is not as robust as for other objectives and measures. We do not agree with the comment that all objectives that move from menu to core should maintain the same threshold. We believe such a blanket policy would be arbitrary and not properly account for the information available

for each objective and measure. For example, if most Stage 1 meaningful EHR users had reported on this measure, there would be a robust data set of performance on which to judge a threshold. A blanket policy would ignore such information.

Comment: The denominator of transitions of care during the EHR reporting period for which the provider is the receiving part of the transition is imprecise and therefore difficult to determine, especially when neither the transitioning provider or patient notifies the provider of the transition.

Response: We addressed this comment earlier in this section in our discussion of meaningful use denominators and provided a minimum set of specific actions that would indicate a transition of care has occurred.

Comment: While the objective speaks to relevant encounters, these are not included in the measure. This makes measurement difficult for those providers that conduct medication reconciliation at more than just transitions of care. If providers were allowed to include these encounters in the measure, measurement would both be easier and more representative of the actual use of CEHRT by the provider.

Response: We continue to believe that what is a relevant encounter is to variable to be included in the measure for all providers. However, a provider who institutes a policy for medication reconciliation at encounters encompassing more than just the minimum actions defined by the transitions of care denominator can include those encounters in their denominator and if medication reconciliation is conducted at the encounter in the numerator as well.

After consideration of the comments, we are modifying the threshold of the measure for EPs at §495.6 (j)(13)(ii) and for eligible hospitals and CAHs at §495.6(l)(10)(ii). 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).

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 CEHRT at 45 CFR 170.314(b)(4).

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

In the proposed rule, we outlined the following benefits of this objective. By assuring lines of communication between providers caring for the same patient, all of the providers of care can operate with better information and more effectively coordinate the care they provide. Electronic health records, especially when linked directly or through health information exchanges, reduce the burden of such communication. The purpose of this objective is to ensure

a summary of care record is provided to the receiving provider when a patient is transitioning to a new provider or has been referred to another provider while remaining under the care of the referring provider.

In the proposed rule, we proposed to eliminate the Stage 1 objective for the exchange of key clinical information for Stage 2 and instead include such information as part of the summary of care when it is a part of the patient's electronic record. We also proposed to incorporate two separate Stage 2 recommendations from the HIT Policy Committee as required fields in the summary of care record--

- Record care plan fields, including goals and instructions, for at least 10 percent of transitions of care; and
- Record team member, including primary care practitioner, for at least 10 percent of patients.

ONC also proposed in their standards and certification criteria rule (77 FR 13848 to include these as standard fields required to populate the summary of care document so CEHRT will be able to include this information. We provided a description of a "care plan" as well as the minimum components it must include for purposes of meaningful use, although we recognized that the actual content would be dependent on the clinical context. We asked for comments on both our description of a care plan and whether a description is necessary for purpose of meaningful use.

We proposed certain elements that are listed in the proposed rule (77 FR 13722) to be included in the summary care document. In circumstances where there is no information available on an element, either because the EP, eligible hospital or CAH can be excluded from recording such information or because there is no information to record, the EP, eligible hospital

or CAH may leave the field(s) blank and still meet the objective and its associated measure.

In addition, we proposed that all summary of care documents used to meet this objective must include the following:

- An up-to-date problem list of current and active diagnoses.
- An active medication list, and
- An active medication allergy list.

We proposed that all summary of care documents must contain the most recent and up-to-date information on these three elements to count in the numerator. We proposed to define problem list as a list of current and active diagnoses. We solicited comment on whether the problem list should be extended to include, "when applicable, functional and cognitive limitations" or whether a separate list should be included for functional and cognitive limitations. We proposed to define an up-to-date problem list as a list populated with the most recent diagnoses known by the EP or hospital. We proposed to define active medication list as a list of medications that a given patient is currently taking. We proposed to define active medication allergy list as a list of medications to which a given patient has known allergies. We proposed to define allergy as an exaggerated immune response or reaction to substances that are generally not harmful. In the event that there are no current or active diagnoses for a patient, the patient is not currently taking any medications, or the patient has no known medication allergies, confirmation of no problems, no medications, or no medication allergies would satisfy the measure of this objective. Note that the inclusion and verification of these elements in the summary of care record replaces the Stage 1 objectives for "Maintain an up-to-date problem list," "Maintain active medication list," and "Maintain active medication allergy list."

Comment: Commenters suggested that the required data for each type of referral and

transitions varies and that rather than creating a list of elements, the provider should decide what is needed.

Response: While we agree that tailoring the summary of care document for each referral and transition of care is desirable, we disagree that this means a list of basic elements that should be in each summary of care documents is not appropriate. We note that most organizations that try and tackle the issue of summary of care documents have required fields, core sets or other nomenclature for elements that they believe should be in all summary of care documents. For example, the CDA architecture used as the standard for the summary of care document contains required and optional fields. The American College of Physicians in their Neighborhood Model uses a core data set. None of these organizations intend for their list of elements to be limiting and nor do we intend our list to be limiting, but rather serve as a minimum. In our proposed rule we went further and said that if the provider does not have the information available to populate one or more of the fields listed, either because they can be excluded from recording such information (for example, vital signs) or because there is no information to record (for example, laboratory tests), the provider may leave the field(s) blank. The only exception to this is the problem list, medication list, and medication allergy list. Therefore, we are including a list of elements in this final rule.

Comment: Commenters stated that their understanding is that if any of the fields specifically for problem list, medication list, or allergy list is blank (meaning no entry of problems, medications or allergies nor an indication that it is known by the provider that the patient has no problems, medication or allergies), the EP or hospital will not meet the measure, but that if any other information is blank, the EP or hospital will still meet the measure. Please clarify whether this is a correct understanding of the proposal.

Response: This understanding of our proposed rule is generally correct. The problem list, medication list and medication allergy list must also either contain problems, medications and medication allergy or a specific notation that the patient has none. Leaving the field entirely blank with no entry whatsoever would not meet the measure. However, in cases where the provider does not have the information available to populate one or more of the other fields listed, either because they can be excluded from recording such information (for example, vital signs) or because there is no information to record (for example, laboratory tests), the provider may leave the field(s) blank. Note this does not allow a provider to disable a listed field from being generated by the CEHRT, but rather allows for when the CEHRT does not contain information on which to generate an entry for the field.

Comment: Some commenters suggested the substitution of past medical history for historical problem list in the list of required elements, since past medical history could provide additional information valuable to patient care.

Response: CMS' Evaluation and Management Services Guide defines a past medical history as the patient's past "experiences with illnesses, operations, injuries and treatments" (see http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/eval_mgmt_serv_guide-ICN006764.pdf, p. 11). In our proposed rule, we referred to "current and historical problem list" as this is more concrete and standards based than the definition for past medical history. We believe the concept of past medical history is inclusive of current and historical problem list. We understand that providers are more familiar with the term past medical history and will evaluate expanding historical problem list to past medical history for Stage 3. However, for Stage 2, we are finalizing current and historical problem list. For summary of care documents at transitions of care we encourage

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 they are active or resolved, that have ever populated the problem list. While a current problem list should always be included, the provider can use his or her judgment in deciding which items historically present on the problem list, PMHx list (if it exists in CEHRT), or surgical history list are included given the clinical circumstances.

Comment: Commenters stated that it is too burdensome to determine whether the problem list, medication list and medication allergy list are included in each summary of care document.

Response: We disagree that this is too burdensome. We note that in Stage 1 measuring the completeness of the problem list, medication list and medication allergy list is already a requirement. Summary of care documents are generated by the CEHRT based on the information available to it. Therefore, there are only two causes of error that would have to be discovered to make the determination of whether the problem list, medication list and medication allergy list are included.. The problem list, medication list and medication allergy list do not contain information for a given patient and/or there is an error in the generation of the summary of care document. This discovery constitutes the burden of this measure. We have already noted that the ability to know whether the lists contain information is already a Stage 1 measure. The second issue is prevalent in nearly every meaningful use measure that requires CEHRT to generate a measurement so that burden is already integral to meaningful use.

Comment: Commenters stated that the different descriptions of problem list throughout the proposed rule create confusion. The four terms used are "an up-to-date problem list of current and active diagnoses", "problem list", "Current problem list and any updates to it" and "problem

list maintained by the hospital on the patient". CMS should use this term uniformly. Furthermore, the limitation of the problem list to only current and active diagnoses is inconsistent with how problem lists are used and historical problems should also be included.

Response: We only proposed one definition of the base term "problem list", which is a list of current and active diagnoses. We then use descriptors to tailor the term to the objective in which it is being utilized. For example, "up-to-date" means that the problem list in the CEHRT is populated with the most recent diagnoses known by the EP or hospital. The description used for office visit summary "Current problem list and any updates to it" was intended to separate problems that were known before the visit and those that were determined during the visit. We agree that our limitation of the "problem list" to just current and active diagnoses is unnecessarily limiting. The C-CDA, which is the standard adopted for EHR technology certification, for summary of care documents states that "at a minimum, all pertinent current and historical problems should be listed". We revise our definition of "problem list" to include historical problems. This is a minimum. We do not limit the provider to just including diagnoses on the problem list. We agree that there should be just one definition of the base term "problem list"; however, we disagree that the same list is appropriate for every case especially with the addition of the historical problems. Some objectives call for the current problem list which includes only those diagnoses of problems currently affecting the patient. Other objectives call for the current and historical problem list, which would include problems currently affecting the patient as well as those that have been resolved. For purposes of clarity, we are consolidating across all of the meaningful use objectives to just two descriptions of our term "problem list": "current problem list" and "current and historical problem list." This consolidation also removes the need for a separate item of past relevant diagnosis as these would

be included in a historical problem list. We define active medication list as a list of medications that a given patient is currently taking. We define active medication allergy list as a list of medications to which a given patient has known allergies. We define allergy as an exaggerated immune response or reaction to substances that are generally not harmful. 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. In the event that there are no current or active diagnoses for a patient, the patient is not currently taking any medications, or the patient has no known medication allergies, confirmation of no problems, no medications, or no medication allergies would satisfy the measure of this objective.

Comment: Many commenters recommended against any specification of problem list content regarding functional and cognitive limitations citing insufficient consensus around the appropriate classification of these functions. Commenters also stated that if included, functional and cognitive limitations should be further defined.

Response: As noted earlier in this final rule under the demographic objective, we wish to clarify that both the concepts of physical and cognitive disabilities as well as the concept of functional limitations that impact an individual's capability to perform activities were included in our description of disability status for the purpose of this rule. The latter concept is a common metric for care planning and care coordination across settings because knowledge of a patient's abilities (for example, functional and/or cognitive status) are also necessary for clinical practice. While many commenters noted the lack of consensus for the terms and standards necessary to support the inclusion of disability, functional and cognitive status assessment and observations into the Consolidated CDA for summary of care records, we understand that this standard was

updated to include section-and data-entry level templates that can describe a patient's functional and cognitive status. However, we agree that there is insufficient definitions for disability, functional and cognitive status assessment and observations to include them as part of the problem list. Therefore, we are including "functional status, including functional, cognitive and disability" as a separate element in the summary of care document.

Comment: In regard to the inclusion of "care plan field" in the list of required information, some commenters believed that the wording was overly prescriptive since CEHRT could utilize multiple fields to structure care plans. Other commenters requested a more detailed definition of care plan and/or the standards that are available or required.

Response: We agree that the language proposed could be viewed as prescriptive, and we do not intend to limit the inclusion of the care plan to a single field. Therefore, we are amending the language to "Care plan field(s), including goals and instructions" in our list of required elements below. However, we decline to provide an alternate definition that would limit the information in the care plan. We believe that the definition we proposed in the proposed rule is sufficient to allow for the inclusion of a variety of care plans in the clinical summary. For purposes of the clinical summary, we define a care plan as the structure used to define the management actions for the various conditions, problems, or issues. A care plan must include at a minimum the following components: problem (the focus of the care plan), goal (the target outcome) and any instructions that the provider has given to the patient. A goal is a defined target or measure to be achieved in the process of patient care (an expected outcome).

Comment: Commenters stated that while the care team members are clearly important data elements and key to clinical coordination, they recommended further research into true standards to support these elements before any requirements are imposed.

Response: Our proposal is to include "Any additional known care team members beyond the referring or transitioning provider and the receiving provider". We believe that the ability to identify providers is well established. We note that there is no requirement to identify the role of each provider which we would agree are not well established beyond PCP and referring provider. We also note that this is only for cases when the other care team members are known by the transitioning provider. These allowances are sufficient to accommodate the current standard limitations and therefore we finalize as proposed.

Comment: As referrals are included in the denominator as well as transitions of care, the summary of care document should include the reason for the referral.

Response: We agree with this comment and add reason for referral for EPs. The reason for the referral is the clinical question the referring provider wants answered for a consultation or the procedure to be performed. If the consultation is more open ended, then a brief summary of the case details pertinent to referral suffices.

After consideration of the comments, 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.

After consideration of public comments, we are finalizing this objective for EPs at §495.6

(j)(14)(i) and for eligible hospitals and CAHs at §495.6(l)(11)(i) as proposed.

Proposed Measures: EPs, eligible hospitals, and CAHs must satisfy both measures in order to meet the objective:

The EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 65 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 electronically transmits a summary of care record using CEHRT to a recipient with no organizational affiliation and using a different CEHRT vendor than the sender for more than 10 percent of transitions of care and referrals.

First Measure:

We proposed that if the provider to whom the referral is made or to whom the patient is transitioned has access to the medical record maintained by the referring provider, then the summary of care record would not need to be provided and that patient should not be included in the denominators of the measures of this objective. We stated in the proposed rule that different settings within a hospital using the same CEHRT would have access to the same information, so providing a clinical care summary for transfers within the hospital would not be necessary.

Comment: If as stated in the proposed rule "the majority chose to defer this measure in Stage 1", commenters asserted this is insufficient information to justify raising the threshold to 65 percent and move the objective to core. Other commenters assert that any measure that moves from menu to core should maintain its Stage 1 threshold regardless of the particular measure's rate of deferral.

Response: After considering the arguments for lowering the threshold to 50 percent and

the lack of a robust data set in support of the proposed threshold, we do lower the threshold to 50 percent. For this measure in particular, we agree that since most providers chose to defer this measure in Stage 1 the information available on performance from Stage 1 meaningful EHR users is not as robust as for other objectives and measures. We do not agree with the comment that all objectives that move from menu to core should maintain the same threshold. We believe such a blanket policy would be arbitrary and not properly account for the information available for each objective and measure. For example, if most Stage 1 meaningful EHR users had reported on this measure, there would be a robust data set of performance on which to judge a threshold. A blanket policy would ignore such information.

Comment: Commenters questioned and requested clarification on situations where the recipient of the transition or referral is using the same instance of CEHRT or otherwise has access to the CEHRT of the transitioning or referring provider. Some of these commenters acknowledged our proposal to address this situation were also split between support for our proposal to exclude these from the denominator versus allowing them to be in the denominator and numerator of both measures. Also commenters expressed concern on whether this was a measurable constraint. Finally, commenters requested clarification on whether our proposal applied to one or both measures.

Response: We proposed that if the provider to whom the referral is made or to whom the patient is transitioned has access to the medical record maintained by the referring provider, then the summary of care record would not need to be provided and that patient should not be included in the denominators of the measures of this objective. We believe that different settings within a hospital using CEHRT would have access to the same information, so providing a clinical care summary for transfers within the hospital would not be necessary. This is a

continuance of our current Stage 1 policy. In response to comments, this policy applies to both measures. We clarify the first sentence that access to the medical record could be through several mechanisms. Some providers will be in the same organization and share CEHRT outright. Other providers might grant remote access to their CEHRT to providers not sharing their same CEHRT. We do not limit the mechanisms through which access is granted. We disagree that this access should count in the denominator or numerator of either measure. A summary of care document generated by CEHRT conforms to specific standards and could in many cases be automatically integrated into the recipient's CEHRT. Access provides no such capability. For this reason, we finalize our policy of excluding these transitions and referrals from the denominator. However, if a transitioning or referring provider provides both access and a summary of care document to providers outside their organization and wishes to include them in their denominator and as appropriate their numerator, they can do so. Finally, while we agree that it some cases it may be difficult to determine whether the recipient has access to the sender's CEHRT. We do not believe that we should remove an accommodation due to measurement difficulties. It is acceptable for a provider to include these transitions and referrals in the denominator, but only if a summary of care document is provided would it count in the numerator.

Comment: Commenters stated that there are some providers who may engage in a small number of transitions of care and referrals and the implementation burden of this objective is too high to require of those with only a small number. This is particularly true as the requirement for electronic health information exchange is introduced.

Response: We have previously allowed for a more than zero, but less than 100 exclusion for our other objective requiring electronic health information exchange (eRx); therefore, in

response to these comments we will apply that policy to this objective and measure as well and raise the exclusion from zero to less than 100 transitions of care and referrals. Transitions of care and referrals are additive so someone with 50 transitions of care and 75 referrals would not qualify for the exclusion.

After consideration of public comments, we are revising the measure for EPs at §495.6 (j)(14)(ii)(A) and for eligible hospitals and CAHs at §495.6(l)(11)(ii)(A) to "The EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50 percent of transitions of care and referrals."

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 CEHRT at 45 CFR 170.314(b)(l) and (b)(2)(i).

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

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

• Numerator: The number of transitions of care and referrals in the denominator where a summary of care record was provided.

• Threshold: The percentage must be more than 50 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 is excluded from all three

measures.

Second Measure:

For Stage 2, we proposed the additional second measure for electronic transmittal because we believe that the electronic exchange of health information between providers will encourage the sharing of the patient care summary from one provider to another and the communication of important information that the patient may not have been able to provide, which can significantly improve the quality and safety of referral care and reduce unnecessary and redundant testing. Use of common standards can significantly reduce the cost and complexity of interfaces between different systems and promote widespread exchange and interoperability. In acknowledgement of this, ONC has included certain transmission protocols in the proposed 2014 Edition EHR certification criteria.

These protocols would allow every provider with CEHRT to have the tools in place to share critical information when patients are discharged or referred, representing a critical step forward in exchange and interoperability. Accordingly, we proposed to limit the numerator for this second measure to only count electronic transmissions which conform to the transport standards proposed for adoption at 45 CFR 170.202 of the ONC standards and certification criteria rule..

To meet the second measure of this objective, we proposed that a provider must use CEHRT to create a summary of care document with the required information according to the required standards and electronically transmit the summary of care document using the transport standards to which its CEHRT has been certified. No other transport standards beyond those proposed for adoption as part of certification would be permitted to be used to meet this measure.

In the proposed rule, we acknowledged the benefits of requiring the use of consistently

implemented transport standards nationwide, but at the same time want to be cognizant of any unintended consequences of this approach. ONC requested comments on whether equivalent alternative transport standards exist to the ones ONC proposes to exclusively permit for certification. These comments are addressed in the ONC standards and certification final rule published elsewhere in this issue of the **Federal Register**. We noted in the proposed rule that the use of USB, CD-ROM, or other physical media or electronic fax would not satisfy the measures for electronic transmittal of a summary of care record. We discussed in the proposed rule, in lieu of requiring solely the transmission capability and transport standard(s) included in a provider's CEHRT to be used to meet this measure, also permitting a provider to count electronic transmissions in the numerator if the provider electronically transmits summary of care records to support patient transitions using an organization that follows Nationwide Health Information Network (NwHIN) specifications (http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__nhin_resources/1194). This could include those organizations that are part of the NwHIN Exchange as well as any organization that is identified through a governance mechanism ONC would establish through regulation. We requested public comment on whether this additional flexibility should be added to our proposed numerator limitations.

In the proposed rule we raised another potential concern that another transport standard emerges after CMS' and ONC's rules are finalized that is not adopted in a final rule by ONC as part of certification, but nonetheless accomplishes the objective in the same way. To mitigate this concern, ONC indicated in its proposed rule that it would pursue an off-cycle rulemaking to add as an option for certification transport standards that emerge at any time after these proposed rules are finalized in order to keep pace with innovation and thereby allow other transport

standards to be used and counted as part of this measure's numerator. We asked for comments on how these standards will further the goal of true health information exchange.

Additionally, in order to foster standards based-exchange across organizational and vendor boundaries, we proposed to further limit the numerator by only permitting electronic transmissions to count towards the numerator if they are made to recipients that are -- (1) not within the organization of the transmitting provider; and (2) do not have CEHRT from the same EHR vendor.

We proposed these numerator limitations because, in collaboration with ONC, our experience has shown that one of the biggest barriers to electronic exchange is the adoption of numerous different transmission methods by different providers and vendors. Thus, we explained that it would be prudent for Stage 2 to include these more specific requirements and conformance to open, national standards as it will cause the market to converge on those transport standards that can best and most readily support electronic health information exchange and avoid the use of proprietary approaches that limit exchange among providers. We recognized that because the 2011 Edition EHR certification criteria did not include specific transport standards for transitions of care, some providers and vendors implemented their own methods for Stage 1 to engage in electronic health information exchange, some of which would no longer be an acceptable means of meeting meaningful use if this proposal were finalized.

Therefore, in order to determine a reasonable balance that makes this measure achievable yet significantly advance interoperability and electronic exchange, we asked for comment on the following concerns stakeholders may have relative to the numerator limitations we proposed previously.

We discussed a potential concern related to the feasibility of meeting this proposed

measure if an insufficient number of providers in a given geographic location (because of upgrade timing or some other factor) have EHR technology certified to the transport standards ONC has proposed to adopt. For example, a city might have had a widely adopted health information exchange organization that still used another standard than those proposed for adoption by ONC. While it is not our intent to restrict providers who are engaged in electronic health information exchange via other transport standards, we believe requiring the use of a consistent transport standard could significantly further our overarching goals for Stage 2.

We recognized that this limitation extends beyond the existing parameters set for Stage 1, which specified that providers with access to the same medical record do not include transitions of care or referrals among themselves in either the denominator or the numerator. We recognized that this limitation could severely limit the pool of eligible recipients in areas where one vendor or one organizational structure using the same EHR technology has a large market share and may make measuring the numerator more difficult. We sought comment on the extent to which this concern could potentially be mitigated with an exclusion or exclusion criteria that account for these unique environments. We believe the limitation on organizational and vendor affiliations is important because even if a network or organization is using the standards, it does not mean that a network is open to all providers. Certain organizations may find benefits, such as competitive advantage, in keeping their networks closed, even to those involved in the care of the same patient. We believe this limitation will help ensure that electronic transmission of the summary of care record can follow the patient in every situation.

Even without the addition of the proposed exclusions under the proposed measure, CEHRT would need to be able to distinguish between (1) electronic transmissions sent using standards and those that are not, (2) transmission that are sent to recipients with the same

organizational affiliation or not, and (3) transmissions that are sent to recipients using the same EHR vendor or not. ONC sought comment in their proposed certification rule as to the feasibility of this reporting requirement for CEHRT.

Despite the possible unintended consequences of the parameters we proposed for the numerator, in the proposed rule we stated that we believed that these limitations would help ensure that electronic health information exchange proceeds at the pace necessary to accomplish the goals of meaningful use. We asked for comments on all these points and particularly suggestions that would both push electronic health information exchange beyond what is proposed and minimize the potential concerns expressed previously.

The HIT Policy Committee recommended different thresholds for EPs and hospitals for the electronic transmission measure, with a threshold of only 25 instances for EPs. However, we proposed a percentage-based measure is attainable for both EPs and eligible hospitals/CAHs and better reflects the actual meaningful use of technology. It also provides a more level method for measurement across EPs. We asked for comments on whether there are significant barriers in addition to those discussed above to EPs meeting the 10 percent threshold for this measure.

Comment: There were several comments that doubted that the technology will be ready for providers to meet this measure. They did not believe there is enough vendor support to create, customize, and implement the changes necessary to meet the new measure. Commenters expressed concern that many of the technologies, from EHRs to HIEs and transmission standards, needed to enable electronic health information exchange currently does not exist.

Response: We disagree that it is premature to include this measure for Stage 2. We note that as an incentive program it is expected that the requirements will reach beyond what is common place today. Many organizations and providers are successfully engaged in electronic

health information exchange today and by including this measure in meaningful use those established practices will be adopted by a greater number of providers.

Comment: A commenter suggested that ONC's certification rule was the appropriate place to ensure cross-vendor interoperability, not the Stage 2 measures and objectives.

Response: While we agree that meaningful use should be enabled by the capabilities included in certification, the concept of meaningful use is to incentivize the use of such capabilities not just the acquisition of them.

Comment: Commenters expressed two concerns on the limitation on the numerator that limited it to recipients with no organizational affiliation and using a different CEHRT vendor. First, there was concern that in some markets an organization or CEHRT vendor may control such a significant share of the market that meeting 10 percent is not possible. Second, even if the 10 percent threshold was feasible in a given market, one organization or CEHRT vendor may have enough market share that the provider's referral patterns would inappropriately be influenced to give preference to those using different CEHRT vendors or outside their organizations. Commenters support appropriate information exchange between all providers, where clinically relevant, regardless of provider affiliations, but have these concerns on our proposed measure for this objective. Commenters presented several different solutions including removing one or both limitations, replacing the limitations with an error reporting system for instances where electronic health information exchange fails, moving the limitations to the denominator and providing exclusions for areas of high vendor or organizational market penetrations.

Response: We agree that the measure as proposed runs both risks stated by commenters. Of the solutions presented by commenters, one directly alleviates both of these concerns. In

drafting the final rule, we considered moving the limitations from the numerator to the denominator of the measure, both concerns are addressed. For example, if a provider makes 500 referrals during the EHR reporting period, 400 of which are to providers that either are affiliated with the same organization or use the same CEHRT vendor, then only 100 referrals are even eligible for the proposed numerator. This creates a bar that is much higher than 10 percent, as 50 percent of the eligible instances must be electronically transmitted to meet the proposed measure in this example, which we agree has the possibility of influencing referral patterns. However, applying the limitations of "no organizational affiliation" and "different CEHRT vendor" to the denominator instead of the numerator would result, in this example, in a denominator of 100 referrals instead of 500 and a true 10 percent threshold. There would be no need to change referral patterns as there would be no negative effect on the threshold for having a referral partner either in the same organization or using the same CEHRT vendor. We firmly believe that this solution is the best measure of the type of health information exchange that we proposed to target and that is supported in principle by nearly all commenters. However, we are not including this solution in the final rule as explained in the response to the next set of comments. Instead, we are removing the organizational and vendor limitations from this measure solely due to the burden of making these determinations for measurement.

Comment: Many commenters expressed concern over the ability to measure this objective especially the organization and vendor limitations. Commenters who were providers expressed concern over the ability of their CEHRT vendor to measure this objective, while vendors of CEHRT expressed concern over the ability of providers to measure the objective. Combined, it appears that neither the provider nor the vendor believed they could even measure on their own and had concerns on their partners on which they placed their hopes for

measurement.

Response: In the proposed rule we determined that the CEHRT would have to be able to make three determinations to successfully calculate the numerator for this measure: (1) electronic transmissions sent using standards and those that are not; (2) transmission that are sent to recipients with the same organizational affiliation or not; and (3) transmissions that are sent to recipients using the same EHR vendor or not. We stated that ONC will seek comment in their proposed certification rule as to the feasibility of this reporting requirement for certified EHR technologies. ONC received comments similar to ours that making the determinations for the numerator was infeasible particularly in regard to the organizational and vendor limitations. Therefore, we are removing the organizational and vendor limitations from this measure solely due to the burden of making these determinations for measurement. Commenters did not suggest difficulties with determining that the electronic transmission was sent using the specified standards. Therefore, we finalize the stipulation that CEHRT be used, including its accompanying standards for this measure ("measure 2").

However, we are not abandoning all efforts to ensure that cross vendor electronic exchange is possible for all meaningful EHR users in Stage 2. As discussed in the prior comment and response, the only reason we are not finalizing the stipulations on the denominator is the measurement burden. We believe that a third measure is needed that reduces the burden relative to the proposed measure, but still ensures that all providers have implemented CEHRT in a way that enables them to electronically exchange summary of care documents with a recipient using EHR technology designed by a different vendor. Therefore, we have added a third measure ("measure 3") that requires providers to use their CEHRT to either--

- Conduct one or more successful electronic exchanges of a summary of care document,

which is counted in measure 2 with a recipient who has EHR technology designed by a different EHR technology developer than the sender's EHR technology certified to 45 CFR 170.314(b)(2); or

- Conduct one or more successful tests with the CMS designated test EHR during the EHR reporting period.

For the first option in measure 3, the sender must verify that the recipient's technology used to receive the summary of care record was not designed by the same EHR technology developer that designed the sender's EHR technology certified to 45 CFR 170.314(b)(2).

With respect to the second option in measure 3, and recognizing past difficulties and lessons learned from a "test" oriented measure in Stage 1, we have collaborated with ONC and NIST to initiate a project that would result in a public facing (hosted online) "test EHR" with which EPs, eligible hospitals, and CAHs could engage in electronic exchange. We expect that most providers will satisfy the first option in the normal course of meeting measure 2. However, in those rare instances where that does not occur this other second option would give every EP, eligible hospital, or CAH an alternative method to meet measure 3 with minimal burden by successfully testing electronic exchange with the CMS-designated test EHR. If this second option is used, we clarify that the use of test information about a fictional patient that would be identical in form to what would be sent about an actual patient (for example, "dummy data") must be used for the purposes of conducting a test with the CMS-designated test EHR. Providers that use the same EHR technology certified to 45 CFR 170.314(b)(2) and share a network for which their organization either has operational control or license to use can conduct one test that covers all providers in the organization. For example, if a large group of EPs with multiple physical locations use the same EHR technology certified to 45 CFR 170.314(b)(2) and those

locations are connected using a network that the group has either operational control of or license to use, then a single test would cover all EPs in that group. Similarly, if a provider uses an EHR technology that is hosted (cloud-based) on the developer's network, then a single test would allow all EPs, eligible hospitals and CAHs using the EHR technology that is hosted (cloud-based) on the developer's network to meet the measure.

While making this does impose a burden on the provider, we believe the burden is outweighed by the benefits of ensuring that every provider who becomes a meaningful EHR user is capable of exchanging a summary of care document electronically regardless of who developed the sender's EHR and the recipient's EHR.

We also seek to note for readers that while we have significantly reduced this objective's burden from what we proposed in measure 2, we continue to believe that making vendor to vendor standards-based exchange attainable for all meaningful EHR users is of paramount importance. In that regard, and as we look toward meaningful use Stage 3, we will monitor the ease with which EPs, eligible hospitals, and CAHs engage in electronic exchange, especially across different vendors EHRs. If we do not see sufficient progress or that continued impediments exist such that our policy goals for standards-based exchange are not being met, we will revisit these more specific measurement limitations and consider other policies to strengthen the interoperability requirements included in meaningful use as well as consider other policies and regulations through which the Department could effect the outcome we seek. Finally, we also intend to consider future meaningful use requirements that increase expectations for standards-based exchange and make information that is exchanged more searchable and usable for a broad array of clinical purposes imperative to care improvement. We envision that these requirements would rely on metadata tagging as well as more dynamic methods of electronic

health information exchange.

Comment: Commenters expressed support for including in this measure's numerator electronic transmissions enabled by query-based exchange models, including organizations using NwHIN Exchange specifications. The commenters indicated that NwHIN Exchange specifications are appropriate for exchange use cases not covered as well by the Direct standards, and use of either standard should be counted. This is particularly important in cases where the summary is pulled instead of pushed. Providers and organizations that are part of the NwHIN Exchange or other organizations using these standards should receive credit for those exchanges in meeting interoperability measures.

Response: In Stage 2, all providers should be able to use CEHRT to share summary of care records in a "push" manner to support safe transitions and informed referrals. "Pull" (query) transactions can also support these goals. By "pull" transactions we refer to instances where the receiving provider retrieves the summary of care document from a location outside their own CEHRT as opposed to "push" transactions where the referring or transitioning provider sends the summary of care document to the receiving provider. Thus, such transactions should be counted towards the numerator of the provider initiating the transitions or referrals when the recipient (the provider "receiving" the transition or referral) actually receives or downloads the patient's summary of care record relevant to the transition or referral. The act of uploading the summary of care record to a repository that can be queried by the recipient—without validation that this query in fact occurred will not be sufficient to count towards the numerator. While we acknowledge that there may not be a simple, universal way for this to be measured, we believe it is important to make this accommodation for those who elect to engage in this form of exchange. Therefore, we are revising the second measure to include in the sending provider's numerator

instances where the recipient receives the summary of care record via exchange facilitated by an organization that is an NwHIN Exchange participant or in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network. The referring or transitioning provider would use their CEHRT to generate a summary of care document and to provide it an organization that is a NwHIN Exchange participant or in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network. More information on NwHIN Exchange participants is available at http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__nhin_exchange/1407. ONC issued a request for information regarding a governance mechanism for the nationwide health information network that is available at 77 FR 28543.

After considering the comments received, we are modifying the second measure for EPs at §495.6(j)(14)(ii)(B) and for eligible hospitals and CAHs at §495.6(l)(11)(ii)(B) to "The EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 10 percent of such transitions and referrals either (a) electronically transmitted using CEHRT to a recipient or (b) where the recipient receives the summary of care record via exchange facilitated by an organization that is a NwHIN Exchange participant or in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network."

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 CEHRT at 45 CFR 170.314(b)(l) and (b)(2).

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

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

● Numerator: The number of transitions of care and referrals in the denominator where a summary of care record was a) electronically transmitted using CEHRT to a recipient or b) where the recipient receives the summary of care record via exchange facilitated by an organization that is a NwHIN Exchange participant or in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network. The organization can be a third-party or the sender's own organization.

● 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 is excluded from all three measures.

Third Measure:

After considering the comments received, we are adding a third measure for EPs at §495.6(j)(14)(ii)(C) and for eligible hospitals and CAHs at §495.6(l)(11)(ii)(C) to "An EP, eligible hospital or CAH must satisfy one of the two following criteria:

• Conducts one or more successful electronic exchanges of a summary of care document, which is counted in "measure 2" (for EPs the measure at §495.6(j)(14)(ii)(B) and for eligible hospitals and CAHs the measure at §495.6(l)(11)(ii)(B)) with a recipient who has EHR technology that was designed by a different EHR technology developer than the sender's EHR technology certified to 45 CFR 170.314(b)(2); or

- Conducts one or more successful tests with the CMS designated test EHR during the EHR reporting period.

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 CEHRT at 45 CFR 170.314(b)(2).

● 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 is excluded from all three measures.

(c) Public Health Objectives

General Public Health Discussion

In the proposed rule, due to similar considerations among the public health objectives, we discussed them together. Some Stage 2 public health objectives are proposed to be in the core set while others are proposed to be in the menu set. Each objective is identified as either core or menu in the following discussion.

- Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.

- Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice.

- Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice.

- Capability to identify and report cancer cases to a state cancer registry except where prohibited, and in accordance with applicable law and practice.

- Capability to identify and report specific cases to a specialized registry (other than a

cancer registry), except where prohibited, and in accordance with applicable law and practice.

We proposed the following requirements, which will apply to all of the public health objectives and measures. We proposed that actual patient data is required for the meaningful use measures that include ongoing submission of patient data.

We discussed in the proposed rule situations where PHAs partner with health information exchange (HIE) organizations to facilitate the submission of public health data electronically from EHRs. As we stated in guidance for Stage 1, (see FAQ #10764 at: https://questions.cms.hhs.gov) we clarified that such arrangements with HIE organizations, if designated by the PHA to simply transport the data, but not transforming content or message format (for example, HL7 format), are acceptable for the demonstration of meaningful use. Alternatively, if the intermediary is serving as an extension of the EP, eligible hospital or CAH's CEHRT and performing capabilities for which certification is required (for example, transforming the data into the required standard), then that functionality must be certified in accordance with the certification program established by ONC. In this situation, the EP, eligible hospital or CAH must still ensure the accomplishment of ongoing submission of reports to the actual immunization information system or registry (whether performed by the intermediary or not), except in situations when the PHA has explicitly designated delivery of reports to the intermediary as satisfying these requirements.

We proposed that an eligible provider is required to utilize the transport method or methods supported by the PHA in order to achieve meaningful use.

Unlike in Stage 1, under our proposed Stage 2 criteria a failed submission will not meet the objective. An eligible provider must either have successful ongoing submission or meet an exclusion criterion

We stated in the proposed rule that we expect that CMS, CDC and PHAs will establish a process where PHAs will be able to provide letters affirming that the EP, eligible hospital or CAH was able to submit the relevant public health data to the PHA. This affirmation letter could then be used by the EP, eligible hospital or CAH for the Medicare and Medicaid meaningful use attestation systems, as well as in the event of any audit. We requested comments on challenges to implementing this strategy.

We proposed to accept a yes/no attestation and information indicating to which PHA the public health data were submitted to support each of the public health meaningful use measures.

Comment: Commenters asked for clarification of ongoing submission; additionally, due to the amount of time needed to prepare for submission of data, commenters asked for clarification on the timing to determine if a public health authority has the capacity to accept electronic data for ongoing submission. Other commenters noted that being "in queue" or in the process of validation for ongoing submission should count as meeting this measure. Commenters also noted that credit should be given for having moved into ongoing submission during Stage 1.

Response: To clarify the timing issue, the EP or hospital must determine if the PHA has the capacity to accept electronic data using the specification prescribed by ONC for the public health information for the objectives of meaningful use within the first 60 days of the EHR reporting period. If the PHA does not have the capacity to accept reporting (including situations when the PHA accepts electronic data but states it lacks capacity to enroll the EP, eligible hospital or CAH during that reporting period), the EP or hospital can claim an exclusion for this measure related to the data that cannot be accepted. In determining whether the PHA has the capacity, CMS anticipates developing a centralized repository for this information, including a

deadline for the PHA to submit information. If the PHA fails to provide information to this centralized repository by the deadline, the provider could claim the exclusion. In the event, that we are unable to develop a centralized repository, providers will make the determination of PHA capacity by working directly with the PHA as is currently the case for Stage 1 of meaningful use. If the PHA does have the capacity, the measure may be satisfied through any of the following general public health criteria:

- Ongoing submission was already achieved for an EHR reporting period in a prior year and continues throughout the current EHR reporting period using either the current standard at 45 CFR 170.314(f)(1) and (f)(2) or the standards included in the 2011 Edition EHR certification criteria adopted by ONC during the prior EHR reporting period when ongoing submission was achieved.

- Registration with the PHA or other body to whom the information is being submitted of intent to initiate ongoing submission was made by the deadline (within 60 days of the start of the EHR reporting period) and ongoing submission was achieved.

- Registration of intent to initiate ongoing submission was made by the deadline and the EP or hospital is still engaged in testing and validation of ongoing electronic submission.

- Registration of intent to initiate ongoing submission was made by the deadline and the EP or hospital is awaiting invitation to begin testing and validation.

The measure will not be met if the provider--

- Fails to register their intent by the deadline; or

- Fails to participate in the on-boarding process as demonstrated by failure to respond to the PHA written requests for action within 30 days on two separate occasions.

Comment: Several commenters expressed concern that no data transport mechanism was

included in the Stage 2 rule and/or EHR certification. Some expressed concern that the lack of a standard may result in EPs paying more for interfaces than received in incentive payments. Other commenters supported including no transport mechanism to allow maximum flexibility for public health authorities.

Response: While we understand the concern of supporting multiple transport mechanisms, in order for data to flow to public health authority, vendors must support the transport mechanism utilized by the public health authority to which the EP or hospital reports. Public health authorities have moved to standardize transport mechanisms where feasible, and Health Information Exchanges are often facilitating the transport of data to public health. We stand by our policy that allows public health authorities to dictate the transport mechanism in their jurisdiction. Further, we clarify that this is independent of the EHR certification criteria as EHR certification does not address transport for public health objectives.

Comment: Commenters suggested that the expectation that public health agencies provide affirmation letters is too restrictive in accomplishing the goal of established a record of communication between the provider and the PHA. They maintain that there are simpler and less burdensome ways such as automated acknowledgment messages from immunization submissions.

Response: We agree that our proposal requiring it must be a letter is too restrictive and revise our expectation to allow for any written communication (which may be in electronic format) from the PHA affirming that the EP, eligible hospital or CAH was able to submit the relevant public health data to the PHA.

Comment: Commenters requested greater clarification on what is meant by ongoing submission. Some suggested that it be transitioned to a percentage measurement as with other

objectives of meaningful use.

Response: We do not agree that a transition to a percentage measurement best serves the public health objectives. First, a percentage measure would only be applicable to those engaged in ongoing submission, and as indicated in an earlier response, we are allowing four different situations to meet the measure. Second, we believe that the requirement to submit information would be under applicable law, the agreements between the provider and PHA, or through meaningful use which requires submissions except where prohibited, so it is not necessary for meaningful use to monitor the already mandated submission. For greater clarification, we describe successful ongoing submission as electronic submission of reportable data during the normal course of a provider's operations. This is not to say all data that is reportable is sent to the PHA. A provider who is submitting any reportable data during their normal course of their operations is engaged in ongoing submission. A provider that can only submit reportable data in a test environment or other circumstance that is not part of their normal operations would not be engaged in ongoing submission.

Where a measure states "in accordance with applicable law and practice," this reflects that some public health jurisdictions may have unique requirements for reporting and that some may not currently accept electronic data reports. In the former case, the proposed criteria for this objective will not preempt otherwise applicable state or local laws that govern reporting. In the latter case, EPs, eligible hospitals, and CAHs will be excluded from reporting.

Comment: Several commenters requested the removal of "except where prohibited" from the objective, while others expressed support for this phrase. Those that did not support note that CMS does not have the authority to direct reporting if not required by law or regulations, while supporters applauded CMS for supporting reporting where allowed but not required by law.

Several commenters suggested removing the phrase "in accordance with applicable law," while other commenters wrote in support of the addition of the phrase.

Response: We disagree with the commenters suggesting removal of these phrases and will keep them as part of the final rule. The phrase "except where prohibited" is meant to allow exemptions from reporting for providers who cannot by law report to the public health authority within their jurisdiction. For example, a sovereign Indian Nation may not be permitted to report immunization registry data to the public health authority in their jurisdiction. The phrase is meant to encourage reporting if a provider is authorized to do so. The "in accordance with applicable law" phrase allows public health authorities to utilize their existing laws and regulations for reporting.

Proposed Objective: Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.

We proposed to include this objective in the Stage 2 core set for EPs, eligible hospitals and CAHs as recommended by the HITPC. We discussed in the proposed rule that the Stage 1 objective and measure acknowledged that our nation's public health IT infrastructure is not universally capable of receiving electronic immunization data from CEHRT, either due to technical or resource readiness. Immunization programs, their reporting providers and federal funding agencies, such as the CDC, ONC, and CMS, have worked diligently since the passage of the HITECH Act in 2009 to facilitate EPs, eligible hospitals and CAHs ability to meet the Stage 1 measure. We proposed for Stage 2 to take the next step from testing to requiring actual submission of immunization data. In order to achieve improved population health, providers who administer immunizations must share that data electronically, to avoid missed opportunities

or duplicative vaccinations. Stage 3 is likely to enhance this functionality to permit clinicians to view the entire immunization registry/immunization information system record and support bi-directional information exchange.

We proposed that the threshold for Stage 2 should move from simply testing the electronic submission of immunization data (with follow-up submission if the test is successful) to ongoing submission. However, we asked for comments on the challenges that moving this objective from the menu set to the core set would present for EPs and hospitals.

Comment: Some commenters suggested that the term immunization information systems was all encompassing making the inclusion of immunization registries redundant.

Response: We agree that an information system could include registries; however, we do not believe that modifying the objective serves a distinct purpose and could confuse those accustomed to the term immunization registries.

Comment: Commenters, although supportive of moving immunization registry reporting from menu to core, expressed concern that PHAs did not have the capacity to accept electronic data from additional providers.

Response: We agree that not all PHAs will have the resources to onboard providers for immunization registry reporting. The final rule allows for an EP or hospital to be excluded from the measure if they operate in a jurisdiction for which no immunization registry is capable of accepting data. We further clarify that this exception applies not only if the technical capacity to receive the data does not exist, but also if the resources are not available within the public health authority to initiate ongoing submission with the EP or hospital. We also permit (as earlier stated) an EP or hospital to meet the measure so long as they have registered to submit and are either still in the process of testing and validation (within the time limits established earlier), or

are still awaiting an invitation to begin submission.

Comment: Numerous commenters encouraged the inclusion of bidirectional exchange of data with immunization registries. Many commenters noted that the EP or eligible hospital cannot take advantage of rich data and clinical decision support contained within an immunization registry without bidirectional exchange.

Response: While we agree that the need for bidirectional data exchange is clear, this measure aligns more with the goals of Stage 3 meaningful use stated in the proposed rule. Additionally, the standards and mechanisms for bidirectional data exchange need to be more standardized across public health authorities.

After consideration of the public comments received, we are finalizing this objective for EPs at §495.6 (j)(15)(i) and for eligible hospitals and CAHs at §495.6(l)(12)(i) as proposed.

Proposed Measure: Successful ongoing submission of electronic immunization data from CEHRT to an immunization registry or immunization information system for the entire EHR reporting period.

Comment: Many commenters noted the lack of national standards for the collection of immunization data with specific examples such as CVS versus MVX coding vocabularies and also noted the need for centralized data collection at a national level. Commenters noted that the lack of standardization results in cost-prohibitive compliance with this measure.

Response: We agree that during the implementation of Stage 1 reporting of immunization data, the need for a more harmonized standard for immunization reporting was highlighted. To address this issue, the option of using version HL7 2.3.1 versus 2.5.1 for certification was removed and now only an HL7 2.5.1 message can be used for Stage 2 reporting of immunization data. The implementation guide for HL7 2.5.1 has been updated to remove

much of the variability across states for immunization registry reporting. However, if EPs prior to CY 2014 and eligible hospitals and CAHs prior to FY2014 have achieved successful ongoing submission using EHR technology certified to the 2011 Edition EHR certification criteria (HL7 2.3.1 only) it is acceptable to continue this ongoing submission and meet the Stage 2 measure for as long as HL7 2.3.1 continues to be accepted by the immunizations information system or immunization registry. EPs and eligible hospitals and CAHs conducting submissions using HL7 2.5.1 will be able to get their arrangement certified to the 2014 Edition EHR certification criteria.

After consideration of the public comments received, we are finalizing this measure at for EPs at 495.6 (j)(15)(ii) and for eligible hospitals and CAHs at 495.6(l)(12)(ii) as proposed, but we modify the exclusions to conform with the general criteria for public health objectives and to address redundancy in two of the proposed exclusions. In the general criteria for public health objectives section we established a centralized repository of information about PHA capacity. If a PHA does not provide capacity information to this repository in time for it to be made available to providers at the start of their EHR reporting period, then the providers in that PHA's jurisdiction will meet the modified exclusion. We proposed two exclusions: (1) the EP, eligible hospital or CAH operates in a jurisdiction for which no immunization registry or immunization information system is capable of receiving electronic immunization data in the specific standards required for CEHRT at the start of their EHR reporting period; and(2) the EP, eligible hospital or CAH operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the version of the standard that the EP, eligible hospital or CAH's CEHRT can send at the start of their EHR reporting period. In both cases the limitation is the ability of the immunization registry or immunization information system to receive immunization data in the standards required by ONC for EHR certification in 2014. Therefore,

we are combining these exclusions.

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 CEHRT at 45 CFR 170.314(f)(1) and (f)(2). However, if EPs prior to CY 2014 and eligible hospitals and CAHs prior to FY 2014 have achieved successful ongoing submission using EHR technology certified to the 2011 Edition EHR certification criteria (HL7 2.3.1 only), it is acceptable to continue this ongoing submission and meet the Stage 2 measure for as long as HL7 2.3.1 continues to be accepted by the immunizations information system or immunization registry. We note that our decision to continue to permit the use of EHR technology certified to the 2011 Edition EHR certification criteria is a special circumstance and emphasize that EPs, eligible hospitals, and CAHs will still need EHR technology certified to the 2014 Edition EHR certification criteria in order to meet the CEHRT definition beginning with the FY/CY 2014 EHR reporting period.

- Exclusions: Any EP, eligible hospital or CAH that meets one or more of the following criteria may be excluded from this objective: (1) the EP, eligible hospital or CAH does not administer any of the 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) the EP, eligible hospital or CAH operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required for CEHRT at the start of their EHR reporting period (3) the EP, eligible hospital or CAH operates in a jurisdiction where no immunization registry or immunization information system provides information timely on capability to receive immunization data; or (4) the EP, eligible hospital or CAH operates in a jurisdiction for which no immunization registry or immunization information system that is capable of accepting the specific standards required

by CEHRT at the start of their EHR reporting period can enroll additional EPs, eligible hospitals or CAHs.

The second exclusion will not apply if an entity designated by the immunization registry or immunization information system can receive electronic immunization data submissions. For example, if the immunization registry cannot accept the data directly or in the standards required by CEHRT, but if it has designated a Health Information Exchange to do so on their behalf and the Health Information Exchange is capable of accepting the information in the standards required by CEHRT, the provider could not claim the second exclusion.

Proposed Eligible Hospital/CAH Objective: Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice.

We proposed that this objective is in the Stage 2 core set for eligible hospitals and CAHs. The same rationale for the proposed changes between this proposed objective and that of Stage 1 are discussed earlier under the immunization registry objective. Please refer to that section for details on our proposals in this regard.

Comment: Commenters, although supportive of moving electronic laboratory reporting from menu to core, expressed concern that PHAs did not have the capacity to accept electronic data from additional providers.

Response: We agree that not all PHAs will have the resources to onboard providers for electronic laboratory reporting. The final rule allows for an EP, eligible hospital or CAH to be excluded from the measure if they operate in a jurisdiction for which no public health authority is capable of accepting electronic laboratory data. We further clarify that this exception applies not only if the technical capacity to receive the data does not exist, but also if the resources are not

available within the public health authority to initiate ongoing submission with the EP, eligible hospital or CAH. We also permit (as earlier stated) an EP, eligible hospital or CAH to meet the measure so long as they have registered to submit and are either still in the process of testing and validation, or are still awaiting an invitation to begin submission.

Comment: Many commenters noted that lack of standards for reporting electronic laboratory data to public health authorities and also noted the variety of transport methods needed to support reporting to public health.

Response: ONC has adopted an updated implementation guide for electronic laboratory reporting from EHR technology in its 2014 Edition EHR certification criteria. Additionally, the Centers for Disease Control and Prevention in coordination with the Council of State and Territorial Epidemiologists have created the national Reporting Condition Mapping Table (http://www.cdc.gov/EHRmeaningfuluse/rcmt.html) that provides further guidance on appropriate vocabularies usable for reportable conditions across the country for reporting of ELR data.

Comment: Several commenters wrote in favor of expansion of this requirement to be inclusive of the surveillance of healthcare associated infections (HAI).

Response: While we agree that the reporting of healthcare associated infections is a critical part of public health surveillance, the methods and standards for reporting this information require very different standards for electronic laboratory reporting of reportable conditions. This measure aligns more with the goals of Stage 3 meaningful use.

Comment: Numerous commenters suggested that Electronic Laboratory Reporting is outside the scope of EHRs and should be excluded from the objectives. These commenters note that laboratory information systems (LIMS) already have ELR capabilities, and most EHRs do

not. One commenter expressed concern that reporting from both laboratories and providers may cause duplicate reporting of a single case. The same commenter stated that may LIMS systems already have functionality to identify which laboratory results need to be reported to public health, which EHRs do not, and that building that capability into EHRs would be duplicative and burdensome.

Response: We disagree with the statement that ELR is "outside the scope of EHRs and should be excluded" because we share ONC's broad interpretation of the term EHR technology. Eligible Hospitals can choose to report data directly from any kind of EHR technology that has been certified to the certification criteria adopted by ONC. This could include EHR technology from a single EHR technology developer, a separate modularly certified component such as a LIMS certified as an EHR Module, or the technical capability offered by an HIE that is certified as an EHR Module for electronic laboratory reporting.

After consideration of the public comments, we are finalizing this objective for eligible hospitals and CAHs at 495.6(l)(13)(i)as proposed.

Proposed Eligible Hospital/CAH Measure: Successful ongoing submission of electronic reportable laboratory results from CEHRT to a public health agency for the entire EHR reporting period as authorized, and in accordance with applicable State law and practice..

Please refer to the general public health discussion regarding use of intermediaries.

Most comments received related to this measure have been addressed in the discussion of public health objectives in general or in the discussion of the objective associated with this measure.

Comment: Commenters pointed out that the proposed measure includes the statement "as authorized, and in accordance with applicable State law and practice". Some commenters

believed the phrase was simply redundant to the objective and was inconsistent with the other public health measures. Other commenters expressed concern that the addition of the phrase implied a more restrictive measure than other public health measures particularly with the limit to state law as opposed to just law.

Response: We agree with commenters that this phrase is redundant to the objective and may introduce confusion. Therefore, we are revising this measure to remove the phrase and make it consistent with the other public health measures.

Based on consideration of those comments, we are modifying this measure for eligible hospitals and CAHs at §495.6(l)(13)(ii) tosuccessful ongoing submission of electronic reportable laboratory results from CEHRT to a public health agency for the entire EHR reporting period". We also modify the exclusions to conform with the general criteria for public health objectives. In the general criteria for public health objectives, we plan to establish a centralized repository of PHA capacity information. If a PHA does not provide capacity information to this repository in time for it to be made available to providers at the start of their EHR reporting period, then the providers in that PHA's jurisdiction will meet the modified exclusion. If the repository is not established, the eligible hospital or CAH must consult their PHA jurisdiction for guidance.

We further specify that in order to meet this objective and measure, an eligible hospital or CAH must use the capabilities and standards of CEHRT at 45 CFR 170.314(f)(4).

- Exclusions: The eligible hospital or CAH that meets one or more of the following criteria may be excluded from this objective: (1) operates in a jurisdiction for which no public health agency is capable of receiving electronic reportable laboratory results in the specific standards required for Certified EHR Technology at the start of the EHR reporting period; (2) operates in a jurisdiction where no public health agency provides information timely on

capability to receive electronic reportable laboratory results or (3) the eligible hospital or CAH operates in a jurisdiction for which no public health agency that is capable of accepting the specific standards required by CEHRT at the start of their EHR reporting period can enroll additional eligible hospitals or CAHs.

Proposed Objective: Capability to submit electronic syndromic surveillance data to public health agencies except where prohibited, and in accordance with applicable law and practice.

We proposed that this objective is in the Stage 2 core set for eligible hospitals and CAHs and the Stage 2 menu set for EPs. The Stage 1 objective and measure acknowledged that our nation's public health IT infrastructure is not universally capable of receiving syndromic surveillance data from CEHRT, either due to technical or resource readiness. Given public health IT infrastructure improvements and new implementation guidance, for Stage 2, we proposed that this objective and measure be in the core set for hospitals and in the menu set for EPs. It is our understanding from hospitals and the CDC that many hospitals already send syndromic surveillance data. The CDC has issued the PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data [http://www.cdc.gov/ehrmeaningfuluse/Syndromic.html] as cited in the ONC final rule on EHR standards and certification. However, per the CDC and a 2010 survey completed by the Association of State and Territorial Health Officials (ASTHO), very few public health agencies are currently accepting syndromic surveillance data from ambulatory, non-hospital providers, and there is no corresponding implementation guide at the time of this final rule. CDC is working with the syndromic surveillance community to develop a new implementation guide for ambulatory and inpatient discharge reporting of syndromic surveillance information, which it

expects will be available in the spring 2013. We anticipate that Stage 3 might include syndromic surveillance for EPs in the core set if the collection of ambulatory syndromic data becomes a more standard public health practice in the interim.

The HIT Policy Committee recommended making this a core objective for Stage 2 for EPs and hospitals. However, we did not propose to adopt their recommendation for EPs. We specifically invited comment on the proposal to leave syndromic surveillance in the menu set for EPs, while requiring it in the core set for eligible hospitals and CAHs.

Comment: Commenters noted that keeping the objective as menu for EPs is still problematic as most public health agencies are unable to accept the data. Commenters also expressed that for providers that have already reporting this objective, it makes sense to keep it as a menu set option.

Response: We agree that although not all public health authorities are able to accept syndromic surveillance data from Eligible Professionals, since many EPs already report this measure and some public health authorities have the ability to accept this data, the measure will remain as a menu set option.

Comment: Commenters noted that moving the objective as core is premature due to public health readiness. Commenters also expressed that for hospitals that have already reporting this objective, it makes sense to move the measure to core.

Response: We agree that not all public health authorities are able to accept syndromic surveillance data from hospitals; however, our exclusion criteria addresses this situation. Since many hospitals already report this measure and many public health authorities have the ability to accept this data, the measure will remain as core. If there are no public health authorities for the hospitals to report syndromic surveillance data to, the hospital can claim an exemption

Comment: Many commenters noted that lack of standards for reporting syndromic surveillance data to public health authorities.

Response: While a single national implementation guide exists for syndromic surveillance data of emergency department data from hospitals, currently an implementation guide does not exist for syndromic surveillance reporting from the eligible professional. The Centers for Disease Control and Prevention is working in conjunction with the International Society for Disease Surveillance and draft guidance is currently available for the reporting of ambulatory based syndromic surveillance.

Comment: Several comments expressed concern about the level of reporting. Concern was expressed from entities with multiple locations that would need to report by facility or provider lever rather than as an organization.

Response: Currently public health departments that collect syndromic surveillance data streamline the data collection process and collect data at an organization or facility level depending on the provider. Syndromic surveillance data is not collected at the provider level, although attestation would be at the provider level where reporting by a single organization or facility could count for multiple providers.

After consideration of the public comments received, we are finalizing this objective for EPs in the menu set at §495.6(k)(3)(i) and for eligible hospitals and CAHs in the core set at §495.6(l)(14)(i) as proposed.

Proposed Measure: Successful ongoing submission of electronic syndromic surveillance data from CEHRT to a public health agency for the entire EHR reporting period.

All comments received related to this measure have been addressed in the discussion of public health objectives in general or in the discussion of the objective associated with this

measure. After consideration of these public comments, we are finalizing this measure as proposed for EPs in the menu set at §495.6(k)(3)(ii) and for eligible hospitals and CAHs in the core set at §495.6(l)(14)(ii) as proposed, but we modify the exclusions to conform with the general criteria for public health objectives and to address redundancy in two of the proposed exclusions. In the general criteria for public health objectives, we plan to establish a centralized repository of PHA capacity information. If a PHA does not provide capacity information to this repository in time for it to be made available to providers at the start of their EHR reporting period, then the providers in that PHA's jurisdiction will meet the modified exclusion. We proposed two exclusions: (1) the EP, eligible hospital, or CAH operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required for Certified EHR Technology at the start of their EHR reporting period; and (2) the EP, eligible hospital, or CAH operates in a jurisdiction for which no public health agency is capable of accepting the version of the standard that the EP's, eligible hospital's or CAH's CEHRT can send at the start of their EHR reporting period. In both cases the limitation is the ability of the PHA to receive syndromic surveillance data in the standards required by ONC for EHR certification in 2014. Therefore, we are combining these exclusions.

We expect that the CDC will be issuing (in Spring 2013) the CDC PHIN Messaging Guide for Ambulatory Syndromic Surveillance and we may rely on this guide to determine which categories of EPs will not collect such information.

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 CEHRT at 45 CFR 170.314(f)(3). However, if EPs prior to CY 2014 and eligible hospitals and CAHs prior to FY 2014 have achieved successful ongoing submission using EHR technology certified to the 2011 Edition

EHR certification criteria (HL7 2.3.1 only), it is acceptable to continue this ongoing submission and meet the Stage 2 measure for as long as HL7 2.3.1 continues to be accepted by the PHA in that jurisdiction. We note that our decision to continue to permit the use of EHR technology certified to the 2011 Edition EHR certification criteria is a special circumstance and emphasize that EPs, eligible hospitals, and CAHs will still need EHR technology certified to the 2014 Edition EHR certification criteria in order to meet the CEHRT definition beginning with the FY/CY 2014 EHR reporting period.

- Exclusions: Any EP, eligible hospital or CAH that meets one or more of the following criteria may be excluded from this objective: (1) the EP is not in a category of providers that collect ambulatory syndromic surveillance information on their patients during the EHR reporting period; (2) the eligible hospital or CAH does not have an emergency or urgent care department; (3) the EP, eligible hospital, or CAH operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required by CEHRT at the start of their EHR reporting period; (4) the EP, eligible hospital or CAH operates in a jurisdiction where no public health agency provides information timely on capability to receive syndromic surveillance data; or (5) the EP, eligible hospital or CAH operates in a jurisdiction for which no public health agency that is capable of accepting the specific standards required by CEHRT at the start of their EHR reporting period can enroll additional EPs, eligible hospitals or CAHs..

As was described under the immunization registry measure, the third and fourth exclusions do not apply if the PHA has designated an HIE organization or other intermediary to collect this information on its behalf and that intermediary can do so in the specific Stage 2 standards and/or the same standard as the provider's CEHRT. An urgent care department

delivers ambulatory care, usually on an unscheduled, walk-in basis, in a facility dedicated to the delivery of medical care, but not classified as a hospital emergency department. Urgent care centers are primarily used to treat patients who have an injury or illness that requires immediate care but is not serious enough to warrant a visit to an emergency department. Often urgent care centers are not open on a continuous basis, unlike a hospital emergency department, which will be open at all times.

(d) New Core and Menu Set Objectives and Measures for Stage 2

We proposed the following objectives for inclusion in the core set for Stage 2: "Provide patients the ability to view online, download, and transmit information about a hospital admission" and "Automatically track medication orders using an electronic medication administration record (eMAR)" for hospitals; "Use secure electronic messaging to communicate with patients" for EPs. We proposed all other new objectives for inclusion in the menu set for Stage 2. While the HIT Policy Committee recommended making all objectives mandatory and eliminating the menu option, we believe a menu set is necessary for some of these new objectives in order to give providers an opportunity to implement new technologies and make changes to workflow processes and to provide maximum flexibility for providers in specialties that may face particular challenges in meeting new objectives.

Proposed Objective: Imaging results and information are accessible through CEHRT.

In the proposed rule, we outlined the following benefits for this objective. Making the image that results from diagnostic scans and accompanying information accessible through CEHRT increases the utility and efficiency of both the imaging technology and the CEHRT. The ability to share the results of imaging scans will likewise improve the efficiency of all health care providers and increase their ability to share information with their patients. This will reduce

the cost and radiation exposure from tests that are repeated solely because a prior test is not available to the provider.

We stated in the proposed rule that most of the enabling steps to incorporating imaging relate to the certification of EHR technologies. As with the objective for incorporating lab results, we encourage the use of electronic exchange to incorporate imaging results into the CEHRT, but in absence of such exchange it is acceptable to manually add the image and accompanying information to CEHRT.

Comment: Some commenters expressed concerns over the ability of CEHRT to store the images.

Response: We did not propose that CEHRT store the images. Storing the images natively in CEHRT is one way to make them accessible through CEHRT, but there are many other ways.

Comment: Commenters stated that unless a HIE organization existed to facilitate imaging exchange, building out an unique interface for each imaging provider is cost prohibitive. Second, commenters were concerned that because stand-alone radiology centers are not subject to the EHR Incentive Program they may not agreeing to provide their images electronically to the provider through their EHR. These commenters therefore suggest that it is premature to include this objective.

Response: We agree that many advances in infrastructure are needed to fully enable this objective. We believe that from publication of this final rule to the start of Stage 2 significant progress will be made in part due to the inclusion of this objective in Stage 2. We do agree that these improvements in infrastructure will vary based on local conditions such as the presence of HIEs, the willingness of radiology centers to link to EHRs, and other factors and note that is a

primary reason for this being a menu objective. We will also consider these comments below in relation to setting the threshold for the measure.

Comment: The resolution required for viewing imaging for diagnostic purposes requires specific hardware which would be cost prohibitive for all EPs. CMS should clarify that the image can be of any resolution.

Response: We do not impose limitations on the resolution of the image. To the extent this is a concern, it would be a capability of CEHRT not a requirement of meaningful use.

Comment: Commenters requested clarification on whether both the image itself and the accompanying results and information must be available, or just one or the other.

Response: The objective as proposed was intended to convey that the image itself is the result and that narratives/explanations and other information would be the additional information. Due to the many comments we received requesting clarification, we are revising the objective for clarity.

Comment: Commenters requested a more specific definition of imaging.

Response: We believe that imaging is a well understood term in the provider community. However, we agree that a more specific definition is required for purposes of measuring meaningful use. We adopt the description of radiology services from the Stage 2 CPOE objective as the minimum description of imaging. Providers are free to use a more expansive definition of imaging.

After review of the comments, we are revising the objective for EPs at 495.6 (k)(1)(i) and for eligible hospitals and CAHs at 495.6(m)(2)(i) to "Imaging results consisting of the image itself and any explanation or other accompanying information are accessible through CEHRT."

Proposed Measure: More than 40 percent of all scans and tests whose result is one or

more images ordered by the EP or by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period are accessible through CEHRT.

For Stage 2, we did not propose the image or accompanying information (for example, radiation dose) be required to be structured data. Images and imaging results that are scanned into the CEHRT may be counted in the numerator of this measure. We defined accessible as either incorporation of the image and accompanying information into CEHRT or an indication in CEHRT that the image and accompanying information are available for a given patient in another technology and a link to that image and accompanying information. Incorporation of the image means that the image and accompanying information is stored by the CEHRT. We did not propose that meaningful use would impose any additional retention requirements on the image. A link to the image and accompanying information means that a link to where the image and accompanying information is stored is available in CEHRT. This link must conform to the certification requirements associated with this objective in the ONC final rule published elsewhere in this issue of the **Federal Register**. We encouraged comments on the necessary level of specification and what those specifications should be to define accessible and what constitutes a direct link.

Comment: Commenters suggested that the proposed threshold of 40 percent was too high given the dependency on the image provider and electronic exchange infrastructure discussed in the objective. The most popular suggested threshold was 10 percent. Commenters also suggested that an exclusion be created for providers who have no access to electronic images. A few of the commenters pointed to the lack of an imaging provider that could make electronic images available. Others were concerned that when a provider uses multiple imaging

providers, 40 percent might be too high of a threshold even if at least one imaging provider that could make electronic images available.

Response: After reviewing the comments, we agree that 40 percent is too high of a threshold for this measure and revise it to 10 percent. Providers, especially EPs, may use many imaging providers, and we do not want an EP to have to defer this objective simply because they have three imaging providers, and the one allowing electronic access represents less than 40 percent of their orders. The comment regarding complete lack of an imaging provider that could make electronic images available speaks to the need for an exclusion. In considering an exclusion for those providers who have no access to electronic images, we take into account that it is a menu objective and also that there may be providers who fall into a situation where access is more than zero, but less than 10 percent. In regards to the menu, while it is true that a provider may defer this measure, the number of measures in the menu set are fewer and more specialized than in Stage 1. Furthermore, as an exclusion no longer counts towards meeting a menu objective, we are not concerned providers would choose this objective only to exclude it. For this reason, we are finalizing an exclusion for providers who have no access to electronic images. For those who cannot meet the 10 percent threshold even with access to an imaging provider who makes electronic images available, deferral remains a possibility as well as shifting more orders to imaging providers that do allow electronic access.

Comment: Several commenters disagreed with the proposed exclusion for EPs and believed it was inconsistent with the objective. These commenters believe the objective is intended for EPs who order imaging, whether or not they interpret the imaging studies themselves. These commenters suggested changing the exclusion to "Any EP who orders (less than 100/50/no) diagnostic scans or tests whose result is an image during the EHR reporting

period".

Response: Our intention with the proposed exclusion was to distinguish between ordering providers who have need of the image and those that do not. Based on the comments the need to view the image depends on a combination of factors including previous experiences with the type of image, the imaging facility, the circumstances of the patient, whether a similar image has been ordered before for the patient and the reading clinician. Given the wide variety of factors, we agree that it is not possible to create a distinct line between ordering providers who need the image and those that do not. We believe this line can be partly drawn by adopting the exclusion recommended by comments with a high count of 100. This is both consistent with our other objectives and as a high number indicates a particular benefit to the provider as well as increasing the likelihood that factors align for the ordering provider to need the image.

Comment: Commenters stated that the use of the term "scan" is confusing and unnecessary. Scan frequently applies to actions and concepts other than certain types of imaging procedures.

Response: We agree that the term scan has multiple uses, as any scan would be an image and could be classified as a test. Therefore, we remove the word scan from the measure as duplicative.

After reviewing the comments, we modify the measure for EPs at §495.6 (k)(1)(ii) and for eligible hospitals and CAHs at §495.6(m)(2)(ii) to: More than 10 percent of all tests whose result is one or more images ordered by the EP or by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period are accessible through CEHRT.

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 CEHRT at 45 CFR 170.314(a)(12).

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

- Denominator: Number of tests whose result is one or more images ordered by the EP or by an authorized provider on behalf of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 and 23) during the EHR reporting period.
- Numerator: The number of results in the denominator that are accessible through CEHRT.
- Threshold: The resulting percentage must be more than 10 percent in order to meet this measure.
- Exclusion: Any EP who orders less than 100 tests whose result is an image during the EHR reporting period; or

Any EP who has no access to electronic imaging results at the start of the EHR reporting period.

No access means that none of the imaging providers used by the EP provide electronic images and any explanation or other accompanying information that are accessible through their CEHRT at the start of the EHR reporting period.

We solicited comments on a potential second measure for this objective that would encourage the exchange of imaging and results between providers. We considered a threshold of 10 percent of all scans and tests whose result is one or more images ordered by the EP or by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period and accessible through CEHRT also be exchanged with another provider of care.

Comment: While most commenters agree with the principle of exchange of images among providers of care, they nearly all agreed that this measure would be premature for Stage 2 due to infrastructure concerns. Some suggested that it be considered for Stage 3 as a logical next step from our proposed Stage 2 measure.

Response: Given the comments, we are not including this measure in our final rule. We will consider the input provided when we develop our proposal for Stage 3.

Proposed Objective: Record patient family health history as structured data

In the proposed rule, we noted that every provider currently requests a family health history from the patient in order to obtain it. However, EHRs can allow the patient to contribute directly to the record and allow the record to be shared among providers, thereby greatly increasing the efficiency of collecting family health histories. Family health history is a major risk indicator for a variety of chronic conditions for which effective screening and prevention tools are available.

Comment: Commenters generally supported the inclusion of recording family health history as a menu set measure for EPs, eligible hospitals and CAHs, while some suggested deferring the measure until Stage 3 when they expect more robust standards will be available. Some commenters also suggested family health history is best collected by primary care physicians, not hospitals. Others still suggested modifying this objective to allow for the use of unstructured data.

Response: ONC has adopted standards requiring CEHRT to be able to use SNOMED-CT or the HL7 Pedigree standard to record a patient's family health history. We refer readers to ONC's standards and certification criteria final rule that is published elsewhere in this issue of the **Federal Register**. As a readily available standard is being adopted, we are maintaining this

objective as proposed and including it in the menu set. We continue to believe that family history is part of regular physician and hospital workflow – even if it's collected at a very high level. While it may primarily be the physicians working in the hospital that consider this information, these same physicians typically use the hospital EHR when evaluating their hospitalized patients so having this information in the hospital EHR is just as important as having it in the physician's own EHR. We will also finalize the exclusion for EPs who have no office visits during the EHR reporting period to account for scope of practice concerns and the common collection of this information directly from patients.

After consideration of public comments, we are finalizing this objective for EPs at §495.6 (k)(2)(i) and for eligible hospitals and CAHs at §495.6(m)(3)(i) as proposed.

Proposed Measure: More than 20 percent of all unique patients seen by the EP, or admitted to the eligible hospital or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have a structured data entry for one or more first-degree relatives.

We proposed to adopt the definition of first degree relative used by the National Human Genome Research Institute of the National Institutes of Health. A first degree relative is a family member who shares about 50 percent of their genes with a particular individual in a family. First degree relatives include parents, offspring, and siblings. We considered other definitions, including those that address both affinity and consanguinity relationships and encourage comments on this definition. We noted that this is a minimum and not a limitation on the health history that can be recorded. We did not propose a time limitation on the indication that the family health history has been reviewed. The recent nature of this capability in EHRs will impose a de facto limitation on review to the recent past.

We proposed an exclusion to this measure for EPs who have no office visits during the EHR reporting period. We believe that EPs who do not have office visits will not have the face-to-face contact with patients necessary to obtain family health history information.

Comment: Many commenters wondered why recording family health history was limited to first-degree relatives. They noted that a patient's grandparents or other relatives may have equally relevant medical information that should be included in the EHR. Other commenters pointed out that not all patients may know their family health history, particularly patients who were adopted, and suggested including a code for "unknown" or "not relevant." They noted that in some cultures, the patient may not be willing to provide the data or that the data they have may be unreliable (such as informal adoptions in Native American tribes).

Response: While information about second degree relatives may be useful for some diagnoses and conditions, we believe collecting medical history from first degree relatives is the floor, not the ceiling and encourage providers to collect additional information as they see fit. Additionally, we understand concerns about patients who may not know their family history. In these situations, we would find it acceptable for the provider to record the patient's family history as "unknown." Either a structured data entry of "unknown" or any structured data entry identified as part of the patient's family history and conforming to the standards of CEHRT at 45 CFR 170.314(a)(13) must be in the provider's CEHRT for the patient to count in the numerator.

Comment: Some commenters suggested we introduce this measure with a lower threshold as this is a new requirement, but did not specify a threshold. They noted that providers who might have previously captured family history might not have that in a structured format or not coded against the standards chosen for CEHRT. This history would have to be

redocumented.

Response: We proposed a low threshold of 20 percent. As this measure is not reliant on other organizations and providers the way imaging is we do not believe that is necessary to lower the threshold further.

Comment: Some commenters suggested this measure may not apply to certain specialty providers (for example, Urgent Care, Orthopedics) and suggested including an exclusion.

Response: We proposed an exclusion to this measure for EPs who have no office visits during the EHR reporting period. We continue to believe that EPs who do not have office visits would not have the face-to-face contact with patients necessary to obtain family health history information. However, this exclusion may not apply to certain specialty providers (like the aforementioned). We continue believe that recording family health history, regardless of specialty, is can be an important indicator for chronic conditions. Additionally, as this measure is being finalized as part of the menu set, providers are not required to report on this objective.

After consideration of public comments, we are finalizing the measure for EPs at §495.6 (k)(2)(ii) and for eligible hospitals and CAHs at §495.6(m)(3)(ii) to "More than 20 percent of all unique patients seen by the EP, or admitted to the eligible hospital or CAH's inpatient or emergency department (POS 21 or 23), during the EHR reporting period have a structured data entry for one or more first-degree relatives".

We are finalizing the exclusion as proposed at §495.6(k)(2)(iii)..

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 CEHRT at 45 CFR 170.314(a)(13).

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

● Denominator: Number of unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) during the EHR reporting period.

● Numerator: The number of patients in the denominator with a structured data entry for one or more first-degree relatives.

● Threshold: The resulting percentage must be more than 20 percent in order to meet this measure.

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

Proposed EP Objective: Capability to identify and report cancer cases to a state cancer registry, except where prohibited, and in accordance with applicable law and practice.

We outlined the following benefits of this objective in the proposed rule. Reporting to cancer registries by EPs would address current underreporting of cancer, especially certain types. In the past most cancers were diagnosed and/or treated in a hospital setting and data were primarily collected from this source. However, medical practice is changing rapidly and an increasing number of cancer cases are never seen in a hospital or are cared for primarily in the outpatient setting. Data collection from EPs presents new challenges since the infrastructure for reporting is less mature than it is in hospitals. Certified EHR technology can address this barrier by identifying reportable cancer cases and treatments to the EP and facilitating electronic reporting either automatically or upon verification by the EP.

We proposed to include "except where prohibited and in accordance with applicable law and practice" because we want to encourage all EPs to submit cancer cases, even in rare cases where they are not required to by state/local law. Legislation requiring cancer reporting by EPs exists in 49 states with some variation in specific requirements, per the 2010 Council of State

and Territorial Epidemiologists (CSTE) State Reportable Conditions Assessment (SRCA) (http://www.cste.org/dnn/ProgramsandActivities/PublicHealthInformatics/StateReportableConditionsQueryResults/tabid/261/Default.aspx)." If EPs are authorized to submit, they should do so even if it is not required by either law or practice." In accordance with applicable law and practice" reflects that some public health jurisdictions may have unique requirements for reporting, and that some may not currently accept electronic provider reports. In the former case, the proposed criteria for this objective would not preempt otherwise applicable state or local laws that govern reporting. In the latter case, eligible professionals would be exempt from reporting.

Comment: Nearly all commenters who wrote in support of the objective stated that the rule would decrease reporting burden for EPs because cancer diagnosis reporting in mandatory in most states. One commenter noted that the rule may increase compliance with mandatory reporting by reducing time and effort needed to submit cancer diagnosis report. Also, it was noted that incorporation of cancer reporting in meaningful use Stage 2 for eligible providers will improve completeness and quality of cancer reporting. Conversely, several of the commenters who recommended moving the objective to Stage 3 or remove the objective completely stated that inclusion of this object would place undue burden on EPs, especially because primary care providers rarely report to cancer registries. A commenter noted that the necessary EHR functionality currently exists primarily in oncology specialty EHRs, and EPs may be required to purchase additional modules to meet this object, and further states that this would be cost-prohibitive to EPs who only rarely diagnose cancer. One commenter suggested that the detailed reporting requirements would be too time-consuming for most EPs. Another commenter questions if responsibility for reporting cases, or presumptive cases, would shift to primary care providers. Other commenters suggest that the objective should be removed until such time that a

national central repository can be established to simplify point-to-point connections.

Response: We agree that inclusion of this requirement is likely to reduce reporting burden for those already required to report to cancer registries. We also agree with commenters that this objective is not relevant to all providers. For those EPs who do not meet the proposed exclusion of not diagnosing or directly treating cancer, yet are not already under a requirement to report to cancer registries, we note that this is a menu objective and can be deferred. Between the proposed exclusions and the option to defer, we do not believe the measure imposes a reporting burden on providers who would not normally report to cancer registries.

Comment: The objectives of specialized registries and cancer registries reporting should be combined.

Response: In review of comments we found no compelling reason to change our proposal. No commenter disputed that the reporting to cancer registries has different level of existing reporting requirements and supporting standards than other specialized registries.

Comment: One commenter suggested changing the final rule to read, "public health central cancer registry" to clearly distinguish them from hospital-based cancer registries.

Response: We agree that the term public health central cancer registry is better than just cancer registries and more inclusive than just state cancer registries as used in the proposed objective, but not the proposed measure.

After consideration of the public comments received, we are modifying this objective for EPs at §495.6 (k)(4)(i) to "Capability to identify and report cancer cases to a public health central cancer registry, except where prohibited, and in accordance with applicable law and practice."

Proposed EP Measure: Successful ongoing submission of cancer case information from CEHRT to a cancer registry for the entire EHR reporting period.

Comment: Commenters are concerned that under the proposed menu set providers will be required to choose one of: (1) syndromic surveillance; (2) submitting to cancer registries; or (3) submitting to specialty registries if they do not meet the exclusions for all three. The commenters believe that CMS should be providing physicians with a legitimate selection of menu set measures from which to choose.

Response: Stage 2 does contain a more specialized and smaller menu set than Stage 1. We see this as a natural result of moving up the staged path towards improved outcomes. We also see it as necessary for meaningful use to be applicable to all EPs. We use exclusions to ensure that only those EPs who create reportable data have the obligation under meaningful use to report it so this would not be a barrier to meeting meaningful use. Furthermore, we added an objective to the menu set in this final rule for EPs so it is no longer true that an EP would be required to pick one of the three menu objectives mentioned by commenters.

After consideration of the public comments received, we are modifying this measure for EPs at §495.6 (k)(4)(ii) to "Successful ongoing submission of cancer case information from CEHRT to a public health central cancer registry for the entire EHR reporting period" and modify the exclusions to conform with the general criteria for public health objectives.

We further specify that in order to meet this objective and measure, an EP must use the capabilities and standards of CEHRT 45 CFR 170.314(a),(c)(l), (f)(5), and (f)(6).

- Exclusions: Any EP that meets at least 1 of the following criteria may be excluded from this objective: (1) The EP does not diagnose or directly treat cancer; (2) the EP operates in a jurisdiction for which no public health agency is capable of receiving electronic cancer case information in the specific standards required for CEHRT at the beginning of their EHR reporting period; (3) the EP operates in a jurisdiction where no PHA provides information

timely on capability to receive electronic cancer case information; (4) the EP operates in a jurisdiction for which no public health agency that is capable of receiving electronic cancer case information in the specific standards required for CEHRT at the beginning of their EHR reporting period can enroll additional EPs.

Proposed EP Objective: Capability to identify and report specific cases to a specialized registry (other than a cancer registry), except where prohibited, and in accordance with applicable law and practice.

In the proposed rule, we outlined the following benefits of this objective. We believe that reporting to registries is an integral part of improving population and public health. The benefits of this reporting are not limited to cancer reporting. We include cancer registry reporting as a separate objective because it is more mature in its development than other registry types, not because other reporting is excluded from meaningful use. We have included this objective to provide more flexibility in the menu objectives that EPs can choose. We believe that specialized registry reporting could provide many EPs with meaningful use menu option that is more aligned with their scope of practice.

Comment: The overwhelming majority of individuals and groups who commented on this objective expressed concern about the lack of specificity of this objective. Their concerns include: (1)lack of specificity of the potential types of registries make planning for vendors and EPs very difficult; (2)lack of information about who would define which registries may be included; (3) leaving dozens or hundreds of possibilities; (4) lack of clarity as to the definition of 'specialized registry; (5) lack of standards for many registries; (6) or potential of needing to comply with standards not identified in the proposed rule; and (7) lack of public health readiness to accept data from EHRs.

Response: The purpose of this objective and measure is to give meaningful use credit to those EPs who are engaged in ongoing submission with specialized registries. It is not expected that every EP will select this objective and measure from the menu nor even that every EP will have the capability to submit to a specialized registry. We are purposefully general in our description of specialized registry because we do not wish to exclude certain registries in an attempt to be more specific. The only limitation we place on our description of specialized registries is that the specialized registry cannot be duplicative of any of the other registries included in other meaningful use objectives and measures. This means that an EP cannot meet the immunization, syndromic surveillance or cancer objectives and this objective by reporting to the same registry. EPs who either do not wish to participate with a specialized registry or cannot overcome the barriers to doing so can defer or exclude this measure as their situation warrants.

Comment: Commenters expressed support for expansion of the requirement to streamline and improve surveillance of healthcare-associated infections (HAIs), with the goal of improving patient care and safety.

Response: A registry that is focused on healthcare associated infections could certainly be considered a specialized registry.

After consideration of the public comments received, we are finalizing this objective for EPs at §495.6 (k)(5)(i) as proposed.

Proposed EP Measure: Successful ongoing submission of specific case information from CEHRT to a specialized registry for the entire EHR reporting period.

Comment: Since the lack of specificity and named standards make it difficult to select this measure from the menu set, the actual viable measures available in the menu set are reduced to four and burdensome for providers who may need to pay for interfaces, costing the EPs extra

time and money above the cost of the CEHRT.

Response: Stage 2 does contain a more specialized and smaller menu set than Stage 1. We see this as a natural result of moving up the staged path towards improved outcomes. We also see it as necessary for meaningful use to be applicable to all EPs. We include exclusions that allow for those providers who do not create reportable data so every provider who would is required to report public health data would have public health data to report. Furthermore, we added an objective to the menu in this final rule for EPs so it is no longer true that an EP would be required to pick one of the three menu objectives. The purpose of this measure is to provide meaningful use credit to those providers engaged in the beneficial use of CEHRT of participating in specialized registries. Other EPs can either meet the exclusions or defer this objective and thereby avoid the burden of compliance with this objective.

Comment: Given the large number of specialized registries, many of which have national scope, the exclusions are rendered meaningless.

Response: We agree with this comment, and for purposes of the exclusion only, we limit it to registries sponsored by national specialty societies and specialized registries maintained by PHAs. We believe this provides needed limitations on the exclusions. This limitation does not apply to the specialized registries that can be used to satisfy the measure as the benefits are not limited only to reporting to registries operated by Public Health Agencies or national medical specialty organizations. Specialized registries operated by patient safety organizations and quality improvement organizations also enable knowledge generation or process improvement regarding the diagnosis, therapy and prevention of various conditions that affect a population.

After consideration of the public comments received, we are finalizing this measure for EPs at §495.6 (k)(5)(ii) as proposed, but we modify the exclusions to conform with the general

criteria for public health objectives and in response to comments.

We further specify that in order to meet this objective and measure, an EP must use the capabilities and standards of CEHRT 45 CFR 170.314(f)(5) and (f)(6).

● Exclusions: Any EP that meets at least 1 of the following criteria may be excluded from this objective: (1) The EP does not diagnose or directly treat any disease associated with a specialized registry sponsored by a national specialty society for which the EP is eligible, or the public health agencies in their jurisdiction; (2) the EP operates in a jurisdiction for which no specialized registry sponsored by a public health agency or by a national specialty society for which the EP is eligible is capable of receiving electronic specific case information in the specific standards required by CEHRT at the beginning of their EHR reporting period; (3) the EP operates in a jurisdiction where no public health agency or national specialty society for which the EP is eligible provides information timely on capability to receive information into their specialized registries ; or (4) the EP operates in a jurisdiction for which no specialized registry sponsored by a public health agency or by a national specialty society for which the EP is eligible that is capable of receiving electronic specific case information in the specific standards required by CEHRT at the beginning of their EHR reporting period can enroll additional EPs.

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

In the proposed rule, we outlined the following benefits of using secure electronic messaging to communicate with patients: Electronic messaging (for example, e-mail) is one of the most widespread methods of communication for both businesses and individuals. The inability to communicate through electronic messaging may hinder the provider-patient relationship. Electronic messaging is very inexpensive on a transactional basis and allows for

communication even when the provider and patient are not available at the same moment in time. The use of common email services and the security measures that may be used when they are sent may not be appropriate for the exchange of protected health information. Therefore, the exchange of health information through electronic messaging requires additional security measures while maintaining its ease of use for communication. While e-mail with the necessary safeguards is probably the most widely used method of electronic messaging, for the purposes of meeting this objective, secure electronic messaging could also occur through functionalities of patient portals, PHRs, or other stand-alone secure messaging applications.

We proposed this as a core objective for EPs for Stage 2. The additional time made available for Stage 2 implementation made possible the inclusion of some new objectives in the core set as proposed in the proposed rule. We chose to identify objectives that address critical priorities of the country's National Quality Strategy (NQS) (http://www.healthcare.gov/law/resources/reports/quality03212011a.html), with a focus on one for EPs and one for hospitals.

For EPs, secure electronic messaging is critically important to two NQS priorities--

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

Secure messaging could make care more affordable by using more efficient communication vehicles when appropriate. Specifically, research demonstrates that secure messaging has been shown to improve patient adherence to treatment plans, which reduces readmission rates. Secure messaging has also been shown to increase patient satisfaction with their care. Secure messaging has been named as one of the top ranked features according to patients. Also, despite some trepidation, providers have seen a reduction in time responding to

inquires and less time spent on the phone. We specifically sought comment on whether there may be special concerns with this objective in regards to behavioral health.

Comment: Some commenters noted that patient engagement and enhanced patient-provider communications facilitated by an EHR are important goals, and secure messaging between EPs and patients is an appropriate objective to consider for Meaningful Use criteria.

Response: We appreciate the commenters support of this objective and agree that electronic patient-provider communication is important to improving the overall quality of patient care.

Comment: Some commenters suggested that this objective should be part of the menu set instead of a core objective for Stage 2. This would permit EPs who do not believe they can meet the measure at this time to select different objectives.

Response: As we noted in the proposed rule, we placed this objective in the core because we believe it addresses critical priorities of the country's National Quality Strategy (NQS) (http://www.healthcare.gov/law/resources/reports/quality03212011a.html): Ensuring that each person/family is engaged as partners in their care; and promoting effective communication and coordination of care. We also believe that secure messaging could make care more affordable by using more efficient communication vehicles when appropriate. Specifically, research demonstrates that secure messaging has been shown to improve patient adherence to treatment plans, which reduces readmission rates (see Rosenberg SN, Shnaiden TL, Wegh AA, Juster IA (2008) "Supporting the patient's role in guideline compliance: a controlled study" American Journal of Managed Care 14(11):737-44; Gustafson DH, Hawkins R, Boberg E, Pingree S, Serlin RE, Graziano F, Chan CL (1999) "Impact of a patient-centered, computer-based health

information/support system" American Journal of Preventive Medicine 16(1):1-9). Secure messaging has also been shown to increase patient satisfaction with their care (see Ralston JD, Carrell D, Reid R, Anderson M, Moran M, Hereford J (2007) "Patient web services integrated with a shared medical record: patient use and satisfaction" Journal of the American Medical Informatics Association 14(6):798-806). Therefore, we are leaving this as a core objective for EPs for Stage 2.

Comment: Several commenters responded to our question about whether there were special concerns about implementing this objective for behavioral health patients. These commenters indicated that they did not believe this objective posed a special concern and that it would help behavioral health patients obtain needed support from clinicians.

Response: We appreciate the feedback from commenters regarding behavioral health.

After consideration of the public comments, we are finalizing the meaningful use objective for EPs at §495.6(j)(17)(i) as proposed.

Proposed EP Measure: A secure message was sent using the electronic messaging function of CEHRT by more than 10 percent of unique patients seen by the EP during the EHR reporting period.

Comment: Many commenters voiced objections to the measure of this objective and the concept of providers being held accountable for patient actions. The commenters believed that while providers could be held accountable for making electronic messaging capabilities available to patients and encouraging patients to use electronic messaging, they could not control whether patients actually utilized electronic messaging. However, some commenters believed that the measure was a reasonable and necessary step to require vendors to make electronic messaging tools more widely available and for providers to incorporate electronic messaging into clinical

practice. In addition, commenters pointed to the unique role that providers can play in encouraging and facilitating their patients' and their families' use of secure messaging.

Response: While we recognize that EPs cannot directly control whether patients use electronic messaging, we continue to believe that EPs are in a unique position to strongly influence the technologies patients use to improve their own care, including secure electronic messaging. We believe that EPs' ability to influence patients coupled with the low threshold make this measure achievable for all EPs.

Comment: Other commenters did not object to the principle of providers being held accountable for patient actions but noted that the potential barriers of limited internet access, computer access, and electronic messaging platforms for certain populations (for example, rural, elderly, lower income, visually impaired, non-English-speaking, etc.) might make the measure impossible to meet for some providers. Commenters suggested a number of possible solutions to allow providers to overcome these barriers: granting exclusions for certain patient populations, lowering the proposed threshold of the measure, or eliminating the percentage threshold of the measure.

Response: We recognize that certain patient populations face greater challenges in utilizing electronic messaging. We address the potential barrier of limited internet access in the comment regarding a broadband exclusion below. While we agree that excluding certain patient populations from this requirement would make the measure easier for EPs to achieve, we do not know of any reliable method to quantify these populations for each EP in such a way that we could standardize exclusions for each population. In addition, we are concerned that blanket exclusions for certain disadvantaged populations could serve to extend existing disparities in electronic access to health information. We also decline to eliminate the percentage threshold of

this measure because we do not believe that a simple yes/no attestation for implementation of electronic messaging is adequate to encourage a minimum level of patient usage. However, in considering the potential barriers faced by these patient populations, we agree that it would be appropriate to lower the proposed threshold of this measure to more than 5 percent of unique patients sending an electronic message. We believe that this lower threshold, combined with the broadband exclusion detailed in the response below, will allow all EPs to meet the measure of this objective.

Comment: Several commenters suggested that the exclusion for FCC-recognized areas with under 50 percent broadband availability, which was proposed in the objective to "Provide patients the ability to view online, download, and transmit their health information," should be extended to the electronic messaging objective.

Response: We agree that the infrastructure required for electronic messaging is similar to the infrastructure required for successful usage of an online patient portal as described in the objective to "Provide patients the ability to view online, download, and transmit their health information." Therefore, we believe an exclusion to this measure based on the availability of broadband is appropriate and are finalizing the exclusion in the language below. We note that since publication of our proposed rule the website has changed to www.broadbandmap.gov and the speed used has changed from 4Mbps to 3Mbps. We updated our exclusion.

Comment: Some commenters expressed concern about including all patients seen by the EP in the denominator and suggested limiting the denominator instead to patients who have indicated secure electronic messaging as their communication preference. Other commenters suggested the denominator should not be limited to patients seen by the EP and should also include patients who make inquiries or who attempt to make an appointment with the EP during

the reporting period.

Response: We do not agree that limiting the denominator to patients who have indicated secure electronic messaging as their communication preference is appropriate. The purpose of the measure is for EPs to promote wider use of electronic messaging as a regular communication vehicle for their patients, and we are concerned that limiting the denominator in the manner suggested would not lead to an increase in the promotion or usage of electronic messaging as an important communication vehicle between patients and providers. We also do not agree that expanding the denominator to patients not seen by the EP during the reporting period is appropriate. Another purpose of the measure is for secure messaging to include clinically relevant information, and we do not believe that patients seeking introductory information or making an appointment are likely to include clinically relevant information in secure messaging.

Comment: Some commenters noted that patients whose only office visit with an EP occurs near the end of the reporting period might not be able to send an electronic message in time to be included in the numerator of the measure.

Response: While we agree that patients with a single office visit near the end of the reporting period may not utilize electronic messaging and be eligible for inclusion in the numerator of the measure during the EHR reporting period, we believe that the threshold of this measure will be sufficiently low to permit EPs to meet the measure even without the participation of these patients.

Comment: Several commenters requested clarification on the definition of a secure message.

Response: We define a secure message as any electronic communication between a provider and patient that ensures only those parties can access the communication. This

electronic message could be email or the electronic messaging function of a PHR, an online patient portal, or any other electronic means. However, we note that the secure message also must use the electronic messaging function of CEHRT in order to qualify for the measure of this objective.

Comment: Some commenters suggested that EPs or patients should be permitted to use an electronic messaging function that is not part of CEHRT in order to meet the measure.

Response: We believe that allowing patients to use multiple electronic messaging functions in order to communicate with the provider under this measure could create confusion for the EP and potentially lead to electronic messages that are missed or not responded to. We also believe that by encouraging patients to use the electronic messaging function that is part of CEHRT EPs can better ensure that electronic messages are sent securely to protect patient's health information. Finally, we are concerned that CEHRT would not be able to track electronic messaging that is not part of the EHR, which would place an extra burden for reporting on EPs in meeting this measure. For all of these reasons, we require that patients use the electronic messaging function that is part of CEHRT in order to be included in the measure of this objective.

Comment: Commenters agreed with our decision not to include in the definition for this measure "relevant health information." Commenters did not believe CEHRT could support the categorization of electronic messages in a way that would satisfy such a requirement.

Response: We appreciate the support offered by commenters. As we stated in the proposed rule, 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 EP is the best judge of what health information should be considered relevant in this context. We do not specifically

include the term "relevant health information" in the measure because we believe the provider is best equipped to determine whether such information is included. We agree that it would be too great a burden for CEHRT to determine whether the information in the secure message has such information.

Comment: Some commenters expressed concerns that we did not propose to measure provider response to patient electronic messaging. These commenters believed that the proposed measure places too much focus on patient messaging and should instead focus on communication between patient and provider. Some commenters suggested that the measure be modified for responsiveness of an EP or staff to patient messaging rather than the proposed percentage of patients who send a secure message.

Response: As we stated in the proposed rule, there is an expectation that the EP would respond to electronic messages sent by the patient, although we do not specify the method of response or require the EP to document his or her response for this measure. We decline to specify the method of provider response because we believe it is best left to the provider's clinical judgment to decide the course of action which should be taken in response to the patient's electronic message. An EP or staff member could decide that a follow-up telephone call or office visit is more appropriate to address the concerns raised in the electronic message. Therefore, we decline to alter the measure to include provider response.

Comment: Commenters asked for clarification as to whether the EP had to respond personally to electronic messaging or whether members of the EP's staff could respond. Commenters also asked for clarification regarding whether or not messages sent by a patient-authorized representative would be recorded in this measure.

Response: There is not an expectation that the EP must personally respond to electronic

messages to the patient. Just as an EP's staff respond to telephone inquiries or conduct office visits on behalf of the EP, staff could also respond to electronic messages from the patient. We also intend for electronic messages sent by a patient-authorized representative to be included in the measure of this objective and have modified the language of the measure below accordingly.

Comment: Some commenters raised concerns regarding the security of electronic messaging, specifically citing instances where family members might have access to the patient's account or elderly patients who would not know how to use a computer and would have to give account access to a caregiver. Other commenters raised concerns regarding their liability in providing access to such information or in responding to an electronic message.

Response: We do not believe that secure electronic messaging poses greater risks to exposure of protected health information than other mediums such as telephone messaging, paper records, etc. In some cases secure electronic messaging can provide even greater protection of health information. We note that many patients grant access to health information to family members and caregivers to facilitate care, and we expect the same access to continue with secure electronic messaging. Nor do we believe that secure electronic messaging exposes providers to greater liability (for example, in areas of privacy protection or malpractice) than other mediums such as telephone, mail, paper records, etc. Previous research has demonstrated that better patient-provider communication reduces the likelihood of malpractice claims being filed.

Comment: Some commenters noted that the potential financial burden of implementing securing messaging as a part of their clinical or administrative workflow. These commenters noted that EPs are not reimbursed for the time spent responding to electronic messages and that it can be time consuming for an EP to have multiple exchanges with a patient via email.

Response: We do not believe that implementing electronic messaging imposes a significant burden on providers. While we note that in some scenarios it may be possible for an EP to receive reimbursement from private insurance payers for online messaging, we acknowledge that EPs are generally not reimbursed for time spent responding to electronic messaging. However, it is also true that EPs are generally not reimbursed for other widely used methods of communication with patients (for example, telephone). As we noted in the proposed rule, many providers have seen a reduction in time responding to inquires and less time spent on the phone through the use of electronic messaging. In addition, we note that EPs themselves do not have to respond to electronic messages personally and can delegate this task to staff, just as many EPs currently delegate telephone exchanges with patients to staff.

After consideration of the public comments, we are finalizing the meaningful use measure for EPs as "A secure message was sent using the electronic messaging function of CEHRT by more than 5 percent of unique patients (or their authorized representatives) seen by the EP during the EHR reporting period" at §495.6(j)(17)(ii) and the exclusion for EPs as "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 3Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period" at §495.6(j)(17)(iii).

We further specify that in order to meet this objective and measure, an EP must use the capabilities and standards of CEHRT at 45 CFR 170.314(e)(3).

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

- Denominator: Number of unique patients seen by the EP during the EHR reporting

period.

- Numerator: The number of patients or patient-authorized representatives in the denominator who send a secure electronic message to the EP that is received using the electronic messaging function of CEHRT during the EHR reporting period.

- Threshold: The resulting percentage must be more than 5 percent in order for an EP 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 3Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period.

Proposed Eligible Hospital/CAH Objective: Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR).

In the proposed rule, we outlined the following benefits of automatically tracking medications with eMAR: eMAR increases the accuracy of medication administration thereby increasing both patient safety and efficiency. The HIT Policy Committee has recommended the inclusion of this objective for hospitals in Stage 2, and we proposed this as a core objective for eligible hospitals and CAHs. The additional time made available for Stage 2 implementation makes possible the inclusion of some new objectives in the core set. eMAR is critically important to making care safer by reducing medication errors which may make care more affordable. eMAR has been shown to lead to significant improvements in medication-related adverse events within hospitals with associated decreases in cost. eMAR cuts in half the adverse drug event (ADE) rates for non-timing medication errors, according to a study published in the

New England Journal of Medicine (Poon et al., 2010, Effect of Bar-Code Technology on the Safety of Medication Administration http://www.nejm.org/doi/abs/10.1056/NEJMsa0907115?query=NC). A study done to evaluate cost-benefit of eMAR (Maviglia et al., 2007, Cost-Benefit Analysis of a Hospital Pharmacy Bar Code Solution http://archinte.ama-assn.org/cgi/content/full/167/8/788) demonstrated that associated ADE cost savings allowed hospitals to break even after 1 year and begin reaping cost savings going forward.

We proposed to define eMAR as technology that automatically documents the administration of medication into CEHRT using electronic tracking sensors (for example, radio frequency identification (RFID)) or electronically readable tagging such as bar coding). The specific characteristics of eMAR for the EHR Incentive Programs will be further described in the ONC standards and certification criteria final rule published elsewhere in this issue of the **Federal Register**.

By its very definition, eMAR occurs at the point of care so we did not propose additional qualifications on when it must be used or who must use it.

Comment: Some commenters suggested that this should be a menu objective for Stage 2.

Response: As we stated in the proposed rule, we believe that eMAR is critically important to making care safer by reducing medication errors which may also make care more affordable. eMAR has been shown to lead to significant improvements in medication-related adverse events within hospitals with associated decreases in cost. Therefore, we believe that the benefits to patient safety from eMAR warrant the inclusion of this as a Stage 2 core objective for eligible hospitals and CAHs.

After consideration of the public comments, we are finalizing the meaningful use

objective for eligible hospitals and CAHs at §495.6(l)(16)(i) as proposed.

Proposed Eligible Hospital/CAH Measure: More than 10 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 tracked using eMAR.

Comment: A number of commenters questioned whether the measure should apply to at least one instance of the administration of a dose connected with a medication order or whether each individual dose connected with a medication order should be included in the measure. Some commenters believed that a single instance of administration of a dose should constitute fulfillment of the measure, while others believed that all doses administered rather than orders administered would be a more precise and meaningful measurement.

Response: We believe that including each individual dose connected with a medication order through this measure could yield denominators that are very large. However, we believe that the benefits to patient safety from eMAR are seen when all doses of a medication order are tracked. Therefore, we clarify that we include in the numerator of this objective medication orders for which all doses are tracked using eMAR, and we are amending the measure language below to reflect this clarification. If a medication is ordered but not all doses of the medication are tracked using eMAR, then that order may not be included in the numerator of the measure.

Comment: Some commenters raised the concern that certain rural and low volume hospitals might face undue financial burden in implementing this objective and proposed an exclusion for hospitals with either a limited number of inpatient beds or a low average inpatient volume. Some commenters suggested there should be an exclusion for very small hospitals for whom eMAR could be a prohibitively expensive undertaking. Other commenters noted that the difficulties in implementing eMAR were outweighed by the significant benefits to patient safety.

Response: We agree with commenters who suggested that the potential benefits to patient safety of eMAR are significant. While we agree that certain hospitals may face challenges in implementing eMAR on a wider scale, we believe that the low threshold for this measure lessens the burden associated with implementation of eMAR for most rural and low volume hospitals. We also note that CEHRT will include eMAR capabilities, so the primary barrier to implementation for most hospitals will be workflow.

However, we are also concerned that very small hospitals may have local technical support and training issues that may make an automated eMAR solution actually less effective than other approaches. We also believe that very small hospitals will have fewer health care professionals involved in the process of medication administration and fewer patients for whom duplicative orders could present an issue, which would also make an eMAR solution less effective. Therefore, we believe these hospitals would not benefit from eMAR as much as larger facilities and are finalizing an exclusion for these hospitals. Any hospital with an average daily inpatient census of fewer than 10 patients may be excluded from meeting the measure of this objective. For purposes of this exclusion, we define an average daily inpatient census as the total number of patients admitted during the previous calendar year divided by 365 (or 366 if the previous calendar year is a leap year).

Comment: Some commenters stated that the percentage threshold of this measure should be replaced with the implementation of eMAR in one ward or unit of the hospital to limit burdensome measurement requirements. Other commenters argued that changing the measure to one ward or unit of the hospital would introduce ambiguity regarding what constitutes a ward or unit, while a percentage threshold would allow hospitals the flexibility to implement eMAR capabilities on a limited basis.

Response: We believe that the low threshold of this objective does not impose burdensome measurement requirements on hospitals, especially since we do not anticipate a significant difference in the way CEHRT will measure eMAR usage regardless of where it is implemented. We agree that limiting the measure to implementation in a single ward or unit could introduce ambiguity regarding the precise definition of ward or unit, especially since some hospitals combine the locations and workflows of certain units. We further note that the percentage threshold does allow hospitals to implement eMAR in a limited capacity, and that a hospital could potentially meet the low measure of this objective by implementing in a single ward or unit or by implementing in several smaller wards or units that combine to yield more than 10 percent of medication orders created during the EHR reporting period. We believe the percentage measure of this objective yields maximum flexibility for a hospital to implement eMAR in a way that is clinically relevant to its individual workflow.

Comment: Some commenters requested clarification on whether eMAR could be implemented solely in portions of an inpatient department or solely in portions of an emergency department in order to meet the measure, as opposed to implementing eMAR in both the inpatient and emergency departments.

Response: As stated previously, we have attempted to provide maximum flexibility for a hospital to implement eMAR in a way that is clinically relevant to its individual workflow. Therefore, we do not require that eMAR is implemented in both inpatient and emergency departments in order to meet this measure, only that more than 10 percent of medication orders created by authorized providers of either the inpatient or emergency department (POS 21 or 23) during the EHR reporting period are tracked using eMAR. Hospitals could implement eMAR in the inpatient department, the emergency department, or both departments in order to meet the

threshold of this measure.

After consideration of the public comments, we modify the meaningful use measure as "More than 10 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 for which all doses are tracked using eMAR" for eligible hospitals and CAHs at §495.6(l)(16)(ii) and finalize the exclusion as "Any eligible hospital or CAH with an average daily inpatient census of fewer than 10 patients" at §495.6(l)(16)(iii).

We further specify that in order to meet this objective and measure, an eligible hospital or CAH must use the capabilities and standards of CEHRT at 45 CFR 170.314(a)(16).

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

- Denominator: Number of medication orders created by 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 for which all doses are tracked using eMAR.

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

- Exclusion: Any hospital with an average daily inpatient census of fewer than ten (10) patients.

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

In the proposed rule, we outlined the following benefits of electronic prescribing: 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 recognize the information and can provide decision support to promote safety and quality in the form of adverse interactions and other treatment possibilities. The CEHRT can also provide decision support that promotes the efficiency of the health care system by alerting the EP to generic alternatives or to alternatives favored by the patient's insurance plan that are equally effective. Transmitting the prescription electronically promotes efficiency and safety through reduced communication errors. It also allows the pharmacy or a third party to automatically compare the medication order to others they have received for the patient. This comparison allows for many of the same decision support functions enabled at the generation of the prescription, but bases them on potentially greater information.

We have combined the comments and responses for this objective with the measure below. After consideration of the public comments, we are finalizing the meaningful use objective for eligible hospitals and CAHs at §495.6(m)(4)(i) as proposed.

Proposed Eligible Hospital/CAH Measure: More than 10 percent of hospital discharge medication orders for permissible prescriptions (for new or changed prescriptions) are compared to at least one drug formulary and transmitted electronically using CEHRT.

Comment: Most commenters voiced support for this as a menu set item, with some commenters noting that the threshold for this measure should remain low for Stage 2 because of the difficulty of using electronic prescribing for all prescriptions, including controlled substances.

Response: We appreciate the support for this objective, and we note that the measure of

the objective for eligible hospitals and CAHs for Stage 2 is set at more than 10 percent of all discharge medication orders for permissible prescriptions. We believe this sets a sufficiently low threshold that would allow most hospitals to achieve this measure and eliminates the inclusion of controlled substances, which are not included as permissible prescriptions for the purposes of this measure.

Comment: Most commenters noted that distinguishing new and altered prescriptions from refills would be unnecessarily burdensome for hospitals.

Response: Although we had initially proposed to limit this measure to only new and altered prescriptions because we believed that hospitals would not issue refill prescriptions, we agree with the commenters that distinguishing refills from new and altered prescriptions could be unnecessarily burdensome for hospitals. Therefore, we are not imposing this limitation and include new, altered, and refill prescriptions in the measure of discharge medication orders for permissible prescriptions.

Comment: Some commenters expressed concerns about patient requests for paper prescriptions instead of electronic prescriptions.

Response: We believe that the more than 10 percent of discharge medication orders threshold is sufficiently low to accommodate patient requests for paper prescriptions and still allow most, if not all, hospitals to meet the measure of this objective.

Comment: Some commenters asked whether prescriptions electronically transmitted to in-house pharmacies should be included in the measure and if the standards specified by ONC for this measure would apply to these transmissions.

Response: We are continuing the policy from Stage 1 that prescriptions transmitted electronically within an organization (the same legal entity) would be counted in the measure and

would not need to use the standards specified by ONC for this objective. However, a hospital's CEHRT must meet all applicable certification criteria and be certified as having the capability of meeting external transmission requirements. In addition, the EHR that is used to transmit prescriptions within the organization would need to be CEHRT.

The hospital would include in the numerator and denominator both types of electronic transmission (those within and outside the organization) for the measure of this objective. We further clarify that for purposes of counting discharge prescriptions "generated and transmitted electronically," we considered the generation and transmission of prescriptions to occur simultaneously if the prescriber and dispenser are the same person and/or are accessing the same record in an integrated EHR to create an order in a system that is electronically transmitted to an internal pharmacy.

Comment: Some commenters asked for clarification regarding whether drug-formulary checks had to be enabled for the entire EHR reporting period, as required by the Stage 1 measure.

Response: No. The Stage 1 objective for drug-formulary checks has been combined with this Stage 2 objective for generating and transmitting permissible discharge prescriptions electronically. Although the measure of the Stage 1 objective required the capability for drug-formulary checks to be enabled for the entire reporting period, the measure of the Stage 2 objective specifies drug-formulary checks should be performed for more than 10 percent of hospital discharge medication orders for permissible prescriptions. We recognize that not every patient will have a formulary that is relevant for him or her. Therefore, we require not that the EHR check each prescription against a formulary relevant for a given patient, but rather that the EHR check each prescription for the existence of a relevant formulary. If a relevant formulary is

available, then the information can be provided. We believe that this initial check is essentially an on or off function for the EHR and should not add to the measurement burden. Therefore, with this clarification of the check we are referring to, we are finalizing the drug formulary check as a component of this measure. We look forward to the day when a relevant formulary is available for every patient. We modified the measure to use the word query instead of compare.

Comment: Some commenters asked whether the measure of this objective applied to inpatient departments, emergency departments, or both.

Response: We specify that the measure of this objective applies to medication orders for patients discharged from either the inpatient (POS 21) department, the emergency department, or both the inpatient and emergency departments of an eligible hospital or CAH during the EHR reporting period.

Comment: One commenter asked for clarification of whether a patient for whom no relevant drug formularies are available could be counted in the numerator of the measure if the discharge prescription for that patient is generated and transmitted electronically. Another commenter suggested that patients for whom no relevant formularies are available should not be counted in the measure.

Response: As noted in the proposed rule, we believe that the inclusion of the comparison to at least one drug formulary enhances the efficiency of the healthcare system when clinically appropriate and cheaper alternatives may be available. In the event that a relevant formulary is unavailable for a particular patient and medication combination, a discharge prescription that is generated and electronically transmitted should still be included in the numerator of the measure. We do not agree that prescriptions for patients for whom relevant formularies are unavailable should be excluded from this measure.

Comment: Several commenters believed that the exclusion based on the availability of a pharmacy capable of receiving electronic prescriptions within 25 miles of the hospital's location was not adequate for all areas, particularly rural areas. Some commenters suggested that 10 miles is a more appropriate distance.

Response: We appreciate the commenters' concerns about this exclusion. As stated in the proposed rule, we recognize that certain areas may not have widespread availability of electronic prescribing in all pharmacies, we believe that most hospitals will be able to fulfill electronic prescriptions through an internal pharmacy. However, we agree with commenters that basing the exclusion on a 25-mile radius could place a significant burden on patients to travel to fill prescriptions, especially in rural areas. Therefore, we are finalizing a 10-mile radius at the start of the EHR reporting period. Hospitals that do not have an internal pharmacy and that are located 10 miles from a pharmacy that can receive electronic prescriptions at the start of the EHR reporting period would be able to claim the exclusion for this measure. We also believe that the low threshold of more than 10 percent of discharge prescriptions transmitted electronically would make it possible for all hospitals to meet this measure.

Comment: Some commenters requested for clarification of whether CEHRT would provide the capability to determine the availability of a pharmacy capable of receiving electronic prescriptions within 25 miles of the hospital's location.

Response: CEHRT will not provide the capability to determine whether a hospital meets the exclusion for this measure. As stated in the previous response , we are finalizing the exclusion for the availability of a pharmacy capable of receiving electronic prescriptions within 10 miles of the hospital's location. Therefore, eligible hospitals and CAHs may use their own resources to make a determination regarding the availability of a pharmacy capable of receiving

electronic prescriptions within 10 miles of the hospital's location.

After consideration of the public comments, we modify the meaningful use measure for eligible hospitals and CAHs as "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" at §495.6(m)(4)(ii) and we modify the exclusion for eligible hospitals and CAHs at §495.6(m)(4)(iii) by changing the radius from 25 miles to 10 miles.

We further specify that in order to meet this objective and measure, an eligible hospital or CAH must use the capabilities and standards of CEHRT at 45 CFR 170.314(a)(10) and (b)(3).

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

In the proposed rule, we noted that studies have found that patients engaged with computer based information sources and decision support show improvement in quality of life indicators, patient satisfaction and health outcomes. (Ralston, Carrell, Reid, Anderson, Moran, & Hereford, 2007) (Gustafson, Hawkins, Bober, S, Graziano, & CL, 1999) (Riggio, Sorokin, Moxey, Mather, Gould, & Kane, 2009) (Gustafson, et al., 2001). In addition, we noted that this objective aligns with the FIPPs,[5] in affording baseline privacy protections to individuals. We stated that we believe this information is integral to the Partnership for Patents initiative and reducing hospital readmissions. While this objective does not require all of the information sources and decision support used in these studies, having a set of basic information available advances these initiatives. 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. However, providers should be aware that while meaningful use is limited to the capabilities of CEHRT to provide online access, there may be patients who cannot access their EHRs electronically because of their disability. Additionally, other health information may not be accessible. Finally, we noted that providers who are covered by civil rights laws must provide individuals with disabilities equal access to information and appropriate auxiliary aids and services as provided in the applicable statutes and regulations.

We proposed this as a core objective for hospitals for Stage 2. We also specified in the proposed rule the information that must be made available as part of the objective, although we noted hospitals could choose to provide additional information (77 FR 13730).

Comment: Some commenters suggested that this objective should be part of the menu set

[5] Ibid.

instead of a core objective for Stage 2. This would permit eligible hospitals and CAHs that do not believe they can meet the measure at this time to select different objectives.

Response: We do not agree that this objective should be part of the menu set. We proposed this objective as part of the core for eligible hospitals and CAHs because it is intended to replace the previous Stage 1 core objective of "Provide patients with an electronic copy of their health information upon request" and the Stage 1 core objective of "Provide patients with an electronic copy of their discharge information." Although CEHRT will provide added capabilities for this objective, we do not believe the objective itself is sufficiently different from previous objectives to justify placing it in the menu set. Also, we believe that patient access to their discharge information is a high priority for the EHR Incentive Programs and this objective best provides that access in a timely manner.

Comment: Some commenters expressed the opinion that this objective should not be included as part of meaningful use and was more appropriately regulated under HIPAA and through the Office for Civil Rights.

Response: We do not agree that this objective should not be included in meaningful use. Although we recognize that many issues concerning the privacy and security of information online are subject to HIPAA requirements, we believe that establishing an objective to provide online access to health information is within the regulatory purview of the EHR Incentive Programs and consistent with the statutory requirements of meaningful use.

After consideration of the public comments, we are finalizing the meaningful use objective for eligible hospitals and CAHs at §495.6(l)(8)(i) as proposed.

Proposed Eligible Hospital/CAH Measure: There are 2 measures for this objective, both of which must be satisfied in order to meet the objective.

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.

More than 10 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH view, download or transmit to a third party their information during the EHR reporting period.

Comment: A commenter questioned how long data should be made available online before it can be removed.

Response: It is the goal of this objective to make available to the patient both current and historical health information regarding hospital discharges. Therefore, we would anticipate that the data should be available online on an ongoing basis. However, an eligible hospital or CAH may withhold or remove information from online access for purposes of meaningful use if they believe substantial harm may arise from its disclosure online.

Comment: Some commenters asked for clarification on whether online access had to be made available using CEHRT or if the information could be made available through other means (patient portal, PHR, etc.).

Response: Both of the measures for this objective must be met using CEHRT. Therefore, for the purposes of meeting this objective, the capabilities provided by a patient portal, PHR, or any other means of online access and that would permit a patient or authorized representative to view, download, or transmit their personal health information would have to be certified in accordance with the certification requirements adopted by ONC. We refer readers to ONC's standards and certification criteria final rule that is published elsewhere in this issue of the **Federal Register**.

Comment: Some commenters asked for clarification on how access by the patient is defined.

Response: We define access as having been given when the patient possesses all of the necessary information needed to view, download, or transmit their discharge information. This could include providing patients with instructions on how to access their health information, the website address they must visit for online access, a unique and registered username or password, instructions on how to create a login, or any other instructions, tools, or materials that patients need in order to view, download, or transmit their discharge information.

Comment: Some commenters suggested that patients under the age of 18 should not have the same access to the same information to which adult patients have access and requested a separate list of required elements for patients under the age of 18.

Response: An eligible hospital or CAH may decide that online access is not the appropriate forum for certain health information for patients under the age of 18. Within the confines of the laws governing guardian access to medical records for patients under the age of 18, we would defer to the eligible hospital's or CAH's judgment regarding which information should be withheld for such patients. In lieu of providing online access to patients under the age of 18, eligible hospitals or CAHs could provide online access to guardians for patients under the age of 18, in accordance with state and local laws, in order to meet the measure of this objective. Providing online access to guardians in accordance to state and local laws would be treated the same as access for patients, and guardians could then be counted in the numerator of the measure. We recognize that state and local laws may restrict the information that can be made available to guardians, and in these cases such information can be withheld and the patient could still be counted in the numerator of the measure.

Comment: Many commenters voiced objections to the second measure of this objective and the concept of providers being held accountable for patient actions. The commenters believed that while providers could be held accountable for making information available online to patients, providers could not control whether patients actually accessed their information. Many commenters also noted that the potential barriers of limited internet access, computer access, and patient engagement with health IT for certain populations (for example, rural, elderly, lower income, non-English-speaking, etc.) might make the measure impossible to meet for some providers. There were also a number of comments stating that metrics used to track views or downloads can be misleading and are not necessarily the most accurate measure of patient usage. Commenters suggested a number of possible solutions to allow providers to overcome these barriers, including eliminating the percentage threshold of the measure or requiring providers to offer and track patient access but not requiring them to meet a percentage measure in order to demonstrate meaningful use. However, some commenters believed that the measure was a reasonable and necessary step to ensure that providers had accountability for engagement of their patients in use of electronic health information and integration of it into clinical practice. In addition, commenters pointed to the unique role that providers can play in encouraging and facilitating their patients' and their families' use of online tools.

Response: While we recognize that eligible hospitals and CAHs cannot directly control whether patients access their health information online, we continue to believe that eligible hospitals and CAHs are in a unique position to strongly influence the technologies patients use to improve their own care, including viewing, downloading, and transmitting their health information online. We believe that the eligible hospital's or CAH's ability to influence patients coupled with the low threshold of more than 10 percent of patients who view online, download,

or transmit to a third party their information make this measure achievable for all eligible hospitals and CAHs.

We recognize that certain patient populations face greater challenges in online access to information. We address the potential barrier of limited internet access in the comment regarding a broadband exclusion below. We address the potential barrier to individuals with disabilities through ONC's rules requiring that EHRs meet disability accessibility standards. While we agree that excluding certain patient populations from this requirement would make the measure easier for eligible hospitals and CAHs to achieve, we do not know of any reliable method to quantify these populations for each eligible hospital and CAH in such a way that we could standardize exclusions for each population. We also decline to eliminate the percentage threshold of this measure because we do not believe that a simple yes/no attestation for this objective is adequate to encourage a minimum level of patient usage. However, in considering the potential barriers faced by these patient populations, we agree that it would be appropriate to lower the proposed threshold of this measure to more than 5 percent of unique patients who view online, download, or transmit to a third party their information. In addition, we are concerned that blanket exclusions for certain disadvantaged populations could serve to extend existing disparities in electronic access to information and violate civil rights laws. All entities receiving funds under this program are subject to civil rights laws. For more information about these laws and their requirements (see http://www.hhs.gov/ocr/civilrights/index.html). We believe that this lower threshold, combined with the broadband exclusion detailed in the response later in this section, will allow all eligible hospitals and CAHs to meet the measure of this objective.

Comment: Some commenters suggested making the numerator and denominator language for this measure consistent with the language used for this measure for EPs.

Response: We agree that there are some slight variations in language between the measure for EPs and the measure for hospitals. To the extent possible, we have harmonized the language between both.

Comment: Some commenters asked for clarification on how view is defined.

Response: We define view as the patient (or authorized representative) accessing their health information online.

Comment: Some commenters noted that the potential financial burden of implementing an online patient portal to provide patients online access to discharge information. These commenters noted the added time burden for staff in handling the additional patient use of online resources, which may increase costs through the hiring of additional staff, as well as the need to modify their existing workflow to accommodate potential online messages from patients. Some commenters also believed that there would be an additional cost for sharing content before standards exist for content types and formats.

Response: As noted in the proposed rule, studies have found that patients engaged with computer based information sources and decision support show improvement in quality of life indicators, patient satisfaction and health outcomes (see Rosenberg SN, Shnaiden TL, Wegh AA, Juster IA (2008) "Supporting the patient's role in guideline compliance: a controlled study" American Journal of Managed Care 14(11):737-44; Gustafson DH, Hawkins R, Boberg E, Pingree S, Serlin RE, Graziano F, Chan CL (1999) "Impact of a patient-centered, computer-based health information/support system" American Journal of Preventive Medicine 16(1):1-9; Ralston JD, Carrell D, Reid R, Anderson M, Moran M, Hereford J (2007) "Patient web services integrated with a shared medical record: patient use and satisfaction" Journal of the American Medical Informatics Association 14(6):798-806). We believe that the information provided as

part of this measure is integral to the Partnership for Patents initiative and reducing hospital readmissions. We do not believe that implementing online access for patients imposes a significant burden, financial or otherwise, on providers. While we note that in some scenarios it may be possible for an eligible hospital or CAH to receive reimbursement from private insurance payers for online messaging, we acknowledge that eligible hospitals and CAHs are generally not reimbursed for time spent responding to electronic messaging. However, it is also true that eligible hospitals and CAHs are generally not reimbursed for other widely used methods of communication with patients (for example, telephone). In addition, it will be part of the capability of CEHRT to automatically populate most of the list of required elements to meet this measure, which significantly reduces the administrative burden of providing this information. Finally, we believe that the standards established for this objective by ONC will serve as a content standard that will allow this information to be more easily transmitted and uploaded to another certified EHR, thereby reducing the cost of sharing information.

Comment: Some commenters noted that patient engagement could occur effectively with or without online access, and patients should be encouraged to use any method (for example, telephone, internet, traditional mail) that suits them. These commenters noted that engagement offline reduces both the need and value for engagement online.

Response: We agree that patient engagement can occur effectively through a variety of media, and we also believe that electronic access to discharge information can be an important component of patient compliance and improving longitudinal care. We do not believe that offline engagement reduces the need for online access, as patients may opt to access information in a variety of ways. Because of the variety of ways that patients/families may access information, we keep the threshold for this measure low. Measuring other means of accessing

health information is beyond the scope of the EHR Incentive Programs. We also note that online access to health information can enhance offline engagement—for example, patients could download information from a hospital admission to bring with them for a consult on follow-up care—which is one of the primary goals of the EHR Incentive Programs.

Comment: Some commenters expressed concern that vendors would not be able to make these capabilities available as part of CEHRT in time for the beginning of Stage 2.

Response: Many CEHRT vendors already make patient portals available that would meet the certification criteria and standards required for this measure. Although the Stage 2 eligible hospital/CAH measure requires some additional required elements and fields capabilities, we believe vendors will be able to make these capabilities available in time for the beginning of Stage 2.

Comment: Some commenters suggested that basing the exclusion on the broadband data available from the FCC website (www.broadband.gov) was suspect since the data originates from vendors.

Response: The broadband data made available from the FCC was collected from over 3,400 broadband providers nationwide. This data was then subject to many different types of analysis and verification methods, from drive testing wireless broadband service across their highways to meeting with community leaders to receive feedback. Representatives met with broadband providers, large and small, to confirm data, or suggest changes to service areas, and also went into the field looking for infrastructure to validate service offerings in areas where more information was needed. Therefore, we believe the data is appropriate for the exclusion to this measure. We note that since publication of our proposed rule the website has changed to www.broadbandmap.gov and the speed used has changed from 4Mbps to 3Mbps. We are

updating our exclusion to reflect these changes.

Comment: Some commenters believe that broadband exclusions should be based on the patients' locations instead of the providers, since county-level data may not be granular enough to capture all areas of low broadband availability within a particular region.

Response: Although we agree that a broadband exclusion based primarily on the individual locations of each patient seen would be more accurate, we do not believe that there is any method of making this determination for every patient without placing an undue burden on the provider. We continue to believe that limited broadband availability in the eligible hospital's or CAH's immediate practice area, coupled with the low threshold of this measure, adequately serves as an acceptable proxy for determining areas where online access can present a challenge for patients. Therefore, after consideration of the public comments received, we are finalizing the broadband exclusion as proposed.

Comment: Some commenters suggested that the required element of "Problem list maintained by the hospital on the patient" should be made consistent with the required element in the objective of the same name and changed to "Problem list." Other commenters asked for clarification of "Relevant past diagnoses known by the hospital" and how this element differs from "Problem list."

Response: We agree that this language should be made standard. By "Relevant past diagnoses known by the hospital" we mean to indicate historical entries in the patient's problem list. Therefore, we are eliminating the "Relevant past diagnoses" element and modifying the problem list element to "Current and past problem list" in the list of required elements below.

Comment: Some commenters suggested that displaying all historical medications for each patient under the required element of "Medication list maintained by the hospital on the

patient (both current admission and historical)" would be too burdensome for hospitals. These commenters suggested amending the required element to only the active medication list maintained by CEHRT. They also expressed confusion over the use of the term "current admission" since the information for this measure would be posted after the patient's discharge.

Response: We believe that just as providing a historical problem list for the patient can be useful, so too can providing a historical list of all medications. To clarify the intention of this objective, we are modifying the language in the list of required elements below to read "Active medication list and medication history. Current admission referred to the admission and subsequent discharge that places the patient in the denominator for this measure.

Comment: Some commenters suggested that "Laboratory test results (available at discharge)" could result in a large number of test results that could be confusing to patients. They suggested limiting this required element to a subset of lab results of a particular type or lab results from the last 24 hours of admission.

Response: We believe that a list of all laboratory test results can be beneficial to longitudinal care, therefore, we decline to modify this required element either by type of lab result or by any time period beyond those lab test results available at discharge.

Comment: Some commenters suggested that the required element of "Care transition summary and plan for next provider of care (for transitions other than home)" should be made consistent with the required element in the objective of the same name and changed to "Care plan field, including goals and instructions." Some commenters also suggested that care transition plans are more appropriate for providers than patients.

Response: By "care transition summary and plan for next provider of care" we mean for eligible hospitals and CAHs to include both the care plan field(s), including goals and

instructions, and a copy of the summary of care document that hospitals must generate and provide for the core objective of "The eligible hospital or CAH that transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral." While we believe that the summary of care documents are best exchanged directly with the provider to whom the hospital is transitioning care or referring the patient, we also believe that providing an electronic copy with discharge information will ensure that the provider can easily access the information after the transition of referral. We have modified the language in the list of required elements below to reflect this.

After consideration of the public comments received, we are finalizing the first meaningful use measure for eligible hospitals and CAHs at §495.6(l)(8)(ii)(A) as proposed. We are modifying the second meaningful use measure for eligible hospitals and CAHs to be "More than 5 percent of all patients (or their authorized representatives) who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH view, download or transmit to a third party their information during the EHR reporting period" at §495.6(l)(8)(ii)(B), and the exclusion for eligible hospitals and CAHs at §495.6(l)(8)(iii) as "Any eligible hospital or CAH that is located in a county that does not have 50 percent or more of its housing units with 3Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period is excluded from the second measure."

We further specify that in order to meet this objective and measure, an eligible hospital or CAH must use the capabilities and standards of CEHRT at 45 CFR 170.314(e)(1).

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:

- 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.

To calculate the percentage of the second measure for reporting on the 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 (or their authorized representatives) who view, download or transmit health information, CMS and ONC have worked together to define the following for this objective:

- 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 unique patients (or their authorized representatives) in the denominator who have viewed online, downloaded, or transmitted to a third party the discharge information provided by the eligible hospital or CAH.
- Threshold: The resulting percentage must be more than 5 percent in order for an eligible hospital or CAH to meet this measure.
- Exclusion: Any eligible hospital or CAH will be excluded from the second measure if it is located in a county that does not have 50 percent or more of its housing units with 3Mbps broadband availability according to the latest information available from the FCC on the first day

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

As noted in the proposed rule, this is not intended to limit the information made available by the hospital. A hospital can make available additional information and still align with the objective. Please note that while some of the information made available through this measure is similar to the information made available in the summary of care document that must be provided following transitions of care or referrals, the list of information above is specific to the

view online, download, and transmit objective. Patients and providers have different information needs and contexts, so CMS has established separate required fields for each of these objectives.

Proposed Eligible Hospital/CAH Objective: Record whether a patient 65 years old or older has an advance directive.

In our proposed rule, we noted that the HIT Policy Committee recommended making this a core objective and also requiring eligible hospitals and CAHs to either store an electronic copy of the advance directive in the CEHRT or link to an electronic copy of the advance directive. However, we proposed to maintain this objective as part of the menu set for Stage 2, and we did not propose the requirement of an electronic copy or link to the advance directive. As we stated in our Stage 1 final rule (75 FR 44345), we have continuing concerns that there are potential conflicts between storing advance directives and existing state laws. Also, we believe that because of state law restrictions, an advance directive stored in an EHR may not be actionable. Finally, we believe that eligible hospitals and CAHs may have other methods of satisfying the intent of this objective at this time, although we recognize that these workflows may change as EHR technology develops and becomes more widely adopted. Therefore, we did not propose to adopt the HIT Policy Committee's recommendations for this objective.

The HIT Policy Committee has also recommended the inclusion of this objective for EPs in Stage 2. In our Stage 1 final rule (75 FR 44345), we indicated our belief that many EPs will not record this information under current standards of practice and will only require information about a patient's advance directive in rare circumstances. We continue to believe this is the case and that creating a list of specialties or types of EPs that will be excluded from the objective will be too cumbersome and still might not be comprehensive. Therefore, we did not propose the recording of the existence of advance directives as an objective for EPs in Stage 2. However, we

solicited public comment on this decision and encouraged commenters to address specific concerns regarding scope of practice and ease of compliance for EPs. And we note that nothing in this rule compels the use of advance directives.

Comment: While some commenters supported the HIT Policy Committee's recommendations, many recommended that we keep this measure as part of the menu set. We received several comments about a link or copy of the advance directives, and these commenters generally supported our proposal of not including this as part of the objective.

Response: While we appreciate the commenters support and the HITPC's reiteration of their recommendation, neither the HITPC nor other commenters provided new information that would address our concerns regarding conflicting state laws.

Comment: While most commenters agreed that this objective should not be extended to EPs at this time, a select few suggested adding it as part of the menu set.

Response: We are not extending this objective to EPs. Our belief that many EPs would not record this information under current standards of practice was supported by commenters. Also, we continue to believe that creating a list of specialties or types of EPs that would be excluded from the objective would be too cumbersome and would not be comprehensive.

After consideration of public comments, we are finalizing this objective for eligible hospitals and CAHs at §495.6(m)(1)(i) as proposed.

Proposed Eligible Hospital/CAH Measure: More than 50 percent of all unique patients 65 years old or older admitted to the eligible hospital's or CAH's inpatient department (POS 21) during the EHR reporting period have an indication of an advance directive status recorded as structured data.

In the proposed rule, we explained that the calculation of the denominator for the

measure of this objective is limited to unique patients age 65 or older who are admitted to an eligible hospital's or CAH's inpatient department (POS 21). Patients admitted to an emergency department (POS 23) should not be included in the calculation. As we discussed in our Stage 1 final rule (75 FR 44345), we believe that this information is a level of detail that is not practical to collect on every patient admitted to the eligible hospital's or CAH's emergency department, and therefore, have limited this measure only to the inpatient department of the hospital.

Comment: A commenter indicated that nearly 70 percent of hospitals could meet this measure in Fall 2011.

Response: Data collected from Stage 1 attestations shows that less than 15 percent of hospitals deferred this measure.

After consideration of public comments, we are finalizing this measure for eligible hospitals and CAHs at §495.6(m)(1)(ii) as proposed. We are maintaining the exclusion for any eligible hospital or CAH that admits no patients age 65 years old or older during the EHR reporting period.

We further specify that in order to meet this objective and measure, an EP must use the capabilities and standards of CEHRT at 45 CFR 170.314(a)(17).

- Denominator: Number of unique patients age 65 or older admitted to an eligible hospital's or CAH's inpatient department (POS 21) during the EHR reporting period.

- Numerator: The number of patients in the denominator who have an indication of an advance directive status entered using structured data.

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

- Exclusion: Any eligible hospital or CAH that admits no patients age 65 years old or

older during the EHR reporting period.

(f) HIT Policy Committee Recommended Objectives Discussed in the Proposed Rule without Proposed Regulation Text

We did not propose these objectives for Stage 2 as explained at each objective, but we solicited comments on whether these objectives should be incorporated into Stage 2.

Hospital Objective: Provide structured electronic lab results to eligible professionals.

Although the HITPC recommended this as a core objective for Stage 2 for hospitals, we did not propose this objective for the following reasons as explained in the proposed rule. Although hospital labs supply nearly half of all lab results, they are not the predominant vendors for providers who do not share or cannot access their technology. Independent and office laboratories provide over half of the labs in this market. We stated that we were concerned that imposing this requirement on hospital labs would unfairly disadvantage them in this market. Furthermore, not all hospitals offer these services so it would create a natural disparity in meaningful use between those hospitals offering these services and those that do not. Finally, all other aspects of meaningful use in Stage 1 and Stage 2 focus on the inpatient and emergency departments of a hospital. This objective is not related to these departments, and in fact excludes services provided in these departments. We asked for comments on both the pros and cons of this objective and whether it should be considered for this final rule as recommended by the HITPC.

Comment: Nearly all of the commenters that supported the inclusion of this objective based their support wholly or in part on the concept that the benefits of hospitals providing structured electronic lab results outweigh the costs of doing so. They point to specific benefits, such as making it more likely that EPs will be able to meet the meaningful use measure of

incorporating clinical lab-test results into CEHRT as structured data, as well as more general benefits of structured electronic results.

Response: The large number of commenters in support of this objective and the associated benefits they identified make a compelling case for inclusion. In particular, inclusion of this objective will enable EPs to incorporate laboratory test results into the CEHRT as structured data, which in turn adds to the ability of CEHRT to provide CDS and to calculate clinical quality measures. In addition, this objective will improve consistency in the market by incentivizing the use of the uniform standard for laboratory exchange transactions included in CEHRT as established in ONC's certification criteria at (ONC reference once available). However, the benefits identified are somewhat tempered by the makeup of the commenters supporting the inclusion of this objective, who are usually those who stand to benefit (EPs, patient advocates and others), whereas those who did not support inclusion are usually those who would bear the burden (hospitals and vendors). We summarize and respond to the comments in opposition later. However, due to the strong disagreements among commenters about the inclusion of this objective, and also concern for market impact discussed in the comments later, we will include it in the menu set of Stage 2 and not in the core set as recommended by the HITPC and supported by some of the commenters.

Comment: Several commenters questioned the applicability of this objective to meaningful use. Most stated that it was not applicable for several reasons. First, commenters asserted it is beyond the statutory authority of the Medicare EHR Incentive Program, which is established in sections of the statute that govern payment for hospital inpatient services, whereas laboratory services are paid under a different payment system. Second, as meaningful use is currently constrained to the inpatient and emergency departments, it would be inconsistent to

expand it to include lab results for patients that are not admitted to either the inpatient or emergency department of the hospital. Third, systems used by hospitals to process and send laboratory results are not traditionally considered part of CEHRT, and including those systems in CEHRT could have many unintended consequences and costs.

Response: We believe the statute supports a definition of meaningful use that is not limited to actions taken within the inpatient department of a hospital. The meaningful use incentive payments and payment adjustments for Medicare eligible hospitals are established in sections of the Act that are under the hospital inpatient prospective payment system (IPPS) (sections 1886(n) and 1886(b)(3)(B)(ix) of the Act, respectively). However, the statutory definition of a "meaningful EHR user" under section 1886(n)(3) of the Act does not constrain the use of CEHRT to the inpatient department of the hospital. The definition requires in part that an eligible hospital must use CEHRT "for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination" (section 1886(n)(3)(A)(ii)), which the objective of providing structured electronic lab results to ambulatory providers would support. Moreover, the majority of hospital objectives for Stages 1 and 2 of meaningful use take into account actions performed in the emergency department as well as the inpatient department. In the Stage 1 final rule, we indicated that we may consider applying the Stage 2 criteria more broadly to all hospital outpatient settings beyond the emergency department (75 FR 44322). One of the primary reasons not to include outpatient settings in meaningful use for hospitals is the potential for overlap with settings where EPs typically would use CEHRT. We believe there is minimal risk of such overlap with this objective, as it involves a function that is controlled by the hospital, and for which EPs are a recipient and not a provider of information. In regards to the third reason identified by commenters, CEHRT and meaningful use already include the ability to

report electronic lab results to public health agencies, so consequences and costs of such inclusion should have already occurred. The impact of including these systems in certification is addressed in the ONC regulation published elsewhere in this issue of the **Federal Register**.

Comment: A few commenters supported this objective because they believe that hospital labs have lagged behind independent labs in providing electronic results.

Response: We agree that hospital lab reporting should be included as a menu set objective, but without actual data demonstrating lags by hospitals in laboratory exchange with ambulatory providers, we do not find this to be a compelling reason to include the objective as part of the core set.

Comment: Commenters believed this objective is inappropriate because the meaningful use regulations do not apply to commercial clinical laboratories, leading to an adverse market impact for hospitals in competition with others that process laboratory results for physician offices. The operational impacts of this objective are significant. In the absence of functional health information exchanges, hospitals would need to create and maintain separate, system-to-system interfaces with each physician office that receives laboratory results electronically, at considerable cost and effort. The transition to using standardized code sets in laboratories that must continue to function is challenging and burdensome, particularly for small hospitals.

Response: For these reasons, we include this objective and measure in the menu set. Those hospitals that see competitive benefits in providing electronic lab results to ambulatory providers may wish to select this as a menu set objective. Those who believe that building out the capability to provide electronic lab results is not beneficial in their competitive market environments can defer the objective. Similarly, those hospitals that consider the burden too

high can defer this objective.

After consideration of public comments, we are including this objective in the menu set for eligible hospitals and CAHs at §495.6(m)(6)(i) as "Provide structured electronic lab results to ambulatory providers."

For each objective, we outline the benefits expected from that objective. We did not include these benefits in our proposed rule and we are adding them to this final rule. Hospitals sending structured lab results electronically to EPs using CEHRT and in accordance with designated standards will directly enhance the ability of EPs to meet meaningful use objectives, including incorporating laboratory test results into the EHR as structured data, generating lists of patients with particular conditions, utilizing clinical decision support, and enhancing the ability to calculate clinical quality measures. The addition of this objective will help improve consistency in the market, in contrast to today's environment in which inconsistencies in interface requirements are hindering the delivery of structured hospital lab results to ambulatory EHRs. This objective will also benefit hospitals by creating a uniform standard for laboratory exchange transactions, which will eliminate variation, reducing interface costs and time to deploy.

Hospital Measure: Hospital labs send (directly or indirectly) structured electronic clinical lab results to the ordering provider for more than 40 percent of electronic lab orders received.

The measure for this objective recommended by the HIT Policy Committee is that 40 percent of clinical lab test results electronically sent by an eligible hospital or CAH will need to be done so using the capabilities CEHRT. This measure requires that in situations where the electronic connectivity between an eligible hospital or CAH and an EP is established, the results

electronically exchanged are done so using CEHRT. To facilitate the ease with which this electronic exchange may take place, ONC proposed that for certification, ambulatory EHR technology will need to be able to incorporate lab test results formatted in the same standard and implementation specifications to which inpatient EHR technology will need to be certified as being able to create.

Comment: Some commenters who support this objective raised concerns that small hospitals might not be able to comply due to the burden involved and suggest an unspecified exclusion for them.

Response: By including this objective as a menu set item, those hospitals that view lab reporting to ambulatory practices as too burdensome can defer this measure.

Comment: Some commenters supporting the measure indicated that they would like to see hospital reference labs that are already providing electronic lab results to ordering providers "grandfathered" into the measure.

Response: There are two reasons that a hospital providing electronic lab results already would need special consideration. First, they are not using the standards of CEHRT where available. Second, they may not have gotten the system they use certified. As it is meaningful use of CEHRT we do not believe that we should include exceptions to the use of CEHRT in meaningful use. We do not believe that providers must "rip and replace" existing systems. Existing systems that support the standards of CEHRT can be certified for inclusion and those that do not support the standards can defer the objective until they upgrade to the standards of CEHRT.

Comment: Commenters expressed concern that if the objective is included in meaningful use that the threshold is unattainable. They noted that for a hospital to send electronic lab results

the EP must be able to receive electronic results and that current adoption rates do not indicate that 40 percent of EPs will be able to receive electronic lab results.

Response: The measure uses a denominator of electronic lab orders received so this consideration is already built into the measure. However, we do agree with commenters that 40 percent is a high threshold for this completely new measure as it is dependent on electronic health exchange. For the final measure we reduce the threshold to 20 percent. While we considered lowering the threshold to 10 percent, the denominator limitation that the lab order must be received electronically already limits the measure to those ordering providers capable of submitting electronic orders and implies at least some electronic health information exchange has been established between the hospital and the ordering provider.

After considering the comments, we are finalizing this measure for eligible hospitals and CAHs at §495.6(m)(6)(ii) as "Hospital labs send structured electronic clinical lab results to the ordering provider for more than 20 percent of electronic lab orders received."

In order to be counted in the numerator, the hospital would need to use CEHRT to send laboratory results to the ambulatory provider in a way that has the potential for electronic incorporation of those results as structure data. Methods that have no potential for automatic incorporation such as "portal view" do not count in the numerator. 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 CEHRT at 45 CFR 170.314(b)(6).

- Denominator: The number of electronic lab orders received
- Numerator: The number of structured clinical lab results sent to the ordering provider.
- Threshold: The resulting percentage must be greater than 20 percent.

EP Objective/Measure: Record patient preferences for communication medium for

more than 20 percent of all unique patients seen during the EHR reporting period.

We proposed that this requirement is better incorporated with other objectives that require patient communication and is not necessary as a standalone objective.

Commenters were supportive of the incorporation of this objective and we continue to believe that it is better incorporated; therefore, we are finalizing this provision as proposed.

Objective/Measure: Record care plan goals and patient instructions in the care plan for more than 10 percent of patients seen during the reporting period.

We proposed that this requirement is better incorporated with other objectives that require summary of care documents and is not necessary as a standalone objective.

Commenters were supportive of the incorporation of this objective as proposed and we continue to believe that it is better incorporated; therefore, we are finalizing this provision as proposed.

Objective/Measure: Record health care team members (including at a minimum PCP, if available) for more than 10 percent of all patients seen during the reporting period; this information can be unstructured.

We proposed that this requirement is better incorporated with other objectives that require summary of care documents and is not necessary as a standalone objective.

Commenters were supportive of the incorporation of this objective as proposed and we continue to believe that it is better incorporated; therefore, we are finalizing as proposed.

Objective/Measure: Record electronic notes in patient records for more than 30 percent of office visits.

In the proposed rule, we encouraged public comment regarding the inclusion of this objective/measure. We noted that narrative entries are considered an important component of

patient records and complement the structured data captured in CEHRT. We also noted our understanding that electronic notes are already widely used by providers and therefore may not need to include this as a meaningful use objective.

Comment: Commenters agreed that existing technology has the capability to capture notes in an electronic form for inclusion in the patient record. Other commenters mentioned that not all CEHRT in use currently include the capability to incorporate narrative clinical documentation.

Response: We reiterate the statement in the proposed rule regarding the important contribution of narrative clinical documentation in the patient record. In light of the comments that not all CEHRT currently has the capability to incorporate this clinical documentation, we agree to incorporate this functionality to record electronic notes as an additional menu objective for Stage 2 of meaningful use. The ONC standards and certification criteria final rule associated with this objective/measure is published elsewhere in this issue of the **Federal Register.** We believe that inclusion of electronic patient notes to the meaningful use menu objectives is another incremental step towards maximizing the potential of EHR technology.

Comment: The HIT Policy Committee commented that this objective/measure should apply to both EPs, eligible hospitals and CAHs because some certified EHRs do not have clinical documentation and because they believe that a complete record (including progress notes) is required to deliver high quality, efficient care.

Response: We agree and are adopting this objective in the menu set for Stage 2 for EPs, eligible hospitals and CAHs in order to allow providers access to the most accurate and complete patient information available electronically to support quality of care efforts across patient care settings.

Comment: A commenter suggested that if this objective/measure becomes part of the final rule it will require a clear definition of how notes are defined and who may create, edit and sign them in order to be included in the measure numerator. Other commenters requested clarification of the term electronic note and whether it would include nursing notes, flow sheets, operative reports, discharge summaries, consults, etc. in addition to basic progress notes.

Response: For this objective, we have determined that any EP as defined for the Medicare or Medicaid EHR Incentive Programs, or an authorized provider of the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) may author, edit, and provide an electronic signature for the electronic notes in order for them to be considered for this measure. We further define electronic notes as electronic progress notes for the purpose of this measure. We will rely on providers own determinations and guidelines defining when progress notes are necessary to communicate individual patient circumstances and for coordination with previous documentation of patient observations, treatments and/or results in the electronic health record.

Comment: Many commenters agreed with the inclusion of the text searchable certification requirement and agreed that portions of clinical notes are already being collected electronically. The HIT Policy Committee recommended inclusion of this measure because some certified EHRs do not have clinical documentation, and believe that the benefit of a complete patient record, including progress notes, is required to deliver high quality, efficient care. Several commenters were opposed to the inclusion of this additional measure in order to limit the number of reporting objectives.

Response: Based on the multiple reasons stated in this preamble we agree with the benefits of including the electronic progress notes measure in the menu set for the Stage 2

meaningful use objectives. We envision continued technological advances in the capture and processing of text and diagrammatic data such as research of natural language processing. We also believe there is added value in collecting both narrative data and structured data in the EHR and using that information to track key clinical conditions and communicating that information for care coordination purposes. Therefore, we are including this objective/measure to record electronic notes in the patient records for more than 30 percent of office visits or unique patients admitted to an eligible hospital's or CAH's inpatient or emergency department (POS21 or 23) as was originally recommended by the HITPC.

After consideration of public comments, we are finalizing this objective for EPs at §495.6 (k)(6)(i) and for eligible hospitals and CAHs at §495.6(m)(5)(i) as "Record electronic notes in patient records."

We are adding the measure for EPs at §495.6(k)(6)(ii) and for eligible hospitals and CAHs at §495.6(m)(5)(ii) of our regulations to include this new measure:

EP Menu Measure: Enter at least one electronic progress note created, edited and signed by an EP for more than 30 percent of unique patients with at least one office visit during the EHR reporting period. Electronic progress notes must be text-searchable. Non-searchable notes do not qualify, but this does not mean that all of the content has to be character text. Drawings and other content can be included with searchable text notes under this measure.

Eligible Hospital/CAH Menu Measure: Enter at least one electronic progress note created, edited and signed by an authorized provider of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) for more than 30 percent of unique patients admitted to the eligible hospital or CAH's inpatient or emergency department during the EHR reporting period. Electronic progress notes must be text-searchable. Non-searchable notes do not qualify,

but this does not mean that all of the content has to be character text. Drawings and other content can be included with searchable text notes under this measure.

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 CEHRT at 45 CFR 170.314(a)(9).

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

- Denominator: Number of unique patients with at least one office visit during the EHR reporting period for EPs or admitted to an eligible hospital or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period.
- Numerator: The number of unique patients in the denominator who have at least one electronic progress note from an eligible professional or authorized provider of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) recorded as text-searchable data.
- Threshold: The resulting percentage must be more than 30 percent in order for an EP, eligible hospital or CAH to meet this measure.

TABLE B5: STAGE 2 OBJECTIVES AND MEASURES

Health Outcomes Policy Priority	Stage 2 Objectives		Stage 2 Measures
	Eligible Professionals	Eligible Hospitals and CAHs	
CORE SET			
Improving quality, safety, efficiency, and reducing health disparities	Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines	Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines	More than 60 percent of medication, 30 percent of laboratory, and 30 percent 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.
	Generate and transmit permissible prescriptions electronically (eRx)		More than 50 percent of all permissible prescriptions, or all prescriptions written by the EP and queried for a drug formulary and transmitted electronically using CEHRT.
	Record the following demographics • Preferred language • Sex • Race • Ethnicity • Date of birth	Record the following demographics • Preferred language • Sex • Race • Ethnicity • Date of birth • Date and preliminary cause of death in the event of mortality in the eligible hospital or CAH	More than 80 percent of all unique patients 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 demographics recorded as structured data.

Health Outcomes Policy Priority	Stage 2 Objectives		Stage 2 Measures
	Eligible Professionals	Eligible Hospitals and CAHs	
	Record and chart changes in vital signs: • Height/length • Weight • Blood pressure (age 3 and over) • Calculate and display BMI • Plot and display growth charts for patients 0-20 years, including BMI	Record and chart changes in vital signs: • Height/length • Weight • Blood pressure (age 3 and over) • Calculate and display BMI • Plot and display growth charts for patients 0-20 years, including BMI	More than 80 percent of all unique patients 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 blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data
	Record smoking status for patients 13 years old or older	Record smoking status for patients 13 years old or older	More than 80 percent of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) during the EHR reporting period have smoking status recorded as structured data
	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. It is suggested that one of the five clinical decision support interventions be related to improving healthcare efficiency. 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.
	Incorporate clinical lab-test results into Certified EHR Technology as structured data.	Incorporate clinical lab-test results into Certified EHR Technology as structured data	More than 55 percent of all clinical lab tests results ordered by the EP or by authorized providers of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period whose results are either in a positive/negative affirmation or numerical format are incorporated in Certified EHR Technology as structured data.

Health Outcomes Policy Priority	Stage 2 Objectives		Stage 2 Measures
	Eligible Professionals	**Eligible Hospitals and CAHs**	
	Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach	Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach.	Generate at least one report listing patients of the EP, eligible hospital or CAH with a specific condition.
	Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care and send these patients the reminder, per patient preference.		More than 10 percent of all unique patients who have had two or more office visits with the EP within the 24 months before the beginning of the EHR reporting period were sent a reminder, per patient preference when available.
		Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR).	More than 10 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 for which all doses are tracked using eMAR.
Engage patients and families in their health care	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 (within 4 business days after the information is available to the EP) online access to their health information subject to the EP's discretion to withhold certain information. 2. More than 5 percent of all unique patients seen by the EP during the EHR reporting period (or their authorized representatives) view, download, or transmit to a third party their health information.
		Provide patients the ability to view online, download, and transmit information about a hospital admission.	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 2. More than 5 percent of all patients (or their authorized representatives) who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH view, download or transmit to a third party their information during the reporting period.

Health Outcomes Policy Priority	Stage 2 Objectives		Stage 2 Measures
	Eligible Professionals	**Eligible Hospitals and CAHs**	
	Provide clinical summaries for patients for each office visit.		Clinical summaries provided to patients or patient-authorized representatives within 1 business day for more than 50 percent of office visits.
	Use Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient	Use Certified EHR Technology 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 percent of all unique patients with office visits seen by the EP during the EHR reporting period. More than 10 percent 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 Certified EHR Technology.
	Use secure electronic messaging to communicate with patients on relevant health information		A secure message was sent using the electronic messaging function of Certified EHR Technology by more than 5 percent of unique patients (or their authorized representatives) seen by the EP during the EHR reporting period.
Improve care coordination	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 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).

Health Outcomes Policy Priority	Stage 2 Objectives		Stage 2 Measures
	Eligible Professionals	Eligible Hospitals and CAHs	
	The EP who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care provides a summary care record for each transition of care or referral.	The eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care provides a summary care record for each transition of care or referral.	1. The EP, eligible hospital, or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50 percent of transitions of care and referrals. 2. The EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 10% of such transitions and referrals either-- (a) electronically transmitted using CEHRT to a recipient or (b) where the recipient receives the summary of care record via exchange facilitated by an organization that is a NwHIN Exchange participant or in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network. 3. An EP, eligible hospital or CAH must satisfy one of the two following criteria: (A) Conducts one or more successful electronic exchanges of a summary of care document, as part ofwhich is counted in "measure 2" (for EPs the measure at §495.6(j)(14)(ii)(B) and for eligible hospitals and CAHs the measure at §495.6(l)(11)(ii)(B)) with a recipient who has EHR technology that was developed designed by a different EHR technology developer than the sender's EHR technology certified to 45 CFR 170.314(b)(2); or (B) Conducts one or more successful tests with the CMS designated test EHR during the EHR reporting period.
Improve population and public health	Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice	Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice	Successful ongoing submission of electronic immunization data from Certified EHR Technology to an immunization registry or immunization information system for the entire EHR reporting period.

Health Outcomes Policy Priority	Stage 2 Objectives		Stage 2 Measures
	Eligible Professionals	Eligible Hospitals and CAHs	
		Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice	Successful ongoing submission of electronic reportable laboratory results from Certified EHR Technology to public health agencies for the entire EHR reporting period.
		Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice	Successful ongoing submission of electronic syndromic surveillance data from Certified EHR Technology to a public health agency for the entire EHR reporting period.
Ensure adequate privacy and security protections for personal health information	Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities	Protect electronic health information created or maintained by the Certified EHR Technology 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 encryption/security 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.
MENU SET			
Improving quality, safety, efficiency, and reducing health disparities		Record whether a patient 65 years old or older has an advance directive	More than 50 percent of all unique patients 65 years old or older admitted to the eligible hospital's or CAH's inpatient department (POS 21) during the EHR reporting period have an indication of an advance directive status recorded as structured data.
	Imaging results consisting of the image itself and any explanation or other accompanying information are accessible through Certified EHR Technology.	Imaging results consisting of the image itself and any explanation or other accompanying information are accessible through Certified EHR Technology.	More than 10 percent of all tests whose result is one or more images ordered by the EP or by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 and 23) during the EHR reporting period are accessible through Certified EHR Technology.
	Record patient family health history as structured data	Record patient family health history as structured data	More than 20 percent of all unique patients seen by the EP or admitted to the eligible hospital or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have a structured data entry for one or more first-degree relatives.

Health Outcomes Policy Priority	Stage 2 Objectives		Stage 2 Measures
	Eligible Professionals	Eligible Hospitals and CAHs	
		Generate and transmit permissible discharge prescriptions electronically (eRx)	More than 10 percent of hospital discharge medication orders for permissible prescriptions (for new, changed, and refilled prescriptions) are queried for a drug formulary and transmitted electronically using Certified EHR Technology.
	Record electronic notes in patient records	Record electronic notes in patient records	Enter at least one electronic progress note created, edited and signed by an eligible professional for more than 30 percent of unique patients with at least one office visit during the EHR reporting period. Enter at least one electronic progress note created, edited and signed by an authorized provider of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) for more than 30 percent of unique patients admitted to the eligible hospital or CAH's inpatient or emergency department during the EHR reporting period. Electronic progress notes must be text-searchable. Non-searchable notes do not qualify, but this does not mean that all of the content has to be character text. Drawings and other content can be included with searchable text notes under this measure.
		Provide structured electronic lab results to ambulatory providers	Hospital labs send structured electronic clinical lab results to the ordering provider for more than 20 percent of electronic lab orders received
Improve Population and Public Health	Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice		Successful ongoing submission of electronic syndromic surveillance data from Certified EHR Technology to a public health agency for the entire EHR reporting period
	Capability to identify and report cancer cases to a public health central cancer registry, except where prohibited, and in accordance with applicable law and practice.		Successful ongoing submission of cancer case information from CEHRT to a public health central cancer registry for the entire EHR reporting period

Health Outcomes Policy Priority	Stage 2 Objectives		Stage 2 Measures
	Eligible Professionals	**Eligible Hospitals and CAHs**	
	Capability to identify and report specific cases to a specialized registry (other than a cancer registry), except where prohibited, and in accordance with applicable law and practice.		Successful ongoing submission of specific case information from Certified EHR Technology to a specialized registry for the entire EHR reporting period.

B. Reporting on Clinical Quality Measures Using Certified EHR Technology by Eligible Professionals, Eligible Hospitals, and Critical Access Hospitals

The following sections address CQMs reporting requirements using CEHRT. These include: EHR technology certification requirements; criteria for CQM selection; time periods for reporting CQMs; issues related to specifications for CQMs and transmission formats; reporting options and CQMs for EPs; reporting methods for EPs; reporting options and CQMs for eligible hospitals and CAHs; and reporting methods for eligible hospitals and CAHs.

1. Time Periods for Reporting CQMs

This section addresses the reporting periods and submission periods as they relate to reporting CQMs only. For a summary of the reporting and submission periods proposed for CQMs, please refer to Table 5 in the Stage 2 proposed rule (77 FR 13742).

We proposed that the reporting period for CQMs, which is the period during which data collection or measurement for CQMs occurs, would continue to track with the EHR reporting periods for the meaningful use objectives and measures:

- EPs: January 1 through December 31 (calendar year).
- Eligible Hospitals and CAHs: October 1 through September 30 (federal fiscal year).
- EPs, eligible hospitals, and CAHs in their first year of meaningful use for Stage 1, any continuous 90-day period within the calendar year (CY) or federal fiscal year (FY), respectively.

To avoid a payment adjustment, Medicare EPs and eligible hospitals that are in their first year of demonstrating meaningful use in the year immediately preceding any payment adjustment year would have to ensure that their 90-day EHR reporting period ends at least 3 months before the end of the CY or FY, and that all submission is completed by October 1 or July 1, respectively. For more information on payment adjustments, see section II.D. of this final

rule.

The submission period is the time during which EPs, eligible hospitals, and CAHs may submit CQM information. We proposed the submission period for CQM data generally would be the 2 months immediately following the end of the EHR reporting period as follows:

- EPs: January 1 through February 28.
- Eligible Hospitals and CAHs: October 1 through November 30.
- EPs, eligible hospitals, and CAHs in their first year of Stage 1: Anytime after the end of their 90-day EHR reporting period until the end of the 2 months immediately following the end of the CY or FY, respectively. However, for purposes of avoiding the payment adjustments, Medicare EPs and eligible hospitals that are in their first year of demonstrating meaningful use in the year immediately preceding a payment adjustment year must submit their CQM data no later than October 1 (EPs) or July 1 (eligible hospitals) of such preceding year.

Comment: Several commenters stated that the first year of a new stage for reporting CQMs should only require a 90-day or 180-day reporting period instead of a 365-day reporting period.

Response: We agree that vendors, EPs, eligible hospitals, and CAHs may need more time to develop, test, and implement EHR technology certified to the 2014 Edition EHR certification criteria and to be able to meet the CQM reporting requirements that we proposed beginning in 2014. Therefore, for the reasons discussed in this section, we are modifying the reporting periods for CQMs in 2014 to match the EHR reporting periods that we are finalizing for 2014. By using 3-month quarters as the reporting periods in 2014 for providers that are beyond their first year of demonstrating meaningful use instead of requiring a full year as proposed, we allow vendors and health care providers as much as 9 months more time to

program, develop, and implement CEHRT, and meet the requirements for meaningful use in 2014. We note that the 3-month quarter reporting period is only applicable for 2014. For 2015 and subsequent years, we are finalizing our proposal of a full year reporting period for EPs, eligible hospitals and CAHs that are beyond their first year of demonstrating meaningful use. We have selected 3-month quarters rather than any continuous 90-day period to promote more ready comparisons of data. This is particularly important for eligible hospitals and CAHs since many of the CQMs that we are finalizing for 2014 and subsequent years are also used in the CMS Hospital IQR Program. We have indicated our desire to transition the CMS Hospital IQR Program to collecting EHR-based quality data. Having data from hospitals for comparable quarter timeframes as used for the CMS Hospital IQR Program will be beneficial for comparing chart abstracted data with data derived from CEHRT and will facilitate data collection mode for potential future usage for Hospital Compare public reporting and the CMS Hospital Value Based Purchasing programs.

After consideration of the public comments received, we are finalizing the reporting and submission periods as follows. The reporting period for CQMs generally will be the same as an EP's, eligible hospital's, or CAH's respective EHR reporting period for the meaningful use objectives and measures, with the exceptions discussed later in this section. Please note that Medicare EPs who choose to report CQMs through the options we are finalizing that rely on other CMS programs (namely, Option 2 – PQRS (see section II.B.6.c. of this final rule) and the group reporting options – Physician Quality Reporting System (PQRS) and Accountable Care Organizations (ACOs) (see section II.B.6.d. of this final rule) would be subject to the reporting periods for CQMs established for those programs. As an example using CY 2014, for Medicare EPs who choose to submit CQMs under Option 2 (PQRS EHR Reporting Option) for purposes

of satisfying the CQM reporting component of meaningful use, the reporting periods for the PQRS EHR reporting that fall within CY 2014 would apply. Medicaid EPs and eligible hospitals must submit CQM data for a reporting period that is the same as their EHR reporting period using the reporting methods and submission periods specified by their state Medicaid agency.

In 2013, the reporting period for CQMs will continue to be an EP's, eligible hospital's or CAH's respective EHR reporting period. The submission period will be the 2 months immediately following the end of the CY or FY, respectively (EPs: January 1 through February 28, 2014; eligible hospitals and CAHs: October 1 through November 30, 2013). EPs, eligible hospitals and CAHs in their first year of meaningful use may submit CQM data anytime after the end of their 90-day EHR reporting period until the end of the 2 months immediately following the end of the CY or FY, respectively.

Beginning in 2014 and in subsequent years, for EPs, eligible hospitals and CAHs that are in their first year of meaningful use, the reporting period for CQMs will be their respective 90-day EHR reporting period, and they must submit CQM data by attestation. The submission period will be anytime after the end of their respective 90-day EHR reporting period until the end of the 2 months immediately following the end of the CY or FY, respectively. However, for purposes of avoiding a payment adjustment, Medicare EPs and eligible hospitals that are in their first year of demonstrating meaningful use in the year immediately preceding a payment adjustment year must submit their CQM data no later than October 1 (EPs) or July 1 (eligible hospitals) of such preceding year. We note that these deadlines do not apply to CAHs. For more details on submission deadlines specific to CAHs, please refer to section II.D.4. of this final rule.

Beginning in 2014 and in subsequent years, EPs, eligible hospitals and CAHs that are beyond their first year of meaningful use must electronically submit CQM data unless the

Secretary lacks the capacity to accept electronic submission. In the unlikely event that the Secretary does not have the capacity to accept electronic submission, then consistent with sections 1848(o)(2)(B)(ii) and 1886(n)(3)(B)(ii) of the Act, we would continue to accept attestation as a method of reporting CQMs. We would inform the public of this fact by publishing a notice in the **Federal Register** and providing instructions on how CQM data should be submitted to us. For additional details on the reporting methods for EPs, please refer to sections II.B.6.c. and II.B.6.d. of this final rule, and for the reporting methods for eligible hospitals and CAHs, please refer to section II.B.8.b. of this final rule. The reporting periods for CQMs in 2014 for EPs, eligible hospitals, and CAHs that are beyond their first year of meaningful use are as follows:

- EPs, eligible hospitals and CAHs may report CQM data for the full CY or FY 2014, respectively, if desired. Alternatively, they may report CQM data for the 3-month quarter(s) that is/are their respective EHR reporting period.

++ For EPs, the 3-month quarters are as follows:

-- January 1, 2014 through March 31, 2014

-- April 1, 2014 through June 30, 2014

-- July 1, 2014 through September 30, 2014

-- October 1, 2014 through December 31, 2014

++ For eligible hospitals and CAHs, the 3-month quarters are as follows:

-- October 1, 2013 through December 31, 2013

-- January 1, 2014 through March 31, 2014

-- April 1, 2014 through June 30, 2014

-- July 1, 2014 through September 30, 2014

In all cases of electronic submission, the submission period will be the 2 months immediately following the end of the CY or FY, respectively. This submission period will apply regardless of whether an EP, eligible hospital or CAH reports CQM data for the full CY or FY, respectively, or only for a 3-month quarter:

- EPs: January 1, 2015 through February 28, 2015.
- Eligible Hospitals and CAHs: October 1, 2014 through November 30, 2014.

The reporting periods for CQMs in 2015 and in subsequent years for EPs, eligible hospitals, and CAHs that are beyond their first year of meaningful use will be the full CY or FY, respectively. For EPs, we expect to accept a single annual submission. For eligible hospitals and CAHs, we expect to align with the submission frequency of the Hospital IQR program for electronic reporting of CQMs.

We summarize the reporting and submission periods beginning with CY/FY 2014 for EPs, eligible hospitals, and CAHs reporting CQMs via attestation in Table 5 and reporting CQMs electronically in Table 6.

TABLE 5: REPORTING AND SUBMISSION PERIODS FOR EPs, ELIGIBLE HOSPITALS AND CAHs IN THEIR FIRST YEAR OF MEANINGFUL USE SUBMITTING CQMs VIA ATTESTATION BEGINNING WITH CY/FY 2014

Provider Type	Reporting Period for First Year of Meaningful Use (Stage 1)	Submission Period for First Year of Meaningful Use (Stage 1)*
EP	90 consecutive days	Anytime immediately following the end of the 90-day reporting period, but no later than February 28 of the following calendar year.
Eligible Hospital/CAH	90 consecutive days	Anytime immediately following the end of the 90-day reporting period, but no later than November 30 of the following fiscal year.

*For purposes of avoiding a payment adjustment, Medicare EPs and eligible hospitals that are in their first year of demonstrating meaningful use in the year immediately preceding a payment adjustment year must submit their CQM data no later than October 1 (EPs) or July 1 (eligible hospitals) of such preceding year.

TABLE 6: REPORTING AND SUBMISSION PERIODS FOR EPs, ELIGIBLE HOSPITALS AND CAHs BEYOND THEIR FIRST YEAR OF MEANINGFUL USE SUBMITTING CQMs ELECTRONICALLY BEGINNING WITH CY/FY 2014

Provider Type	**Optional Reporting Period in 2014***	**Reporting Period for Subsequent Years of Meaningful Use (Stage 1 and Subsequent Stages)**	**Submission Period for Subsequent Years of Meaningful Use (Stage 1 and Subsequent Stages)***
EP	Calendar year quarter: January 1 – March 31 April 1 – June 30 July 1 – September 30 October 1 – December 31	1 calendar year (January 1 - December 31)	2 months following the end of the reporting period (January 1 - February 28)
Eligible Hospital/CAH	Fiscal year quarter: October 1 – December 31 January 1 – March 31 April 1 – June 30 July 1 – September 30	1 fiscal year (October 1 - September 30)	2 months following the end of the reporting period (October 1 - November 30)

*NOTE: The optional quarter reporting periods have the same submission period as a full year reporting period for electronic submission.

2. EHR Technology Certification Requirements for Reporting of CQMs

ONC adopts certification criteria for EHR technology and proposed a 2014 Edition of certification criteria in a proposed rule (77 FR 13832). As such, we proposed to require that CEHRT, as defined by ONC, must be used by EPs, eligible hospitals, and CAHs to satisfy their CQM reporting requirements (77 FR 13743). We proposed that CQM reporting methods could include the following:

- Aggregate reporting methods (EPs, eligible hospitals, and CAHs):

++ Attestation

++ Electronic submission

- Patient-level reporting methods:

++ The PQRS EHR reporting option, the group reporting options for PQRS, the Medicare SSP or Pioneer ACOs (note: these are reporting methods for EPs)

++ The manner similar to the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs.

For the attestation and aggregate electronic reporting methods, we proposed that EPs, eligible hospitals, and CAHs must only submit CQMs that their EHR technology had been certified to "incorporate and calculate" (45 CFR 170.314(c)(2) in ONC's rule). For example, if an EP's CEHRT was certified to calculate CQMs #1 through #9, and the EP submitted CQMs #1 through #8 and #25, the EP would not have met the meaningful use requirement for reporting CQMs because his/her CEHRT was not certified to calculate CQM #25. For the attestation and aggregate electronic reporting methods, we proposed that CEHRT must be certified to the "reporting" certification criterion proposed for adoption by ONC at 45 CFR 170.314(c)(3) and which focused on EHR technology's capability to create and transmit a standard aggregate XML-based file that CMS can electronically accept.

Comment: Most commenters supported the requirement that EHR technology certified to the 2014 Edition EHR certification criteria should be able to capture, accurately calculate and transmit CQM data. Many of these commenters pointed out EHR technology certified to the 2011 Edition EHR certification criteria did not produce accurate results and was not explicitly tested and certified for accurate CQM calculation. As a result of experiences in Stage 1, some commenters recommended requiring that EHR technologies be able to calculate all measures finalized by CMS in order to be certified rather than requiring only one CQM to be certified, as was proposed by ONC to satisfy the Base EHR definition. Others supported EHR technology's output of data to another product for calculation or output in the Quality Reporting Data Architecture (QRDA) format. Many commenters also supported consistency among EHR technologies based on certification and adequate testing of the systems during certification, including use of test data. One commenter recommended closer oversight of vendors by ONC and a remediation process for vendors who do not properly implement CEHRT.

Many commenters stated that the specific XML-based format required by CMS for CQM reporting should be incorporated into ONC's certification criteria. One commenter suggested that all vendors focus on codified data collection and provide complete CCD extractions to another system (such as PopHealth) and allow that system to manage the calculations and data tables as well as provide the extraction of data for a QRDA report, stating that this method would save time and money because it would not require testing each individual EHR product. Another commenter supported the use of CQM definitions that include standards for technical and electronic specifications that allow for interoperability across EHRs and consistent use among end users.

Response: Comments on EHR technology certification requirements are outside the scope of this final rule and are addressed in ONC's Standards and Certification Criteria (S&CC) final rule published elsewhere in this issue of the **Federal Register**. ONC has addressed the CQM requirements for the Base EHR definition, the standards necessary for the submission of CQM data to CMS, and has made other conforming revisions to the proposed certification criteria in response to public comments received.

Comment: Several commenters stated that it was unrealistic to expect the transition to EHR technology certified to the 2014 Edition EHR certification criteria to be feasible for all EPs and all eligible hospitals and CAHs at the same time. These commenters explained that EHR vendors would need to develop, test, distribute upgraded products, and provide user support for a large number of clients in a short amount of time. Furthermore, EPs, eligible hospitals, and CAHs would need to devote time and resources as well as have qualified staff to purchase and implement the upgraded technology, including testing the system and training staff, which may include designing new clinical workflows. The commenters requested a more reasonable

approach to transitioning to the upgraded technology that would ensure proper implementation and avoid compromising patient safety.

Response: We acknowledge that the transition to upgraded EHR technology will be a challenge for all parties involved. Due to several interrelated factors addressed by ONC and CMS to relieve regulatory burden in our respective final rules, we have respectively included certain new flexibilities for EPs, eligible hospitals, and CAHs in order to allow for a more reasonable transition to the upgraded technology. ONC has decided to finalize a more flexible CEHRT definition for the EHR reporting periods in FY/CY 2013, which would permit EPs, eligible hospitals, and CAHs to use EHR technology that has been certified only to the 2014 Edition EHR certification criteria.

For EPs, eligible hospitals, and CAHs that seek to use EHR technology certified only to the 2014 Edition EHR certification criteria in FY/CY 2013, we note that EHR technology certified to these criteria reflect the new set of CQMs we adopt in this rule for reporting beginning with FY/CY 2014. We also note that the reporting requirements in FY/CY 2013 are otherwise the same as for FY/CY 2011 and 2012, including reporting on the CQMs that were finalized in the July 28, 2010 Stage 1 final rule. For EPs, the reporting schema for CY 2013 will remain 3 core or alternate core CQMs, and 3 additional CQMs, as explained in section II.B.5.b. of this final rule. We note that EHR technology certified to the 2014 Edition certification criteria will exclude the three CQMs that we are removing from the list of EP CQMs for reporting beginning in CY 2014 (NQF 0013, 0027, 0084). NQF 0013 is in the list of core CQMs in the Stage 1 final rule, but just as in the case where one of the core CQMs would not apply to an EP's scope of practice or unique patient population, EPs can select one CQM from the list of alternate core CQMs to replace NQF 0013. Therefore, in order to meet the CQM reporting criteria for

meaningful use in CY 2013, EPs who seek to use EHR technology certified only to the 2014 Edition EHR certification criteria could only select from CQMs that are included in both the Stage 1 and Stage 2 final rules. For eligible hospitals and CAHs, the reporting schema for FY 2013 will remain all 15 of the CQMs finalized for reporting in FYs 2011 and 2012 because all CQMs that were included in the Stage 1 final rule are also included in the Stage 2 final rule.

Comment: Most commenters stated that CQM exceptions (allowable reason for non-performance of a quality measure for patients that meet the denominator criteria and do not meet the numerator criteria) should be incorporated into the CQM certification requirements. Many commenters also stated that EPs should not be penalized if it is later determined that a vendor has not met the certification requirement as it would be burdensome and expensive to then purchase additional certified modules and modify workflows after an existing EHR is determined to be non-certified. The same commenters believed that EPs should have an exemption from CQM reporting requirements of meaningful use until measures have been tested and vendors have shown they have met the certification requirements.

Some commenters requested delaying implementation of CQMs that require information from Labor and Delivery information systems until they are certified. One commenter stated that EHR technology should be based on the 2011 Edition EHR certification criteria. Another commenter stated that very few vendors are providing QI measure data integrity and error-checking algorithms, citing the information in FAQ 10839 which includes that CMS does not require providers to record all clinical data in their CEHRT but that providers should report the CQM data exactly as it is generated as output from CEHRT.

Response: We do not agree with the suggestion that EHR technology should based on the 2011 Edition EHR certification criteria. The 2014 Edition EHR certification criteria are

significantly enhanced compared to 2011 Edition and we believe that it is important for EPs, eligible hospitals and CAHs to adopt, implement, and use EHR technology based on the updated certification criteria. We expect that the enhancements in the 2014 Edition certification criteria will address the accuracy of outputs from CEHRT.

We agree generally with the rest of the comments. All CQMs included in this final rule will have electronic specifications available at or around the time of publication. Certification requirements are outside the scope of this rule. We refer readers to ONC's S&CC final rule published elsewhere in this issue of the **Federal Register** for information of certification requirements for items such as CQM exceptions. We discuss the testing of CQM specifications in section II.B.4. of this final rule. We encourage EPs, eligible hospitals and CAHs to refer to the Certified HIT Products List when selecting an EHR product (http://oncchpl.force.com/ehrcert). We also encourage EPs, eligible hospitals, and CAHs to discuss their intent to participate in the EHR Incentive Programs with their vendors, and for vendors to communicate intentions related to certification of a product with EPs, eligible hospitals or CAHs.

After consideration of the public comments received, we are finalizing the proposals related to EHR technology certification requirements for reporting of CQMs subject to the discussion earlier. They include:

- The data reported to CMS for CQMs must originate from an EP's, eligible hospital's, or CAH's CEHRT that has been 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).

- For attestation and the aggregate electronic reporting methods, the only CQMs that can be reported are those for which an EP's, eligible hospital's, or CAH's CEHRT has been certified

to "import and calculate" in accordance with 45 CFR 170.314(c)(2).

- In FY/CY 2013, if an EP, eligible hospital, or CAH seeks to use EHR technology certified only to the 2014 Edition EHR certification criteria for reporting CQMs, they can only report those CQMs that are included in both the Stage 1 and Stage 2 final rules. For EPs, this would exclude the option of reporting NQF 0013, 0027, 0084 from the CQMs in the Stage 1 final rule. Since NQF 0013 is a core CQM in the Stage 1 final rule, EPs would select one of the alternate core CQMs to replace it. All 15 CQMs for eligible hospitals and CAHs in the Stage 1 final rule are included in the Stage 2 final rule.

3. Criteria for Selecting CQMs

We solicited comment on a wide-ranging list of 125 potential CQMs for EPs and 49 potential CQMs for eligible hospitals and CAHs. We stated that we expected to finalize only a subset of these proposed CQMs. We discussed several criteria that we used to select the proposed CQMs.

In the proposed rule, we stated our commitment to align quality measurement and reporting among our programs (for example, IQR, PQRS, CHIPRA, ACO programs). We noted that our alignment efforts focus on several fronts including using the same measures for different programs, standardizing the measure development and electronic specification processes across CMS programs, coordinating quality measurement stakeholder involvement efforts, and identifying ways to minimize multiple submission requirements and mechanisms. In the proposed rule, we gave the example that we are working toward allowing CQM data submitted via CEHRT by EPs, eligible hospitals and CAHs to apply to other CMS quality reporting programs. A longer-term vision would be hospitals and clinicians reporting through a single, aligned mechanism for multiple CMS programs. We stated our belief that the alignment options

proposed for PQRS/EHR Incentive Program would be a first step toward such a vision.

Comment: There was strong support for aligning CQMs and reporting mechanisms across multiple quality reporting programs as well as alignment with the goals of the National Quality Strategy and the HIT Policy Committee recommendations. However, some commenters addressed utility of the CQMs within the EHR Incentive Program as follows:

- Removal of measures that are not included under other quality reporting programs.
- Alignment in other areas such as specifications, reporting methods and to whom measures are reported.
- Concern that the penalties that will be applied in 2015, given the many problems that were encountered implementing Stage 1 CQMs.
- Administrative burden required by multiple submission requirements and multiple reporting mechanisms. Where possible, one commenter encouraged CMS to promote and/or mandate similar action for state, accreditation body, and private payer reporting.

Response: We appreciate the comments received and have made every effort to accommodate the concerns by aligning quality reporting for EPs with the PQRS EHR Reporting Option and establishing an infrastructure for eligible hospitals and CAHs that could be used by IQR and other hospital reporting programs to electronically report CQMs.

We continue to explore how data intermediaries and state Medicaid Agencies could participate in and further enable these quality measurement and reporting alignment efforts, while meeting the needs of multiple Medicare and Medicaid programs (for example, ACO programs, Dual Eligible initiatives, Medicaid shared savings efforts, CHIPRA and Affordable Care Act measure sets). Through these efforts, we intend to lessen provider burden and harmonize with our data exchange priorities.

In addition to statutory requirements for EPs (see section II.B.5.a. of this final rule), eligible hospitals (see sections II.B.7.a. of this final rule), and CAHs (see section II.B.7.a. of this final rule), we relied on other criteria to select the proposed CQMs for EPs, eligible hospitals, and CAHs such as measures that can be technically implemented within the capacity of the CMS infrastructure for data collection, analysis, and calculation of reporting and performance rates. This includes measures that are ready for implementation, such as those with developed specifications for electronic submission that have been used in the EHR Incentive Program or other CMS quality reporting initiatives, or that will be ready soon after the expected publication of the final rule in 2012. This also includes measures that can be most efficiently implemented for data collection and submission.

Comment: There were several comments on infrastructure regarding quality measures, the selection of quality measures, challenges of implementing EHRs and the lack of coordination between measure developers and software vendors. These comments included the following:

- CQMs require data that is not coded in a structured format within the EHRs and thus require significant resources and effort, including specialized coding and training, in order to build CQMs within the EHR systems that can produce accurate results.
- CMS should only include measures which have been sufficiently field tested and validated. The National Qualify Forum's (NQF) Quality Data Model (QDM) and Measure Authoring Tool (MAT) have not been sufficiently tested to ensure valid and accurate EHR CQM calculations.
- A general lack of communication between vendors and measure stewards.

There were also several comments providing additional recommendations for selecting quality measures, including CQMs that:

- Can be automatically abstracted from an EHR.
- Rely on data that is considered viable and accurate.
- Definitively support quality care improvement.
- Align with current quality programs.

Response: The CQMs that we are finalizing for reporting beginning with 2014 have either undergone feasibility testing in EHR systems and clinical settings or were finalized in the Stage 1 final rule for reporting in 2011 and 2012 and specifications have been updated based on experiences with reporting those CQMs. In addition, ONC's 2014 Edition certification criteria explicitly require that the data elements be captured for certification (see 45 CFR 170.314(c), as discussed in ONC's final rule). We have taken into account the recommendations of commenters in our selection of the CQMs finalized for reporting beginning in 2014, and we are finalizing measures that align with current clinical quality programs as well as definitively support quality care improvements.

Comment: Commenters pointed out the limitations of current CQMs in addressing longitudinal patient care management and population health.

Response: We are finalizing CQMs for EPs, eligible hospitals, and CAHs that will have electronic specifications available at or around the time of publication of the final rule and also meet the selection criteria described in this rule. We agree with the importance of the clinical quality measurement goals mentioned by the commenters and are working with measure stewards and measure developers to create a broader set of electronic CQMs that would address these goals.

We also identified the following as criteria used in selecting CQMs:

- CQMs that can be technically implemented within the capacity of the CMS

infrastructure for data collection, analysis, and calculation of reporting and performance rates. This includes CQMs that are ready for implementation, such as those with developed specifications for electronic submission that have been used in the EHR Incentive Program or other CMS quality reporting initiatives, or that will be ready soon after the expected publication of the final rule in 2012. This also includes CQMs that can be most efficiently implemented for data collection and submission.

- CQMs that support CMS and HHS priorities for improved quality of care for people in the United States, which are based on the March 2011 report to the Congress, "National Strategy for Quality Improvement in Health Care" (National Quality Strategy, NQS) (http://www.healthcare.gov/law/resources/reports/nationalqualitystrategy032011.pdf) and the Health Information Technology Policy Committee's (HITPC's) recommendations (http://healthit.hhs.gov/portal/server.pt?open=512&objID=1815&parentname=CommunityPage&parentid=7&mode=2&in_hi_userid=11113&cached=true).

- CQMs that address known gaps in quality of care, such as measures in which performance rates are currently low or for which there is wide variability in performance, or that address known drivers of high morbidity and/or cost for Medicare and Medicaid.

- CQMs that address areas of care for different types of EPs (for example, Medicare- and Medicaid-eligible physicians, and Medicaid-eligible nurse-practitioners, certified nurse-midwives, dentists, physician assistants).

In an effort to align the CQMs used within the EHR Incentive Program with the goals of CMS and HHS, the NQS, and the HITPC's recommendations, we have assessed all proposed CQMs against six domains based on the NQS's six priorities, which were further developed by the HITPC Workgroups, as follows:

- Patient and Family Engagement. These are CQMs that reflect the potential to improve patient-centered care and the quality of care delivered to patients. They emphasize the importance of collecting patient-reported data and the ability to impact care at the individual patient level as well as the population level through greater involvement of patients and families in decision making, self care, activation, and understanding of their health condition and its effective management.

- Patient Safety. These are CQMs that reflect the safe delivery of clinical services in both hospital and ambulatory settings and include processes that would reduce harm to patients and reduce burden of illness. These measures should enable longitudinal assessment of condition-specific, patient-focused episodes of care.

- Care Coordination. These are CQMs that demonstrate appropriate and timely sharing of information and coordination of clinical and preventive services among health professionals in the care team and with patients, caregivers, and families in order to improve appropriate and timely patient and care team communication.

- Population and Public Health. These are CQMs that reflect the use of clinical and preventive services and achieve improvements in the health of the population served and are especially focused on the leading causes of mortality. These are outcome-focused and have the ability to achieve longitudinal measurement that will demonstrate improvement or lack of improvement in the health of the US population.

- Efficient Use of Healthcare Resources. These are CQMs that reflect efforts to significantly improve outcomes and reduce errors. These CQMs also impact and benefit a large number of patients and emphasize the use of evidence to best manage high priority conditions and determine appropriate use of healthcare resources.

- Clinical Processes/Effectiveness. These are CQMs that reflect clinical care processes closely linked to outcomes based on evidence and practice guidelines.

We solicited comments on these domains, and whether they would adequately align with and support the breadth of CMS and HHS activities to improve quality of care and health outcomes.

Comment: Many commenters supported the NQS initiative. Many commenters stated that the domains were imprecise and some CQMs can be placed in multiple domains. Some commenters recommended that the Care Coordination domain include pre- and post-acute care providers and that the CQMs be carefully assigned to the appropriate domains.

Response: We appreciate the supportive comments with respect to the NQS. We agree with commenters that certain CQMs do not fit in only a single domain. When we considered CQMs for selection, we also considered to what extent a domain is already represented in the meaningful use objectives and measures, which use performance thresholds. For example, in the area of care coordination, to be a meaningful EHR user, a provider must provide a summary of care record for more than 50 percent of their transitions of care and referrals. In addition, in the area of patient and family engagement, to be a meaningful EHR user a provider must make patients' health information available to them and potentially their caregivers and families and is responsible for ensuring that at least 5 percent of their patients or their caregivers and families actually access that information. For these reasons, we are relaxing the requirement to report CQMs in each domain as discussed in section II.B.5.c. of this final rule for EP reporting requirements and II.B.7.c. of this final rule for eligible hospital and CAH reporting requirements.

We stated in the proposed rule that we also considered the recommendations of the Measure Applications Partnership (MAP) for inclusion of CQMs. The MAP is a public-private

partnership convened by the National Quality Forum (NQF) for the primary purpose of providing input to HHS on selecting performance measures for public reporting. The MAP published draft recommendations in their Pre-Rulemaking Report on January 11, 2012 (http://www.qualityforum.org/map/), which includes a list of, and rationales for, all the CQMs that the MAP did not support. The MAP did not review the CQMs for 2011 and 2012 that were previously adopted for the EHR Incentive Program in the Stage 1 final rule. We stated in the proposed rule that we included some of the CQMs not supported by the MAP in Tables 7 (EPs) and 8 (eligible hospitals and CAHs) to ensure alignment with other CMS quality reporting programs, address recommendations by other Federal advisory committees such as the HITPC, and support other quality goals such as the Million Hearts Campaign. We also stated that we included some CQMs to address specialty areas that may not have had applicable CQMs in the Stage 1 final rule.

We stated in the proposed rule that we anticipated that only a subset of these CQMs would be finalized. We stated that in considering which measures to finalize, we would take into account public comment on the CQMs themselves and the priorities listed previously. We also stated that we intended to prioritize CQMs in order to align with and support to the extent possible the measurement needs of CMS program activities related to quality of care, delivery system reform, and payment reform, especially the following:

- Encouraging the use of outcome measures, which provide foundational data needed to assess the impact of these programs on population health.

- Measuring progress in preventing and treating priority conditions, including those affecting a large number of CMS beneficiaries or contributing to a large proportion of program costs.

- Improving patient safety and reducing medical harm.
- Capturing the full range of populations served by CMS programs.

Comment: Several commenters support the inclusion of CQMs recommended by the MAP. A commenter supported CQMs which are both MAP evaluated and NQF endorsed. Another commenter raised concern that CMS did not have enough time to consider the MAP recommendations as the CQMs published in the proposed rule differ from those recommended by the MAP. Some commenters were concerned that limiting the CQMs to MAP-supported and/or NQF-endorsed CQMs would discourage CQM innovation and the creation of novel CQMs and those that cover more specialties.

Response: We carefully considered the MAP recommendations and took NQF endorsement status into consideration when making our CQM selections for reporting beginning with 2014. In order to align with other quality reporting programs and address recommendations by other Federal advisory committees, such as the HITPC, as well as consider CQMs endorsed by other multistakeholder groups, we considered CQMs that were not supported by the MAP. After consideration of the public comments received, we are finalizing the policies on criteria for selecting CQMs as proposed.

4. CQM Specification

We stated in the proposed rule that we do not intend to use notice and comment rulemaking as a means to update or modify CQM specifications. In general, it is the role of the measure steward to make changes to a CQM in terms of the initial patient population, numerator, denominator, and potential exclusions. We recognized that it may be necessary to update CQM specifications after they have been published to ensure their continued relevance, accuracy, and validity. Measure specifications 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 would be described in full through supplemental updates to the electronic specifications for EHR submission provided by CMS. We stated that measures would be tracked on a version basis as updates to those CQMs are made, and we would require EPs, eligible hospitals, and CAHs to submit the versions of the CQMs as identified on our website.

We stated in the proposed rule that the complete CQM specifications would be posted on our website (https://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp) at or around the time of the final rule. In order to assist the public in considering the proposed CQMs, we published tables titled "Proposed CQMs for 2014 CMS EHR Incentive Programs for Eligible Professionals" and "Proposed CQMs for 2014 CMS EHR Incentive Programs for Eligible Hospitals and CAHs" on this website. These tables contain additional information for the EP, eligible hospital, and CAH CQMs, respectively, which may not be found on the NQF website. We noted that some of the CQMs were still being developed and that the additional descriptions provided in the tables may still change before the final rule is published. We noted that the titles and descriptions for the CQMs included in these tables were updated by the measure stewards and therefore may not match the information provided on the NQF website.

We proposed that, under certain circumstances, it may be necessary to remove a CQM from the EHR Incentive Programs between rulemaking cycles. We stated in the proposed rule that when there is reason to believe the continued collection of a CQM as it is currently specified raises potential patient safety concerns and/or is no longer scientifically valid, we would take immediate action to remove the CQM from the EHR Incentive Programs and not wait for the next rulemaking cycle. Likewise, we stated if a CQM undergoes a substantive change by the

measure steward between rulemaking cycles such that the measure's intent has changed, we would remove the measure immediately from the EHR Incentive Programs until the next rulemaking cycle when we could propose the revised CQM for public comment. Under this proposed policy, we would promptly remove such CQMs from the set of CQMs available for EPs or eligible hospitals and CAHs to report under the EHR Incentive Programs, confirm the removal or propose the revised CQM, in the next EHR Incentive Programs rulemaking cycle, and notify providers (EPs, eligible hospitals, and CAHs) and the public of our decision to remove the CQM(s) through the usual communication channels (memos, email notification, web site postings).

Comment: Numerous commenters indicated the importance of having CQM specifications and implementation guides as soon as possible. Several commenters pointed out that CQMs without electronic specifications should be re-tooled as eMeasures prior to inclusion in meaningful use.

Response: We will provide complete CQM specifications at or around the time of the publication of this final rule on our website (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/ElectronicSpecifications.html). All of the CQMs that we are finalizing will be fully specified.

Comment: Many commenters noted that more than 6 months is needed to deploy and adequately test upgrades that may affect clinician workflows and patient safety. Other commenters stated that software developers need at least 18 to 24 months to alter their systems and allow for installation of software to complete process updates, development, testing, error checks, training, and roll-out before the reporting periods begin. Multiple commenters requested

notification and a scheduled approach to making changes to CQM specifications. Commenters suggested that CMS post the CQMs and updates in one place for easy reference.

Response: We understand health care providers and software developers need sufficient time to accommodate CQM specification updates. However, we must balance this with our policy priority for CQMs to remain consistent with clinical practice guidelines and any new scientific data related to efficacy. To address the timing concerns mentioned by commenters, we expect to make the updated specifications, which will be tracked on a version basis, publicly available through our website (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/ElectronicSpecifications.html) approximately 6 months in advance of the beginning of the CY and FY for EPs and hospitals, respectively. We will make every effort to have updated specifications made available earlier and ensure that measure updates are limited in scope. In the event that we remove CQMs between rulemakings, we will post this information on the same website and notify the public through listserv and any additional communication channels that may be appropriate.

Comment: Many commenters stated that CQM specifications should not have to be updated in CEHRT during the period for which the EHR product is certified. Some commenters pointed out the burden and complexity of supporting multiple versions of the CQMs concurrently (that is, the specifications authorized for use within the current reporting period, and the updated specifications intended for implementation in the following reporting period).

Response: CQM specifications are updated to maintain alignment with current clinical guidelines and ensure that the CQM remains relevant and actionable within the clinical care setting. We believe the benefits of having the ability to update specifications more frequently

than the rulemaking cycle for the EHR Incentive Programs outweighs the burden and complexity identified by commenters.

As a result of aligning with other quality reporting programs (for example, PQRS), the CQMs and specifications are being used in multiple programs. If we do not have the ability to update specifications annually, then our respective programs may no longer align. Furthermore, without having the ability to update the specifications at least annually, the CQMs could become obsolete and would not adequately reflect current best practices. The majority of the administrative changes expected in the annual specification updates would reflect updates that vendors would routinely push to their clients' EHR technologies (for example, drug code updates).

We did not receive any comments on our proposed policy to remove CQMs between rulemaking cycles under certain circumstances.

After consideration of the public comments received, we are finalizing the following policies on CQM specifications. Updates to CQM specifications may be provided annually approximately 6 months in advance of the FY/CY for hospitals and EPs, respectively. Providers will not be required to use the updated specifications for purposes of submitting the CQMs for the EHR Incentive Program unless specified in future rulemaking. We note that EPs choosing to submit CQMs through another quality reporting program (for example, PQRS) would need to use the updated specifications if required by the other program. We are finalizing the policy on removing CQMs between rulemaking cycles under certain circumstances as proposed. In the event that one or more CQMs are removed between rulemakings, the number of CQMs that an EP, eligible hospital, or CAH must report would be reduced by the number of CQMs removed. For example, if one EP CQM was removed from the set of CQMs finalized for EPs in Table 7,

EPs would only be required to submit 8 CQMs instead of 9. Likewise, if a hospital CQM is removed from the set of CQMs finalized in Table 8, eligible hospitals and CAHs would only be required to submit 15 CQMs instead of 16. The requirement that the CQMs submitted cover at least 3 domains will remain the same unless all CQMs for a particular domain have been eliminated. EPs that are not affected by such a removal of a CQM between rulemakings and could report on other CQMs are expected to continue reporting on 9 CQMs. Likewise, eligible hospitals and CAHs that are not affected and could report on other CQMs are expected to continue reporting on 16 CQMs.

5. CQMs for EPs

(a) Statutory and Other Considerations

Sections 1848(o)(2)(A)(iii) and 1903(t)(6)(C) of the Act provide for the reporting of CQMs by EPs as part of demonstrating meaningful use of CEHRT. For further explanation of the statutory requirements, we refer readers to the discussion in our proposed and final rules for Stage 1 (75 FR 1870 through 1902 and 75 FR 44380 through 44435, respectively).

Under sections 1848(o)(1)(D)(iii) and 1903(t)(8) of the Act, the Secretary must seek, to the maximum extent practicable, to avoid duplicative requirements from federal and state governments for EPs to demonstrate meaningful use of CEHRT under Medicare and Medicaid. Therefore, to meet this requirement, we continued our practice from Stage 1 of proposing CQMs that would apply for both the Medicare and Medicaid EHR Incentive Programs, as listed in sections II.B.5.b. and II.B.5.c. of this final rule.

Section 1848(o)(2)(B)(iii) of the Act requires that in selecting CQMs for EPs, and in establishing the form and manner of reporting, the Secretary shall seek to avoid redundant or duplicative reporting otherwise required, including reporting under subsection (k)(2)(C) (that is,

reporting under the PQRS). Consistent with that requirement, we proposed to select CQMs for EPs for the EHR Incentive Programs that align with other quality reporting programs mentioned in the proposed rule (77 FR 13745). We stated in the proposed rule that when a CQM is included in more than one CMS quality reporting program and is reported using CEHRT, we would seek to avoid requiring EPs to report the same CQM to separate programs through multiple transactions or mechanisms.

Section 1848(o)(2)(B)(i)(I) of the Act requires the Secretary to give preference to CQMs endorsed by the entity with a contract with the Secretary under section 1890(a) (namely, the NQF). We proposed CQMs for EPs for 2013, 2014, and 2015 (and potentially subsequent years) that reflect this preference, although we note that the Act does not require the selection of NQF endorsed CQMs for the EHR Incentive Programs. CQMs listed in this final rule that do not have an NQF identifying number are not NQF endorsed, but are included in this final rule with the intent of eventually obtaining NQF endorsement of those CQMs determined to be critical to our program.

We stated our intent to increase the total number of CQMs for EPs to include areas such as behavioral health, dental care, long-term care, special needs populations, and care coordination. We proposed new pediatric CQMs, an obstetric CQM, behavioral/mental health CQMs, CQMs related to HIV medical visits and antiretroviral therapy, two oral health CQMs, as well as other CQMs that address NQS goals. Although we did not propose additional CQMs in the areas of long-term and post-acute care due to the lack of electronic specifications, we stated that we would continue to develop or identify CQMs for these areas for future years. We received public comments related to statutory and other considerations. We have responded to those comments in later sections of this final rule, including comments related to form and

manner and the clinical areas covered by specific CQMs (see sections II.B.6.c. or II.B.6.d. of this final rule).

(b) CQMs for EPs for CY 2013

We proposed that for the EHR reporting periods in CY 2013, EPs must submit data for the CQMs that were finalized in the Stage 1 final rule for CYs 2011 and 2012 (75 FR 44398 through 44411, Tables 6 and 7). We stated that we expected to post updates to the CQMs' electronic specifications on the EHR Incentive Program website at least 6 months prior to the start of CY 2013. As required by the Stage 1 final rule, EPs must report on 3 core or alternate core CQMs, plus 3 additional CQMs. We referred readers to the discussion in the Stage 1 final rule for further explanation of the requirements for reporting those CQMs (75 FR 44398 through 44411).

We received no public comments and are finalizing these proposals for EPs for CY 2013. We have posted updates to the CQM specifications on the EHR Incentive Program website (https://www.cms.gov/apps/ama/license.asp?file=/QualityMeasures/Downloads/QMEPSupplemental.zip) and note that they will be optional with respect to CY 2013 reporting.

(c) CQMs and Reporting Options for EPs Beginning with CY 2014

(i) Reporting Options

We proposed two reporting options that would begin in CY 2014 for Medicare and Medicaid EPs, as described as follows: Options 1 and 2. We proposed the CQMs listed in Table 8 of the proposed rule (77 FR 13749 through 13757) for all EPs (Medicare and Medicaid) for the EHR reporting periods in CYs 2014, 2015, and potentially subsequent years, regardless of whether an EP is in Stage 1 or Stage 2 of meaningful use. We stated that the policies and CQMs proposed for CYs 2014 and 2015 would continue to apply in CY 2016 and subsequent years until

a new rule is published. Therefore, we referred to CQMs that apply "beginning with" or "beginning in" CY 2014. We stated that for Medicaid EPs, although the reporting method for CQMs may vary by state, the set of CQMs from which to select would be the same as for Medicare EPs. We stated that Medicare EPs who are in their first year of Stage 1 may report CQMs by attestation.

For Option 1, we proposed two alternatives (Options 1a and 1b), but stated that we intended to finalize only a single method. We proposed that Medicare EPs who participate in both the PQRS EHR reporting option and the EHR Incentive Program may choose Option 2 instead of Option 1.

- Option 1a: We proposed that EPs would select and report 12 CQMs from those listed in Table 8 of the proposed rule (77 FR 13749 to 13757), including at least 1 CQM from each of the 6 domains, which are described in section II.B.3. of this final rule. EPs would select the CQMs that best apply to their scope of practice and/or unique patient population. If an EP's CEHRT does not contain patient data for at least 12 CQMs, then the EP must report the CQMs for which there is patient data and report the remaining required CQMs as "zero denominators" as displayed by the EPs CEHRT. If there are no CQMs applicable to the EP's scope of practice or unique patient populations, EPs must still report 12 CQMs even if zero is the result in either the numerator and/or the denominator of the CQM. If all applicable CQMs have a value of zero from their CEHRT, then EPs must report any 12 of the CQMs. We noted one advantage of this approach is that EPs can choose CQMs that best fit their practice and patient populations. However, because of the large number of CQMs to choose from, this approach would result in fewer EPs reporting on any given CQM, and likely only a small sample of patient data

represented in each CQM. We proposed that EPs would submit the CQM data in an XML-based format on an aggregate basis reflective of all patients without regard to payer.

- Option 1b: We proposed that EPs would report 11 "core" CQMs listed in Table 6 of the proposed rule (77 FR 13746 to 13747), plus 1 "menu" CQM from Table 8 of the proposed rule (77 FR 13749 to 13757). We noted that the "core" CQM set reflected the national priorities outlined in section II.B.3. of the proposed rule. EPs would select 1 CQM to report from the "menu" set based on their respective scope of practice and/or unique patient population. We explained one advantage of this approach is that quality data would be collected on a smaller set of CQMs, so the resulting data for each CQM would represent a larger number of patients and therefore could be more accurate. However, this approach could mean that more CQMs are reported with zero denominators (if they are not applicable to certain practices or populations), making the data less comprehensive. We stated that the policy on reporting "zeros" in the numerator and/or denominator of a CQM, as discussed previously under Option 1a, would also apply for Option 1b.

- Option 2: Submit and satisfactorily report CQMs under the PQRS's EHR Reporting Option.

We proposed that Medicare EPs who participate in both the PQRS EHR reporting option and the EHR Incentive Program may choose Option 2 instead of Option 1. In order to streamline quality reporting options for EPs participating in both programs, we proposed that Medicare EPs who submit and satisfactorily report PQRS CQMs under the PQRS's EHR reporting option using CEHRT would satisfy the CQM reporting requirement under the Medicare EHR Incentive Program. We referred readers to 42 CFR 414.90 and the CY 2012 Medicare PFS final rule with comment period (76 FR 73314) for more information about the existing requirements of the

PQRS and stated that EPs who choose this Option 2 would be required to comply with any changes to the requirements of the PQRS that may apply in future years.

Comment: Many commenters preferred Option 1a instead of 1b since it offers more flexibility and a larger selection of CQMs, especially for specialties including surgery, otolaryngology, urology, and psychiatry. However, they also indicated that it would be difficult to report 1 CQM from each of the 6 domains that apply to their scope of practice and/or unique patient population.

Other commenters supported Option 1b over 1a as long as it limits the number of CQMs to those that vendors would be required to support. A few commenters suggested removing the "one menu CQM" requirement entirely.

Many commenters suggested a modification of Options 1a and 1b to require reporting a specific number of core CQMs (fewer than the 11 proposed) and a specific number of menu CQMs (more than 1 as proposed) along with some changes to the domain requirement. Many commenters suggested a reporting option requiring EPs to report 6 clinically relevant CQMs covering at least 2 domains, and if no CQMs are clinically relevant for an EP, they must demonstrate zeros in the denominator for 6 CQMs covering at least 2 domains. A few commenters suggested requiring up to 9 CQMs covering a range of 2 to 4 domains. One commenter also advocated for the retention of all three reporting options (1a, 1b, and 2) so that EPs could select the one most appropriate to their practice.

Response: We agree that a modified approach for Option 1 would provide a more optimal reporting schema for most EPs. In our modified approach, we included the positive and minimized the negative components of each of the two proposed options where possible. The Option 1 that we are finalizing (as explained in detail later) decreases the number of CQMs that

EPs must select to report, decreases the total number of domains required to be covered among the selected CQMs, recommends but does not require reporting from a "core" set of CQMs, and offers specialist EPs the flexibility to select CQMs that are applicable to their scope of practice.

We note the following CQMs in the finalized recommended core sets for adults and children were included in the proposed core set: NQF 0018, 0022, 0024, 0028, 0418, and TBD – Closing the referral loop: receipt of specialist report.

Comment: We also received many comments on Option 2. Numerous commenters supported Option 2, including the submission of CQM data via the PQRS program and receiving credit for both PQRS and meaningful use. However, some of these commenters indicated that not all EPs qualify to participate in PQRS. Another concern was that the patient population reported differs between the two programs in that PQRS requires reporting on Medicare patients only, whereas meaningful use reflects all patients without regard to payer.

Response: For the reporting of CQMs, we are finalizing Option 2 as proposed in order to reduce reporting burden on EPs who participate in both programs and attain the goal of alignment with the PQRS EHR reporting option. EPs who do not participate in PQRS may submit CQMs for the EHR Incentive Program using Option 1. Regardless of whether an EP chooses Option 1 or Option 2 for CQM reporting, we note that all EPs must also report the meaningful use objectives and measures through attestation, as well as meet all other meaningful use requirements.

We acknowledge that under the PQRS, only Medicare patient information is submitted. In general, our preference is to measure quality at the all patient level, based on samples of all patient data (that is, patients that meet the denominator criteria of each reported CQM). We believe this provides a better assessment of overall care quality rendered by EPs. However,

although meaningful use reflects all patients without regard to payer, we believe Option 2 is appropriate because it is a step in the direction of the longer-term goal of a single, aligned mechanism for multiple CMS programs.

After consideration of the public comments received, and for the reasons discussed earlier, we are finalizing two reporting options beginning with CY 2014 for EPs in all stages of meaningful use. These options will continue to apply in the event that we have not engaged in another round of rulemaking by CY 2016.

Option 1: Report 9 CQMs covering at least 3 domains.

Medicare and Medicaid EPs selecting this reporting option will be required to submit a total of 9 CQMs covering at least 3 domains from Table 7. We expect EPs would select the CQMs that best apply to their scope of practice and/or unique patient population. For this reporting option, CQMs will be submitted on an aggregate basis reflective of all patients without regard to payer. We are not requiring the submission of a core set of CQMs, but we identify two recommended core sets, one for adults and one for children, that we encourage EPs to report to the extent those CQMs are applicable to an EP's scope of practice and patient population. If an EP's CEHRT does not contain patient data for at least 9 CQMs covering at least 3 domains, then the EP must report the CQMs for which there is patient data and report the remaining required CQMs as "zero denominators" as displayed by the EP's CEHRT. If there are no CQMs applicable to the EP's scope of practice and patient population, EPs must still report 9 CQMs even if zero is the result in either the numerator or the denominator of the measure. If all applicable CQMs have a value of zero from their CEHRT, then EPs must report any 9 CQMs from Table 7.

Option 2: Submit and satisfactorily report CQMs under the PQRS's EHR Reporting

Option.

Under this option, Medicare EPs who participate in both the PQRS and the Medicare EHR Incentive Program will satisfy the CQM reporting component of meaningful use if they submit and satisfactorily report PQRS CQMs under the PQRS's EHR reporting option using CEHRT. EPs choosing to report under this option for purposes of the Medicare EHR Incentive Program will be subject to the reporting periods established for the PQRS EHR reporting option, which may be different from their EHR reporting period for the meaningful use objectives and measures. For example, in CY 2014, an EP who is beyond his or her first year of meaningful use will have a 3-month quarter EHR reporting period for the meaningful use objectives and measures, but the reporting periods for the PQRS EHR reporting option that fall within CY 2014 would apply for purposes of reporting CQMs. We emphasize that EPs who are in their first year of demonstrating meaningful use in the year immediately preceding a payment adjustment year cannot choose this Option 2 for reporting CQMs for the EHR Incentive Program. For purposes of avoiding a payment adjustment, they must submit their CQM data by attestation no later than October 1 of such preceding year. For more information on the requirements of the PQRS, we refer readers to 42 CFR 414.90 and the CY 2013 Medicare PFS proposed rule (77 FR 44805 through 44988). EPs who choose this option to satisfy the CQM reporting component of meaningful use under the Medicare EHR Incentive Program will be required to comply with any changes to the PQRS that may apply in future years.

(ii) CQMs

We proposed to remove three CQMs beginning with CY 2014 for EPs at all stages of meaningful use for the following reasons:

- NQF # 0013 – The measure steward did not submit this CQM to the NQF for continued endorsement. We included other CQMs that address high blood pressure and hypertension in Table 8 in the proposed rule.

- NQF #0027 – We determined this CQM is very similar to NQF #0028 a and b; therefore, to avoid duplication, we proposed to only retain NQF # 0028 a and b.

- NQF #0084 – The measure steward did not submit this CQM to the NQF for continued endorsement. Additionally, CMS has decided to remove this CQM because there are other FDA-approved anticoagulant therapies available in addition to Warfarin. We proposed to replace this measure, pending availability of electronic specifications, with NQF #1525 – Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy.

We did not receive public comments and are finalizing the elimination of measures NQF #0013, NQF #0027, and NQF #0084 beginning with CY 2014 for EPs at all stages of meaningful use. We proposed to replace NQF #0084 with NQF #1525, which was determined to contain data elements that were difficult to capture in EHRs after additional feasibility testing. Therefore, we are implementing an Adverse Drug Events CQM to replace NQF #0084:
Title: ADE Prevention and Monitoring: Warfarin Time in Therapeutic Range.
Description: Average percentage of time in which individuals with atrial fibrillation who are on chronic anticoagulation have International Normalized Ratio (INR) test results within the therapeutic range during the measurement period.

For a list of all the CQMs proposed for EPs to report for the EHR Incentive Programs beginning with CY 2014, please refer to Table 8 in the Stage 2 proposed rule (77 FR 13749 to 13757). We stated that we expected to finalize only a subset of the CQMs listed in Table 8 based on public comments and the priorities discussed in section II.B.3. of the proposed rule.

We noted that some of these CQMs had not yet been submitted for consensus endorsement consideration or were under review for endorsement consideration by the NQF. We stated that we expect that any measure proposed in Table 8 for inclusion beginning with CY 2014 would be submitted for endorsement consideration by the measure steward. Because measure specifications may need to be updated more frequently than our expected rulemaking cycle will allow for, we stated that we would provide updates to the specifications at least 6 months prior to the beginning of the calendar year for which the measures would be required, and we expected to update specifications annually.

Comment: Many commenters indicated support for CMS's efforts to include CQMs that are broadly applicable across primary care and specialist EPs. However, many commenters also stated that most of the proposed CQMs apply to primary care practices and preventive medicine and requested more CQMs that apply to specialist practices or to adjust the reporting requirements to match the number of clinically available CQMs for nonprimary care EPs. Another commenter requested pediatricians be excluded from having to report on CQMs for patients older than 18 years old rather than having to demonstrate zero denominators on a population that does not apply to them.

Many commenters stated that there were too many CQMs, citing issues with implementation of such a large set of measures as well as diluting the impact of quality measurement. Some of these commenters believed that CMS should focus on a smaller set of CQMs to refine for accuracy in implementation. They also did not believe that they should have to build CQMs into their CEHRT if those CQMs did not apply to their scope of practice because those CQMs would only yield zero denominators. Some suggested alternatives to building out all CQMs included allowing EPs to attest to having a low denominator, such as 25 or fewer

patients, or for CMS to assign the primary care or specialty fields that each CQM applies to, whereby EPs whose field is not listed for a particular CQM would be exempt from reporting that CQM.

Many of the proposed EP CQMs received support from the public. Some commenters gave feedback on specific proposed CQMs, including questions on the feasibility of reporting the CQM, issues with specific requirements of the CQM, and preferences for preventative CQMs. A few commenters did not support finalizing CQMs that were not NQF endorsed. We also received suggestions for additional CQMs that were not included in the list of 125 proposed EP CQMs. A few commenters expressed concern about the lack of transparency in the development of the CQMs.

Response: We stated in the Stage 2 proposed rule that we would be finalizing a subset of the proposed CQMs. We convened a Quality Measures Task Force (QMTF), which is made up of stakeholders from across the Department and includes representation from different quality reporting programs. Through the QMTF and with senior leadership, we considered public comments, feasibility of the electronic specifications to be captured in EHRs, and the goals stated in section II.B.3. of this final rule when selecting the finalized list of EP CQMs. By including such a large representation of stakeholders, we believe that we have prioritized CQMs that align with other programs, which includes CQMs that are not used in other programs currently but could be implemented in other programs as they include more electronically specified CQMs in their respective CQM lists. This will move us closer to our longer-term goal of having a single, aligned mechanism for CQM reporting.

Since the measure stewards are responsible for any information that affects the requirements of the CQM, we have shared the feedback on specific CQMs with the respective

measure stewards. Consideration of both evidence and expert consensus are integral parts of the NQF's measure endorsement process. More information on this Consensus Development Process is available on the NQF website: http://www.qualityforum.org/Measuring_Performance/Consensus_Development_Process.aspx. Although we give preference to CQMs that have been endorsed by NQF, section 1848(o)(2)(B)(i)(I) of the Act does not require the selection of NQF-endorsed CQMs for the EHR Incentive Program. Please refer to section II.B.3. of this final rule for the discussion on criteria for inclusion of a CQM.

We appreciate the commenters' suggestions for additional CQMs that apply to specialties that may not have been as represented in the measure set as primary care or preventative medicine. Although we cannot in this final rule select CQMs that were not proposed in the proposed rule, we will consider the suggested CQMs for future inclusion. As for the commenters' request to adjust the reporting requirements or exclude certain specialties from reporting certain CQMs, we believe that our policy on allowing "zero denominators" to be reported allows specialists to meet the CQM reporting requirements of meaningful use and is a continuation of our policy from the Stage 1 final rule.

Comment/Response: Table 7 summarizes the public comments received on specific proposed EP CQMs and the CMS rationale (that is, our response to the CQM-specific comment(s)) for finalizing or not finalizing the CQM for reporting beginning with CY 2014.

TABLE 7: SUMMARY OF EP CQM-SPECIFIC COMMENTS AND RATIONALE TO FINALIZE OR NOT FINALIZE THE CQM

CQM Number	Commenters Support Finalization	Commenters Do Not Support Finalization	Finalized	Rationale
NQF 0002	No comments	No comments	Yes	Addresses efficient use of resources; alignment with other programs
NQF 0004	Supports measure	Privacy concerns; concerned that it could be difficult to implement.	Yes	Addresses high priority agency goals and aligns with other quality reporting programs. We retained NQF 0004 in order to represent the important issue of alcohol or other drug dependence treatment in our measure set. We also believe that through our collaboration with ONC, we have addressed the issues associated with data collection.
NQF 0018	Public comment supports measure	No comments	Yes	Supports high priority goals (controlling high blood pressure)
NQF 0022	No comments	Measure is not supported by evidence	Yes	Addresses patient safety NQF requires clinical evidence supporting a measure in order to achieve NQF endorsement.
NQF 0024	Support for measure but evidence only for overweight, obese, or underweight children and not ideal weight	Contains data elements that are difficult to capture as structured data	Yes	Supports high priority goals (weight assessment, nutrition, physical activity for children); received strong public support. Based on industry standards, CMS is collaborating with other federal agencies and private organizations to standardize data elements.
NQF 0028	Support for measure	Concerns about capturing discrete data	Yes	Supports high priority goals (tobacco use cessation); alignment with other programs
NQF 0031	No comments	Does not align with current clinical guidelines for frequency of screening	Yes	This CQM is currently NQF endorsed[#]. This is a high priority prevention measure for breast cancer.
NQF 0032	No comments	Does not align with current clinical guidelines for frequency of screening	Yes	This CQM is currently NQF endorsed[#] and will be updated for consistency with clinical guidelines as discussed earlier in this section. This is a high priority prevention measure for cervical cancer.

CQM Number	Commenters Support Finalization	Commenters Do Not Support Finalization	Finalized	Rationale
NQF 0033	No comments	Does not align with current clinical guidelines for frequency of screening	Yes	This CQM is currently NQF endorsed[#] and will be updated for consistency with clinical guidelines as discussed earlier in this section. This is a high priority prevention measure.
NQF 0034	No comments	Does not align with current clinical guidelines	Yes	This CQM is currently NQF endorsed[#] and will be updated for consistency with clinical guidelines as discussed earlier in this section. This is a high priority prevention measure.
NQF 0036	No comments	Duplicative of other measures (duplicate measure not included)	Yes	Addresses high priority agency goals and aligns with other quality reporting programs. Some aspects of this measure may be considered duplicative of other CQMs, however we believe that there are unique aspects of this CQM that are important to measure.
NQF 0038	Supports measures to reduce rate of Hepatitis B	No comments	Yes	Supports public health goals.
NQF 0041	Support for measure	No evidence to support influenza vaccinations for all patients; Concerns about capturing discrete data and accounting for alternative delivery locations	Yes	This CQM is currently NQF endorsed[#]. This is a high priority prevention measure. Delivery of the vaccine should be captured in the EHR even if it was delivered in an alternate location.
NQF 0043	Support for measure	Concerns about capturing discrete data and accounting for alternative delivery locations	Yes	Alignment with PQRS/ACOs/NCQA-PCMH Accreditation. This is a high priority prevention measure. Delivery of the vaccine should be captured in the EHR even if it was delivered in an alternate location. Passed feasibility testing for the data elements needed.
NQF 0052	Support with suggestions for improvements	No comments	Yes	Addresses efficient use of resources.
NQF 0055	No comments	Inconsistent with evidence	Yes	This CQM is currently NQF endorsed[#]. This is a high priority prevention measure.
NQF 0056	Support for measure	Concerns about ability to collect discrete data	Yes	Supports high priority goals (diabetes); alignment with other programs. Passed feasibility testing for the data elements needed.

CQM Number	Commenters Support Finalization	Commenters Do Not Support Finalization	Finalized	Rationale
NQF 0059	Support for measure	No comments	Yes	Supports high priority goals (diabetes); alignment with other programs.
NQF 0060	Support for measure	Concern that this measure is untested in a pediatric population	Yes	Supports high priority goals (diabetes, pediatric population).
NQF 0062	Supports measure	No comments	Yes	Supports high priority goals (diabetes); alignment with other programs.
NQF 0064	Supports measure as a way to monitor overuse and non-evidence based therapies	No comments	Yes	Supports high priority goals (diabetes); alignment with other programs.
NQF 0068	Support for measure	No comments	Yes	Supports high priority goals (heart disease); alignment with other programs.
NQF 0069	No comments	No comments	Yes	Addresses efficient use of resources; alignment with other programs.
NQF 0070	Support for measure	No comments	Yes	Supports high priority goals (heart disease); alignment with other programs.
NQF 0075	Support for measure	Denominator is complex and ability to capture prior year data is questioned	Yes	Supports high priority goals (heart disease); alignment with other programs. We are also collaborating very closely with the ONC to ensure that these data are captured within CEHRT.
NQF 0081	Support for measure	No comments	Yes	Supports high priority goals (heart disease); alignment with other programs.
NQF 0083	Support for measure	No comments	Yes	Supports high priority goals (heart disease); alignment with other programs.
NQF 0086	Support for measure	Does not advance quality of care	Yes	This CQM is currently NQF endorsed[#].
NQF 0088	Supports measure	Concerned about ability to transmit data between providers	Yes	Supports high priority goals (diabetes); alignment with other programs. Data is not required to be electronically transmitted between providers.
NQF 0089	Supports measure	Does not advance quality of care; Concerned about ability to transmit data between providers	Yes	This CQM is currently NQF endorsed[#]. Communication between eye specialist and the physician who manages diabetes care is important. Data is not required to be electronically transmitted between providers.

CQM Number	Commenters Support Finalization	Commenters Do Not Support Finalization	Finalized	Rationale
NQF 0101	Support for measure	Concerns about ability to collect discrete data	Yes	Addresses patient safety. Passed feasibility testing for the data elements required.
NQF 0104	Support for measure	Duplicative of other measures; Concerns about ability to collect discrete data	Yes	Supports public health goals; alignment with other programs. Duplicative measures have not been finalized. Takes initial steps toward collecting discrete data.
NQF 0105	Support for measure	Concerns about suggesting pharmacotherapy over other treatment options	Yes	This CQM is currently NQF endorsed#.
NQF 0108	No comments	No comments	Yes	Addresses pediatric population.
NQF 0110	Support for measure	Concerns about complexity and confidentiality; Concerns about ability to collect discrete data	Yes	We are collaborating very closely with the ONC to ensure that these data are captured within CEHRT.
NQF 0384	Support for measure	Concerns about ability to collect discrete data	Yes	Addresses patient engagement; alignment with other programs.
NQF 0385	Supports measure	Concerns about ability to collect discrete data	Yes	Addresses high priority agency goals and aligns with other quality reporting programs.
NQF 0387	Support for measure	Concerns about ability to collect discrete data	Yes	Addresses high priority agency goals and aligns with other quality reporting programs.
NQF 0389	Support for measure	Concerns about complexity; Concerns about ability to collect discrete data	Yes	We are collaborating very closely with the ONC to ensure that these data are captured within CEHRT.
NQF 0403	Support for measure	Concerns about ability to document AIDS status	Yes	Addresses high priority agency goals and aligns with other quality reporting programs.
NQF 0405	Support for measure	Concerns about agreement with current clinical guidelines	Yes	This CQM is currently NQF endorsed# and will be updated for consistency with clinical guidelines as discussed earlier in this section.
TBD (proposed as NQF 0407 – HIV/AIDS RNA Control)	Support for measure	Concerns about ability to collect discrete data	Yes	Alignment with other programs. This CQM will be updated for consistency with the clinical guidelines as discussed earlier in this section.

CQM Number	Commenters Support Finalization	Commenters Do Not Support Finalization	Finalized	Rationale
NQF 0418	Support for assessment of depression	Concern that patient refusal of screening could count against EP; Concerns about ability to collect discrete data	Yes	Supports public health goals; alignment with other programs. We also recognize that patients may refuse the treatments measured within this CQM, but there are no performance thresholds established for the EHR Incentive Program.
NQF 0419	Support for measure with concerns about ability to capture discrete data	Too check-boxy and does not advance quality of care	Yes	This CQM is currently NQF endorsed[#].
NQF 0421	Support for measure	Too check-boxy and does not advance quality of care; Concerns about ability to collect discrete data	Yes	Supports public health goals. Alignment with PQRS/ACOs/UDS. This CQM is currently NQF endorsed[#]. Passed feasibility testing for the data elements needed.
NQF 0564	Supports measure that targets high priority condition to Medicare population and will add substantial value to the clinical quality measure set	No comments	Yes	Addresses patient safety; alignment with other programs.
NQF 0565	Supports measure that targets high priority condition to Medicare population and will add substantial value to the clinical quality measure set	No comments	Yes	Alignment with other programs.
NQF 0608	No comments	No comments	Yes	Addresses high priority agency goals.
NQF 0710	Supports measure concept but concerned metric is too high	Privacy concerns	Yes	Addresses high priority agency goals. To protect patient confidentiality and adhere to HIPAA requirements, CMS and all contractors for CMS are held to maintaining and abiding by the IT Security Policy in the transmission of electronic data.

CQM Number	Commenters Support Finalization	Commenters Do Not Support Finalization	Finalized	Rationale
NQF 0712	Supports measure	Privacy concerns; Concerns about ability to collect discrete data	Yes	Addresses high priority agency goals and takes initial steps towards collecting accurate discrete data. To protect patient confidentiality and adhere to HIPAA requirements, CMS and all contractors for CMS are held to maintaining and abiding by the IT Security Policy in the transmission of electronic data.
TBD (proposed as 1335 Children dental)	Supports measure	Concerns about collecting data via EHR and required changes to workflow; Concerns about ability to collect discrete data	Yes	Addresses child health and dental measures not previously included in program We are collaborating very closely with the ONC to ensure that these data are captured within CEHRT
NQF 1365	Support for measure	Concerns about ability to collect discrete data	Yes	Supports public health goals; alignment with other programs. Duplicative measures have not been finalized. Takes initial steps toward collecting discrete data.
NQF 1401	No comments	Concerns about linking measure to age of child when measure relates to maternal depression and ability to capture discrete data	Yes	Addresses public health goals. We are collaborating very closely with the ONC to ensure that these data are captured within CEHRT.
TBD (proposed as 1419 Primary caries prevention)	Support if revised to clarify numerator and denominator	Concerns about whether measure reflects standard of care for medical providers	Yes	Addresses child health and dental measures not previously included in program. Received strong public support. The CQM is currently NQF endorsed for medical providers.[#]
TBD (LDL)	Supports measure	Not NQF endorsed; Concerns about ability to collect discrete data	Yes	Addresses high priority goal (high cholesterol); Though we gave preference to NQF endorsement, some measures selected that were not NQF endorsed based on their measurement of high priority conditions.

CQM Number	Commenters Support Finalization	Commenters Do Not Support Finalization	Finalized	Rationale
TBD (Fasting LDL)	Supports measure	Not NQF endorsed; Concerns about ability to collect discrete data	Yes	Addresses high priority goal (high cholesterol); Though we gave preference to NQF endorsement, some measures selected that were not NQF endorsed based on their measurement of high priority conditions.
TBD (Dementia)	Supports measure	Not NQF endorsed; Concerns about ability to collect discrete data	Yes	Addresses high priority agency goals and takes initial steps towards collecting accurate discrete data; Though we gave preference to NQF endorsement, some measures selected that were not NQF endorsed based on their measurement of high priority conditions.
TBD (Hypertension)	No comments	No comments	Yes	Addresses high priority goal (hypertension)
TBD (Closing referral loop)	Supports as an example of a core measure	Concerns about ability to capture data exchange; not NQF endorsed	Yes	Addresses care coordination; Though we gave preference to NQF endorsement, some measures selected that were not NQF endorsed based on their measurement of high priority conditions.
TBD (FSA knee)	Supports measure	Not NQF endorsed; Concerns about ability to collect discrete data	Yes	Addresses functional status assessment and patient engagement; Though we gave preference to NQF endorsement, some measures selected that were not NQF endorsed based on their measurement of high priority conditions.
TBD (FSA hip)	Supports measure	Not NQF endorsed; Concerns about ability to collect discrete data	Yes	Addresses functional status assessment and patient engagement; Though we gave preference to NQF endorsement, some measures selected that were not NQF endorsed based on their measurement of high priority conditions.
TBD (FSA complex)	Supports measure	Not NQF endorsed; Concerns about ability to collect discrete data	Yes	Addresses functional status assessment and patient engagement; Though we gave preference to NQF endorsement, some measures selected that were not NQF endorsed based on their measurement of high priority conditions.

CQM Number	Commenters Support Finalization	Commenters Do Not Support Finalization	Finalized	Rationale
TBD (ADE)	Supports	Not NQF endorsed; Concerns about ability to collect discrete data	Yes	Addresses patient safety; Though we gave preference to NQF endorsement, some measures selected that were not NQF endorsed based on their measurement of high priority conditions.
TBD (HBP followup)	No comments	Measure focuses on limited population; not NQF endorsed	Yes	Addresses high priority goals (hypertension); Though we gave preference to NQF endorsement, some measures selected that were not NQF endorsed based on their measurement of high priority conditions.
NQF 0001	Supports measure	Does not advance quality of care; Concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting discrete data
NQF 0012	Measure could be adapted to use EHRs to create more accurate quality measures.	No comments	No	Measure no longer supported by measure steward.
NQF 0014	No comments	Does not advance quality of care	No	Measure no longer supported by measure steward.
NQF 0045	No comments	Measure is untested in part of population age range; focus on communications instead of outcomes	No	Difficulty ensuring accurate and standard data collected.
NQF 0046	Supports measure	Concerns about ability to collect discrete data	No	Difficulty ensuring accurate and standard data collected.
NQF 0047	Supports measure	Measure is complicated; concern about lack of look back period	No	Difficulty ensuring accurate and standard data collected.
NQF 0048	Supports measure with suggested changes	No comments	No	Difficulty ensuring accurate and standard data collected.
NQF 0050	Supports measure	Does not advance quality of care; Concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0051	Supports measure	Concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting discrete data.

CQM Number	Commenters Support Finalization	Commenters Do Not Support Finalization	Finalized	Rationale
NQF 0058	No comments	Definition of condition too restrictive	No	Concur with public comment that acute bronchitis is too restrictive for an antibiotic overuse CQM. Seek to limit measure set to reduce burden.
NQF 0061	Support for measure	No comments	No	Redundant with other measures assessing condition (e.g., NQF 0018)
NQF 0066	Support for measure	Measure contains two diagnoses and should separated into two measures; Concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting discrete data
NQF 0067	Support for measure	Concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting discrete data
NQF 0073	Support for measure and suggestion to adapt to further exploit EHRs	No comments	No	Redundant with other measures assessing condition (e.g., NQF 0018)
NQF 0074	Support for measure	Concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting discrete data
NQF 0097	Support for measure	Measure does not advance quality of care, too "check boxy," reconciling across care settings; Concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting discrete data
NQF 0098	Support for measure	Measure is vague; ability to capture discrete data; need standardized tool for assessment; no evidence interventions support outcomes	No	Concur with public comment and complexity associated with collecting discrete data
NQF 0100	Support for measure	No evidence interventions support outcomes; Concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting discrete data
NQF 0102	Support for measure	Concerns about ability to collect discrete data and calculate measure	No	Concur with public comment and complexity associated with collecting discrete data

CQM Number	Commenters Support Finalization	Commenters Do Not Support Finalization	Finalized	Rationale
NQF 0103	Support for measure; harmonize with other measures	Does not advance quality of care; privacy issues; Concerns about ability to collect discrete data	No	Concur with concerns in public comments
NQF 0106	Support for measure	Measure is too complex; concerns about ability to collect discrete data	No	Concur with concerns in public comments that the measure is too complex; and agree with the concerns about ability to collect discrete data
NQF 0107	No comments	Duplicative of other measures	No	Concur with concerns in public comments that it is duplicative of other measures.
NQF 0112	Support for measure	Measure is too complex; privacy issues; vague; concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0239	Support for measure	Concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting discrete data.
Former NQF 0246	Support for measure	Does not advance quality of care; not NQF endorsed; Concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0271	Support for measure	Questions if appropriate for ambulatory setting; Concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0312	Support for measure	Measure is vague	No	Difficulty ensuring accurate and standard data collected.
NQF 0321	Support for measure	No comments	No	Complexity associated with collecting discrete data.
NQF 0322	Support for measure	Measure is vague; concerns about ability to capture discrete data	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0323	Support for measure	Interoperability concerns	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0382	Support for measure	Concerns about ability to capture numerator data	No	Concur with public comment and complexity associated with collecting discrete data.

CQM Number	Commenters Support Finalization	Commenters Do Not Support Finalization	Finalized	Rationale
NQF 0383	Support for measure	Concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0388	Support for measure	Concerns about ability to collect discrete data	No	Measure retired by steward.
NQF 0399	Support for measure	No comments	No	Seek to limit measure set to reduce burden.
NQF 0400	Support for measure	No comments	No	Seek to limit measure set to reduce burden.
NQF 0401	Support for measure	Concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0406	Support for measure	Concerns about keeping up-to-date with changing guidelines	No	Concur with concerns from public comments with concerns about keeping up-to-date with changing guidelines.
NQF 0507	Support for measure	Does not advance quality of care	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0508	Support for measure	Inability to capture screening results as discrete data	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0510	Support for measure	Concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0513	Support for measure	Concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0519	Support for measure	Does not advance quality of care; Concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0561	Support for measure; supports care coordination and alignment with PQRS.	Does not advance quality of care; Concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0562	Support for measure	Concerns about ability to collect discrete data; important measure of overuse	No	Concur with public comment and complexity associated with collecting discrete data.
NQF 0575	Support for measure with reasonable target regarding potential adverse effects of tight diabetes control.	No comments	No	Concur with concerns in public comments regarding potential adverse effects of tight diabetes control.

CQM Number	Commenters Support Finalization	Commenters Do Not Support Finalization	Finalized	Rationale
NQF 0711	Supports measure concept but concerned metric is too high.	Potentially duplicative; privacy issues	No	Concur with concerns in public comments about potentially duplicative measure; and privacy issues.
NQF 1525	Support for measure	Concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting these discrete data.
TBD (Risk Assessment for Falls)	Support for measure	Not NQF endorsed. Concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting these discrete data.
TBD (Plan of Care for Falls)	Support for measure	Not NQF endorsed; questions evidence base for plan of care for falls	No	Concur with public comment and complexity associated with collecting these discrete data.
TBD (ADK: BP Mgmt)	Support for measure	Not NQF endorsed. Concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting these discrete data.
TBD (ADK: ESA)	Support for measure	Not NQF endorsed. Concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting these discrete data.
TBD (Wound Wet to Dry)	Support for measure	Not NQF endorsed. Concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting these discrete data.
TBD (Dementia Staging)	Support for measure	Not NQF endorsed; does not advance quality of care. Concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting these discrete data.
TBD (Dementia FSA)	Support for measure	Not NQF endorsed. Concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting these discrete data.
TBD (Dementia Safety)	Support for measure	Not NQF endorsed. Concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting these discrete data.
TBD (Dementia Driving)	Support for measure	Not NQF endorsed. Concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting these discrete data.
TBD (Dementia Caregiver)	Support for measure	Not NQF endorsed. Concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting these discrete data.

CQM Number	Commenters Support Finalization	Commenters Do Not Support Finalization	Finalized	Rationale
TBD (Wound Compression)	Support for measure	Not NQF endorsed. Concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting these discrete data.
TBD (RA: FSA)	Support for measure	Not NQF endorsed. Concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting these discrete data.
TBD (Glaucoma)	No comments	Not NQF endorsed	No	Concur with public comment and complexity associated with collecting these discrete data.
TBD (Wound Diabetic)	Support for measure	Not NQF endorsed. Concerns about ability to collect discrete data	No	Concur with public comment and complexity associated with collecting these discrete data.
TBD (Hypertension: BPM)	No comments	Not NQF endorsed; questions appropriateness due to narrow population	No	Prefer CQMs on the topic of hypertension with NQF endorsement.

NQF endorsement includes a consensus development process that takes into account clinical guidelines and scientific evidence. NQF describes its consensus development process at http://www.qualityforum.org/Measuring_Performance/Consensus_Development_Process.aspx.

After consideration of the public comments received and the CQM selection criteria discussed, we are finalizing the list of 64 CQMs for EPs included in Table 7. We note that the CQMs that do not have a CQM number in Table 7 are those that are not NQF endorsed. EPs will identify these CQMs by the eMeasure ID and version number that will be included in the CQM specifications that will be made available on our website.

We also note that three of the CQMs listed with a CQM number of TBD in Table 7 were proposed with NQF numbers but are changed to "TBD" in this final rule as follows:

- NQF 0407 is now HIV/AIDS: RNA control for Patients with HIV
- NQF 1335 is now Children who have dental decay or cavities
- NQF 1419 is now Primary Caries Prevention Intervention as Part of Well/Ill Child Care as Offered by Primary Care Medical Providers

NQF 0407 referenced antiretroviral therapy as the means for RNA control. This CQM is

scheduled for NQF review and, due to changing clinical guidelines regarding therapies, significant change in this measure is expected. Due to the nature of HIV/AIDS, the virus mutates frequently, necessitating frequent changes in clinical guidelines with respect to treatments. By respecifying the CQM to remove antiretroviral therapy as the specific treatment and only focus on the outcome of RNA control, the intent of this CQM remains the same. The respecified CQM will be submitted to NQF for endorsement. NQF 1335 was endorsed as population-based CQMs rather than individual provider-level CQMs and will be respecified to include individual provider reporting, and NQF 1419 was endorsed at the individual provider level but only for primary care physicians and will be respecified to include dental providers. Both will undergo additional testing, and the results for each CQM will be submitted to NQF to determine whether the respecification warrants a new NQF number. However, the intent of each of these CQMs will remain the same as proposed.

The CQMs finalized in the recommended core sets are included in Table 7 and are denoted with a "*" for adult populations (9 CQMs) and "**" for pediatric populations (9 CQMs). We believe this approach supports the NQS and provides flexibility for specialists whose scope of practice may not be adequately represented in the proposed core CQM set. Controlling blood pressure has been and continues to be a high priority goal in many national health initiatives, including the Million Hearts campaign. Therefore, we emphasize the importance of reporting NQF #0018 as a primary recommended core CQM. We will monitor reporting on NQF #0018 and consider ways to increase its reporting. This may include, through future rulemaking, requiring EPs in relevant specialties such as primary care and cardiovascular care to report this CQM. We note that the designation of being recommended for the adult population or pediatric population does not limit an EP from reporting the CQM only for those populations as long as

the patients still fit the criteria to be included in the measure (for example, the CQM numbered "TBD - Closing the referral loop: receipt of specialist report" is designated as a recommended core CQM for adult populations, but it can apply to pediatric populations as well).

TABLE 8: CQMs FINALIZED FOR MEDICARE AND MEDICAID EPs BEGINNING WITH CY 2014

CQM Number	CQM Title & Description	Measure Steward & Contact Information	Other Quality Measure Programs that use the Same CQM***	New CQM	Domain
NQF 0002 **	Title: Appropriate Testing for Children with Pharyngitis Description: Percentage of children 2-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.	National Committee for Quality Assurance (NCQA) Contact information: www.ncqa.org	EHR PQRS, CHIPRA		Efficient Use of Healthcare Resources
NQF 0004	Title: Initiation and Engagement of Alcohol and Other Drug Dependence Treatment Description: Percentage of patients 13 years of age and older with a new episode of alcohol and other drug (AOD) dependence who received the following. Two rates are reported. a. Percentage of patients who initiated treatment within 14 days of the diagnosis. b. Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.	NCQA Contact Information: www.ncqa.org	EHR PQRS, HEDIS, state use, ACA 2701, NCQA-PCMH Recognition		Clinical Process/ Effectiveness
NQF 0018 *	Title: Controlling High Blood Pressure Description: Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90mmHg) during the measurement =period.	NCQA Contact Information: www.ncqa.org	EHR PQRS, ACO, Group Reporting PQRS, UDS		Clinical Process/ Effectiveness
NQF 0022 *	Title: Use of High-Risk Medications in the Elderly Description: Percentage of patients 66 years of age and older who were ordered high-risk medications. Two rates are reported. a. Percentage of patients who were ordered at least one high-risk medication. b. Percentage of patients who were ordered at least two different high-risk medications.	NCQA Contact Information: www.ncqa.org	PQRS	New	Patient Safety

CQM Number	CQM Title & Description	Measure Steward & Contact Information	Other Quality Measure Programs that use the Same CQM***	New CQM	Domain
NQF 0024 **	Title: Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents Description: Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported. • Percentage of patients with height, weight, and body mass index (BMI) percentile documentation • Percentage of patients with counseling for nutrition • Percentage of patients with counseling for physical activity	NCQA Contact information: www.ncqa.org	EHR PQRS, UDS		Population/ Public Health
NQF 0028 *	Title: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention Description: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI Contact Information: cpe@ama-assn.org	EHR PQRS, ACO, Group Reporting PQRS, UDS		Population/ Public Health
NQF 0031	Title: Breast Cancer Screening Description: Percentage of women 40-69 years of age who had a mammogram to screen for breast cancer.	NCQA Contact Information: www.ncqa.org	EHR PQRS, ACO, Group Reporting PQRS, ACA 2701, HEDIS, state use, NCQA-PCMH Recognition		Clinical Process/ Effectiveness
NQF 0032	Title: Cervical Cancer Screening Description: Percentage of women 21-64 years of age, who received one or more Pap tests to screen for cervical cancer.	NCQA Contact Information: www.ncqa.org	EHR PQRS, ACA 2701, HEDIS, state use, NCQA-PCMH Recognition, UDS		Clinical Process/ Effectiveness
NQF 0033 **	Title: Chlamydia Screening for Women Description: Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	NCQA Contact Information: www.ncqa.org	EHR PQRS, CHIPRA, ACA 2701, HEDIS, state use, NCQA-PCMH Recognition		Population/ Public Health

CQM Number	CQM Title & Description	Measure Steward & Contact Information	Other Quality Measure Programs that use the Same CQM***	New CQM	Domain
NQF 0034	Title: Colorectal Cancer Screening Description: Percentage of adults 50-75 years of age who had appropriate screening for colorectal cancer.	NCQA Contact Information: www.ncqa.org	EHR PQRS, ACO, Group Reporting PQRS, NCQA-PCMH Recognition		Clinical Process/ Effectiveness
NQF 0036 **	Title: Use of Appropriate Medications for Asthma Description: Percentage of patients 5-64 years of age who were identified as having persistent asthma and were appropriately prescribed medication during the measurement period.	NCQA Contact Information: www.ncqa.org	EHR PQRS		Clinical Process/ Effectiveness
NQF 0038 **	Title: Childhood Immunization Status Description: Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); three H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.	NCQA Contact Information: www.ncqa.org	EHR PQRS, UDS		Population/ Public Health
NQF 0041	Title: Preventative Care and Screening: Influenza Immunization Description: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	AMA-PCPI Contact Information: cpe@ama-assn.org	EHR PQRS, ACO, Group Reporting PQRS		Population/ Public Health
NQF 0043	Title: Pneumonia Vaccination Status for Older Adults Description: Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	NCQA Contact Information: www.ncqa.org	EHR PQRS, ACO, Group Reporting PQRS, NCQA-PCMH Recognition		Clinical Process/ Effectiveness
NQF 0052 *	Title: Use of Imaging Studies for Low Back Pain Description: Percentage of patients 18-50 years of age with a diagnosis of low back pain who did not have an imaging study (plain X-ray, MRI, CT scan) within 28 days of the diagnosis.	NCQA Contact Information: www.ncqa.org	EHR PQRS		Efficient Use of Healthcare Resources
NQF 0055	Title: Diabetes: Eye Exam Description: Percentage of patients 18-75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal exam (no evidence of retinopathy) in the 12 months prior to the measurement period	NCQA Contact Information: www.ncqa.org	EHR PQRS, Group Reporting PQRS		Clinical Process/ Effectiveness

CQM Number	CQM Title & Description	Measure Steward & Contact Information	Other Quality Measure Programs that use the Same CQM***	New CQM	Domain
NQF 0056	Title: Diabetes: Foot Exam Description: Percentage of patients aged 18-75 years of age with diabetes who had a foot exam during the measurement period.	NCQA Contact Information: www.ncqa.org	EHR PQRS, Group Reporting PQRS		Clinical Process/ Effectiveness
NQF 0059	Title: Diabetes: Hemoglobin A1c Poor Control Description: Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	NCQA Contact Information: www.ncqa.org	EHR PQRS, ACO, Group Reporting PQRS, UDS		Clinical Process/ Effectiveness
NQF 0060	Title: Hemoglobin A1c Test for Pediatric Patients Description: Percentage of patients 5-17 years of age with diabetes with an HbA1c test during the measurement period	NCQA Contact Information: www.ncqa.org		New	Clinical Process/ Effectiveness
NQF 0062	Title: Diabetes: Urine Protein Screening Description: The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	NCQA Contact Information: www.ncqa.org	EHR PQRS, Group Reporting PQRS		Clinical Process/ Effectiveness
NQF 0064	Title: Diabetes: Low Density Lipoprotein (LDL) Management Description: Percentage of patients 18-75 years of age with diabetes whose LDL-C was adequately controlled (< 100 mg/dL) during the measurement period.	NCQA Contact Information: www.ncqa.org	PQRS, Group Reporting PQRS		Clinical Process/ Effectiveness
NQF 0068	Title: Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic Description: Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had documentation of use of aspirin or another antithrombotic during the measurement period.	NCQA Contact Information: www.ncqa.org	EHR PQRS, ACO, Group Reporting PQRS		Clinical Process/ Effectiveness
NQF 0069 **	Title: Appropriate Treatment for Children with Upper Respiratory Infection (URI) Description: Percentage of children 3 months-18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or three days after the episode.	NCQA Contact Information: www.ncqa.org	PQRS, NCQA-PCMH Recognition	New	Efficient Use of Healthcare Resources

CQM Number	CQM Title & Description	Measure Steward & Contact Information	Other Quality Measure Programs that use the Same CQM***	New CQM	Domain
NQF 0070	Title: Coronary Artery Disease (CAD): Beta-Blocker Therapy− Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%) Description: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have a prior MI or a current or prior LVEF <40% who were prescribed beta-blocker therapy	AMA-PCPI Contact Information: cpe@ama-assn.org	EHR PQRS, NCQA-PCMH Recognition		Clinical Process/ Effectiveness
NQF 0075	Title: Ischemic Vascular Disease (IVD): Complete Lipid Panel and LDL Control Description: Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had a complete lipid profile performed during the measurement period and whose LDL-C was adequately controlled (<100 mg/dL).	NCQA Contact Information: www.ncqa.org	EHR PQRS, ACO, Group Reporting PQRS		Clinical Process/ Effectiveness
NQF 0081	Title: Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD) Description: Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge	AMA-PCPI Contact Information: cpe@ama-assn.org	EHR PQRS, Group Reporting PQRS, NCQA-PCMH Recognition		Clinical Process/ Effectiveness
NQF 0083	Title: Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) Description: Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge	AMA-PCPI Contact Information: cpe@ama-assn.org	EHR PQRS, ACO, Group Reporting PQRS		Clinical Process/ Effectiveness

CQM Number	CQM Title & Description	Measure Steward & Contact Information	Other Quality Measure Programs that use the Same CQM***	New CQM	Domain
NQF 0086	Title: Primary Open Angle Glaucoma (POAG): Optic Nerve Evaluation Description: Percentage of patients aged 18 years and older with a diagnosis of POAG who have an optic nerve head evaluation during one or more office visits within 12 months	AMA-PCPI Contact Information: cpe@ama-assn.org	EHR PQRS		Clinical Process/ Effectiveness
NQF 0088	Title: Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy Description: Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed which included documentation of the level of severity of retinopathy and the presence or absence of macular edema during one or more office visits within 12 months	AMA-PCPI Contact Information: cpe@ama-assn.org	EHR PQRS		Clinical Process/ Effectiveness
NQF 0089	Title: Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care Description: Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months	AMA-PCPI Contact Information: cpe@ama-assn.org	EHR PQRS		Clinical Process/ Effectiveness
NQF 0101	Title: Falls: Screening for Future Fall Risk Description: Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	AMA-PCPI Contact Information: cpe@ama-assn.org; NCQA Contact Information: www.ncqa.org	PQRS, ACO, Group Reporting PQRS	New	Patient Safety
NQF 0104	Title: Major Depressive Disorder (MDD): Suicide Risk Assessment Description: Percentage of patients aged 18 years and older with a new diagnosis or recurrent episode of MDD who had a suicide risk assessment completed at each visit during the measurement period.	AMA-PCPI Contact Information: cpe@ama-assn.org	PQRS	New	Clinical Process/ Effectiveness

CQM Number	CQM Title & Description	Measure Steward & Contact Information	Other Quality Measure Programs that use the Same CQM***	New CQM	Domain
NQF 0105	Title: Anti-depressant Medication Management Description: Percentage of patients 18 years of age and older who were diagnosed with major depression and treated with antidepressant medication, and who remained on antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	NCQA Contact Information: www.ncqa.org	EHR PQRS, HEDIS, state use, ACA 2701		Clinical Process/ Effectiveness
NQF 0108 **	Title: ADHD: Follow-Up Care for Children Prescribed Attention-Deficit/Hyperactivity Disorder (ADHD) Medication Description: Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a. Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b. Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	NCQA Contact Information: www.ncqa.org		New	Clinical Process/ Effectiveness
NQF 0110	Title: Bipolar Disorder and Major Depression: Appraisal for alcohol or chemical substance use Description: Percentage of patients with depression or bipolar disorder with evidence of an initial assessment that includes an appraisal for alcohol or chemical substance use.	Center for Quality Assessment and Improvement in Mental Health (CQAIMH) Contact Information: www.cqaimh.org; cqaimh@cqaimh.org	NCQA-PCMH Recognition	New	Clinical Process/ Effectiveness
NQF 0384	Title: Oncology: Medical and Radiation – Pain Intensity Quantified Description: Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified	AMA-PCPI Contact Information: cpe@ama-assn.org	PQRS	New	Patient and Family Engagement

CQM Number	CQM Title & Description	Measure Steward & Contact Information	Other Quality Measure Programs that use the Same CQM***	New CQM	Domain
NQF 0385	Title: Colon Cancer: Chemotherapy for AJCC Stage III Colon Cancer Patients Description: Percentage of patients aged 18 through 80 years with Stage III colon cancer who are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy, or have previously received adjuvant chemotherapy within the 12-month reporting period	AMA-PCPI Contact Information: cpe@ama-assn.org; American Society of Clinical Oncology (ASCO): www.asco.org; National Comprehensive Cancer Network (NCCN): www.nccn.org	EHR PQRS		Clinical Process/ Effectiveness
NQF 0387	Title: Breast Cancer: Hormonal Therapy for Stage IC-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer Description: Percentage of female patients aged 18 years and older with Stage IC through IIIC, ER or PR positive breast cancer who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12-month reporting period	AMA-PCPI Contact Information: cpe@ama-assn.org; ASCO: www.asco.org; NCCN: www.nccn.org	EHR PQRS		Clinical Process/ Effectiveness
NQF 0389	Title: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients Description: Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer	AMA-PCPI Contact Information: cpe@ama-assn.org	EHR PQRS		Efficient Use of Healthcare Resources
NQF 0403	Title: HIV/AIDS: Medical Visit Description: Percentage of patients, regardless of age, with a diagnosis of HIV/AIDS with at least two medical visits during the measurement year with a minimum of 60 days between each visit	AMA-PCPI Contact Information: cpe@ama-assn.org; NCQA Contact Information: www.ncqa.org		New	Clinical Process/ Effectiveness

CQM Number	CQM Title & Description	Measure Steward & Contact Information	Other Quality Measure Programs that use the Same CQM***	New CQM	Domain
NQF 0405	Title: HIV/AIDS: Pneumocystis jiroveci pneumonia (PCP) Prophylaxis Description: Percentage of patients aged 6 weeks and older with a diagnosis of HIV/AIDS who were prescribed Pneumocystis jiroveci pneumonia (PCP) prophylaxis	AMA-PCPI Contact Information: cpe@ama-assn.org; NCQA Contact Information: www.ncqa.org	PQRS, NCQA-PCMH Recognition	New	Clinical Process/ Effectiveness
TBD (proposed as NQF 0407)	Title: HIV/AIDS: RNA control for Patients with HIV Description: Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS, with at least two visits during the measurement year, with at least 60 days between each visit, whose most recent HIV RNA level is <200 copies/mL.	NCQA Contact Information: www.ncqa.org	PQRS	New	Clinical Process/ Effectiveness
NQF 0418 * **	Title: Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan Description: Percentage of patients aged 12 years and older screened for clinical depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare and Medicaid Services (CMS) 1-888-734-6433 or http://questions.cms.hhs.gov/app/ask/p/21,26,1139; Quality Insights of Pennsylvania (QIP) Contact Information: www.usqualitymeasures.org	EHR PQRS, ACO, Group Reporting PQRS	New	Population/ Public Health
NQF 0419 *	Title: Documentation of Current Medications in the Medical Record Description: Percentage of specified visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications to the best of his/her knowledge and ability. This list ***must*** include ALL prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND ***must*** contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare and Medicaid Services (CMS) 1-888-734-6433 or http://questions.cms.hhs.gov/app/ask/p/21,26,1139; QIP Contact Information: www.usqualitymeasures.org	PQRS, EHR PQRS	New	Patient Safety

CQM Number	CQM Title & Description	Measure Steward & Contact Information	Other Quality Measure Programs that use the Same CQM***	New CQM	Domain
NQF 0421 *	Title: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Description: Percentage of patients aged 18 years and older with a calculated BMI in the past six months or during the current reporting period documented in the medical record AND if the most recent BMI is outside of normal parameters, a follow-up plan is documented within the past six months or during the current reporting period. Normal Parameters: Age 65 years and older BMI ≥ 23 and < 30 Age 18-64 years BMI ≥ 18.5 and < 25	Centers for Medicare and Medicaid Services (CMS) 1-888-734-6433 or http://questions.cms.hhs.gov/app/ask/p/21,26,1139; QIP Contact Information: www.usqualitymeasures.org	EHR PQRS, ACO, Group Reporting PQRS, UDS		Population/ Public Health
NQF 0564	Title: Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures Description: Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified list of surgical procedures in the 30 days following cataract surgery which would indicate the occurrence of any of the following major complications: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence.	AMA-PCPI Contact Information: cpe@ama-assn.org; NCQA Contact Information: www.ncqa.org	PQRS	New	Patient Safety
NQF 0565	Title: Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery Description: Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved within 90 days following the cataract surgery.	AMA-PCPI Contact Information: cpe@ama-assn.org; NCQA Contact Information: www.ncqa.org	PQRS	New	Clinical Process/ Effectiveness
NQF 0608	Title: Pregnant women that had HBsAg testing Description: This measure identifies pregnant women who had a HBsAg (hepatitis B) test during their pregnancy.	Ingenix Contact Information: www.ingenix.com		New	Clinical Process/ Effectiveness

CQM Number	CQM Title & Description	Measure Steward & Contact Information	Other Quality Measure Programs that use the Same CQM***	New CQM	Domain
NQF 0710	Title: Depression Remission at Twelve Months Description: Adult patients age 18 and older with major depression or dysthymia and an initial PHQ-9 score > 9 who demonstrate remission at twelve months defined as PHQ-9 score less than 5. This measure applies to both patients with newly diagnosed and existing depression whose current PHQ-9 score indicates a need for treatment.	Minnesota Community Measurement (MNCM) Contact Information: www.mncm.org; info@mncm.org		New	Clinical Process/ Effectiveness
NQF 0712	Title: Depression Utilization of the PHQ-9 Tool Description: Adult patients age 18 and older with the diagnosis of major depression or dysthymia who have a PHQ-9 tool administered at least once during a 4 month period in which there was a qualifying visit.	MNCM Contact Information: www.mncm.org; info@mncm.org		New	Clinical Process/ Effectiveness
TBD **	Title: Children who have dental decay or cavities Description: Percentage of children ages 0-20, who have had tooth decay or cavities during the measurement period.	Maternal and Child Health Bureau, Health Resources and Services Administration http://mchb.hrsa.gov/		New	Clinical Process/ Effectiveness
NQF 1365	Title: Child and Adolescent Major Depressive Disorder: Suicide Risk Assessment Description: Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	AMA-PCPI Contact Information: cpe@ama-assn.org		New	Patient Safety
NQF 1401	Title: Maternal depression screening Description: The percentage of children who turned 6 months of age during the measurement year, who had a face-to-face visit between the clinician and the child during child's first 6 months, and who had a maternal depression screening for the mother at least once between 0 and 6 months of life.	NCQA Contact Information: www.ncqa.org		New	Population/ Public Health
TBD	Title: Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists Description: Percentage of children, age 0-20 years, who received a fluoride varnish application during the measurement period.	University of Minnesota Contact Information: www.umn.edu		New	Clinical Process/ Effectiveness

CQM Number	CQM Title & Description	Measure Steward & Contact Information	Other Quality Measure Programs that use the Same CQM***	New CQM	Domain
TBD	Title: Preventive Care and Screening: Cholesterol – Fasting Low Density Lipoprotein (LDL-C) Test Performed Description: Percentage of patients aged 20 through 79 years whose risk factors have been assessed and a fasting LDL-C test has been performed.	CMS 1-888-734-6433 or http://questions.cms.hhs.gov/app/ask/p/21,26,1139; QIP Contact Information: www.usqualitymeasures.org	EHR PQRS	New	Clinical Process/ Effectiveness
TBD	Title: Preventive Care and Screening: Risk-Stratified Cholesterol – Fasting Low Density Lipoprotein (LDL-C) Description: Percentage of patients aged 20 through 79 years who had a fasting LDL-C test performed and whose risk-stratified fasting LDL-C is at or below the recommended LDL-C goal.	CMS 1-888-734-6433 or http://questions.cms.hhs.gov/app/ask/p/21,26,1139; QIP Contact Information: www.usqualitymeasures.org	EHR PQRS	New	Clinical Process/ Effectiveness
TBD	Title: Dementia: Cognitive Assessment Description: Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12 month period.	AMA-PCPI Contact Information: cpe@ama-assn.org	PQRS	New	Clinical Process/ Effectiveness
TBD	Title: Hypertension: Improvement in blood pressure Description: Percentage of patients aged 18-85 years of age with a diagnosis of hypertension whose blood pressure improved during the measurement period.	CMS 1-888-734-6433 or http://questions.cms.hhs.gov/app/ask/p/21,26,1139		New	Clinical Process/ Effectiveness
TBD *	Title: Closing the referral loop: receipt of specialist report Description: Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	CMS 1-888-734-6433 or http://questions.cms.hhs.gov/app/ask/p/21,26,1139		New	Care Coordination

CQM Number	CQM Title & Description	Measure Steward & Contact Information	Other Quality Measure Programs that use the Same CQM***	New CQM	Domain
TBD	Title: Functional status assessment for knee replacement Description: Percentage of patients aged 18 years and older with primary total knee arthroplasty (TKA) who completed baseline and follow-up (patient-reported) functional status assessments.	CMS 1-888-734-6433 or http://questions.cms.hhs.gov/app/ask/p/21,26,1139		New	Patient and Family Engagement
TBD	Title: Functional status assessment for hip replacement Description: Percentage of patients aged 18 years and older with primary total hip arthroplasty (THA) who completed baseline and follow-up (patient-reported) functional status assessments.	CMS 1-888-734-6433 or http://questions.cms.hhs.gov/app/ask/p/21,26,1139		New	Patient and Family Engagement
TBD *	Title: Functional status assessment for complex chronic conditions Description: Percentage of patients aged 65 years and older with heart failure who completed initial and follow-up patient-reported functional status assessments	CMS 1-888-734-6433 or http://questions.cms.hhs.gov/app/ask/p/21,26,1139		New	Patient and Family Engagement
TBD	Title: ADE Prevention and Monitoring: Warfarin Time in Therapeutic Range. Description: Average percentage of time in which individuals with atrial fibrillation who are on chronic anticoagulation have International Normalized Ratio (INR) test results within the therapeutic range during the measurement period.	CMS 1-888-734-6433 or http://questions.cms.hhs.gov/app/ask/p/21,26,1139		New	Patient Safety
TBD	Title: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented Description: Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated	CMS 1-888-734-6433 or http://questions.cms.hhs.gov/app/ask/p/21,26,1139; QIP Contact Information: www.usqualitymeasures.org	PQRS, EHR PQRS, Group Reporting PQRS, ACO	New	Population/ Public Health

* Recommended Adult Core CQMs for EPs
** Recommended Pediatric Core CQMs for EPs
***PQRS = Physician Quality Reporting System
EHR PQRS = Physician Quality Reporting System's Electronic Health Record Reporting Option
CHIPRA = Children's Health Insurance Program Reauthorization Act
HEDIS = Healthcare Effectiveness Data and Information Set
ACA 2701 = Affordable Care Act section 2701
NCQA-PCMH = National Committee for Quality Assurance – Patient Centered Medical Home
Group Reporting PQRS = Physician Quality Reporting System's Group Reporting Option
UDS = Uniform Data System (Health Resources Services Administration)

ACO = Accountable Care Organization (Medicare Shared Savings Program)

6. Reporting Methods for CQMs for EPs

(a) Reporting Methods for Medicaid EPs

For Medicaid EPs, we stated in the proposed rule that states are, and will continue in Stage 2 to be, responsible for determining whether and how electronic reporting 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 stated that we anticipate that whatever means states have deployed for capturing Stage 1 CQMs electronically would be similar for reporting in CY 2013. However, we note that subject to our prior approval, this is within the states' purview. Beginning in CY 2014, we proposed that the states would establish the method and requirements, subject to CMS prior approval, for the electronic capture and reporting of CQMs from CEHRT.

Comment: Commenters suggested unified Medicaid CQM reporting to reduce the burden on EPs operating in multiple states.

Response: For the purposes of the Medicaid EHR Incentive Program, EPs report CQMs to the state making the EHR incentive payment. However, data from all practice locations that are equipped with CEHRT will be used for reporting CQMs, even if the practice locations are in different states.

After consideration of the public comments received, we are finalizing the policies for electronic reporting of CQMs for Medicaid EPs as proposed. As part of certification for EHR technology, ONC is including testing for data capture, CQM calculation, and electronic submission. For CQMs, this includes certification criteria for the QRDA Category I (QRDA-I) and QRDA Category III (QRDA-III) transmission formats. We expect the states that have

electronic reporting options for CQMs might choose to adopt QRDA-I for patient-level data and/or QRDA-III for aggregate data as the form in which EPs would report CQM data. By adopting the same QRDA-I and/or QRDA-III that CMS is requiring for CQM reporting, the states would be able to leverage the development of the specifications by CMS and the industry as well as the testing done by ONC for certification of EHR technology. This would reduce the burden on EHR vendors to implement and test different specifications.

(b) Reporting Methods for Medicare EPs in CY 2013

In the Stage 2 proposed rule, we did not propose any reporting methods for Medicare EPs in 2013. However, in the CY 2013 Medicare PFS proposed rule (77 FR 44988), we proposed that EPs may continue to report by attestation CQM results as calculated by CEHRT, as they did for 2011 and 2012. For further explanation of reporting CQMs by attestation, please see the Stage 1 final rule (75 FR 44430 through 44434). We also proposed in the CY 2013 Medicare PFS proposed rule (77 FR 44988) to continue the voluntary electronic reporting pilot for CQMs (the PQRS – Medicare EHR Incentive Pilot) for 2013, which we had previously established for 2012. We expect to finalize in the CY 2013 Medicare PFS final rule the reporting methods that would apply in 2013 for EPs participating in the Medicare EHR Incentive Program.

(c) Reporting Methods for Medicare EPs Beginning with CY 2014

Under section 1848(o)(2)(A)(iii) of the Act, EPs must submit information on the CQMs selected by the Secretary "in a form and manner specified by the Secretary" as part of demonstrating meaningful use of CEHRT. We proposed that Medicare EPs who are in their first year of Stage 1 may report CQMs through attestation for a continuous 90-day EHR reporting period. We proposed that Medicare EPs who choose Option 1 for reporting CQMs would submit through an aggregate reporting method, which would require the EP to log into a

CMS-designated portal and submit through an upload process data produced as output from their CEHRT in an XML-based format specified by CMS. We proposed that Medicare EPs who choose to report CQMs as described in Option 2 would submit in accordance with the requirements of the PQRS program.

Comment: We received several comments on the proposal to use an XML-based format for transmitting aggregate results. Those commenters were generally in favor of using an aggregate XML and that the technical structure aligns with the PQRS registry reporting option. One commenter noted that the aggregate-level standard QRDA-III is not currently mature. Some commenters indicated a preference that the aggregate reporting method should only require submission of one data file instead of multiple files, citing that submitting multiple files is onerous and may not be manageable due to the number of files EPs would need to upload.

Response: We acknowledge that there is currently no consensus standard for the electronic transmission of aggregate results of CQMs. However, the 2014 Edition certification criteria adopt the QRDA-III specification. As a result, we expect to be able to receive data submitted using the QRDA-III specification.

We proposed to consider an "interim submission" option for Medicare EPs who are in their first year of Stage 1 and who participate in PQRS. Under this option, EPs would submit the PQRS CQM data for a continuous 90-day EHR reporting period, and the data must be received no later than October 1 to meet the requirements of the EHR Incentive Program. We proposed that the EP would report the remainder of his/her CQM data by the deadline specified for PQRS in order to meet the requirements of the PQRS program. We solicited public comment on this potential option.

Comment: Many commenters indicated the proposed interim submission option for

Medicare EPs in their first year of Stage 1 is unclear and would involve a prohibitive amount of effort. The commenters also suggested removing this option. Other commenters supported the interim submission option.

Response: This option was intended to accommodate Medicare EPs who are demonstrating meaningful use for the first time in 2014 and want to choose Option 2 (the PQRS EHR reporting option) for reporting CQMs. As proposed, however, it would require two submissions. We agree with the commenters that the "interim submission option" is complex and potentially burdensome. We are not finalizing the interim submission option.

After consideration of the public comments received, we are finalizing the following reporting methods for Medicare EPs beginning in CY 2014:

- Option 1: Aggregate reporting through a CMS-designated electronic transmission method using CEHRT.

The format required for aggregate reporting will be the QRDA-III, which is an XML-based format. The electronic transmission method for aggregate reporting differs from reporting via attestation in that the QRDA-III report would be generated by the EPs CEHRT and transmitted electronically rather than the aggregate results manually input into the Registration and Attestation system. EPs who are in their first year of Stage 1 must report CQMs under Option 1 through attestation (please refer to the Stage 1 final rule for an explanation of reporting CQMs through attestation (75 FR 44430 through 44434)). Consistent with section 1848(o)(2)(B)(ii) of the Act, in the unlikely event that the Secretary does not have the capacity to receive CQM data electronically, EPs who are beyond the first year of Stage 1 may continue to report aggregate CQM results through attestation.

- Option 2: Patient-level reporting via PQRS through the transmission methods

established for the PQRS EHR-based reporting mechanisms and using CEHRT.

Please refer to 42 CFR 414.90 and the CY 2013 Medicare PFS proposed rule (77 FR 44988) for more information on the PQRS.

(d) Group Reporting Option for Medicare and Medicaid EPs Beginning with CY 2014

For Stage 1, EPs were required to report the CQMs on an individual basis and did not have an option to report the CQMs as part of a group practice. Under section 1848(o)(2)(A) of the Act, the Secretary may provide for the use of alternative means for EPs furnishing covered professional services in a group practice (as defined by the Secretary) to meet the requirements of meaningful use. Beginning with CY 2014, we proposed three group reporting options to allow EPs within a single group practice to report CQM data on a group level. We proposed that all three methods would be available for Medicare EPs, while only the first one would be possible for Medicaid EPs, at states' discretion.

We proposed each of these options as an alternative to reporting CQM data as an individual EP under the proposed options and reporting methods discussed earlier in this rule. These group reporting options would only be available for reporting CQMs for purposes of the EHR Incentive Program and only if all EPs in the group are beyond the first year of Stage 1. EPs would not be able to use these group reporting options for any of the other meaningful use objectives and associated measures in the EHR Incentive Programs.

The three group reporting options that we proposed for EPs are as follows:

- Two or more EPs, each identified with a unique NPI associated with a group practice identified under one tax identification number (TIN) may be considered an EHR Incentive Group for the purposes of reporting CQMs for the Medicare EHR Incentive Program. This group reporting option would only be available for electronic reporting of CQMs and would not be

available for those EPs in their first year of Stage 1. The CQMs reported under this option would represent all EPs within the group. EPs who choose this group reporting option for CQMs would have to individually satisfy the objectives and associated measures for their respective stage of meaningful use. We proposed that states may also choose this option to accept group reporting for CQMs, based upon a predetermined definition of a "group practice," such as sharing one TIN.

- Medicare EPs participating in the Medicare SSP and the testing of the Pioneer ACO model who use CEHRT to submit ACO measures in accordance with the requirements of the Medicare SSP would be considered to have satisfied their CQM reporting requirement as a group for the Medicare EHR Incentive Program. The Medicare SSP does not require the use of CEHRT. However, all CQM data would have to be extracted from CEHRT in order for the EP to qualify for the Medicare EHR Incentive Program if an EP intends to use this group reporting option. EPs would have to individually satisfy the objectives and associated measures for their respective stage of meaningful use, in addition to submitting CQMs as part of an ACO. EPs who are part of an ACO but do not enter the data used for reporting the CQMs (which excludes the survey tool or claims-based measures that are collected to calculate the quality performance score in the Medicare SSP) into CEHRT would not be able to meet meaningful use requirements. For more information about the requirements of the Medicare SSP, see 42 CFR 425 and the November 2, 2011 final rule (76 FR 67802). EPs who use this group reporting option for the Medicare EHR Incentive Program would be required to comply with any changes to the Medicare SSP that may apply in the future. EPs would be required to be part of a group practice (that is, two or more EPs, each identified with a unique NPI associated with a group practice identified under one TIN) to be able to use this group reporting option.

- Medicare EPs who satisfactorily report PQRS CQMs using CEHRT under the PQRS Group Practice Reporting Option (GPRO), would be considered to have satisfied their CQM reporting requirement as a group for the Medicare EHR Incentive Program. For more information about the PQRS GPRO, see 42 CFR 414.90 and the CY 2012 Medicare PFS final rule (76 FR 73314) and CY 2013 Medicare PFS proposed rule (77 FR 44805 through 44807). EPs who use this group reporting option for the Medicare EHR Incentive Program would be required to comply with any changes to the PQRS GPRO that may apply in the future and would have to individually satisfy the objectives and associated measures for their respective stage of meaningful use.

Comment: We received numerous comments on the proposed group reporting options. Generally, most commenters supported including group reporting. Many commenters indicated group reporting options are consistent with the intent of many of the measures and would promote a more patient focused healthcare experience. A commenter requested clarification regarding whether group reporting was confined to CQMs or other objectives in meaningful use as well. Other commenters requested more detail on how new EPs or EPs leaving group practices might affect reporting and validation. Commenters indicated the requirement that only EPs beyond Stage 1 be able to use this option be eliminated because new providers join practices frequently. A commenter requested that new members of a practice be able to report at the same level that the group is currently reporting. Many commenters requested greater specificity in the final rule and clarification whether all EPs under the same TIN need to submit as a group, or if some can submit as a group and others individually. A commenter recommended that not all EPs under the same TIN should have to have access to CEHRT at all group practice locations. Other commenters stated that the proposed option for group reporting is complex and suggested

the files submitted contain only data related to providers within the group or practice that have met the measures. A commenter indicated that the addition of multiple reporting options has made it exceedingly difficult for providers already presented with multiple reporting options across state and federal programs.

Response: We agree with commenters as to the benefits of reporting and measurement at the group level. We believe it can lessen the complexity and burden of reporting and also promote a greater patient focus. Group level reporting can avoid the need for multiple professionals in the same practice to report the same information on single patient that they may each treat. It can promote team work and the recognition that quality care often depends on interplay of multiple professionals rather that solely on a particular individual professional. Therefore, we agree that we should include the option of group reporting of CQMs for the EHR Incentive Program.

With respect to applicability to measures other than CQMs, as proposed the group reporting options in section II.B.6.d. of the proposed rule (77 FR 13758) would apply only to CQM reporting and not to other meaningful use objectives and associated measures. EPs reporting CQMs under a group reporting option must still attest to the meaningful use objectives and associated measures individually or through the batch reporting process we are finalizing in section II.C.1.c of this final rule to successfully demonstrate meaningful use.

As for the three options for group reporting we proposed, we agree with the potential for complexity of group reporting under which different individuals within a group would be treated differently, such as the proposed requirement that all EPs in the group must be beyond their first year of meaningful use. We believe that this would be complex and difficult to operationalize, so we are not finalizing this requirement. We note that for the group reporting option under

PQRS and for professionals participating in the Medicare SSP and the testing of the Pioneer ACO model, all individuals within a group are treated as being part of the group for the purposes of quality reporting.

As a result, for the Medicare EHR Incentive Program, we are finalizing the following two group reporting options for the purposes of CQM reporting:

- Medicare EPs participating in the Medicare SSP and the testing of the Pioneer ACO model who use CEHRT to submit ACO CQMs in accordance with the requirements of the Medicare SSP would be considered to have satisfied their CQM reporting requirement as a group for the Medicare EHR Incentive Program.

- Medicare EPs who satisfactorily report PQRS CQMs using CEHRT under the PQRS GPRO would be considered to have satisfied their CQM reporting requirement as a group for the Medicare EHR Incentive Program. Under the CY 2013 Medicare PFS proposed rule, additional group reporting options are proposed. We note that the proposed claims and registry options for GPRO, which do not involve the use of CEHRT, would not satisfy the CQM reporting requirement for the EHR Incentive Program. However, the options for GPRO involving the use of CEHRT, which include submissions from CEHRT directly to CMS or through a data intermediary to CMS, could satisfy the CQM reporting requirement for the EHR Incentive Program. Under the PQRS GPRO, CQM submission is at the group level, not at the level of any individual EP that is part of the group. Each individual EP who is a member of the group would meet the CQM reporting requirement for the EHR Incentive Program if the group meets the requirements for PQRS, with the exception of the EPs in the group who are in their first year of demonstrating meaningful use as noted later in this section.

We do not finalize any additional requirements beyond those of the programs themselves

for group reporting, with the exception that the group must use CEHRT in connection with submitting CQMs. Although a group may include EPs that are demonstrating meaningful use for the first time, we emphasize that these EPs cannot use either of these group reporting options for reporting CQMs for the EHR Incentive Program. CQM data collected by EPs that are part of a group and are in their first year of demonstrating meaningful use could still be part of the group's collective data submission. However, for purposes of avoiding a payment adjustment, EPs who are in their first year of demonstrating meaningful use in the year immediately preceding a payment adjustment year must individually submit their CQM data by attestation no later than October 1 of such preceding year. We encourage EPs who would like to use the group reporting options beginning in 2014 to become meaningful EHR users in 2013. Please see section II.D.2. of this final rule for more details on payment adjustments.

For the Medicaid EHR Incentive Program, the states will have the option to allow group reporting of CQMs through an update to their State Medicaid HIT plan, which must describe how they would address the issue of EPs who switch group practices during an EHR reporting period.

7. CQMs for Eligible Hospitals and Critical Access Hospitals

(a) Statutory and Other Considerations

Sections 1886(n)(3)(A)(iii) and 1903(t)(6)(C) of the Act provide for the reporting of CQMs by eligible hospitals and CAHs as part of demonstrating meaningful use of CEHRT. For further explanation of the statutory requirements, we refer readers to the discussion in our Stage 1 proposed and final rules (75 FR 1870 through 1902 and 75 FR 44380 through 44435, respectively).

Section 1886(n)(3)(B)(i)(I) of the Act requires the Secretary to give preference to CQMs that have been selected for the purpose of applying section 1886(b)(3)(B)(viii) of the Act (that is, measures that have been selected for the Hospital Inpatient Quality Reporting (IQR) Program) or that have been endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act (namely, the NQF). We proposed CQMs for eligible hospitals and CAHs for 2013, 2014, and 2015 (and potentially subsequent years) that reflect this preference, although we note that the Act does not require the selection of such CQMs for the EHR Incentive Programs. CQMs listed in this final rule that do not have an NQF identifying number are not NQF endorsed.

Under section 1903(t)(8) of the Act, the Secretary must seek, to the maximum extent practicable, to avoid duplicative requirements from federal and state governments for eligible hospitals and CAHs to demonstrate meaningful use of CEHRT under Medicare and Medicaid. Therefore, to meet this requirement, we proposed to continue our practice from Stage 1 of proposed CQMs that would apply for both the Medicare and Medicaid EHR Incentive Programs.

In accordance with CMS and HHS quality goals as well as the HHS National Quality Strategy recommendations, the hospital CQMs that we proposed beginning with FY 2014 can be categorized into the following six domains, which are described in section II.B.3. of this final rule:

- Patient & Family Engagement.
- Patient Safety.
- Care Coordination.
- Population & Public Health.
- Efficient Use of Healthcare Resources.

- Clinical Process/Effectiveness.

The selection of CQMs we proposed for eligible hospitals and CAHs was based on statutory requirements, the HITPC's recommendations, alignment with other CMS and national hospital quality measurement programs such as the Joint Commission, the Medicare Hospital Inpatient Quality Reporting (IQR) Program and Hospital Value-Based Purchasing (HVBP) Program, the National Quality Strategy (NQS), and other considerations discussed in sections II.B.7.b. and II.B.7.c. of the proposed rule.

Section 1886(n)(3)(B)(iii) of the Act requires that in selecting measures for eligible hospitals and CAHs, and in establishing the form and manner of reporting, the Secretary shall seek to avoid redundant or duplicative reporting with reporting otherwise required. In consideration of the importance of alignment with other measure sets that apply to eligible hospitals and CAHs, we analyzed the Hospital IQR Program, hospital CQMs used by state Medicaid agencies, and the Joint Commission's hospital CQMs when selecting the proposed CQMs to be reported under the EHR Incentive Program. Furthermore, as we noted in the proposed rule, we placed emphasis on those CQMs that are in line with the NQS and the HITPC's recommendations.

Comment: Many commenters supported alignment of measure sets and reporting methods with other quality reporting programs and agency goals, such as Hospital IQR Program, HVBP, and NQS. These commenters commended CMS's intentions to reduce duplicative requirements between programs, prevent hospitals from calculating both electronic and paper-based reports for the same CQMs, avoid confusion and move towards a single, aligned quality reporting mechanism. However, several commenters requested that we provide a timeline for these alignment efforts as well as additional clarification regarding

how we intend to pursue and achieve alignment across quality report programs and what this means operationally for eligible hospitals and CAHs. One commenter requested that we also align with the Center for Disease Control and Prevention's (CDC's) National Healthcare Safety Network (NHSN) to make hospital acquired infections (HAI) a national healthcare priority. Other commenters requested that we seek alignment and accuracy in other areas of quality measurement, including electronic specifications, data reporting methodologies, and vendor certification requirements. One commenter also urged that we continuously align electronic specifications for all CQMs across quality reporting programs as measure stewards update and maintain their CQMs.

Response: We appreciate the supportive comments regarding alignment. Our principal goals in alignment of the Hospital IQR, and the Medicare and Medicaid EHR Incentive Programs are to: (1) provide a single set of CQMs for hospital reporting; (2) to the extent possible, avoid duplicate reporting by hospitals by using a single submission for multiple purposes as appropriate; and (3) transition from manual chart abstraction to automated extraction and electronic reporting based on the use of EHR technology.

In the FY 2012 Inpatient Prospective Payment Systems/Long-Term Care Hospital Prospective Payment System (IPPS/LTCH PPS) proposed rule (76 FR 25893), we stated our intention to explore mechanisms for Hospital IQR Program data collection using EHRs, and gave FY 2015 as an example of when hospitals might be able to switch to EHR-based reporting of manually chart-abstracted Hospital IQR measures. The CQMs we are finalizing beginning in 2014 for reporting under the EHR Incentive Program are electronically specified versions of current IQR chart abstracted CQMs. The 2015 target date would allow for at least 1 year of electronic submission of CQMs through the EHR Incentive Program

prior to our targeted date to begin EHR-based reporting for IQR. We must assess any data collection mode differences between EHR-based reporting and chart abstracted measures using a diverse and robust sample of hospitals before proposing in rulemaking to use EHR data collection in the Hospital IQR program. Among other factors, our ability to transition to EHR-based reporting for IQR will depend on whether EHR-based reporting is accurate and reliable. Our goal would be to phase out manual chart abstraction for hospital reporting.

We did not propose the IQR CQMs on HAI for the EHR Incentive Program. Hospitals may electronically submit HAI information to the CDC, although this is not required. Information of electronic submission through the NHSN can be found at http://www.cdc.gov/nhsn/CDA_eSurveillance.html. NHSN data is based on surveillance data rather than chart abstraction. We will consider the NHSN measures for the EHR Incentive Program in future years.

(b) CQMs for Eligible Hospitals and CAHs for FY 2013

For the EHR reporting periods in FY 2013, we proposed to require that eligible hospitals and CAHs submit information on each of the 15 CQMs that were finalized for FYs 2011 and 2012 in the Stage 1 final rule (75 FR 44418 through 44420). We refer readers to the discussion in the Stage 1 final rule for further explanation of the requirements for reporting those CQMs (75 FR 44411 through 44422).

We did not receive any public comments on our proposals, and we are finalizing the CQMs for FY 2013 as proposed.

(c) CQMs for Eligible Hospitals and CAHs Beginning with FY 2014

(i) Reporting Options

We proposed to require eligible hospitals and CAHs to report 24 CQMs from a menu of 49 CQMs beginning with FY 2014, including at least 1 CQM from each of the following 6 domains, which are discussed in section II.B.3. of this final rule:

- Patient and Family Engagement.
- Patient Safety.
- Care Coordination.
- Population and Public Health.
- Efficient Use of Healthcare Resources.
- Clinical Process/Effectiveness.

For the remaining CQMs, we proposed that eligible hospitals and CAHs would select and report CQMs that best apply to their patient mix. We solicited comments on the number of CQMs and the appropriateness of the CQMs and domains for eligible hospitals and CAHs.

Comment: A few commenters stated that the requirement to report 24 CQMs was too difficult and adds to the administrative burden placed on eligible hospitals and CAHs, especially rural hospitals. Many commenters suggested that CQM reporting requirement beginning with 2014 remain at 15 CQMs due to the number of issues experienced by hospitals when implementing the Stage 1 CQMs, although other commenters stated that requiring up to 18 CQMs would be reasonable. A few commenters noted that CQMs were not evenly distributed among the 6 domains, making the requirement to report at least one CQM from each domain difficult for some hospitals. One commenter recommended that if a domain did not have at least 4 CQMs eligible hospitals and CAHs should not be required to report that domain. Multiple commenters stated that eligible hospitals and CAHs in Stage 1 in FY 2014 may have difficulty meeting the CQM requirement beginning in 2014 and

recommend that the Stage 1 CQMs meet the requirements for those hospitals. Alternatively, the commenters recommended that if the CQMs beginning in 2014 are required, that the number of CQMs being reported be reduced for the eligible hospitals and CAHs in Stage 1 beginning in FY 2014. One commenter stated that CQM requirements failed to align with other meaningful use objectives.

Response: We acknowledge that increasing the number of CQMs required to be reported from 15 in 2011, 2012, and 2013 to 24 beginning in 2014 increases implementation burden on hospitals. We have stated our intention to implement EHR-based reporting of CQMs in other quality reporting programs, such as the Hospital IQR Program. One purpose of our proposal to increase the number of CQMs reported electronically for the EHR Incentive Program is to create an electronic reporting infrastructure that we can also use for other quality reporting programs. We also acknowledge that the requirement of reporting 24 CQMs for hospitals in their first year of Stage 1 in 2014 is a significant increase from the reporting requirement for hospitals that entered Stage 1 before 2014. We also acknowledge the difficulty in meeting the requirement to report at least 1 CQM in each of the 6 domains. For these reasons, we have finalized a policy that decreases the number of CQMs required from the proposal and decreases the total number of domains required to be covered among the selected CQMs.

After consideration of the public comments received and for the reasons discussed previously, we are finalizing the following policy on reporting requirements for CQMs for eligible hospitals and CAHs beginning in 2014:

Eligible hospitals and CAHs must report a total of 16 CQMs covering at least 3 domains from Table 8. We expect eligible hospitals and CAHs will select measures that best apply to their patient mix. As we proposed, if an eligible hospital's or CAH's CEHRT does not contain

patient data for at least 16 CQMs covering at least 3 domains, then the eligible hospital or CAH must report the CQMs for which there is patient data and report the remaining required CQMs as "zero denominators" as displayed by their certified EHR technology. In the unlikely event that there are no CQMs applicable to the eligible hospital's or CAH's patient mix, eligible hospitals or CAHs must still report 16 CQMs even if zero is the result in either the numerator or the denominator of the measure. If all CQMs have a value of zero from their CEHRT, then eligible hospitals or CAHs must select any 16 CQMs from Table 8 to report. We stated in the proposed rule that our experience from Stage 1 in implementing the current set of 15 CQMs in specialty and low volume eligible hospitals illuminated several challenges. For example, children's hospitals rarely see patients 18 years or older. One of the exceptions to this generality is individuals with sickle cell disease. National Institutes of Health Guidelines (NIH Publication 02-2117) list the conditions under which thrombolytic therapy cannot be recommended for adults or children with sickle cell disease. This, plus the fact that children's hospitals have on average two or fewer cases of stroke per year, have created workflow, cost, and clinical barriers to demonstrating meaningful use as it relates to the CQMs for stroke and VTE.

We proposed to consider whether a case number threshold would be appropriate, given the apparent burden on hospitals that very seldom have the types of cases addressed by certain CQMs such that hospitals that do not have enough cases to exceed the threshold would be exempt from reporting those CQMs. We solicited comments on what the numerical range of threshold should be, how hospitals would demonstrate to CMS or state Medicaid agencies that they have not exceeded this threshold, whether it should apply to only certain hospital CQMs (and if so, which ones), and the extent of the burden on hospitals if a case number threshold is not adopted given that they are allowed to report "zeroes" for the measures. We solicited

comments on limiting the case threshold exemption to only children's, cancer hospitals, and a subset of hospitals in the Indian Health System as they have a much narrower patient base than acute care and critical access hospitals. We requested comments on whether such thresholds should be established for 2013, noting that the issue could be mitigated beginning in 2014 by our proposal to establish a larger menu set of CQMs from which hospitals would select.

Comment: Many commenters noted that the implementation of a case number threshold for CQM reporting would help reduce the burden placed on hospitals that very seldom have cases in the denominator of certain CQMs. However, commenters suggested differing mechanisms by which to implement a case number threshold. Many commenters suggested that we use Medicare claims data from the year prior to a hospital's CQM submission or another historical data source to determine whether a hospital should be exempt from reporting certain CQMs. Another commenter suggested that the simplest option would be to continue to allow hospitals to report zeroes in the denominators for CQMs. A few commenters requested that we implement a case number threshold for all hospital types, not just specialty hospitals or CAHs, since some acute care hospitals do not provide a full range of services. Another commenter suggested that we work with children's hospitals and CAHs and other types of hospitals with unique patient populations to ensure that meaningful use requirements are feasible for them. Some commenters stated that low volume eligible hospitals and CAHs would not know at the beginning of a reporting period which CQMs would not meet a case number threshold and therefore should not have to select the CQMs in advance based on this criterion. This commenter suggested that the hospitals select the CQMs to report that are most appropriate for their patient populations. One commenter requested that a case number threshold be implemented for all CQM reporting for FY 2013.

In terms of a specific case number threshold, one commenter suggested five or fewer cases per month as an appropriate threshold number to exempt any type of hospital from reporting a CQM. This same commenter also suggested that if a hospital does not have a least one CQM in a domain with a denominator greater than five, then that hospital should be exempt from reporting on that entire domain. Another commenter suggested exempting eligible hospitals and CAHs from reporting a CQM if the relevant patient population comprised less than 10 percent of their discharges. Other commenters suggested that children's hospitals be excluded from all CQMs that are only applicable to patients 18 years of age or older. Another commenter recommended that we set a case number threshold of 30 cases and require hospitals to validate this exemption through attestation. Other commenters did not suggest a specific case number threshold, but requested that we empirically derive this value and that it be aligned with values across quality reporting programs.

Response: We recognize the potential cost and work flow challenges when hospitals have a low volume of cases per year that apply to a particular CQM. We note that under the Hospital IQR Program, we do not require a hospital that has 5 or fewer inpatient discharges (Medicare and non-Medicare combined) in a topic area during a quarter in which data must be submitted to submit patient-level data for that topic area for the quarter (76 FR 51641). For the Hospital IQR Program, the hospital is still required to submit its aggregate population and sample size counts for Medicare and non-Medicare discharges for the topic areas each quarter, and hospitals that qualify for this exception for a particular topic can still elect to voluntarily submit their patient-level data. In order to align with the Hospital IQR Program, we will adopt a similar policy for all eligible hospitals and CAHs participating in the EHR Incentive Program, whereby hospitals with 5 or fewer inpatient discharges per quarter or 20 or fewer inpatient

discharges per year (Medicare and non-Medicare combined) as defined by a CQM's denominator population would be exempted from reporting on that CQM.

After consideration of the public comments received and for the reasons discussed earlier, we are finalizing the following policy on case threshold exemptions for eligible hospitals and CAHs in all stages of meaningful use beginning in FY 2014. However, eligible hospitals and CAHs that are demonstrating meaningful use for the first time must submit their CQMs through attestation and will not be able to qualify for this exemption. The burden of submitting the aggregate population and sample size counts in order to qualify for the exemption would be at least equal to the effort required to obtain and attest to the calculated CQM data.

Eligible hospitals and CAHs that have 5 or fewer discharges per quarter in the same quarter as their reporting period in FY 2014, or 20 or fewer discharges per full FY reporting period beginning in FY 2015, for which data is being electronically submitted (Medicare and non-Medicare combined) as defined by the CQM's denominator population are exempted from reporting the CQM. For example, if the CQM's denominator population is ischemic stroke patients greater than or equal to 18 years of age, then the threshold would be 5 or fewer ischemic stroke patients aged 18 years or older discharged from the hospital in the quarter for which data is being submitted (the hospital's FY 2014 3-month quarter reporting period). To be eligible for the exemption, hospitals must submit their aggregate population and sample size counts for Medicare and non-Medicare discharges for the CQM for the reporting period no later than the 2-month submission period of October 1 through November 30 immediately following the reporting period (please see section II.B.1. of this final rule for a description of reporting and submission periods). Hospitals will report this information in the same manner as for the Hospital IQR Program (76 FR 51639 through 51641). Please refer to the QualityNet website

(www.qualitynet.org) and the CMS/Joint Commission Specifications Manual for National Hospital Inpatient Quality Measures, located on the QualityNet website, for technical information about data submission requirements. Hospitals that do not seek an exemption under the EHR Incentive Program do not have to submit aggregate population and sample size counts for any CQMs for the purposes of the EHR Incentive Program.

(ii) Clinical Quality Measures

We proposed CQMs in Table 9 of the Stage 2 proposed rule (77 FR 13760 to 13763) that would apply for all eligible hospitals and CAHs beginning with FY 2014, regardless of whether an eligible hospital or CAH is in Stage 1 or Stage 2 of meaningful use. The set of 49 CQMs that we proposed included the current set of 15 CQMs that were finalized for FYs 2011 and 2012 in the Stage 1 final rule.

The CQM titles and descriptions in Table 8 reflect the most current updates, as provided by the measure stewards who are responsible for maintaining and updating the measure specifications, and therefore may not reflect the title and/or description as presented on the NQF website.

Comment: Many commenters requested that we finalize fewer than 49 CQMs. The most common reasons given for reducing the complete list of CQMs included limitations of the vendors to program and deploy systems and for hospitals to effectively implement those systems, especially among resource-limited organizations.

Several commenters recommended that CQMs that are suspended from the Hospital IQR program, not NQF endorsed, only apply to certain regions of the country or not electronically specified should not be considered for CQM reporting beginning in 2014. Additionally, some commenters suggested that no new CQMs be added until CEHRT can

produce accurate calculations of the existing CQMs. A few commenters stated that increasing the number of CQMs in such a narrow timeframe would be challenging for organizations in terms of designing, creating, and implementing new workflows, building, testing and modifying configurations to ensure proper discrete data capture, and training staff. One of these commenters requested a phased-in approach for calculating CQMs through EHRs and requested that we do not add any new manually abstracted CQMs in other CMS quality reporting programs.

One commenter stated that it was unclear if mid-cycle modifications of measures would require hospitals to resubmit data and recommended that if a measure were modified or deleted mid-cycle that hospitals not have to modify measures selected.

Response: Some of the CQMs that were proposed but not finalized were not submitted by the measure stewards for continued NQF endorsement (NQF 0136 Heart Failure (HF)-1 Detailed Discharge Instructions, NQF 0481 First Temperature Measured within One Hour of Admission to the NICU, and NQF 0482 First NICU Temperature < 36 degrees C). We are not finalizing NQF 0143 and NQF 0144, both related to pediatric asthma, for CQM reporting beginning in 2014 because hospital performance on these measures in the IQR program is at or near 100 percent. While pediatric asthma is a priority for CMS, we recognize that there are greater opportunities to improve care than in measuring the provision of relievers and systemic corticosteroids, which are now common practice. Our future quality measurement and improvement efforts will focus on other aspects of the clinical care for children with asthma, targeting for inclusion in CQM reporting with Stage 3 rulemaking. We have also taken into consideration the ability of the eligible hospitals and CAHs to report CQMs from CEHRT when selecting the set of CQMs for reporting beginning in 2014.

CQM specifications will be updated on an annual basis. We will not require resubmission of data as a result of these updates. If we remove a CQM from the program, we would not require data to be submitted on any additional CQMs nor would this affect data submitted prior to removal of the CQM. See section II.B.4. of this final rule for additional details on this policy.

Comment: Some commenters requested denominator definitions such as elective delivery vs. delivery based on a physician's order, and clarification on age ranges. A few commenters requested that some of the measure stewards listed in Table 9 of the proposed rule be corrected.

Response: Clarifications on denominator definitions will be provided in the electronic specifications that will be posted on or about the publication of the final rule. Any further clarification needed should be addressed to the measure steward. The measure stewards listed incorrectly in Table 9 of the proposed rule were corrected (the correction notice can be found at 77 FR 23195 through 23196).

Comment/Response: Table 9 summarizes the public comments received on specific proposed eligible hospital and CAH CQMs and the CMS rationale (that is, our response to the CQM-specific comment(s)) for finalizing or not finalizing the CQM for reporting beginning with FY 2014.

TABLE 9: SUMMARY OF ELIGIBLE HOSPITAL AND CAH CQM-SPECIFIC COMMENTS AND RATIONALE TO FINALIZE OR NOT FINALIZE THE CQM

CQM Number[#]	Commenters Support Finalization	Commenters Do Not Support Finalization	Finalized	CMS Rationale
ED Throughput: NQF 0495, 0497, 0496	Many supported continuing with Stage 1 CQMs, instead of requiring additional CQMs for Stage 2 (ED-1&2). ED throughput measures are required by the Joint Commission.	Few stated factors affecting results are outside control of ED, difficult to implement without workflow changes and CPOE implemented hospital-wide, & may reflect negatively on hospitals routinely receiving complex patients. One commenter noted may not correlate with improved outcomes.	Yes	Continues with Stage 1 CQM reporting for ED-1&2, aligns with IQR/OQR/HVBP, retooled measures passed reliability, validity, & feasibility testing.
Stroke-2,3,4,5,6,8: NQF 0435, 0436, 0437, 0438, 0439, 0440	Many supported continuing with Stage 1 CQMs, instead of requiring additional CQMs for Stage 2.	Few stated that it is difficult to capture certain data elements within current clinical workflows, and recommends delay to Stage 3 after further e-specification testing is completed.	Yes	Continues with Stage 1 CQM reporting, aligns with IQR/HVBP, retooled measures passed reliability, validity, & feasibility testing.
Stroke-10: NQF 0441	Many supported continuing with Stage 1 CQMs, instead of requiring additional CQMs for Stage 2.	A commenter stated that this is a poor care coordination measure but provided no reasons.	Yes	Continues with Stage 1 CQM reporting, aligns with IQR/HVBP, retooled measures passed reliability, validity, & feasibility testing.

CQM Number[#]	Commenters Support Finalization	Commenters Do Not Support Finalization	Finalized	CMS Rationale
VTE-1,2,3,4,5,6: NQF 371, 0372, 0373, 0374, 0375, 0376	Many supported continuing with Stage 1 CQMs, instead of requiring additional CQMs for Stage 2.	Few stated that it is difficult to capture certain data elements within current clinical workflows, one recommended delay to Stage 3 after further e-specification testing is completed.	Yes	Continues with Stage 1 CQM reporting, aligns with IQR/HVBP, retooled measures passed reliability, validity, & feasibility testing.
AMI-1, 3, 5: NQF 0132, 0137, 0160	One commenter supported AMI-3, but for Stage 3 once CPOE is more widely implemented & e-specifications can be published in a timely manner to allow for inclusion of new guidelines. Inclusion will help tracking compliance.	Many stated these measures should not be finalized since they have been suspended from IQR , are not recommended by the MAP, are difficult to implement without CPOE implemented hospital-wide & one commenter stated it is difficult to capture unless an eMAR is implemented. AMI-1 & 5 are not included in CMS programs.	No	Suspended from IQR, thus not supportive of program alignment.

CQM Number[#]	Commenters Support Finalization	Commenters Do Not Support Finalization	Finalized	CMS Rationale
AMI-2, 7a: NQF 0142, 0164	A few commenters support including these measures for Stage 3 to allow for additional time for testing & implementation. AMI-2 is required by the Joint Commission. Inclusion will help tracking compliance.	One commenter requested delay to Stage 3 until CPOE is more widely implemented. One commenter noted AMI-2 is topped out.	Yes	Aligns with IQR/HVBP, which both consider it an important CQM on post-discharge AMI prevention for hospitals to report. Retooled measure passed reliability, validity, & feasibility testing.
AMI-8a,10: NQF 0163, 0639	N/A	One commenter stated it is difficult to capture certain data elements within current clinical workflows; one commenter stated it is difficult to capture if CPOE is not widely implemented.	Yes	Aligns with IQR/HVBP, retooled measure passed reliability, validity, & feasibility testing.
PN-3b: NQF 0148	One commenter supports including this measure for Stage 3 to allow additional time for testing & implementation. A few commenters support this measure if e-specifications are available in a timely manner. This is required by the Joint Commission.	Delay to Stage 3 after further e-specification testing is completed.	No	Retired from NQF endorsement.

CQM Number[#]	Commenters Support Finalization	Commenters Do Not Support Finalization	Finalized	CMS Rationale
PN-6: NQF 0147	N/A	One commenter states data collection is difficult due to absent decision support algorithm.	Yes	Aligns with IQR/HVBP, retooled measure passed reliability, validity, & feasibility testing.
Elective Delivery Prior to 39 Weeks: NQF 0469	A commenter supports the inclusion of this safety-related CQM.	Not required in IQR, a commenter was concerned that labor and delivery applications are not part of certification.	Yes	Aligns with IQR, Medicaid Adult Core, & Strong Start programs, retooled measure passed reliability, validity, & feasibility testing.
Exclusive Breast Feeding at Discharge: NQF 0480	Many commenters support this, noting that it will help improve maternity care practices and create an awareness of quality of care issues. A commenter supported this measure, but for Stage 3 once labor and delivery applications are part of certification.	Not required in IQR, highly subjective measure, specific to California only and not well vetted, and contains data elements difficult to capture.	Yes	Aligns with Medicaid reporting initiatives. Measure passed reliability, validity, & feasibility testing.
Home Management Plan of Care, CAC-3: NQF 0338	A commenter supports this measure, but not until documentation for peri-operative, intra-operative and anesthesia are parts of certification.	Not required in IQR, not supported by the MAP, and overly burdensome.	Yes	Aligns with Medicaid reporting initiatives. Measure passed reliability, validity, & feasibility testing.

CQM Number[#]	Commenters Support Finalization	Commenters Do Not Support Finalization	Finalized	CMS Rationale
Healthy Term Newborn: NQF 0716	A commenter supports this measure. A commenter supports this measure, but for Stage 3 once labor and delivery applications are part of certification.	Not required in IQR.	Yes	Aligns with Medicaid reporting initiatives. Measure passed reliability, validity, & feasibility testing.
Hearing Screening: NQF 1354	One commenter supports this measure if e-specifications are available in a timely manner.	Not required in IQR.	Yes	Aligns with Medicaid reporting initiatives. Measure passed reliability, validity, & feasibility testing.
SCIP INF-1,2,9: NQF 0527, 0528, 0453	A commenter supports these measures, but not until documentation for peri-operative, intra-operative and anesthesia are parts of certification. Inclusion will help tracking compliance.	N/A	Yes	Aligns with IQR/HVBP, retooled measure passed reliability, validity, & feasibility testing.
SCIP INF-3,4,6: NQF 0529, 0300, 0301	A commenter supports this measure, but not until documentation for peri-operative, intra-operative and anesthesia are parts of certification. SCIP-INF-3 is required by the Joint Commission.	Not required in IQR and not recommended by the MAP. One commenter noted SCIP INF-6 may not correlate with improved outcomes.	No	SCIP-INF-3 reflects a limited patient population, keeps the total number of Stage 2 measure options reasonable. SCIP-INF-4 is being reworked by the steward. SCIP-INF-6 is suspended from reporting in IQR.

CQM Number[#]	Commenters Support Finalization	Commenters Do Not Support Finalization	Finalized	CMS Rationale
HF-1: NQF 0136	One commenter supported.	One commenter did not support since being retired from NQF endorsement.	No	Retired from NQF endorsement.
First Temperature within 1 hour in NICU > 36°and <36°: NQF 0481, 0482	One commenter supported if e-specifications are published in a timely manner.	A few commenters stated it is not required in IQR and not recommended by MAP.	No	Retired from NQF endorsement.
Global Immunizations Pneumonia & Influenza; NQF 1653, 1659	N/A	A few commenters stated these are not consistent with current guidelines.	No	Required in IQR but not for HVBP, and keeps the total number of Stage 2 measure options reasonable.
Proportion of Infants 22-29 weeks old treated with Surfactant: NQF 0484	N/A	Contains data elements difficult to capture.	No	Retired from NQF endorsement.

All hospital CQMs finalized in this rule are NQF-endorsed. NQF endorsement includes a consensus development process that takes into account clinical guidelines and scientific evidence. NQF describes its consensus development process at http://www.qualityforum.org/Measuring_Performance/Consensus_Development_Process.aspx.

After consideration of the public comments received and the measure selection criteria discussed, we are finalizing the list of 29 CQMs for eligible hospitals and CAHs included in Table 10.

TABLE 10: CQMs FINALIZED FOR ELIGIBLE HOSPITALS AND CAHs BEGINNING WITH FY 2014

NQF #	Title	Measure Steward and Contact Information	Other Quality Measure Programs that use the same CQM***	New CQM	Domain
0495	Title: Emergency Department (ED)-1 Emergency Department Throughput – Median time from ED arrival to ED departure for admitted ED patients Description: Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the facility from the emergency department.	CMS/Oklahoma Foundation for Medical Quality (OFMQ) Qualitynet.org and click on "Questions & Answers"	IQR		Patient and Family Engagement
0497	Title: ED-2 Emergency Department Throughput – admitted patients – Admit decision time to ED departure time for admitted patients Description: Median time (in minutes) from admit decision time to time of departure from the emergency department for emergency department patients admitted to inpatient status.	CMS/OFMQ Qualitynet.org and click on "Questions & Answers"	IQR		Patient and Family Engagement
0435	Title: Stroke-2 Ischemic stroke – Discharged on anti-thrombotic therapy Description: Ischemic stroke patients prescribed antithrombotic therapy at hospital discharge.	The Joint Commission www.jointcommission.org and click on "Contact Us"	IQR		Clinical Process/ Effectiveness
0436	Title: Stroke-3 Ischemic stroke – Anticoagulation Therapy for Atrial Fibrillation/Flutter Description: Ischemic stroke patients with atrial fibrillation/flutter who are prescribed anticoagulation therapy at hospital discharge.	The Joint Commission www.jointcommission.org and click on "Contact Us"	IQR		Clinical Process/ Effectiveness
0437	Title: Stroke-4 Ischemic stroke – Thrombolytic Therapy Description: Acute ischemic stroke patients who arrive at this hospital within 2 hours (120 minutes) of time last known well and for whom IV t-PA was initiated at this hospital within 3 hours (180 minutes) of time last known well.	The Joint Commission www.jointcommission.org and click on "Contact Us"	IQR		Clinical Process/ Effectiveness
0438	Title: Stroke-5 Ischemic stroke – Antithrombotic therapy by end of hospital day two Description: Ischemic stroke patients administered antithrombotic therapy by the end of hospital day two.	The Joint Commission www.jointcommission.org and click on "Contact Us"	IQR		Clinical Process/ Effectiveness
0439	Title: Stroke-6 Ischemic stroke – Discharged on Statin Medication Description: Ischemic stroke patients with LDL greater than or equal to 100 mg/dL, or LDL not measured, or, who were on a lipid-lowering medication prior to hospital arrival are prescribed statin medication at hospital discharge.	The Joint Commission www.jointcommission.org and click on "Contact Us"	IQR		Clinical Process/ Effectiveness

NQF #	Title	Measure Steward and Contact Information	Other Quality Measure Programs that use the same CQM***	New CQM	Domain
0440	Title: Stroke-8 Ischemic or hemorrhagic stroke – Stroke education Description: Ischemic or hemorrhagic stroke patients or their caregivers who were given educational materials during the hospital stay addressing all of the following: activation of emergency medical system, need for follow-up after discharge, medications prescribed at discharge, risk factors for stroke, and warning signs and symptoms of stroke.	The Joint Commission www.jointcommission.org and click on "Contact Us"	IQR		Patient & Family Engagement
0441	Title: Stroke-10 Ischemic or hemorrhagic stroke – Assessed for Rehabilitation Description: Ischemic or hemorrhagic stroke patients who were assessed for rehabilitation services.	The Joint Commission www.jointcommission.org and click on "Contact Us"	IQR		Care Coordination
0371	Title: Venous Thromboembolism (VTE)-1 VTE prophylaxis Description: This measure assesses the number of patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after hospital admission or surgery end date for surgeries that start the day of or the day after hospital admission.	The Joint Commission www.jointcommission.org and click on "Contact Us"	IQR		Patient Safety
0372	Title: VTE-2 Intensive Care Unit (ICU) VTE prophylaxis Description: This measure assesses the number of patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after the initial admission (or transfer) to the Intensive Care Unit (ICU) or surgery end date for surgeries that start the day of or the day after ICU admission (or transfer).	The Joint Commission www.jointcommission.org and click on "Contact Us"	IQR		Patient Safety
0373	Title: VTE-3 VTE Patients with Anticoagulation OverlapTherapy Description: This measure assesses the number of patients diagnosed with confirmed VTE who received an overlap of parenteral (intravenous [IV] or subcutaneous [subcu]) anticoagulation and warfarin therapy. For patients who received less than five days of overlap therapy, they must be discharged on both medications or have a reason for discontinuation of overlap therapy. Overlap therapy must be administered for at least five days with an international normalized ratio (INR) greater than or equal to 2 prior to discontinuation of the parenteral anticoagulation therapy, discharged on both medications or have a reason for discontinuation of overlap therapy.	The Joint Commission www.jointcommission.org and click on "Contact Us"	IQR	New	Clinical Process/ Effectiveness

NQF #	Title	Measure Steward and Contact Information	Other Quality Measure Programs that use the same CQM***	New CQM	Domain
0374	Title: VTE-4 VTE Patients Receiving Unfractionated Heparin (UFH) with Dosages/Platelet Count Monitoring by Protocol (or Nomogram) Description: This measure assesses the number of patients diagnosed with confirmed VTE who received intravenous (IV) UFH therapy dosages AND had their platelet counts monitored using defined parameters such as a nomogram or protocol.	The Joint Commission www.jointcommission.org and click on "Contact Us"	IQR	New	Clinical Process/ Effectiveness
0375	Title: VTE-5 VTE discharge instructions Description: This measure assesses the number of patients diagnosed with confirmed VTE that are discharged to home, home care, court/law enforcement, or home on hospice care on warfarin with written discharge instructions that address all four criteria: compliance issues, dietary advice, follow-up monitoring, and information about the potential for adverse drug reactions/interactions.	The Joint Commission www.jointcommission.org and click on "Contact Us"	IQR	New	Patient and Family Engagement
0376	Title: VTE-6 Incidence of potentially preventable VTE Description: This measure assesses the number of patients diagnosed with confirmed VTE during hospitalization (not present at admission) who did not receive VTE prophylaxis between hospital admission and the day before the VTE diagnostic testing order date.	The Joint Commission www.jointcommission.org and click on "Contact Us"	IQR	New	Patient Safety
0142	Title: AMI-2-Aspirin Prescribed at Discharge for AMI Description: Acute myocardial infarction (AMI) patients who are prescribed aspirin at hospital discharge.	CMS/OFMQ www.qualitynet.org and click on "Questions & Answers"	IQR	New	Clinical Process/ Effectiveness
0469	Title: PC-01 Elective Delivery Prior to 39 Completed Weeks Gestation Description: Patients with elective vaginal deliveries or elective cesarean sections at >= 37 and < 39 weeks of gestation completed.	The Joint Commission (TJC) www.jointcommission.org and click on "Contact Us"	TJC		Clinical Process/ Effectiveness
0164	Title: AMI-7a- Fibrinolytic Therapy Received Within 30 minutes of Hospital Arrival Description: Acute myocardial infarction (AMI) patients with ST-segment elevation or LBBB on the ECG closest to arrival time receiving fibrinolytic therapy during the hospital stay and having a time from hospital arrival to fibrinolysis of 30 minutes or less.	CMS/OFMQ www.qualitynet.org and click on "Questions & Answers"	IQR, HVBP	New	Clinical Process/ Effectiveness

NQF #	Title	Measure Steward and Contact Information	Other Quality Measure Programs that use the same CQM***	New CQM	Domain
0163	Title: AMI-8a- Primary PCI Received Within 90 Minutes of Hospital Arrival Description: Acute myocardial infarction (AMI) patients with ST-segment elevation or LBBB on the ECG closest to arrival time receiving primary PCI during the hospital stay with a time from hospital arrival to PCI of 90 minutes or less.	CMS/OFMQ www.qualitynet.org and click on "Questions & Answers"	IQR, HVBP	New	Clinical Process/ Effectiveness
0639	Title: AMI-10 Statin Prescribed at Discharge Description: Acute Myocardial Infarction (AMI) patients who are prescribed a statin at hospital discharge.	CMS/OFMQ www.qualitynet.org and click on "Questions & Answers"	IQR	New	Clinical Process/ Effectiveness
0147	Title: PN-6- Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients Description: Immunocompetent patients with Community-Acquired Pneumonia who receive an initial antibiotic regimen during the first 24 hours that is consistent with current guidelines.	CMS/OFMQ www.qualitynet.org and click on "Questions & Answers"	IQR, HVBP	New	Efficient Use of Healthcare Resources
0527	Title: SCIP-INF-1 Prophylactic Antibiotic Received within 1 Hour Prior to Surgical Incision Description: Surgical patients with prophylactic antibiotics initiated within one hour prior to surgical incision. Patients who received Vancomycin or a Fluoroquinolone for prophylactic antibiotics should have the antibiotics initiated within 2 hours prior to surgical incision. Due to the longer infusion time required for Vancomycin or a Fluoroquinolone, it is acceptable to start these antibiotics within 2 hours prior to incision time.	CMS/OFMQ www.qualitynet.org and click on "Questions & Answers"	IQR, HVBP	New	Patient Safety
0528	Title: SCIP-INF-2-Prophylactic Antibiotic Selection for Surgical Patients Description: Surgical patients who received prophylactic antibiotics consistent with current guidelines (specific to each type of surgical procedure).	CMS/OFMQ www.qualitynet.org and click on "Questions & Answers"	IQR, HVBP	New	Efficient Use of Healthcare Resources
0453	Title: SCIP-INF-9- Urinary catheter removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD2) with day of surgery being day zero. Description: Surgical patients with urinary catheter removed on Postoperative Day 1 or Postoperative Day 2 with day of surgery being day zero.	CMS/OFMQ www.qualitynet.org and click on "Questions & Answers"	IQR, TJC	New	Patient Safety
0496	Title: ED-3-Median time from ED arrival to ED departure for discharged ED patients. Description: Median time from emergency department arrival to time of departure from the emergency room for patients discharged from the emergency department.	CMS/OFMQ www.qualitynet.org and click on "Questions & Answers"	OQR	New	Care Coordination

NQF #	Title	Measure Steward and Contact Information	Other Quality Measure Programs that use the same CQM***	New CQM	Domain
0338	Title: Home Management Plan of Care (HMPC) Document Given to Patient/Caregiver Description: An assessment that there is documentation in the medical record that a Home Management Plan of Care (HMPC) document was given to the pediatric asthma patient/caregiver.	The Joint Commission (TJC) www.jointcommission.org and click on "Contact Us"	state use	New	Patient & Family Engagement
0480	Title: Exclusive Breast Milk Feeding Description: Exclusive breast milk feeding during the newborn's entire hospitalization.	The Joint Commission (TJC) www.jointcommission.org and click on "Contact Us"	state use	New	Clinical Process/ Effectiveness
0716	Title: Healthy Term Newborn Description: Percent of term singleton live births (excluding those with diagnoses originating in the fetal period) who DO NOT have significant complications during birth or the nursery care.	California Maternal Quality Care Collaborative www.cmqcc.org and click on "Contact Us"	state use	New	Patient Safety
1354	Title: EHDI-1a - Hearing screening prior to hospital discharge Description: This measure assesses the proportion of births that have been screened for hearing loss before hospital discharge.	CDC www.cdc.gov and click on "Contact CDC"	state use	New	Clinical Process/ Effectiveness

***IQR = Inpatient Quality Reporting
TJC = The Joint Commission
HVBP = Hospital Value-Based Purchasing
OQR = Outpatient Quality Reporting

8. Reporting Methods for Eligible Hospitals and Critical Access Hospitals

(a) Reporting Methods in FY 2013

In the Stage 2 proposed rule, we did not propose any reporting methods for Medicare eligible hospitals and CAHs in 2013. However, in the CY 2013 OPPS proposed rule (77 FR 45188), we stated that eligible hospitals and CAHs may continue to report by attestation CQM results as calculated by CEHRT, as they did for 2011 and 2012. For further explanation of reporting CQMs by attestation, please see the Stage 1 final rule (75 FR 44430 through 44434). We also proposed in the CY 2013 OPPS proposed rule (77 FR 45188) to continue for 2013 the voluntary electronic reporting pilot for CQMs (the Medicare EHR Incentive Program Electronic

Reporting Pilot for Eligible Hospitals and CAHs), which we had previously established for 2012. We expect to finalize in the CY 2013 Hospital OPPS final rule the reporting methods that would apply in 2013 for eligible hospitals and CAHs participating in the Medicare EHR Incentive Program.

(b) Reporting Methods Beginning with FY 2014

Under section 1886(n)(3)(A)(iii) of the Act, eligible hospitals and CAHs must submit information on the CQMs selected by the Secretary "in a form and manner specified by the Secretary" as part of demonstrating meaningful use of CEHRT. We proposed that Medicare eligible hospitals and CAHs would select one of the following two options for submitting CQMs electronically.

- Option 1: Submit the selected 24 CQMs through a CMS-designated portal.

We proposed that CQM data would be submitted in an XML-based format on an aggregate basis reflective of all patients without regard to payer. This method would require eligible hospitals and CAHs to log into a CMS-designated portal and submit through an upload process data that is based on specified structures produced as output from their CEHRT.

- Option 2: Submit the selected 24 CQMs in a manner similar to the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs using CEHRT.

We proposed that, as an alternative to the aggregate-level reporting schema described previously under Option 1, Medicare eligible hospitals and CAHs that successfully report CQMs through an electronic reporting method similar to the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs using CEHRT would satisfy their

CQMs reporting requirement under the Medicare EHR Incentive Program. Please refer to the CY 2012 OPPS final rule (76 FR 74489 through 74492) for details on the pilot.

We noted that the Hospital IQR program does not currently have an electronic reporting mechanism. We solicited comments on whether an electronic reporting option is appropriate for the Hospital IQR Program and whether it would provide further alignment with the EHR Incentive Program.

Comment: One commenter preferred Option 1 because it seems less burdensome. This commenter believed that a third party data warehouse to store patient-level data and aggregate the results would be necessary prior to implementing Option 1. The commenter also believed that the hospital should be able to calculate its own results.

Response: Hospitals have access to patient-level data. A hospital could use a CEHRT that can calculate CQM results and also directly report patient-level data to CMS, so these functions are not mutually exclusive. No data warehouse is necessary.

Comment: One commenter supported both the aggregate XML-based reporting option and the option similar to the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot as well as the longer-term goal of attaining full automatic electronic reporting. Another commenter urged us to make the strategy for automating the reporting of CQM data clear, so that hospitals can avoid reporting the same quality data through multiple reporting mechanisms. One commenter urged us to make the necessary investment to establish the infrastructure for the flow of EHR data, with careful consideration given to how we will ensure reliable, valid, and complete CQM data.

Response: We are working to align the EHR Incentive Program with various other quality reporting programs in order to reduce duplicative reporting to the extent feasible and

practical, beginning with the Hospital IQR Program. Under the Hospital IQR Program, hospitals report some measures by submitting chart-abstracted patient-level data, reflective of all patients without regard to payer. More information on the Hospital IQR Program, including the chart-abstracted measure data submission process, can be found in the "Guide to CMS Hospital IQR Program" on the QualityNet website (http://www.qualitynet.org/, select "Hospital Inpatient Quality Reporting Program" from the "Hospitals – Inpatient" dropdown menu and click on the link to the guide from the "Handbooks" menu on the right side of the page). We expect to establish a similar mechanism for electronic submission of CQM data for the EHR Incentive Program.

The Hospital IQR Program does not currently have an EHR reporting option or requirement, but eligible hospitals and CAHs have been able to meet the CQM requirement for the EHR Incentive Program via the electronic reporting pilot. However, we expect that the Hospital IQR Program will transition to EHR-based reporting in a manner similar to the electronic reporting pilot, using an electronic transmission format such as the QRDA-I (for patient-level data). If the Hospital IQR Program establishes an EHR reporting option or requirement, we would consider whether we should allow hospitals to report CQMs through that mechanism using CEHRT for purposes of satisfying the CQM reporting component of the EHR Incentive Program.

We proposed to consider an "interim submission" option for Medicare eligible hospitals and CAHs that are in their first year of Stage 1 beginning in FY 2014 through an electronic reporting method similar to the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs. Under this option, eligible hospitals and CAHs would electronically submit CQM data for a continuous 90-day EHR reporting period, and the data

would have to be received no later than July 1 to meet the requirements of the EHR Incentive Program for purposes of avoiding a payment adjustment in the following year. We solicited public comment on this potential option.

Comment: One commenter supported an "interim submission" option for those in their first year, which the commenter stated could also serve as a transitional step for those catching up.

Response: Since we are allowing eligible hospitals and CAHs to submit their CQM data through attestation if they are in their first year of Stage 1, we are not finalizing the proposed interim submission option.

After consideration of the public comments received, we are finalizing the following policy for CQM reporting methods for eligible hospitals and CAHs beginning in FY 2014.

Eligible hospitals and CAHs that are in their first year of Stage 1 must report the selected 16 CQMs through attestation (please refer to the Stage 1 final rule for an explanation of reporting CQMs through attestation (75 FR 44430 through 44434)). For purposes of avoiding a payment adjustment, eligible hospitals that are in their first year of demonstrating meaningful use in the year immediately preceding a payment adjustment year must submit their CQM data no later than July 1 of such preceding year. We note that this deadline does not apply to CAHs. For more details on submission deadlines specific to CAHs, please refer to section II.D.4. of this final rule.

Eligible hospitals and CAHs that are beyond their first year of meaningful use will be required to electronically submit the selected 16 CQMs using CEHRT using one of the options listed in this section of this final rule. Consistent with section 1886(n)(3)(B)(ii) of the Act, in the unlikely event that the Secretary does not have the capacity to receive CQM data

electronically, eligible hospitals and CAHs may continue to report aggregate CQM results through attestation.

- Option 1: Submit the selected 16 CQMs on an aggregate basis through a CMS-designated transmission method using CEHRT.

The CQM data will be submitted in the QRDA-III format reflective of all patients without regard to payer. This method will require transmitting the data via a CMS-designated transmission method.

- Option 2: Submit the selected 16 CQMs on a patient-level basis in a manner similar to the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs using CEHRT. As long as the CQM data originates from CEHRT, it may be submitted directly from the hospital's CEHRT to CMS or through a data intermediary to CMS.

The electronically reported patient-level CQM data must use the QRDA category I (release 2) based on the Quality Data Model (QDM), which will include only patients that meet the denominator criteria of each reported CQM without regard to payer. For example, if a hospital selects NQF #0438 to report, the denominator criteria include ischemic stroke patients, so the QRDA-I for this CQM would include only ischemic stroke patients. This method will require submitting the data via a transmission method similar to the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs (76 FR 74122). The requirement that eligible hospitals and CAHs submit patient-level data under the EHR Incentive Program is consistent with the requirement that hospitals submit patient-level data under other quality reporting programs such as the Hospital IQR Program.

We proposed to consider the following 4 options of patient population – payer data submission characteristics:

- All patients – Medicare only.
- All patients – all payer.
- Sampling – Medicare only, or
- Sampling – all payer.

Currently, the Hospital IQR program uses the "sampling – all payer" data submission characteristic. We solicited public comment on each of these 4 sets of characteristics and the impact they may have to vendors and hospitals, including but not limited to potential issues with the respective size of data files for each characteristic. We proposed to select 1 of the 4 sets as the data submission characteristic for the electronic reporting method for eligible hospitals and CAHs beginning in FY 2014.

Comment: Many commenters favored the all patient-all payer submission option. Nearly all of these commenters supported this option because of challenges identifying whether a patient is covered by Medicare or not. One commenter also noted that sampling Medicare patients alone would severely decrease the population of patients reported in the denominator for many CQMs, and that it is difficult to validate that the sampling is being done correctly. The commenter also argued that since data is captured at the time of care, there should be no difficulty submitting the data and therefore no need for sampling. Another commenter advised against permitting sampling for CQM reporting beginning in 2014 as it adds an additional level of complexity. One commenter stated that the ideal solution would be having both – all patient- all payer, and all patient-Medicare only, which would allow for Medicare vs. non-Medicare comparisons.

Some commenters who favored the all patient-all payer data submission option suggested that sampling-all payer be made available as an alternative option, with one noting that a no-sampling method may be burdensome for hospital staff who must manually enter

clinical data that is not captured electronically. If sampling is adopted, the commenter asks that it align with existing Hospital IQR Program sampling methodologies. One commenter preferred the sampling-all payer submission option, noting that it aligns with the reporting method for the Hospital IQR Program.

Response: We acknowledge hospitals' concerns about accurately distinguishing Medicare patients from other patients in their populations, and recognize that reporting data on Medicare patients only would reduce the population of patients for whom data are reported in most cases. Since payer will be collected as a supplemental data element for all CQMs beginning in 2014, we will be able to stratify measure results by payer. In the 2014 Edition certification criteria, ONC has increased the focus on CEHRT's capability to capture the structured data elements required for reporting the CQMs finalized in this rule. Therefore, the burden on hospital staff to manually enter data from a source other than the CEHRT should be greatly reduced. We also expect to propose electronic sampling algorithms in future rulemaking.

After consideration of the public comments received, we are finalizing the "sampling–all payer" option for patient-level data. This submission characteristic will only include patients that meet the denominator criteria of the CQMs that the eligible hospital or CAH selects to report to CMS and only the data elements listed in the CQM and transmission specifications for those patients would be sent to CMS.

(c) Electronic Reporting of Clinical Quality Measures for Medicaid Eligible Hospitals

States that have launched their Medicaid EHR Incentive Programs plan to collect CQMs electronically from CEHRT used by eligible hospitals. Each state is responsible for sharing the details on the process for electronic reporting with its provider community. We anticipate that

whatever means states have deployed for capturing CQMs included in the Stage 1 final rule electronically will be similar for CQMs beginning in 2014. However, we note that subject to our prior approval, the process, requirements, and the timeline is within the states' purview.

Comment: Commenters suggested unified Medicaid CQM reporting to reduce the burden on eligible hospitals operating in multiple states.

Response: For the purposes of the Medicaid EHR Incentive Program, eligible hospitals only have to report CQMs to the state making the EHR incentive payment. However, data from all practice locations that are equipped with CEHRT will be used for reporting CQMs, even if the practice locations are in different states.

After consideration of the public comments received, we are finalizing the policies for electronic reporting of CQMs for Medicaid eligible hospitals as proposed. We are clarifying that dually-eligible hospitals may submit their CQMs via the methods outlined in section II.B.8.b. of this final rule. As part of certification for EHR technology, ONC is including testing for data capture, CQM calculation, and electronic submission. For CQMs, this includes certification criteria for the QRDA-I and QRDA-III transmission format. We expect the states that have electronic reporting options for CQMs might choose to adopt QRDA-I for patient-level data and/or QRDA-III for aggregate data as the form in which eligible hospitals would report CQM data. By adopting the same QRDA-I and/or QRDA-III formats that CMS is requiring for CQM reporting, the states would be able to leverage the development of the specifications by CMS and the industry as well as the testing done by ONC for certification of EHR technology. This would reduce the burden on EHR vendors to implement and test different specifications.

C. Demonstration of Meaningful Use and Other Issues

1. Demonstration of Meaningful Use

a. Common Methods of Demonstration in Medicare and Medicaid

We proposed to continue our common method for demonstrating meaningful use in both the Medicare and Medicaid EHR Incentive Programs. The demonstration methods we adopt for Medicare will automatically be available to the states for use in their Medicaid programs. The Medicare methods are segmented into CQMs and meaningful use objectives, both of which meaningful users must meet. (We note that the discussion in this part of the preamble discuss the methods for meaningful use objectives. For the discussion on CQM reporting, please refer to II.B. of this final rule). We did not receive any comments on this general policy and for this final rule will continue the policy that was proposed (that is, common methods of demonstration with some flexibility for states as described in II.A.3.c of this final rule).

b. Methods for Demonstration of the Stage 2 Criteria of Meaningful Use

Except for the batch reporting option discussed in section II.C.1.c. of this final rule, we proposed no other changes to the attestation process for Stage 2 meaningful use objectives. We proposed several changes to reporting for CQMs beginning 2014, regardless of Stage, as discussed in section II.B. of this final rule. An EP, eligible hospital or CAH must successfully attest to the Stage 2 meaningful use objectives and successfully submit clinical quality measures to be a meaningful EHR user. We have revised §495.8 to accommodate the Stage 2 objectives and measures, as well as changes to Stage 1.

As discussed in our proposed rule (77 FR 13764), as HIT matures we expect to base demonstration more on automated reporting by CEHRT, such as the direct electronic reporting of measures, both clinical and nonclinical, and documented participation in HIE. As this occurs,

fewer objectives will be demonstrated through attestation. As explained in the proposed rule, however, we do not believe that the current advances in HIT and the certification of EHR technologies allow an alternative to attestation for the Stage 2 final rule. We will continue to evaluate possible alternatives to attestation and the accompanying changes to certification and meaningful use.

In addition, in lieu of EP-by-EP attestation, we proposed a batch file process for attestation. This batch file process would continue to require that meaningful use measures be assessed at the individual EP, eligible hospital or CAH level. It would be available no later than January 1, 2014. Batch reporting would allow large group practices to submit a large number of attestations at once, while still maintaining individual assessments of meaningful use. We proposed that a batch file process as discussed later would occur through the CMS attestation website. Each EP would still meet the required meaningful use thresholds independently; our proposal did not allow the use of group averages or any other method of group demonstration.

We explained that CMS and the states could continue to test options, such as registries or the direct electronic reporting of some measures; however, any such testing would be voluntary.

c. Group Reporting Option of Meaningful Use Core and Menu Objectives and Associated Measures for Medicare and Medicaid EPs Beginning with CY 2014

As explained previously, we proposed a batch reporting process that would allow groups of EPs to report each individual EP's core and menu objective data through a batch process, but would maintain individual assessments of meaningful use. (We note that the discussion in this part of the preamble does not discuss CQM reporting, which is discussed in II.B. of this final rule).

Specifically, we proposed to establish a file format in which groups could submit core and menu objective information for individual Medicare EPs (including the stage of meaningful use the individual EP is in, numerator, denominator, exclusion, and yes/no information for each core and menu objective) as well as a process for uploading such batch files.

We proposed that states would have the option, but not be required to, offer batch reporting of meaningful use data for Medicaid EP, and that states would outline their approaches in their state Medicaid HIT Plans (under current regulatory requirements in §495.332(c)(2) and (c)(3)).

We proposed the following policies would apply to batch reporting:

- Define a Medicare EHR Incentive Group as 2 or more EPs, each identified with a unique NPI associated with a group practice identified under one tax identification number (TIN) through the Provider Enrollment, Chain, and Ownership System (PECOS).

- States choosing to exercise this option will have to clearly define a Medicaid EHR Incentive Group via their state Medicaid HIT Plan.

- None of the EPs in either a Medicare or Medicaid EHR Incentive Group could be hospital-based according to the definition for these programs (see 42 CFR 495.4).

- Any EP that successfully attests as part of one Medicare EHR Incentive Group will not be permitted to also attest individually or attest as part of a batch report for another Medicare EHR Incentive Group.

- Because EPs can only participate in either the Medicare or Medicaid incentive programs in the same payment year, an EP that is part of a Medicare EHR Incentive Group will not be able to receive a Medicaid EHR incentive payment or be included as part of a batch report for a Medicaid EHR Incentive Group or vice versa.

- The group reporting option discussed in this section is limited to data for the core and menu objectives and does not include the reporting of clinical quality measures, which is also required to demonstrate meaningful use and receive an EHR incentive payment. Clinical quality measures must be reported separately through other electronic submission options. (These options are described in section II.B. of this final rule.).

- Because we proposed multiple group reporting methods for clinical quality measures, EPs will not have to report core and menu objective data in the same EHR Incentive Group as they report clinical quality measures. An EP will be able to submit the core and menu objectives as part of a group and the clinical quality measures as an individual or submit the core and menu objectives as an individual and the clinical quality measures as part of a group.

- Batch reporting would not be required by CMS and t EPs will be permitted to attest individually through the CMS attestation website (as long as they did not also report as part of a group).

- As in Stage 1, EPs will be required to individually meet all of the thresholds of the core and menu objectives and could not use group averages or any other method of group demonstration.

- Batch reporting would not change the policy that payment adjustments will be applied to individual EPs and not to Medicare EHR Incentive Groups. This policy is described in section II.D. of this final rule.

- Batch reporting would not change incentive payment assignment. That is, as with Stage 1, an EP's incentive payment will not be automatically assigned to the Medicare EHR Incentive Group with which they batch report under this option. The EP will still have to select the payee TIN during the registration process.

● An EP who chooses the group reporting option will be required to include in such reporting core and menu objective information on all outpatient encounters (that is, all encounters except those in the inpatient and emergency departments) where CEHRT is available, even if some encounters occurred at locations not associated with the EP's Medicare EHR Incentive Group. We explained that this policy is required because EPs who practice in multiple practices or locations are responsible for submitting complete information for all actions taken at practices/locations equipped with CEHRT. Under §495.4, to be considered a meaningful EHR user, an EP must have 50 percent or more of their outpatient encounters in practice(s) or location(s) where CEHRT is available. In the July 28, 2010 final rule (75 FR 44329), we also made clear that an EP must include outpatient encounters for all locations equipped with CEHRT.

● There would not be a minimum participation threshold for reporting as part of an EHR Incentive Group; in other words, an EP who is able to meet the 50 percent threshold of patient encounters in locations equipped with CEHRT could report all of their core and menu objective data as part of an EHR Incentive Group in which they had only 5 percent of their patient encounters with that group, provided they report all of the data from the other locations through the same batch reporting process with the EHR Incentive Group.

Many commenters supported our proposal to institute a batch reporting process.

Some commenters offered comments or requested clarification. The summary of the comments and our responses follow:

Comment: A few commenters questioned the statement that a group for purposes of batch reporting is two or more EPs, each identified with a unique NPI associated with a group practice identified under one tax identification number (TIN) through the Provider Enrollment,

Chain, and Ownership System (PECOS). These commenters suggested that the difference between this definition of a group and the one under the Physician Quality Reporting System (PQRS) is confusing and should be harmonized or aligned.

Response: Generally we agree with the principle of aligning definitions when possible. However, this rulemaking does not address PQRS definitions. Alignment with the current PQRS definition would entail changing our policy from 2 or more EPs to 25 or more EPs. We do not believe the benefits of alignment are greater than the administrative relief to group practices made up of 2 to 24 EPs. However, we note that in the Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013 proposed rule (77 FR 44722) we proposed to revise the PQRS definitions to 2 or more EPs. If finalized, the PQRS definition would align with our policy. Therefore, we are finalizing our policy that would allow batch reporting for groups with 2 (or more) EPs that meet the rules for such reporting. After consideration of the comments, we will establish a file format in which groups could submit core and menu objective information for individual Medicare EPs (including the stage of meaningful use the individual EP is in, numerator, denominator, exclusion, and yes/no information for each core and menu objective) and also establish a process through which groups would submit this batch file for upload as proposed. As noted previously, this batch file reporting process does not apply to CQM reporting, which is discussed in section II.B of this final rule.

After consideration of the public comments received, we are finalizing this option as proposed. There is no accompanying regulation text for this policy, as it governs the procedures for attestation, but not the meaningful use requirements.

We also sought public comment on a group reporting option that measures performance at a group, rather than at an individual, level (referred to as the "group performance" option.) Rather than proposing a set of rules for such group performance, we requested comment on a host of topics. Many commenters supported a group performance option; however, we received very few detailed comments on many of the specific issues we put forth for discussion. Therefore, we continue to believe that additional policy development is necessary to address specifically how group performance would operate. We are not finalizing the group performance policy at this time, as we wish to consider it further. EPs will continue to be required to individually meet all of the thresholds of the core and menu objectives. The following comments were received on issues relating to group performance.

We requested comments on the definition of "group," noting that the PQRS Group Reporting Option requires a physician group practice to have a single tax payer identification number (TIN), with 25 or more individual eligible professionals who have reassigned their billing rights to the TIN. Commenters responded that 25 is too large a number, with some suggesting 4 to 6, or even 2 or more, as an appropriate range. Commenters recommended that each EP within the TIN, be given the choice of participation in the group or individually. Some commenters also questioned whether a consistent TIN indicates a coherent group practice with care coordination.

We requested comments on whether there should be a self-nomination process for groups, as in PQRS, or an alternative process for identifying groups. Commenters generally supported self-nomination, if it is a simple process.

We also asked whether groups should be required to use the same CEHRT. Some commenters believed such a requirement would be onerous, explaining that in some cases

imaging providers, such as radiologists have their own CEHRT. Other commenters supported using the same CEHRT to ensure consistent reporting.

We questioned whether a group could be eligible for group reporting if CEHRT (same or different) were not available to all associated EPs at all locations. Some commenters responded yes, that in large systems clinics may be added or upgraded at different points in time and there may be transition times during which some clinics may not have CEHRT. Commenters stated that a threshold could be used to ensure that the EHR is available for most of the services provided by the group. Others stated that, no, groups should be held to the same standard; if the group as a whole is not eligible, individuals could still demonstrate meaningful use on an individual basis.

We requested comment on the appropriate policy when a group uses multiple certified EHR technologies that cannot share data easily. Some commenters stated that because the group as a whole should still have to meet the meaningful use objectives, interoperability should not be a barrier to group performance. These commenters stated that while interoperability is the ultimate goal of EHR technology, it should not become a requirement prematurely and providers and vendors are best positioned to remedy interoperability problems. Commenters also urged us to ensure that clearinghouses and software vendors are within the scope of the covered entities that must comply with the rule, although no authority was cited for requiring such compliance.

We questioned how meaningful use activities should be calculated, particularly when an EP practices individually and with a group, or in multiple group practices. Some commenters stated that meaningful use would always be at the group level. Others stated that if there are EPs practicing across two or more groups, then neither group should use the group reporting option, as this could result in different menu measure selections and other complications. Other

commenters recommended that the EP's covered services be calculated as a whole to generate the incentive payment amount and separate payments be made to each TIN based on the percentage of the EP's covered services that were assigned to each TIN.

We noted that the HITECH Act provides EPs who are meaningful users an incentive payment equal to 75 percent of Medicare allowable charges for covered professional services furnished by the EP in a payment year. Thus, we questioned how covered professional services performed by EPs in some other practice could be assigned to another group's TIN. Commenters suggested that groups could submit lists of EPs covered under its group submission and that have reassigned payment to the TIN. The covered services should include all covered services for the EP, regardless of TIN under which the services were billed. Commenters asserted that this process is not different from the current method in which individual EPs that work for multiple TINs can still reassign their incentive payments to a single TIN. Others recommended that for purposes of determining the 75 percent, CMS should simply limit its analysis to those services furnished at that practice.

We solicited public comment on how meaningful use activities performed at other groups should be included. Some commenters stated that groups should attest only for the services within the group practice, not services outside of the group. These commenters expressed concern about not being able to validate outside data.

If meaningful use activities outside the group were not included in group performance, we asked what the CMS policy should be for these activities performed outside the group. Commenters recommended that only the group activities should be considered, and that those activities performed outside the group should essentially be ignored.

We solicited input on what our policy should be if an EP reports as part of a group, but he

or she actually fails to meet a measure individually. Commenters generally stated that individual performance should be subsumed in the group performance. They assert that groups will have their own internal incentives to ensure that EPs are properly using the EHR system.

Along the same lines, we requested information on what should happen if an EP rejects a particular objective completely. Should such an EP be considered a meaningful EHR user as long as the EP's non-participation still allows group compliance with a percentage threshold? Again, commenters recommended measurement solely at the group level. Again, they stated that the group practice would have its own incentives to ensure EPs within the group properly use CEHRT.

We questioned how yes/no objectives should be handled in group reporting. Commenters again recommended measurement at the group level: A yes would mean that the group has "enabled" and is using that functionality of its CEHRT.

We questioned how group performance would operate in cases when some EPs in the group participate in Medicaid while others participate in Medicare. Commenters stated that groups could provide lists of EPs and indicate which EPs are covered under Medicare versus Medicaid. However, in any case we, could also encourage states to accept the group's submission as applying to Medicaid, as well as Medicare. While another commenter suggested that Medicare should be the default choice for a group, unless they all participate in Medicaid.

As to our question of whether any incentive payment would be reassigned to the group automatically, or whether the EP would assign it to the group at registration, commenters gave conflicting recommendations. Some stated that individual EPs could reassign incentive payments to a TIN, and that the group could, at the end of the period, present a list of EPs who are within the TIN and reassigned payment to such TIN. Others favored automatic reassignment

to the group demonstrating group performance, particularly when an EP is employed or contracts with only one group, or when a state does not permit assignment to an entity promoting the adoption of EHR technology. A commenter requested clarification on how an EP joining midyear would be handled.

We requested comments on the policies that would apply if an EP participates in one group's performance and the incentive payment were reassigned to the group automatically, but the EP also has covered services billed to other TINs. Commenters stated that if an EP leaves a group, there should be a mechanism for reporting this and allowing the EP to report individually or become part of another group; regardless, the automatic reassignment should stand.

We solicited information on how to address situations when an EP leaves a group during an active EHR reporting period. Commenters recommended that incentives could be pro-rated on this basis, perhaps with "beginning and ending dates" included in the group performance file to streamline the proration.

We requested information regarding payment adjustments, and whether they should also be applied at the group level. Some stated that group performance should be consistent at the incentive and payment adjustment phases of the EHR Incentive Program. Thus, if groups can receive incentives based on group performance, then group performance should also dictate payment adjustments at a group level. Others favored maintaining payment adjustments at the individual EP level.

Finally, we solicited alternative options for reporting meaningful use, while capturing necessary data. One commenter recommended a "sub-TIN" group reporting option where a specific department, specialty or clinic could report performance on a group basis.

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

In addition to the data already being collected under our regulations at §495.10, we proposed to collect the business email address of EPs, eligible hospitals and CAHs to facilitate communication with providers. We proposed to begin collecting the information as soon as the registration system can be updated following the publication of this final rule for both the Medicare and Medicaid EHR Incentive Programs. We did not propose to post this information online. In our preamble, we proposed to amend §495.10 accordingly. However, no regulation text appeared. We did not receive any comments on our proposal. We are finalizing regulation text at §495.10(a)(3) to collect business email address.

We note that we did not propose any changes to the registration for the Medicare and Medicaid EHR Incentive Programs, to the rules on EPs switching between programs, or to the record retention requirements in §495.10.

We did not propose any changes to the registration for the Medicare and Medicaid EHR Incentive Programs, to the rules on EPs switching between programs, or to the record retention requirements in §495.10.

We did not receive any comments and we are finalizing these provisions as proposed.

3. Hospital-Based Eligible Professionals

Our only proposed changes to the definition of hospital-based eligible professional were to allow the determination of hospital-based to continue once the payment adjustments go into effect, and to propose that the hospital-based analysis at the payment adjustment phase would, for Medicare, be based on federal FY 2 years prior to the payment adjustment year. (See proposed §495.4 and section II.D.2. of this final rule.)

We also requested comments on whether the definition of hospital-based should be refined to exclude from the definition those EPs who are not furnishing professional services "through the use of the facilities and equipment, including qualified electronic health records, of the hospital" (section 1903(t)(3)(D) and 1848(o)(1)(C)(ii) of the Act). We noted that during implementation of Stage 1, we were asked about situations where clinicians may work in specialized hospital units, the clinicians have independently procured and utilize EHR technology that is completely distinct from that of the hospital, and the clinicians are capable, without the facilities and equipment of the hospital, of meeting the eligible professional (for example ambulatory, not inpatient) definition of meaningful use. We stated our belief that such situations would be uncommon and might not be generalized under the uniform definition used by place of service codes.

We specifically requested comments on the following subjects: (1) how to determine whether specialized hospital units are using stand-alone certified EHR technology separate from that of the hospital; and (2) how to determine whether EPs using stand-alone certified EHR technology separate from that of the hospital are truly not accessing the facilities and equipment of the hospital. We proposed that hospital facilities and equipment would include the physical environment needed to support the necessary hardware; internet connections and firewalls; the hardware itself, including servers; and system interfaces necessary for demonstrating meaningful use, for example, to health information exchanges, laboratory information systems, or pharmacies. We proposed possibly using attestation for such elements, and noted our belief that any such attestations would be subject to audit and the False Claims Act.

We also requested comments on whether the criteria for ambulatory EHRs and the meaningful use criteria that apply to EPs could be met in cases where EPs are primarily

providing inpatient or Emergency Department services. By definition, the EPs affected by this issue are those who provide 90 percent or more of their services in the inpatient or emergency department, and who provide less than 10 percent of their services, and possibly none, in outpatient settings. However, since the beginning of the program, we have been clear that for EPs, meaningful use measures will not include patient encounters that occur within the inpatient or emergency departments (POS 21 or 23). See for example, FAQ 10068, 10466, and FAQ 10462 at http://questions.cms.gov or in section II.A.3.d.(2). of this final rule.

Some of our meaningful use criteria for EPs are measured based on office visits (clinical summaries) and others assume an outpatient type of setting (patient reminders). The certification rules at 45 CFR part 170 differentiate between ambulatory and inpatient EHRs, and we requested comments on whether the EPs in this case would have inpatient or ambulatory technology.

Comment: We received detailed comments addressing the majority of the questions we asked about how EPs would demonstrate they are not hospital-based were we to revise our definition of hospital-based to exclude EPs using stand-alone CEHRT separate from that of the hospital. These comments explained in a comprehensive manner how EPs use stand-alone CEHRT separate from that of the hospital, and also provide the facilities and equipment that make the use of CEHRT possible, including internet connections and firewalls. Commenters supported using the ambulatory certification criteria and the EP meaningful use objectives and measures with the inclusion of inpatient and emergency department encounters in meeting such measures.

Response: Given such comprehensive comments, we believe that it is possible for EPs to provide CEHRT in the hospital environment, that is, sufficiently independent of the facilities and equipment, including qualified electronic health records, of the hospital. In the Stage 1 final

rule, we explained why we were not interpreting the statute to provide for individualized determinations of whether EPs were hospital-based. We focused on language in the statute stating that "The determination of whether an eligible professional is a hospital-based eligible professional shall be made on the basis of the site of service." (See 75 FR 44440 through 44441). We continue to believe that this interpretation was reasonable based on the Congressional directive regarding site of service. However, we are now persuaded that the statute is also capable of the interpretation advanced by the commenters. Thus, while we continue to believe our prior interpretation was proper, we are convinced that other permissible interpretations may also be put forward through rulemaking. Therefore, we have added a new §495.5 to allow us to exclude EPs who can demonstrate to us that the EP funds the acquisition, implementation, and maintenance of Certified EHR Technology, including supporting hardware and any interfaces necessary to meet meaningful use without reimbursement from an eligible hospital or CAH; and uses such Certified EHR Technology in the inpatient or emergency department of a hospital (instead of the hospital's CEHRT).

Once an EP registers for a given year they will know whether they are hospital based or not. An EP who is designated as hospital based, but wishes to be determined non hospital-based due to their funding of the acquisition, implementation and maintenance of CEHRT, including supporting hardware; and use of such CEHRT at a hospital, in lieu of using the CEHRT of such hospital will utilize an administrative process throughout the incentive payment year (and extending 2 months after the end of the incentive payment year) to provide documentation and seek a non-hospital based determination. Following a successful non-hospital based determination, the EP must attest each subsequent year that they continue to be in the same situation of funding of the acquisition, implementation and maintenance of CEHRT, including

supporting hardware; and use of such CEHRT at a hospital without reimbursement from an eligible hospital or CAH, in lieu of using the Certified EHR Technology of such hospital, but would not have to provide the supporting documentation again. If and when a nonhospital-based determination has been made, the EP would then have to meet the same requirements of the EHR incentive program as any other EP including being subject to payment adjustments if applicable with a sole exception: The EP would include in their attestation to meaningful use all encounters at all locations, including those in the inpatient and emergency departments of the hospital, rather than just outpatient locations (other than the emergency department) as is the case for all other EPs.

4. Interaction with Other Programs

There were no proposed changes to the ability of providers to participate in the Medicare and Medicaid EHR Incentive Programs and other CMS programs, and we are not finalizing any new policies in this area. 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 section II.B. of this final rule for the proposed alignment initiatives for clinical quality measures.

Comment: Several commenters suggested changes to other CMS programs.

Response: Our proposed rule included policies for the EHR incentive program, and not other programs. Therefore, we are not addressing comments on rules other than the EHR incentive program, as these programs are outside the scope of this rulemaking.

D. Medicare Fee-For-Service

1. General Background and Statutory Basis

As we discussed in the Stage 1 final rule, sections 4101(b) and 4102(b) of the HITECH Act provide for reductions in payments to EPs, hospitals, and CAHs that are not meaningful users of CEHRT; beginning in CY 2015 for EPs, FY 2015 for hospitals, and in cost reporting periods beginning in FY 2015 for CAHs. We discuss the specific statutory requirements for each of these payment reductions in the following three sections. In these sections, we also present our specific policies for implementing these mandatory payment reductions.

2. Payment Adjustment Effective in CY 2015 and Subsequent Years for EPs who are not Meaningful Users of CEHRT for an Applicable Reporting Period

Section 1848(a)(7) of the Act, as amended by section 4101(b) of the HITECH Act, provides for payment adjustments effective for CY 2015 and subsequent years for EPs, as defined in §495.100 of the regulations, who are not meaningful EHR users during the relevant EHR reporting period for the year. In general, beginning in 2015, if an EP is not a meaningful EHR user for the EHR reporting period for the year, then the Medicare physician fee schedule (PFS) amount for covered professional services furnished by the EP during the year (including the fee schedule amount for purposes of determining a payment based on the fee schedule amount) is adjusted to equal the "applicable percent" (defined later) of the fee schedule amount that will otherwise apply. As we also discuss later, the HITECH Act includes an exception, which, if applicable, could exempt certain EPs from this payment adjustment. The payment adjustments do not apply to hospital-based EPs.

The term "applicable percent" is defined in the statute to mean: "(I) for 2015, 99 percent (or, in the case of an eligible professional who was subject to the application of the payment

adjustment [if the EP is not a successful electronic prescriber] under section 1848(a)(5) of the Act for 2014, 98 percent); (II) for 2016, 98 percent; and (III) for 2017 and each subsequent year, 97 percent."

In addition, section 1848(a)(7)(iii) of the Act provides that if, for CY 2018 and subsequent years, the Secretary finds that the proportion of EPs who are meaningful EHR users is less than 75 percent, the applicable percent shall be decreased by 1 percentage point for EPs who are not meaningful EHR users from the applicable percent in the preceding year, but that in no case shall the applicable percent be less than 95 percent.

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

a. Applicable Payment Adjustments in CY 2015 and Subsequent Calendar Years for EPs who are not Meaningful Users of CEHRT

Consistent with these provisions, in the Stage 1 final rule (75 FR 44572), we provided in §495.102(d)(1) and (2) that, beginning in CY 2015, if an EP is not a meaningful EHR user for an EHR reporting period for the year, then the Medicare PFS amount that will otherwise apply for covered professional services furnished by the EP during the year will be adjusted by the following percentages: for 2015, 99 percent (or, in the case of an EP who was subject to the application of the payment adjustment for e-prescribing under section 1848(a)(5) of the Act for

2014, 98 percent); (2) for 2016, 98 percent; and (3) for 2017 and each subsequent year, 97 percent.

However, while we discussed the application of the additional adjustment for CY 2018 and subsequent years if the Secretary finds that the proportion of EPs who are meaningful EHR users is less than 75 percent in the preamble to the final rule (75 FR 44447), we did not include a specific provision for this adjustment in the regulations text. Therefore, we proposed to revise the current regulations, to provide specifically that, beginning with CY 2018 and subsequent years, if the Secretary has found that the proportion of EPs who are meaningful EHR users under §495.8 is less than 75 percent, the applicable percent is decreased by 1 percentage point for EPs who are not meaningful EHR users from the applicable percent in the preceding year, but that in no case is the applicable percent less than 95 percent. In the proposed rule, we stated our expectation that we would base the determination of the proportion of EPs each year on the most recent CY for which we have sufficient data (that is, most likely, the data available as of October 1, 2017, as this is the last date for EPs to register and attest to meaningful use to avoid a payment adjustment in CY 2018). We proposed that the computation will be based on the ratio of EPs who have qualified as meaningful users in the numerator, to Medicare-enrolled EPs in the denominator. In the proposed rule we also explained that because hospital-based EPs and EPs are granted an exception meet the definition of "EP," we would not include such EPs in the denominator, because such EPs would not be subject to a determination of meaningful use status "under subsection (o)(2)." We also stated that we would provide more specific detail on this computation in future guidance after the final regulation is published.

In general terms, the two aforementioned provisions for payment adjustments to EPs who are not meaningful users of EHR technology have the following effects for CY 2015 and

subsequent years. The adjustment to the Medicare PFS amount that will otherwise apply for covered professional services furnished by the EP will be 99 percent in CY 2015. However, for CY 2015 the adjustment for an EP who, in CY 2014, was subject to the application of the payment adjustment for e-prescribing under section 1848(a)(5) of the Act will be 98 percent of the Medicare PFS amount. In CY 2016, the adjustment to the Medicare PFS amount that will otherwise apply will be 98 percent. Similarly, the adjustment to the Medicare PFS amount that will otherwise apply will be 97 percent in CY 2017. Depending on whether the proportion of EPs who are meaningful EHR users is less than 75 percent, the adjustment to the Medicare PFS amount can be as low as 96 percent in CY 2018, and 95 percent in CY 2019 and subsequent years.

We did not receive any comments on our proposed methodology for making the determination of the applicable payment adjustment for Medicare EPs, including our proposed methodology for making the "75 percent determination" beginning for CY2018. Therefore, we are finalizing these provisions as proposed.

We noted in our proposed rule that some eligible professionals may be eligible for both the Medicare and Medicaid EHR incentives, and have opted for the Medicaid EHR incentive. Under that program, in the first year of their participation, EPs may be eligible for an incentive payment for having adopted, implemented, or upgraded (AIU) to CEHRT. However, AIU does not constitute meaningful use of CEHRT. Therefore, those EPs who receive an incentive payment for AIU will not be considered meaningful EHR users for purposes of determining whether EPs are subject to the Medicare payment adjustment. Medicaid EPs who meet the first year requirements through AIU in either 2013 or 2014 will still be subject to the Medicare payment adjustment in 2015 if they are not meaningful EHR users for the applicable reporting

period. However, Medicaid EPs can, avoid this consequence by making sure that they meet meaningful use in 2013 (or 2014 if this is the first year of demonstrating meaningful use). Since the Medicaid EHR Incentive Program allows EPs to initiate as late as 2016, AIU can still be an important initial step for providers who missed the window to avoid the Medicare penalties, assuming they then demonstrate meaningful use in the subsequent year.

Comment: Commenters stated universal support for our proposal that EPs who are meaningful EHR users under the Medicaid EHR Incentive Program for an applicable reporting period will also be considered meaningful EHR users for that period for purposes of avoiding the Medicare payment adjustments.

Response: We agree with commenters and are finalizing this provision as proposed for the reasons outlined in the proposed rule.

Comment: A few commenters suggested that we allow Medicaid AIU to be used to avoid the payment adjustment.

Response: The statute (section 1848(a)(7) of the Act) specifically requires that the Medicare payment adjustment be applied to an EP "who is not a meaningful EHR user… for an EHR reporting period for the payment year." As we have discussed previously, AIU does not involve the demonstration of meaningful use. Therefore, we cannot accept the commenters' recommendation that demonstration of AIU be accepted to allow an EP to avoid the Medicare payment adjustment.

After consideration of the public comments received, we are finalizing these provisions as proposed.

TABLE 11: PERCENT ADJUSTMENT FOR CY 2015 AND SUBSEQUENT YEARS, ASSUMING THAT, FOR CY 2018 AND SUBSEQUENT YEARS, THE SECRETARY FINDS THAT LESS THAN 75 PERCENT OF EPs ARE MEANINGFUL EHR USERS

EPs who are non-meaningful users	2015	2016	2017	2018	2019	2020+
EP is not subject to the payment adjustment for e-prescribing in 2014	99%	98%	97%	96%	95%	95%
EP is subject to the payment adjustment for e-prescribing in 2014	98%	98%	97%	96%	95%	95%

TABLE 12: PERCENT ADJUSTMENT FOR CY 2015 AND SUBSEQUENT YEARS, ASSUMING THAT THE SECRETARY ALWAYS FINDS THAT, FOR CY 2018 AND SUBSEQUENT YEARS, AT LEAST 75 PERCENT OF EPs ARE MEANINGFUL EHR USERS

EPs who are non-meaningful users	2015	2016	2017	2018	2019	2020+
EP is not subject to the payment adjustment for e-prescribing in 2014	99%	98%	97%	97%	97%	97%
EP is subject to the payment adjustment for e-prescribing in 2014	98%	98%	97%	97%	97%	97%

Comment: A commenter noted use of the word, "during," in section 1848(a)(7) of the Act, which states: "… if the eligible professional is not a meaningful EHR user (as determined under subsection (o)(2) for an EHR reporting period for the year, the fee schedule amount for such services furnished by such professional during the year (including the fee schedule amount for purposes of determining a payment based on such amount) shall be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services under this subsection (determined after application of paragraph (3) but without regard to this paragraph)." The commenter asserted that the phrase "during the year" allows the Secretary to apply the payment adjustment for any amount of time during the year and does not require that the payment adjustment be applied for the entire year.

Response: We disagree with this interpretation. Other parts of the statute clearly show the payment adjustment applies for a year at a time, and the Congress' intent was to have the

physician fee schedule adjusted for an entire calendar year (that is, 99 percent (or 98 percent) in 2015, 98 percent in 2016, 97 percent in 2017, and so on.) The interpretation presented by the commenters would lead to absurd results, because it would allow the payment adjustment to be minimized to the point where it has no impact on the EP.

Therefore, we are finalizing the payment adjustment percentages and time periods as proposed.

b. EHR Reporting Period for Determining Whether an EP is Subject to the Payment Adjustment for CY 2015 and Subsequent Calendar Years

In the Stage 1 final rule, we did not specifically discuss the EHR reporting periods that will apply for purposes of determining whether an EP is subject to the payment adjustments for CY 2015 and subsequent years. Section 1848(a)(7)(E)(ii) of the Act provides broad authority for the Secretary to choose the EHR reporting period for this purpose. Specifically, this section provides that "term 'EHR reporting period' means, with respect to a year, a period (or periods) specified by the Secretary." Thus, the statute neither requires that such reporting period fall within the year of the payment adjustment, nor precludes the reporting period from falling within the year of the payment adjustment.

In developing our proposals in the case of EPs, we sought to establish appropriate reporting periods for purposes of the payment adjustments in CY 2015 and subsequent years to avoid creating a situation in which it might be necessary either to recoup overpayments or make additional payments after a determination is made about whether the payment adjustment should apply. We noted that this consideration is especially important in the case of EPs because, unlike the case with eligible hospitals and CAHs, there is not an existing mechanism for reconciliation or settlement of final payments subsequent to a payment year, based on the final data for the

payment year. (Although, as we discussed in relation to our proposals on the payment adjustments for eligible hospitals in CY 2015 and subsequent years, this consideration also carries significant weight even where such a reconciliation or settlement mechanism is available.) Similarly, we did not want to create any scenarios under which providers would be required either to refund money, or to seek additional payment from beneficiaries, due to the need to recalculate beneficiary coinsurance after a determination of whether the payment adjustment should apply. If we were to establish EHR reporting periods that run concurrently with the payment adjustment year, we would not be able to safeguard against such retroactive adjustments (potentially including adjustments to beneficiary copayments, which are determined as a percentage of the Medicare PFS amount).

Therefore, we proposed that EHR reporting periods for payment adjustments will begin and end prior to the year of the payment adjustment. Furthermore, we proposed that the EHR reporting periods for purposes of such determinations will be far enough in advance of the payment adjustment year to give us sufficient time to implement the system edits necessary to apply any required adjustments correctly, and that EPs will know in advance of the payment adjustment year whether or not they are subject to the adjustments that we have discussed. Specifically, we proposed that the following rules would apply for establishing the appropriate reporting periods for purposes of determining whether EPs are subject to the payment adjustments in CY 2015 and subsequent years:

- Except as provided in the following bulleted paragraph for EPs who become meaningful users for the first time in 2014, we proposed that the EHR reporting period for the 2015 payment adjustment would be the same EHR reporting period that applies in order to receive the incentive for payment year 2013. We stated that this proposal would align reporting

periods for multiple physician reporting programs. For EPs we proposed that the period would generally be a full calendar year of 2013 (unless 2013 is the first year of demonstrating meaningful use, in which case a 90-day EHR reporting period would apply). Under our proposed policy, an EP who receives an incentive for payment year 2013 would be exempt from the payment adjustment in 2015. An EP who received an incentive for payment years in 2011 or 2012 (or both), but who failed to demonstrate meaningful use in 2013 would be subject to a payment adjustment in 2015. (As all of these years will be for Stage 1 of meaningful use, we stated our belief that it is unnecessary to create a special process to accommodate providers that miss the 2013 year for meaningful use). For each year subsequent to CY 2015, we proposed an EHR reporting period for the payment adjustment that is the calendar year 2 years prior to the payment adjustment period, subject again to the special exception for new meaningful users of the CEHRT as follows:

- We proposed an exception for those EPs who never successfully attested to meaningful use prior to CY 2014. For these EPs, as it would be their first year of demonstrating meaningful use, for the 2015 payment adjustment, we proposed to allow a continuous 90-day reporting period that begins in 2014 and that ends at least 3 months before the end of CY 2014. In addition, the EP would have to successfully register for and attest to meaningful use no later than the date that occurs 3 months before the end of CY 2014. For EPs, we stated that under our proposal, the latest day the EP must successfully register for the incentive program and attest to meaningful use, and thereby avoid application of the adjustment in CY 2015, would be October 1, 2014. Thus, the EP's EHR reporting period would need to begin no later than July 3, 2014 (allowing the EP a 90-day EHR reporting period, followed by 1 extra day to successfully submit the attestation and any other information necessary to earn an incentive

payment). We proposed that this policy would continue to apply in subsequent years for EPs who are in their first year of demonstrating meaningful use in the year immediately preceding the payment adjustment year.

Comment: Many commenters disagreed with our interpretation of the statute. These commenters asserted that both the Congressional intent and the language of the statute required an EHR reporting period aligned with the payment adjustment year. Thus, these commenters maintained that an EP should be subject to a payment adjustment during a payment year only if he or she fails to demonstrate meaningful use during that payment year. These commenters proposed several alternative methods for employing an EHR reporting period that is concurrent to the payment adjustment year for EPs. These recommended methods involved either making a determination of meaningful use early in a payment year, and then applying the payment adjustment (where applicable) for only a later part of the year, or developing a reconciliation process at the end of the year in which the payment adjustment is either collected from or refunded to the EP as appropriate.

Response: We disagree with the commenters' interpretation of the statutory language. As the commenters note, section 1848(a)(7) of the SSA specifically requires that the Medicare payment adjustment be applied to an EP "who is not a meaningful EHR user… for an EHR reporting period for the payment year." However, as we discussed in the proposed rule, section 1848(a)(7)(E)(ii) of the Act specifically provides that "term 'EHR reporting period' means, with respect to a year, a period (or periods) specified by the Secretary." Thus, the statute neither requires that such reporting period fall within the year of the payment adjustment, nor precludes the reporting period from falling within the year of the payment adjustment. Rather, the statute allows the Secretary the discretion to set the EHR reporting period and link to a year of payment

adjustments. Indeed, given that Congress directed that the payment reduction that is applied to the physician fee schedule also apply for purposes of determining coinsurance, we believe there was an underlying intent to ensure that the physician fee schedule amount (and whether a percentage reduction applies) would be known at the time coinsurance is calculated. This would explain why Congress provided flexibility to the Secretary in determining which reporting period dictates whether the EP is subject to a payment adjustment. Finally, we note that other payment adjustment programs, such as the e-prescribing program, and the physician quality reporting system, also use a prior reporting period. Thus, it is consistent for us to adopt a prior reporting period for the EHR program as well.

Comment: Commenters also raised two more practical objections to our proposal to use a prior EHR reporting period. One objection is that there is insufficient vendor capacity for all providers to purchase CEHRT and achieve meaningful use prior to 2015, in order to avoid the payment adjustment in 2015. Some of these commenters asserted that the practical deadline for beginning the process of adopting and implementing CEHRT has already passed for some popular vendors; thus, vendor choice is limited by the proposed timeline. Commenters also assert that this issue is compounded because EHR vendors must upgrade current clients to 2014 CEHRT at roughly the same time.

Response: We understand the commenters' concerns. However, EPs have known for several years that they would face a payment adjustment beginning in 2015, and we believe that they have thus had adequate time to make appropriate preparations. During the last 2 years there has been a significant adoption of CEHRT with over 100,000 EPs receiving an incentive for adoption/implementation/upgrade or meaningful use. We also acknowledge the concerns expressed by many commenters about vendor capacity, and especially about whether every

vendor will be available to every EP seeking to establish meaningful use. We note that to avoid the payment adjustment in 2015, all providers will be required to establish only Stage 1 of meaningful use in the applicable reporting period. For the payment adjustment in 2016, only those who first demonstrated meaningful use in 2011 or 2012 will have to demonstrate Stage 2 in the applicable reporting period and we are finalizing a shorter EHR reporting period for these EPs to account for the time limitations. We also believe other factors outweigh the concerns noted by commenters. As discussed previously, we do not believe the statute should be read to allow payment adjustments for only part of the year. Each of the other alternative suggestions presented by commenters would require reprocessing of claims for EPs, as well as addressing the difficult issue of how to adjust co-insurance in the context of this reprocessing (that is, to refund some coinsurance or to collect additional coinsurance, depending upon the results of the reprocessing on each claim). The administrative and financial cost of the reprocessing that would be required would be quite significant for both CMS and the affected EPs. Especially for smaller dollar claims, it is possible that in 2015 the cost of reprocessing for CMS and EPs could exceed that payment adjustment. For example, a claim of $100 will be reduced $1 or $2 in CY 2015. If that claim was reprocessed, CMS Medicare Administrative Contractors (MACs) would have to reprocess the claim, utilize the banking system to send the payment; the EP's accounting process would have to accept the new payment and update the old claim and possibly incur the costs of collecting or refunding coinsurance. As the payment adjustments increase, the balance between the cost of the payment adjustments weighed against the cost of claim reprocessing may shift. In addition, as time passes we also anticipate that the supply of CEHRT and supporting services will increase to better match demand, lessening the concerns presented by the commenters. Therefore, we are finalizing the EHR reporting period for determining

whether an EP is subject to the payment adjustment for CY 2015 and subsequent calendar years as proposed. The issue requiring all providers regardless of stage of meaningful use to upgrade to 2014 CEHRT is addressed by ONC in their final rule published elsewhere in this issue of the **Federal Register**. We note that all providers, regardless of stage, will use a 3-month EHR reporting period in 2014.

c. Exception to the Application of the Payment Adjustment to EPs in CY 2015 and Subsequent Calendar Years

As previously discussed, section 1848(a)(7)(B) of the Act provides that the Secretary may, on a case-by-case basis, exempt an EP from the application of the payment adjustments in CY 2015 and subsequent CYs if the Secretary determines that compliance with the requirements for being a meaningful EHR user will result in a significant hardship, such as in the case of an EP who practices in a rural area without sufficient Internet access. As provided in the statute, the exception is subject to annual renewal, but in no case may an EP be granted an exception for more than 5 years. We note that the HITECH Act does not obligate the Secretary to grant exceptions. Nonetheless, in the proposed rule, we expressed our belief that there are hardships for which an exception should be granted. We therefore proposed three types of exceptions in the proposed rule and discussed a potential fourth. The three proposed exceptions were, by definition, time limited and we stated that the circumstances justifying such exceptions should not be present for more than 5 years. The fourth exception related to certain EPs and did not, by definition, involve time limited circumstances. Nevertheless, we noted that the 5-year limitation is statutory and cannot be altered by regulations, and that barriers to achieving meaningful use should be minimized over time.

Comment: Some commenters suggested that the exception be granted for an all 5 years

rather than an annual determination to reduce the burden on EPs seeking the exception and the burden on CMS to process the exceptions.

Response: Section 1848(a)(7)(B) of the Act makes the hardship exception subject to annual renewal. Therefore, we would not grant an exception for more than 1 year unless we are certain that the circumstances that qualify an EP for an exception will not change for 5 years. The only such definitive case is for new EPs, and we grant a 2-year exception for such new EPs, because the date when an individual becomes an EP is a fixed point in time and not subject to change. However, all other exceptions discussed in the proposed rule depend on variable circumstances and could change from year to year. For example, although the exception we are finalizing for certain EPs (see §495.102(d)(4)(iv)) could depend on scope of practice, which may be relatively fixed, it also depends on the ability to control the availability of CEHRT, which could easily change from year to year. Therefore, for these cases, we are not adopting this recommendation, and are finalizing a requirement for annual renewal.

As mentioned previously, we proposed three specific exceptions and a potential fourth in the proposed rule. First, we proposed that the Secretary may grant an exception to EPs who practice in areas without sufficient Internet access. We noted that section 1848(a)(7)(B) of the Act specifically allows the Secretary to establish a significant hardship "in the case of an eligible professional who practices in a rural area without sufficient Internet access." However, our proposal recognized that a nonrural area may also lack sufficient Internet access to make complying with the requirements for being a meaningful EHR user a significant hardship for an EP.

We noted that exceptions on the basis of insufficient Internet connectivity must intrinsically be considered on a case-by-case basis. Therefore, we proposed to require that EPs

must demonstrate insufficient Internet connectivity to qualify for the exception through an application process. As we discussed in the proposed rule, the rationale for this exception is that lack of sufficient Internet connectivity renders compliance with the meaningful EHR use requirements a hardship, particularly for meeting those meaningful use objectives requiring Internet connectivity, such as, summary of care documents, electronic prescribing, making health information available online, and submission of public health information. Therefore, we proposed that the application must demonstrate insufficient Internet connectivity to comply with the meaningful use objectives and that there are insurmountable barriers to obtaining such infrastructure, such as a high cost of extending the Internet infrastructure to their facility. We also proposed that an EP must establish the existence of the hardship was for the year that is 2 years prior to the payment adjustment year. Therefore, we proposed to require that applications be submitted no later than July 1 of the calendar year before the payment adjustment year in order to provide sufficient time for a determination to be made and for the EP to be notified about whether an exception has been granted prior to the payment adjustment year. This proposed timeline for submission and consideration of hardship applications was intended to allow sufficient time to adjust our payment systems so that payment adjustments are not applied to EPs who have received an exception for a specific payment adjustment year.

In our proposed rule, we also encouraged EPs to apply for the exception as soon as possible, which is after the first 90 days (the earliest EHR reporting period) of CY 2013. If applications are submitted close to or on the latest date possible (that is, July 1, 2014 for the 2015 payment adjustment year), then the applications could not be processed in sufficient time to conduct an EHR reporting period in CY 2014 in the event that the application is denied.

Comment: Commenters stated universal support for this exception. However,

commenters expressed the concern about the situation of an EP who might have sufficient internet access in the 2 years prior, but lose it in 2014.

Response: We are finalizing our proposed significant hardship exception for insufficient Internet connectivity with one modification. We believe that it is extremely unlikely that an EP would lose sufficient internet access at one location. However, an EP may relocate to a location without sufficient Internet access. Therefore, we are finalizing our proposal with the modification to allow for the demonstration of insufficient internet access for any 90-day continuous period between the start of the year 2 years prior to the payment adjustment year and through the application submission date of July 1 of the year prior to the payment adjustment year. The 90-day period should be within this timeframe (for example, for payment adjustment year 2015, the hardship would need to be shown for any continuous 90-day period that begins on or after January 1, 2013 and ends on or before July 1, 2014.

Second, we proposed to provide an exception for new EPs for a limited period of time after the EP has begun practicing. Newly practicing EPs will not be able to demonstrate that they are meaningful EHR users for a reporting period that occurs prior to the payment adjustment year. Therefore, we proposed that for 2 years after they begin practicing, EPs could receive an exception from the payment adjustments that will otherwise apply in CY 2015 and thereafter. We also proposed that, for purposes of this exception, an EP who switches specialties and begins practicing under a new specialty will not be considered newly practicing. For example, an EP who begins practicing in CY 2015 will receive an exception from the payment adjustments in CYs 2015 and 2016. However, as discussed previously, the new EP will still be required to demonstrate meaningful use in CY 2016 in order to avoid being subject to the payment adjustment in CY 2017. In the absence of demonstrating meaningful use in CY 2016,

an EP who had begun practicing in CY 2015 will be subject to the payment adjustment in CY 2017. We proposed to employ an application process for granting this exception, and will provide additional information on the timeline and form of the application in guidance subsequent to the publication of the final rule.

Comment: Commenters stated universal support for this exception in public comments, and we are finalizing this exception as proposed for the reasons outlined in the proposed rule.

Third, we proposed an additional exception in this final rule for extreme circumstances that make it impossible for an EP to demonstrate meaningful use requirements through no fault of her own during the reporting period. Such circumstances might include: a practice being closed down; a hospital closed; a natural disaster in which an EHR system is destroyed; EHR vendor going out of business; and similar circumstances. Because exceptions on extreme, uncontrollable circumstances must be evaluated on a case-by-case basis, we proposed to require EPs to qualify for the exception through an application process.

Comment: Many commenters supported this exception. However a number of the supporters requested that various circumstances be added to the list of example circumstances that we provided. These examples dealt primarily with concerns related to vendors of CEHRT. Specifically, commenters were concerned about vendors of CEHRT not maintaining their certification status, ability to meet implementation schedules, and ability to find a vendor of CEHRT willing to work with them. In addition, commenters suggested that the provider facing severe financial distress, such as bankruptcy or restructuring of debt should be included as an example.

Response: In evaluating these circumstances, we considered whether first and foremost they met the criteria of making it impossible for the EP to demonstrate meaningful use

requirements through no fault of his or her own during the EHR reporting period. Second, we considered whether they establish a definitive circumstance that would always rise to the level of the exception or whether they would be dependent on the individual scenario. We are including two examples submitted by commenters in the preamble of the final rule that match the former criteria. First, we would consider the case an EP whose CEHRT loses its certification either through revocation or because the vendor did not upgrade their CEHRT to the latest requirements as an extreme circumstance that might qualify for this exception. Second, we would consider the case of an EP suffering severe financial distress resulting in a bankruptcy or restructuring of debt as an extreme circumstance that might qualify for this exception.

We require applications to be submitted no later than July 1 of the calendar year before the payment adjustment year in order to provide sufficient time for a determination to be made and for the EP to be notified about whether an exception has been granted prior to the payment adjustment year. This timeline for submission and consideration of hardship applications also allows for sufficient time to adjust our payment systems so that payment adjustments are not applied to EPs who have received an exception for a specific payment adjustment year.

The purpose of this exception is to accommodate EPs who would have otherwise been able to become a meaningful EHR user and avoid the payment adjustment for a given year in the absence of the extreme circumstances they face. Therefore, it is necessary to establish whether the relevant circumstances exist during the EHR reporting period for a given payment adjustment year rather than the payment adjustment year itself. In the proposed rule, we explained the inherently case-by-case nature of this exception request. While we discussed circumstances that arise in "either of the 2 calendar years before the payment adjustment year," our intent was to ensure that the regulations recognized the two different EHR reporting periods for new

meaningful users (that is, those demonstrating meaningful use for the first time in the year immediately prior to the payment adjustment year), versus current meaningful users (that is, those demonstrating meaningful use in the calendar year that is two years before the payment adjustment year). Obviously, a "current" meaningful user, who is required under our regulations to demonstrate meaningful use in the calendar year two years before the payment adjustment year, may not receive an exception for circumstances that occur after that reporting period. While a new meaningful user might be able to demonstrate that extreme circumstances that occurred prior to the reporting period continue to warrant an exception, we believe the case-by-case nature of the exception requests would allow such "new" meaningful users this opportunity to demonstrate that a significant hardship continues to exist during the reporting period. Therefore, in this final rule, we are clarifying our regulation to distinguish between new and current meaningful users, to be clear that the extreme circumstances must exist during the period in which the provider would otherwise be required to demonstrate meaningful use. EPs should apply for this exception on the basis of circumstances arising in the CY 2 years prior to the payment adjustment year, or, in the case of EPs who have never attested to meaningful use, the year immediately prior to the payment adjustment year.

Finally, we solicited comment on the appropriateness of granting a fourth exception for EPs meeting certain specific general criteria that might render demonstration of meaningful use very difficult. The criteria that we discussed were--

- Lack of face-to-face or telemedicine interaction with patients, thereby making compliance with meaningful use criteria more difficult. Meaningful use requires that a provider collect a considerable amount of information about the patient and is able transport information online (to a PHR, to another provider, or to a patient) and is significantly easier if the provider

has direct contact with the patient and a need for follow up care or contact. Certain physicians often do not have a consultative interaction with the patient. For example, pathologist and radiologists seldom have direct consultations with patients. Rather, they typically submit reports to other physicians who review the results with their patients;

- Lack of follow up with patients. Again, the meaningful use requirements for collecting information about the patient and transporting information online are significantly easier to meet if a provider has direct contact with a patient and a need to follow-up with the patient; and
- Lack of control over the availability of CEHRT at their practice locations.

In our proposed rule, we stated that we did not believe any one of these barriers taken independently would constitute an insurmountable hardship; however, our experience with Stage 1 of meaningful use suggests that, taken together, they may pose a substantial obstacle to achieving meaningful use. Therefore, we discussed several options in the proposed rule. One option was to provide a time-limited, 2-year payment adjustment exception for all EPs who meet the previous criteria. This approach would allow us to reconsider this issue in future rulemaking. Another option was to provide such an exception with no specific time limit. However, we noted that even under this less restrictive option, by statute no individual EP can receive an exception for more than 5 years. As discussed earlier, we believe the proliferation of both CEHRT and health information exchange will reduce the barriers faced by specialties with less CEHRT adoption over time as other providers may be providing the necessary data for these specialties to meet meaningful use. We particularly requested comment on how soon EPs who meet the previous criteria will reasonably be able to achieve meaningful use.

In the proposed rule, we encouraged comment on whether these criteria, or additional criteria not accounted for in the meaningful use exclusions, constitute a significant hardship to

meeting meaningful use. We indicated that we that we would consider whether to adopt an exception based on these or similar criteria in the final rule, and, if so, whether such an exception should apply to individual EPs or across-the-board based on specialty or other groupings that generally meet the appropriate criteria.

Comment: Numerous commenters expressed support for including this exception. Some commenters agreed with CMS' assertion that all three barriers must be in place for this to be considered a significant hardship, while others maintained that any one of these barriers constitutes a significant hardship. Commenters from specific groups also presented arguments that they face one or more (up to all three) of the barriers presented in a sufficiently uniform way to have the exception apply across the board to their group.

Response: After reviewing the comments on this issue, we believe that the hardships presented are significant. Some EPs in the specialties that face all three barriers have already successfully attested to meaningful use. Thus, even when all three barriers are present, meaningful use may be difficult, but not impossible to achieve. In establishing the criteria for meaningful use itself, we have adopted exclusions and constructed the measures to lower the first two barriers as much as possible. For example, EPs with no office visits (that is, without direct patient contact) do not have to provide visit summaries, nor do they have to provider patient reminders. Due to both the allowances built into the meaningful use criteria and the fact at least a few EPs in nearly all specialties have attested to meaningful use, we do not believe that each barrier stands alone as a significant hardship. However, in considering the hardships and how they would be overcome there are significant differences between the first two and the latter (lack of control of CEHRT). Lack of face-to-face and need for follow up are both overcome through robust health information exchange. However, we do not believe that the existing

availability health information exchange is sufficient to overcome these hardships. Therefore, we are finalizing an exception for those EPs who lack both face-to-face interactions with patients and those who lack the need to follow up with patients. An EP may apply for this exception only on the grounds that they meet both of these criteria (lack of face-to-face interactions and lack the to follow up with patients). We consider lack of face-to-face and need for follow-up care to be situations where the EP has no or nearly no face-to-face patient interactions or need for follow-up care. The EP would need to demonstrate either a complete lack of face-to-face interactions and follow-up or that cases of face-to-face interaction and follow-up are extremely rare and not part of normal scope of practice for that EP.

In reviewing the arguments presented for a group determination as well as considering common knowledge about the scope of practice of various specialties, we agree with commenters that the specialties of anesthesiology, radiology, and pathology lack face-to-face interactions and need to follow up with patients with sufficient frequency to warrant granting an exception to each EP with one of these primary specialties. We note that anesthesiologists do interact with patients, but not in a manner that is conducive to collecting the information needed for many aspects of meaningful use. As discussed previously, this exemption is subject to annual renewal. In future rulemaking we will consider whether the proliferation of health information exchange or any other developments are sufficient to remove lack of face-to-face interaction as a barrier, and whether the proliferation of CEHRT is sufficient to remove lack of control over the availability of CEHRT as a barrier. We will consider these issues in relation both to the exception itself and its application to the specialties of anesthesiology, radiology, and pathology. As such, physicians in these three specialties should not expect that this exception will continue indefinitely, nor should they expect that we will grant the exception for the full 5-

year period permitted by statute. We will consider the extent to which these specialties continue to face these barriers in the Stage 3 rule and in other future rulemaking. We will also work to develop strategies to assist physicians who lack face-to-face interactions and the need to follow up with patients in demonstrating meaningful use. We may develop such strategies in the context of future rulemaking (for example, the Stage 3 rule) or in the form of additional guidance to physicians in these specialties. We also encourage all anesthesiologists, radiologists, and pathologists to continue to build out their ability to participate in health information exchange, adopt CEHRT and apply for the Medicare or Medicaid EHR incentives. Those seeking the Medicare EHR incentives can start through 2014, while those seeking the Medicaid EHR incentives can start through 2016.

As hospital-based anesthesiologists, radiologists, and pathologists are not eligible for the incentive and are thus exempted from the payment adjustment, the exception discussed in this section relates to these specialists in nonhospital settings.

With regard to the third barrier (lack of control over the availability of CEHRT at practice locations), we believe that in cases where an EP practices at multiple locations just this one barrier could be sufficient to constitute a significant hardship. In such cases, the EP would have to truly have no control over the availability of CEHRT. Control does not imply final decision-making authority. For example, we would generally view EPs practicing in a large, corporate, group as having control over the availability of CEHRT, because they can influence the group's purchase of CEHRT, they may reassign their claims to the group, they may have a partnership/ownership stake in the group, or any payment adjustment would affect the group's earnings, and the entire impact would not be borne by the individual EP. These EPs can influence the availability of CEHRT and the group's earnings are directly affected by the

payment adjustment. Thus, such EPs would not, as a general rule, be viewed as lacking control over the availability of CEHRT and would not be eligible for the hardship exception based solely on their membership in a group practice that has not adopted CEHRT.

On the other hand, there are EPs who practice at multiple locations who truly have little to no control over whether CEHRT is available at their locations. These might include, surgeons using ambulatory surgery centers or physicians treating patients in a nursing home. In these cases, the surgeon or physician likely would bear the entire impact of any payment adjustment – and such adjustment would not affect the earnings of the ambulatory surgery center or nursing home. In addition, because the surgeon or physician merely sees patients at the center or home, and does not have any other interest in the facility, we believe they would exert little to no influence over whether the nursing home, center, or other similar outpatient site adopts and implements CEHRT.

We note that we already have in place an eligibility requirement that allows for an EP to still qualify as a meaningful EHR user even if up to 49.9 percent of the EP's outpatient encounters are in locations that lack CEHRT. Thus, our exception would apply only in the case of EPs practicing in multiple locations where the lack of control (as discussed previously) exists for a majority (50 percent or more) of their outpatient encounters at such locations, causing such EPs to not be eligible to become meaningful EHR users. (In addition, we wish to make clear that we will not grant the exception to EPs that lack control in their practice locations but where those locations have adopted CEHRT would mean that the EP could become a meaningful EHR user.)

For the reasons discussed earlier, we have adopted a final regulation that allows an EP practicing at multiple locations to demonstrate that the EP was truly unable to control the availability of CEHRT at either one or a combination of locations that constitute more than 50

percent of their outpatient encounters. Inpatient hospital and emergency department encounters would not be included in either the numerator or the denominator for purposes determining whether the 50 percent threshold is met. This approach is consistent with the categories of encounters that are considered to be outpatient for purposes of determining hospital based status. (As noted previously, the locations cited by the EP for purposes of qualifying for this exception could not have CEHRT available – otherwise, we would view the EP as being potentially able to demonstrate meaningful use.)

After considering the public comments, we are finalizing an exception by adding a new §495.102(d)(4)(iv) to the regulations. EPs whose primary specialty is listed in PECOS as anesthesiology, radiology or pathology 6 months prior to the first day of the year in which payment adjustments that would otherwise apply will be deemed to qualify for this exception, subject to the 5-year limit that applies to all exceptions under this paragraph.

Comment: Many commenters requested that these and other commenter proposed exceptions apply to other programs besides the Medicare EHR incentive program.

Response: This final rulemaking focuses on the EHR Incentive program, and we did not propose to make changes to other programs. We encourage interested parties to submit comments on proposed rules (if any) for those other programs.

Comment: Commenters suggested the following additional exceptions:

- All EPs over 60 or eligible for Social Security and for all practices with 5 or fewer physicians.

- EPs who make a good faith effort, but fail to reach the thresholds thereby making a distinction between those who make an effort and those who do not attempt to become meaningful EHR user.

- EP is not practicing for a significant period of time during the reporting period.
- EP working in a practice without CEHRT changes to a new to a practice that has CEHRT during the reporting period.

Response: We address each of these in turn. We agree that there is evidence that older EPs and those in smaller practices have been slower to adopt CEHRT[6] [7]. The HITECH Act even acknowledged the problems for smaller practices by creating assistance programs for EPs in individual or small practices in Title XIII, section 3012(c)(4) of the Act. However, based on attestation information submitted to us, EPs in both groups are successfully meeting meaningful use in significant numbers. Therefore, we do not believe that either an EP's age or practice size constitutes a significant hardship. In addition, we believe it would be problematic to exempt a category of EPs based on age or size of practice given that the intent of the payment adjustments and incentives is to ensure widespread modernization to electronic health records. We do not believe that these elements, in themselves, demonstrate that the EP experiences a "significant hardship" in becoming a meaningful EHR user.

The next exception suggested by commenters is for EPs who attempt to become a meaningful EHR user, but fail to do so. Because we have already adopted an exception for EPs who face circumstances beyond their control, the application of this suggested exception would necessarily be limited to EPs who face normal difficulties, rather than significant hardship, in becoming meaningful EHR users. Again, the statute requires demonstration of a significant hardship as the basis for an exception, and we do not believe that a good faith attempt, in and of itself, demonstrates the existence of a significant hardship exists sufficient to prevent the EP

---

6 Chun-Ju Hsiao, Sandra L. Decker, Esther Hing and Jane E. Sisk Most Physicians Were Eligible For Federal Incentives In 2011, But Few Had EHR Systems That Met Meaningful Use Criteria, *Health Affairs*,31 , No. 5 (2012)

7 Sandra L.Decker, Eric W. Jamoom and Jane E. Sisk Physicians In Nonprimary Care And Small Practices And Those Age 55 And Older Lag In Adopting Electronic Health Records Systems *Health Affairs*, 31, No. 5 (2012)

from becoming a meaningful EHR user. Furthermore, Congress set the benchmark for receiving full payment, without being subject to payment adjustment, on the achievement of meaningful use rather than on the attempt to achieve meaningful use. Therefore, we do not believe that EPs who attempt, but fail, to meet meaningful use and do not qualify for one of our other exceptions should be granted a significant hardship exception

We also do not believe that it is appropriate to establish an exception for EPs not practicing for significant time periods during the EHR reporting period. First, we already proposed (and are finalizing) an exception for newly practicing EPs. Second, EPs who are not newly practicing, but only practice for part of the EHR reporting period should be able to report in the numerator and denominators simply the numbers that pertain to the time during which they are practicing. For example, a measure based on number of patients seen or actions taken would include only those patients/actions during the time the EP is practicing during the applicable reporting period. We recognize that some meaningful use measures, such as drug-drug and drug-allergy interaction checks, require a functionality to be enabled for the entire EHR reporting period. In this case, the EP would have the functionality enabled for the period s/he is practicing.

The final exception suggested by commenters is for an EP working in a practice without CEHRT who changes to a new practice with CEHRT. Again, the commenters did not explain why such a circumstance, by itself, supports a significant hardship that prevents the EP from becoming a meaningful EHR user. Moreover, if the EP has never demonstrated meaningful use he or she should have an initial 90-day reporting period that allows the EP to demonstrate meaningful use in a shorter period. In addition, under current guidance, if the EP has more than 50 percent of their outpatient encounters at the new practice equipped with CEHRT then they would be able to exclude the old practice from their meaningful use measures.

After considering the public comments, we are not finalizing these exceptions recommended by the commenters. The following table summarizes the timeline for EPs to avoid the applicable payment adjustment by demonstrating meaningful use or qualifying for an exception from the application of the payment adjustment:

TABLE 13: TIMELINE FOR ELIGIBLE PROFESSIONALS (OTHER THAN HOSPITAL-BASED) TO AVOID PAYMENT ADJUSTMENT

EP Payment Adjustment Year (Calendar Year)	Demonstrate MU during EHR Reporting Period 2 Years Prior to Year of Payment Adjustment	OR	For an EP Demonstrating Meaningful Use for the First Time in the Year Prior to the Payment Adjustment Year, EHR Reporting Period is a Continuous 90-day Reporting Period Beginning No Later Than:	OR	Apply or Otherwise Qualify for an Exception No Later Than:
2015	CY 2013 (with submission no later than February 28, 201)		July 3, 2014 (with submission no later than October 1, 2014)		July 1, 2014
2016	CY 2014 (with submission no later than February 28, 2015)		July 3, 2015 (with submission no later than October 1, 2015)		July 1, 2015
2017	CY 2015 (with submission no later than February 29, 2016)		July 3, 2016 (with submission no later than October 1, 2016)		July 1, 2016
2018	CY 2016 (with submission no later than February 28, 2017)		July 3, 2017 (with submission no later than October 1, 2017)		July 1, 2017
2019	CY 2017 with submission no later than February 28, 2018)		July 3, 2018 (with submission no later than October 1, 2018)		July 1, 2018

Notes: (CY refers to the calendar year, January 1 through December 31 each year.)
The timelines for CY 2020 and subsequent calendar years will follow the same pattern.

TABLE 14: PERIOD HARDSHIP MUST BE SHOWN WITH APPLICATION DATE

Exception	Period of Consideration for Exception	Application For CY2015 Submitted No Later Than
Insufficient internet access	Demonstrate insufficient internet access for any continuous 90-day period from the start of the CY 2 years prior to the payment adjustment year to July 1 of the year prior to the payment adjustment year (For CY 2015 – January 1, 2013 – July 1, 2014)	July 1, 2014
New EP	New EP granted an exception for the year they become an EP and the following year (For CY 2015, the EP would have to be new in either CY 2014 or CY 2015)	Guidance to be issued following publication of the final rule

Exception	Period of Consideration for Exception	Application For CY2015 Submitted No Later Than
Extreme Circumstances outside of the EP's Control	For an EP who has previously demonstrated meaningful use, the EP must demonstrate extreme circumstances that affect either of the CYs in the 2 years prior to the payment adjustment year. (For CY 2015 – CY 2013) For EPs who have never demonstrated meaningful use, the EP must demonstrate extreme circumstances that affect the CY prior to the payment adjustment year. (For CY 2015 – CY2014)	July 1, 2014
Lack of Face-Face/Telemedicine Patient Interactions and Lack of Need for Follow Up Care, Lack of Control Over Availability of CEHRT for EPs practicing in multiple locations	The CY 2 years prior to the payment adjustment year(For CY 2015 – CY 2013) through the application deadline. For all EPs, if they are registered in PECOS with a primary specialty of anesthesiology, pathology or radiology 6 months prior to first day of the payment adjustment year they meet the exception. (For CY2015 – July 1, 2014)	For applications only: July 1, 2014

d. HPSA Bonus Technical Change

In this final rule we are also making a technical change to our regulations to correctly reflect our policy on EPs who predominantly furnish services in a geographic HPSA. This change is necessary to reflect the current policy that the 50 percent determination is based on the covered professional services provided during the payment year, in accordance with the preamble discussion in the Stage 1 final rule (75 FR 44444 through 44445). The current regulation erroneously uses the phrase "the year prior to the payment year," which conflicts with our preamble discussion in both the proposed (75 FR 1908 through 1909) and final Stage 1 rules. We note that we are not changing the policy (already adopted) that the HPSA must be so designated by December 31 of the year prior to the payment year.

e. Payment Adjustment Not Applicable To Hospital-Based EPs

Section 1848(a)(7)(D) of the Act provides that no EHR payment adjustments otherwise applicable for CY 2015 and subsequent years "may be made… in the case of a hospital-based eligible professional (as defined in subsection (o)(1)(C)(ii)) of the Act." We proposed that the

same definition of hospital-based should apply during the incentive and payment adjustment phases of the Medicare EHR incentive program (that is, those eligible to receive incentives will also be subject to adjustments). Therefore, we proposed that our regulations at §495.100 and §495.102(d) would retain, during the payment adjustment phase of the EHR Incentive Program, the definition of hospital-based eligible professional at §495.4. For purposes of the Medicare EHR incentive payment program, the determination of whether an EP is hospital-based is made on the basis of data from "the Federal FY prior to the payment year." In the preamble to the Stage 1 final rule (75 FR 44442), we also stated that "in order to provide information regarding the hospital-based status of each EP at the beginning of each payment year, we will need to use claims data from an earlier period. Therefore, we will use claims data from the prior fiscal year (October through September). Under this approach, the hospital-based status of each EP will be reassessed each year, using claims data from the fiscal year preceding the payment year. The hospital-based status will be available for viewing beginning in January of each payment year."

We proposed to retain the concept established in the Stage 1 final rule (75 FR 44442) of making hospital-based determinations based upon a prior fiscal year of data. However, in the proposed rule we expressed concerned about ensuring that EPs are aware of their hospital-based status in time to purchase EHR technology and meaningfully use it during the EHR reporting period that applies to a payment adjustment year. EPs who believe that they are not hospital based will have already either worked towards becoming meaningful EHR users or planned for the payment adjustment. EPs who believe that they will be determined hospital based may not have done so. EPs in these circumstances will need to know they are not hospital based in time to become a meaningful EHR user for a 90-day EHR reporting period in the year prior to the payment adjustment year. To use the example of the CY 2015 payment adjustment year, a

determination based on FY 2013 data will allow an EP to know whether he or she is hospital-based by January 1, 2014. This timeline would give the EP approximately 6 months to begin the EHR reporting period, which could last from July through September of 2014. We stated in the proposed rule that we did not believe this to be sufficient time for the EP to implement CEHRT. Therefore, we proposed to base the hospital based determination for a payment adjustment year on determinations made 2 years prior. Again using CY 2015 payment adjustment year as an example, the determination would be available on January 1, 2013 based on FY 2012 data. This proposed determination date will give the EP up to 18 months to implement CEHRT and begin the EHR reporting period to avoid the CY 2015 payment adjustment. In the proposed rule, we asserted that this a reasonable time frame to accommodate a difficult situation for some EPs. However, we also are aware that there may be EPs who are determined nonhospital-based under this "2-years prior" policy when they will be determined hospital-based if we made the determination just 1-year prior. Again, using the example of the CY 2015 payment adjustment year, an EP determined nonhospital-based as of January 1, 2013 (using FY 2012 data) may be found to be hospital-based as of January 1, 2014 (using FY 2013 data). In this situation, we stated in the proposed rule that we did not believe the EP should be penalized for having been nonhospital based as of January 1, 2013, especially if the EP has never demonstrated meaningful use, and the EP's first EHR reporting period will have fallen within CY 2014. Therefore, in the proposed rule we requested comments on expanding the hospital-based determination to encompass determinations made either 1or 2 years prior. Under this alternative, if the EP were determined hospital based as of either one of those dates, then the EP would be exempt from the payment adjustments in the corresponding payment adjustment year. This would mean that for the CY 2015 payment adjustment year, an EP determined hospital based as

of either January 1, 2013 (using FY 2012 data) or January 1, 2014 (using FY 2013 data) would not be subject to the payment adjustment. In all cases, we would need to know that the EP is considered hospital based in sufficient time for the payment adjustment year.

Comment: Commenters provided only general supportive comments on this proposal.

Response: We thank the commenters for the support. For the reasons stated in the proposed rule, we are finalizing a rule that will determine hospital based using either of the following fiscal year's data: (1) the fiscal year before the year that is 1 year prior to the payment adjustment year (for example, FY 2013 data for payment adjustment year 2015); or (2) the fiscal year before the year that is 2 years prior to the payment adjustment year (for example, FY 2012 data for payment adjustment year 2015). If the data from either year result in a hospital-based determination, then the EP would not be subject to the payment adjustments for the relevant year.

We discuss one aspect of determining hospital-based status, specifically the circumstances of EPs who fund the acquisition, implementation, and maintenance of their own CEHRT in a hospital based setting, in section II.C.3. of the preamble to this final rule.

3. Incentive Market Basket Adjustment Effective in FY 2015 and Subsequent Years for Eligible Hospitals that are not Meaningful EHR Users For an Applicable Reporting Period

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 year, beginning in FY 2015. Specifically, section 1886(b)(3)(B)(ix)(I) of the Act provides that, "for FY 2015 and each subsequent FY," 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 will apply to "three-quarters of the percentage increase otherwise applicable." 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 is required to reduce the percentage increases otherwise applicable by 25 percent (33 1/3 percent of 75 percent) in 2015, 50 (66 2/3 percent of 75 percent) 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 such "reduction shall apply only with respect to the FY involved and the Secretary shall not take into account such reduction in computing the applicable percentage increase … for a subsequent FY."

TABLE 15: PERCENTAGE DECREASE IN APPLICABLE HOSPITAL PERCENTAGE INCREASE FOR HOSPITALS THAT ARE NOT MEANINGFUL EHR USERS

	2015	**2016**	**2017+**
Hospital payment update is subject to EHR payment reduction	25%	50%	75%

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 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 provides that such determinations are subject to annual renewal, and that in no case may a hospital be granted such an exemption for more than 5 years.

Finally section 1886(b)(3)(B)(ix)(III) of the Act, as amended by section 4102(b)(1) of the HITECH Act, provides that, for FY 2015 and each subsequent FY, a state in which hospitals are paid for services under section 1814(b)(3) of the Act shall adjust the payments to each eligible hospital in the state that is not a meaningful EHR user in a manner that is designed to result in an aggregate reduction in payments to hospitals in the state that is equivalent to the aggregate reduction that will have occurred if payments had been reduced to each eligible hospital in the state in a manner comparable to the reduction in section 1886(b)(3)(B)(ix)(I) of the Act. This section also requires that the state shall report to the Secretary the method it will use to make the required payment adjustment. (At present, section 1814(b)(3) of the Act applies to the state of Maryland.) As we discussed in the Stage 1 final rule establishing the EHR incentive program (75 FR 44448), for purposes of determining whether hospitals are eligible for receiving EHR incentive payments, we employ the CMS Certification Number (CCN). We also proposed to use CCNs to identify hospitals for purposes of determining whether the reduction to the percentage increase otherwise applicable for FY 2015 and subsequent years applies. (In other words, whether a hospital was a meaningful EHR user for the applicable EHR reporting period will be dependent on the CCN for the hospital.). We noted the results of this policy for certain cases in which hospitals change ownership, merge, or otherwise reorganize and the applicable CCN changes. In cases where a single hospital changes ownership, we determine whether to retain the previous CCN or to assign a new CCN depending upon whether the new owner accepts assignment of the provider's prior participation agreement. Where a change of ownership has occurred, and a new CCN is assigned due to the new owner's decision not to accept assignment of the prior provider agreement, we proposed not to recognize a meaningful use determination that was established under the prior CCN for purposes of determining whether the payment

adjustment applies. Where the new owner accepts the prior provider agreement and is assigned the same CCN, we proposed to continue to recognize the demonstration of meaningful use under that CCN. The same policy was proposed for merging hospitals that use a single CCN. For example, if hospital A is not a meaningful EHR user (for the applicable reporting period), and it absorbs hospital B, which was a meaningful EHR user, then the entire hospital will be subject to a payment adjustment if hospital A's CCN is the surviving identifier. The converse is true as well – if it were hospital B's CCN that survived, the entire merged hospital will not be subject to a payment adjustment. (The guidelines for determining CCN assignment in the case of merged hospitals are described in the State Operations Manual, sections 2779A ff. http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS1201984.html) We advised hospitals that are changing ownership, merging, or otherwise reorganizing to take this policy into account.

Comments received on the treatment of CCNs and new hospitals are addressed in the context of discussing our exception for new hospitals later in this section.

a. Applicable Market Basket Adjustment for Eligible Hospitals who are not Meaningful EHR Users for FY 2015 and Subsequent FYs

In the stage 1 final rule on the Medicare and Medicaid Electronic Health Record Incentive Payment Programs, we revised §412.64 of the regulations to provide for an adjustment to the applicable percentage increase update to the IPPS payment rate for those eligible hospitals that are not meaningful EHR users for the EHR reporting period for a payment year, beginning in FY 2015. Specifically, §412.64(d)(3) now provides that--

- Beginning in fiscal year 2015, in the case of a "subsection (d) hospital," as defined under section 1886(d)(1)(B) of the Act, that is not a meaningful electronic health record (EHR)

user as defined in part 495, three-fourths of the applicable percentage change specified in paragraph (d)(1) is reduced--

++ For fiscal year 2015, by 33 1/3 percent;

++ For fiscal year 2016, by 66 2/3 percent; and

++ For fiscal year 2017 and subsequent fiscal years, by 100 percent.

In order to conform with this new update reduction, as required in section 4102(b)(1)(A) of the HITECH Act, we also revised §412.64(d)(2)(C) of our regulations to provide that, beginning with FY 2015, the reduction to the IPPS applicable percentage increase for failure to submit data on quality measures to the Secretary shall be one-quarter of the applicable percentage increase, rather than the 2 percentage point reduction that applies for FYs 2007 through 2014 in §412.64(d)(2)(B). The effect of this revision is that the combined reductions to the applicable percentage increase for meaningful EHR use and quality data reporting will not produce an update of less than zero for a hospital in a given FY as long as the hospital applicable percentage increase remains a positive number.

We did not propose any changes to the establishment of the payment adjustment amounts We did propose the applicable EHR reporting period, for purposes of determining whether a hospital is subject to the applicable percentage increase adjustment for FY 2015 and subsequent FYs, as a prior EHR reporting period (as defined in §495.4 of the regulations). We also proposed an amendment to §412.64(d) to provide for the hardship and other exceptions we discuss later, as well as the application of the applicable percentage increase adjustment in FY 2015 and subsequent FYs to a state operating under a payment waiver provided by section 1814(b)(3) of the Act. We discuss these proposals and the comments relating to them in the following sections of this preamble.

b. EHR Reporting Period for Determining Whether a Hospital is Subject to the Market Basket Adjustment for FY 2015 and Subsequent FYs

Section 1886(b)(3)(B)(ix)(IV) of the Act makes clear that the Secretary has discretion to "specify" as the EHR reporting period "any period (or periods)" that will apply "with respect to a fiscal year." Thus, as in the case of designating the EHR reporting period for purposes of the EP payment adjustment, the statute governing the applicable percentage increase adjustment for hospitals that are not meaningful users of EHR technology neither requires that such reporting period fall within the year of the payment adjustment, nor precludes the reporting period from falling within the year of the payment adjustment.

As in the case of EPs, we sought to avoid creating a situation in which it might be necessary to make large payment adjustments, either to lower or to increase payments to a hospital, after a determination is made about whether the applicable percentage increase adjustment should apply. We stated in the proposed rule that we believe that this consideration remains compelling in the case of hospitals, despite the fact that the IPPS for acute care hospitals provides, unlike the case of EPs, a mechanism to make appropriate changes to hospital payments for a payment year through the cost reporting process. Despite the availability of the cost reporting process as a mechanism for correcting over- and underpayments made during a payment year, we seek to avoid wherever possible circumstances under which it may be necessary to make large adjustments to the rate-based payments that hospitals receive under the IPPS. Since the EHR payment adjustment in FYs 2015 and subsequent years is an adjustment to the applicable percentage increase used in determining prospective payments, we believe that it is far preferable to determine whether the adjustment applies on the basis of an EHR reporting period before the payment period, rather than to make the adjustment (where necessary) in a

settlement process after the payment period on the basis of a determination concerning whether the hospital was a meaningful user during the payment period.

Therefore, we proposed, for purposes of determining whether the relevant applicable percentage increase adjustment applies to hospitals who are not meaningful users of EHR technology in FY 2015 and subsequent years, that we would establish EHR reporting periods that begin and end prior to the year of the payment adjustment. Furthermore, we proposed that the EHR reporting periods for purposes of such determinations would be far enough in advance of the payment year that we have sufficient time to implement the system edits necessary to apply any required applicable percentage increase adjustment correctly, and that hospitals will know in advance of the payment year whether or not they are subject to the applicable percentage increase adjustment. Specifically, we proposed the following rules establishing the appropriate reporting periods for purposes of determining whether hospitals are subject to the applicable percentage increase adjustment in FY 2015 and subsequent years (parallel to the rules that we proposed previously for determining whether EPs are subject to the payment adjustments in CY 2015 and subsequent years):

- Except as provided in second bulleted paragraph for eligible hospitals that become meaningful users for the first time in 2014, we proposed that the EHR reporting period for the FY 2015 applicable percentage increase adjustment will be the same EHR reporting period that applies in order to receive the incentive for FY 2013. For hospitals this will generally be the full fiscal year of 2013 (unless FY 2013 is the first year of demonstrating meaningful use, in which case a 90-day EHR reporting period will apply). Under our proposed policy, a hospital that receives an incentive for FY 2013 would be exempt from the payment adjustment in FY 2015. A hospital that received an incentive for FYs 2011 or 2012 (or both), but that failed to demonstrate

meaningful use for FY 2013 will be subject to a payment adjustment in FY 2015. (As all of these years will be for Stage 1 of meaningful use, we do not believe that it is necessary to create a special process to accommodate providers that miss the 2013 year for meaningful use). For each year subsequent to FY 2015, the EHR reporting period payment adjustment will continue to be the FY 2 years before the payment adjustment period, subject again to the special provision for new meaningful users of CEHRT.

- We proposed an exception for those hospitals that have never successfully attested to meaningful use prior to FY 2014. For these hospitals, as it is their first year of demonstrating meaningful use, we proposed to allow a continuous 90-day reporting period that begins in 2014 and that ends at least 3 months prior to the end of FY 2014. In addition, the hospital would have to actually successfully register for and attest to meaningful use no later than the date that occurs 3 months before the end of the year. For hospitals, this means specifically that the latest day the hospital must successfully register for the incentive program and attest to meaningful use, and thereby avoid application of the adjustment in FY 2015, is July 1, 2014. Thus, the hospital's EHR reporting period must begin no later than April 2, 2014 (allowing the hospital a 90-day EHR reporting period, followed by 1 extra day to successfully submit the attestation and any other information necessary to earn an incentive payment). In the proposed rule we used the date April 3, 2014 which would only allow an 89-day period through June 30, 2014. The correct date is April 2, 2014 to allow September 30, 2014 to be the last day of the 90 day EHR reporting period with the extra day (Oct 1, 2014) to attest. This policy would continue to apply in subsequent years. If a hospital is demonstrating meaningful use for the first time for the fiscal year immediately before the applicable percentage increase adjustment year, then the reporting period will be a continuous 90-day period that begins in such prior fiscal year and ends at least

3 months before the end of such year. In addition, all attestation, registration, and any other details necessary to determine whether the hospital is subject to a applicable percentage increase adjustment for the upcoming year will need to be completed by July 1. (As we discuss later, exception requests will be due by the April 1 before the beginning of the payment adjustment fiscal year.)

In conjunction with adopting these rules for establishing the EHR Reporting Period for determining whether a hospital is subject to the applicable percentage increase adjustment for FY 2015 and subsequent FYs, we proposed to revise §412.64(d)(3) of our regulations to insert the phrase "for the applicable EHR reporting period," so that it is clear that the EHR reporting period will not fall within the year of the market basket adjustment.

We stated our belief that these proposed EHR reporting periods provide adequate time both for the systems changes that will be required for CMS to apply any applicable percentage increase adjustments in FY 2015 and subsequent years, and for hospitals to be informed in advance of the payment year whether any adjustment(s) will apply. They also provide appropriate flexibility by allowing more recent adopters of EHR technology a reasonable opportunity to establish their meaningful use of the technology and to avoid application of the payment adjustments.

Comment: As with the comments on the EHR reporting period for EPs, many commenters made the same assertion that an EHR reporting period aligned with the payment adjustment year would be more consistent with the Congressional intent and the language of the statute. Some commenters contended that the statutory language requires the reporting period and payment adjustment year to coincide.

Response: We believe our response to this comment in the context of the EP payment

adjustments applies equally to his eligible hospital comment. The language in section 1886(b)(3)(B)(ix)(I) of the Act is substantially similar to the language in section 1848(a)(7) of the Act. As in the case of EPs, Congress provided the Secretary with flexibility to determine the EHR reporting period applicable to the payment adjustment year. Section 1886(b)(3)(B)(ix)(IV) of the Act specifically provides that "term 'EHR reporting period' means, with respect to a fiscal year, any period (or periods) specified by the Secretary." In addition, because the payment adjustment will be used to reduce the applicable percent increase that is used in the prospective ratesetting for hospitals, it is reasonable to conclude that this Secretarial flexibility was granted precisely because Congress understood that the Department needed to have final determinations on meaningful use prior to the fiscal year that is the payment adjustment year. As we have previously noted, other payment adjustment programs, such as the e-prescribing program, and the physician quality reporting system, also use a prior reporting period. Thus, it is consistent for us to adopt a prior reporting period for the EHR program as well.

Comment: Commenters made the same comments as they did for EPs (relating to insufficient vendor capacity; the practical deadline having passed for adopting and implementing CEHRT, especially for popular vendors; and the issues surrounding upgrading current clients to 2014 CEHRT). As with EPs, the options presented by commenters all involved a reconciliation process, in this case, using the cost reporting process.

Response: The issue of upgrading to 2014 CEHRT is addressed by ONC in their final rule published elsewhere in this issue of the **Federal Register**. We appreciate the concerns of vendor capacity raised by the commenters. We discuss this situation and the reasons we are not revising our timetables in our previous discussion of the parallel policy for EPs. In the hospital context, the commenters correctly point out the existence of a payment reconciliation method,

the hospital cost report, that it unavailable within the payment systems for EPs. We have carefully considered whether it is feasible to adopt a later reporting period (perhaps even the payment year itself) as the basis for determining whether eligible hospitals are subject to the EHR payment adjustment, and then to employ the cost reporting process to correct over and under payments in regards to the payment adjustments, as a number of commenters recommended. As a matter of course in the rate setting system, the basic rates and applicable percentage increase updates are fixed in advance and are not matters that are taken into account in the settlement of final payment amounts under the cost report reconciliation process. As the payment adjustment directly affects this rate we believe that it would not be possible to employ a cost report settlement process, but that claims would have to be reprocessed.

It is true, as several commenters pointed out, that several components of the IPPS, including DSH and IME payments, are settled in the cost reporting process on the basis of final data (for example, bed days, resident FTEs) from the payment year. However, changes in other aspects of the payment system, such as outlier payments, cannot reconciled within the cost reporting process, but require reprocessing of claims. Application of the EHR payment adjustment changes the standardized amount upon which IPPS payments are based. Any change in the standardized amount applicable to a hospital changes the number of outlier payments the hospital would receive, and the amount of those payments. If we were to base final determination of whether the EHR payment adjustment should apply on meaningful use status during the payment year, it would be necessary to increase the standardized amount for some hospitals, that is, those that were assumed not to meet meaningful use requirements for purposes of making interim payments, but that subsequently established meaningful use during the payment year. Conversely, it would be necessary to decrease the standardized amount for those

hospitals that had been assumed to meet meaningful use requirements for purposes of making interim payments, but that subsequently failed to meet those requirements during the payment year. In both cases, mass reprocessing of payments would be necessary in order to adjust outlier payments. Generally, hospitals whose standardized amounts are decreased at the time of final payment determination (due to application of a payment adjustment that was not applied to interim payments) would generally receive greater outlier payments. Conversely, hospitals whose standardized amounts are increased at the time of final payment determination (due to application of the full update that was not applied to interim payments) would generally receive lower outlier payments. (Reprocessing would also be necessary for new technology add-on payments, although the claims volume and dollar amounts involved in such reprocessing would be significantly lower.) Such reprocessing imposes significant costs on both the eligible hospital and CMS. As in the case of EPs, then, we continue to believe that the timeline we proposed is the most realistic approach to making payment adjustment determinations in an effective manner.

Therefore, we are finalizing the proposed EHR reporting period for determining whether an eligible hospital is subject to the payment adjustment for CY 2015 and subsequent calendar years as proposed.

c. Exception to the Application of the Market Basket Adjustment to Hospitals in FY 2015 and Subsequent FYs

As mentioned previously, 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 provides that such determinations are subject to annual renewal, and that in no case may a hospital be granted such an exception for more than 5 years.

We proposed to add a new §412.64(d)(4), specifying the circumstances under which we will exempt a hospital from the application of the applicable percentage increase adjustment for a fiscal year. To be considered for an exception, a hospital must submit an application demonstrating that it meets one more of the exception criteria.

As noted previously, the statute does not mandate the circumstances under which an exception must be granted, but (as in the case of a similar exception provided under the statute for EPs) it does state that the exception may be granted when "requiring such hospital to be a meaningful EHR user during such fiscal year will result in a significant hardship, such as in the case of a hospital in a rural area without sufficient Internet access." Therefore, we proposed to provide in new §412.64(d)(4) that the Secretary may grant an exception to a hospital that is located in an area without sufficient Internet access. Furthermore, while the statute specifically states that such an exception may be granted to hospitals in "a rural area without sufficient Internet access," it does not require that such an exception be restricted only to rural areas without such access. While we believe that a lack of sufficient Internet access will rarely be an issue in an urban or suburban area, we do not believe that it is necessary to preclude the possibility that, in very rare and exceptional cases, a nonrural area may also lack sufficient Internet access to make complying with meaningful use requirements a significant hardship for a hospital. Therefore, we proposed that the Secretary may grant such an exception to a hospital in any area without sufficient Internet access.

Because exceptions on the basis of insufficient Internet connectivity must intrinsically be

considered on a case-by-case basis, we proposed to require hospitals to demonstrate insufficient Internet connectivity to qualify for the exception through an application process. The rationale for this exception is that lack of sufficient Internet connectivity renders compliance with the meaningful EHR use requirements a hardship particularly those objectives requiring internet connectivity, summary of care documents, electronic prescribing, making health information available online, and submission of public health information. Therefore, we proposed that such an application must demonstrate insufficient Internet connectivity to comply with the meaningful use objectives listed previously and insurmountable barriers to obtaining such internet connectivity such as high cost to build out Internet to their facility. As with EPs, the hardship would be demonstrated for period that is 2-years prior to the payment adjustment year (for example, FY 2013 for the payment adjustment in FY 2015). As with EPs, we will require applications to be submitted 6 months before the beginning of the payment adjustment year (that is, by April 1 before the FY to which the adjustment will apply) in order to provide sufficient time for a determination to be made and for the hospital to be notified about whether an exception has been granted. This timeline for submission and consideration of hardship applications also allows for sufficient time to adjust our payment systems so that payment adjustments are not applied to hospitals who have received an exception for a specific FY. (Please also see our previous discussion of the parallel exception for EPs, with respect to encouraging providers to file these applications as early as possible, and the likelihood that there will not be an opportunity to subsequently demonstrate meaningful use if hospitals file close to or at the application deadline of April 1.)

Comment: Commenters provided universal support for this proposed exception. However, some commenters raised concern about the situation of hospitals that might have

Internet access in the 2-years prior, but lose it in the next year.

Response: We are finalizing this exception as proposed with one modification. We appreciate the commenters' concern about hospitals that might have sufficient internet access in the 2 years prior to the adjustment period, but lose it in next year. We believe this is even less likely for hospitals than EPs, but as there is no downside to extending the time, we are finalizing a modification of our proposal to allow for the demonstration of insufficient internet access for any 90-day period between the start of the year 2 years prior to the payment adjustment year through the application submission date of April 1 of the year prior to the payment adjustment year.

For the same reasons we proposed an exception for new EPs, we proposed an exception for a new hospital for a limited period of time after it has begun services. We proposed to allow new hospitals an exception for at least 1 full year cost reporting period after they accept their first patient. For example, a hospital that accepted its first patient in March of 2015, but with a cost reporting period from July 1 through June 30, would receive an exception from payment adjustment for FY 2015, as well as for FY 2016. However, the new hospital would be required to demonstrate meaningful use within the 9 months of FY 2016 (register and attest by July 1, 2016) to avoid being subject to the payment adjustment in FY 2017.

In proposing such an exception for new hospitals, however, we wanted to ensure that the exception would not be available to hospitals that have already been in operation in one form or another, perhaps under a different owner or merely in a different location, and thus have in fact had an opportunity to demonstrate meaningful use of EHR technology. Therefore, for purposes of qualifying for this exception, we proposed that the following hospitals would not be considered new hospitals under the exception:

- A hospital that builds new or replacement facilities at the same or another location even if coincidental with a change of ownership, a change in management, or a lease arrangement.
- A hospital that closes and subsequently reopens.
- A hospital that has been in operation for more than 2 years but has participated in the Medicare program for less than 2 years.
- A hospital that changes its status from a CAH to a hospital that is subject to the Medicare hospital in patient prospective payment systems.

It is important to note that we proposed to consider a hospital that changes its status from a hospital (other than a CAH) that is excluded from the Medicare hospital inpatient prospective payment system (IPPS) to a hospital that is subject to the IPPS to be a new hospital for purposes of qualifying for the proposed exception. These IPPS-exempt hospitals, such as long-term care hospitals, inpatient psychiatric facilities, inpatient rehabilitation facilities children's hospitals, and cancer hospitals, are excluded from the definition of "eligible hospital" for purposes of the Medicare EHR Incentive Program and have not necessarily had an opportunity to demonstrate meaningful use. On the other hand, CAHs are eligible for incentive payments and subject to payment adjustments. Under the guidelines for assigning CCNs to Medicare providers, a CAH that changes status to an IPPS hospital will necessarily receive a new CCN. This is because several digits of the CCN encode the provider's status (for example, IPPS, CAH) under the Medicare program, However, we proposed to allow the CAH to register its meaningful use designation obtained under its previous CCN in order to avoid being subject the hospital payment adjustment. It is worth noting that we adapted the proposed definition of "new hospital" for these purposes from similar rules that have been employed in the capital

prospective payment system in §412.300(b) of our regulations. We invited comment concerning the appropriateness of adapting these rules to the exception under the EHR program, and about whether modifications or other revisions to these rules will be appropriate in the EHR context.

Comment: Several commenters recommended that the new hospitals exception for at least 1 full year cost reporting period be triggered not when the hospital accepts its first patient, but rather when it accepts its first Medicare covered patient. These commenters point out that there can be significant lapse between the time when a hospital accepts its first patient and the time when it accepts its first Medicare covered patient. Because the EHR payment adjustment applies to the Medicare payments, the commenters argued it is more appropriate to base the beginning of the new hospital exception on the admission of its first Medicare covered patient.

Response: We agree with the commenters and are revising the new hospital exception in this final rule to run for at least one full year cost reporting period after the hospital accepts its first Medicare-covered patient. This change renders our third criterion (a hospital that has been in operation for more than 2 years but has participated in the Medicare program for less than 2 years) for not considering a hospital new moot as the exception is now based on the admission of the first Medicare-covered patient, which we believe is sufficiently analogous to starting participation in the Medicare program to allow us to remove this criterion.

Comment: Some commenters argued that a hospital that undergoes a change of ownership and has a new CCN assigned due to the new owner's decision not to accept the assignment of the prior provider agreement should be allowed to register its meaningful use designation for the old CCN in the same manner a CAH that becomes an inpatient PPS hospital would.

Response: When a hospital has a new CCN assigned due to the new owner's decision not

to accept the assignment of the prior provider agreement it is not considered a change of ownership. Rather the hospital is terminated from the Medicare program and then reapplies for a new CCN. We disagree with the commenters that the history of the old CCN should carry forward in this case. In cases where a new owner decides not to accept the previous provider agreement and a new CCN is assigned by CMS, the new owner is in effect, making a conscious decision to create a rupture with significant, and relevant, aspects of the hospital's history. Specifically, when a new owner acquires a Medicare participating hospital, CMS automatically assigns the provider agreement to the new owner. The new owner must then decide whether to accept or reject assignment of the existing agreement. If the new owner accepts assignment, the provider agreement remains intact and the owner retains all the benefits and liabilities of that agreement (as provided under 42 CFR 489.18 of the regulations). If the new owner rejects assignment, the owner has voluntarily terminated the previous provider agreement, the CCN of the hospital is terminated, and the owner is not responsible for Medicare liabilities (known or unknown), as well as eligibility for Medicare payment. Under these circumstances, where the new owner has made a conscious decision to terminate the previous provider agreement, we believe it is appropriate not to recognize the meaningful use designation obtained under that provider agreement and CCN. We have consistently reminded new owners of hospitals that they cannot obtain the benefits of a decision not to accept assignment of the provider agreement without accepting the burdens of the decision as well. Unlike the case of a CAH that becomes an inpatient PPS hospital, the assignment of a new CCN follows from a voluntary decision of the new owner not to retain the previous provider agreement and CCN.

We believe a similar result should apply in other cases where acquisitions and/or combinations of hospitals lead to the discontinuation of a CCN under which meaningful use had

been demonstrated. For example, in some cases there is a combination of two or more certified hospitals under one agreement and one CCN. If the combined hospital has multiple locations, one location becomes the "main location," and all other locations become remote and/or provider based. The hospital is considered "one hospital" by Medicare and must be truly integrated at all levels, including its system for maintaining medical records. Where the new owner rejects the assignment of the provider agreement for one or more of the facilities that are being combined into the integrated hospital, known and unknown Medicare liabilities of those facilities do not transfer to the new owner. Under these circumstances, for the same reasons discussed in the previous case, it is appropriate not to recognize the meaningful use designation that was obtained under the provider agreement(s) and CCN(s) that have not been retained under the integrated hospital.

Even where the new owners retain the acquired hospital's Medicare provider agreement, the acquired hospital's agreement is subsumed (although not terminated) into the single provider agreement of the combined hospital, and the acquired hospital's CCN is retired (again, not terminated). The new owners are responsible for all known and unknown Medicare liabilities of previous owners of the hospital, and there is no break in Medicare payments, as is the case where assignment of the prior provider agreement is rejected. However, as noted previously, in these cases, if the combined hospital has multiple locations, one location becomes the "main location," and all other locations become remote and/or provider based. The hospital is considered "one hospital" by Medicare and must be truly integrated at all levels). In these cases it is most appropriate to recognize the prior meaningful use status of the surviving CCN of the main location for purposes of determining whether the payment penalty applies to the newly integrated hospital. In that way, the meaningful use determination will be based on the prior status of the

major portion of the newly integrated hospital. Otherwise, the meaningful use designation of a relatively minor remote and/or provider-based hospital may become the basis for the designation of a much larger combined and integrated hospital. Therefore, we are finalizing our proposed policy, in cases of various ownership changes, acquisitions, and combinations of hospitals, to employ the meaningful use status of the surviving CCN to determine whether the payment adjustment applies.

Finally, we proposed an additional exception in this final rule for extreme circumstances that make it impossible for a hospital to demonstrate meaningful use requirements through no fault of its own during the reporting period. Such circumstances might include: a hospital closed; a natural disaster in which an EHR system is destroyed; EHR vendor going out of business; and similar circumstances. Because exceptions on extreme, uncontrollable circumstances must be evaluated on a case-by-case basis, we believe that it is appropriate to require hospitals to qualify for the exception through an application process.

Comment: Commenters stated universal support for this exception. However many commenters requested various circumstances be added to the list of example circumstances. This list is very similar, but not entirely identical to that for EPs. These examples dealt primarily with concerns related to vendors of CEHRT. Specifically, commenters were concerned about vendors of CEHRT not maintaining their certification status, ability to meet implementation schedules, and ability to find a vendor of CEHRT willing to work with them. In addition, commenters suggested that the provider facing severe financial distress, such as bankruptcy or restructuring of debt should be included as an example.

Response: We used the same evaluation criteria we used for EPs and came to the same conclusion to add two examples to the list that was proposed: (1) a hospital whose CEHRT

(complete or modular) loses its certification either through revocation or because the vendor did not upgrade their CEHRT to the latest requirements; and (2) a hospital suffering severe financial distress resulting in a bankruptcy or restructuring of debt.

We will require applications to be submitted no later than April 1 of the year before the payment adjustment year in order to provide sufficient time for a determination to be made and for the hospital to be notified about whether an exception has been granted prior to the payment adjustment year. This timeline for submission and consideration of hardship applications also allows for sufficient time to adjust our payment systems so that payment adjustments are not applied to hospitals who have received an exception for a specific payment adjustment year. As discussed earlier, in relation to EPs, in order for a hospital to apply for this exception, extreme circumstances would need to exist for the period in which the hospital would otherwise demonstrate meaningful use (that is, the EHR reporting period). We have modified our regulation to be clear that the circumstances must exist during the EHR reporting period (that is, 2 years prior to the payment adjustment year or, for hospitals that have never attested to meaningful use before, in the year immediately prior to the payment adjustment year).

Comment: Commenters suggested the following additional exceptions:

- Hospitals who make a good faith effort to purchase CEHRT, but could not find a vendor willing to work with them.
- Hospitals that determine they must switch EHR vendors to achieve meaningful use.
- Hospitals unable to meet meaningful use requirements because of failures on the part of EHR vendors.

Response: For the first suggested exception, we do not believe that hospitals that attempt to purchase CEHRT but cannot find a vendor would warrant an exception. The mere failure of

an attempt to purchase CEHRT does not demonstrate that the hospital faces hardship significant enough to prevent it from becoming a meaningful EHR user. We also believe it would be problematic to define the parameters for determining that no vendor was willing to work with a hospital. Moreover, we already have provided for an exception for hospitals that face extreme circumstances beyond their control. Under this exception, eligible hospitals could attempt to show that their situation is extreme and out of the ordinary and that failure to obtain CEHRT was truly beyond their control. We are skeptical that such showings could be made when all the hospital has done is to make an attempt to purchase CEHRT. However, this exception provides hospitals with the opportunity to demonstrate that their failure of attempts to obtain CEHRT was due to circumstances beyond their control.

The next two exceptions may fall under the exception for extreme circumstances beyond the hospital's control, but the hospital would need to demonstrate that it meets this extreme exception. Any determination would be highly dependent on individual circumstances and evaluation of whether it is truly necessary to switch vendors, whether the switching vendors would prevent the hospital from reaching meaningful use, and whether the "failures" of the EHR vendor are both outside the norm of EHR implementation and beyond the control of the hospital.

Table 16 summarizes the timeline for hospitals to avoid the applicable payment adjustment by demonstrating meaningful use or qualifying for an exception from the application of the adjustment.

TABLE 16: TIMELINE FOR ELIGIBLE HOSPITALS TO AVOID PAYMENT ADJUSTMENT

Hospital Payment Adjustment Year (Fiscal Year)	**Demonstrate MU during EHR Reporting Period 2 Years Prior to Year of Payment Adjustment**	**OR**	**For An Eligible Hospital Demonstrating Meaningful Use for the First Time in the Year Prior to the Payment Adjustment Year Use a Continuous 90-Day Reporting Period Beginning No Later Than:**	**OR**	**Apply For An Exception No Later Than:**
2015	FY 2013 (with submission no later than November 30, 2013)		April 2, 2014 (with submission no later than July 1, 2014)		April 1, 2014
2016	FY 2014 (with submission no later than November 30, 2014)		April 2, 2015 (with submission no later than July 1, 2015)		April 1, 2015
2017	FY 2015 (with submission no later than November 30, 2015)		April 2, 2016 (with submission no later than July 1, 2016)		April 1, 2016
2018	FY 2016 (with submission no later than November 30, 2016)		April 2, 2017 (with submission no later than July 1, 2017)		April 1, 2017
2019	FY 2017 (with submission no later than November 30, 2017)		April 2, 2018 (with submission no later than July 1, 2014)		April 1, 2018

Notes: (FY refers to the Federal fiscal year: October 1 to September 30. For example, FY 2015 is October 1, 2014 through September 30, 2015.)
The timelines for FY 2020 and subsequent fiscal years follow the same pattern.

TABLE 17: PERIOD HARDSHIP MUST BE SHOWN WITH APPLICATION DATE

Exception	**Period of Consideration for Exception**	**Submit Application** For FY 2015 No Later Than
Insufficient Internet access	Demonstrate insufficient Internet access for any 90 days from the start of the FY 2 years prior to the payment adjustment year to April 1 of the year prior to the payment adjustment year (For FY 2015 – October 1, 2012 – April 1, 2014)	April 1, 2014
New hospital	New hospital granted an exception for one full cost reporting period after they admit their first Medicare patient	Guidance to be issued following publication of the final rule
Extreme Circumstances outside of the hospital's Control	For a hospital that has previously demonstrated meaningful use, the hospital must demonstrate extreme circumstances that affect the FY 2 years prior to the payment adjustment year. (For FY 2015 – FY 2013) For a hospital that has never demonstrated meaningful use, the hospital must demonstrate extreme circumstances that affect the FY prior to the payment adjustment year. (For FY 2015 – FY 2014)	April 1, 2014

d. Application of Market Basket Adjustment in FY 2015 and Subsequent FYs to a State

Operating Under a Payment Waiver Provided by Section 1814(b)(3) of the Act

As discussed previously, the statute requires payment adjustments for eligible hospitals in states where hospitals are paid under section 1814(b)(3) of the Act. The statute also requires such adjustments to be designed to result in an aggregate reduction in payments equivalent to the aggregate reduction that would have occurred if payments had been reduced under section 1886(b)(3)(B)(ix)(I) of the Act. We proposed that an aggregate reduction in payments would mean the same dollar amount in reduced Medicare payments that that would have occurred if payments had been reduced to each eligible hospital in the state in a manner comparable to the reduction under §412.64(d)(3).

To implement this provision, we proposed a new §412.64(d)(5) that includes this statutory requirement and that required states operating under a payment waiver under section 1814(b)(3) of the Act to provide to the Secretary, no later than January 1, 2013, a report on the method that it proposes to employ in order to make the requisite payment adjustment.

We did not receive any comments on this proposal; and therefore, we are finalizing these provisions as proposed.

4. Reduction of Reasonable Cost Reimbursement in FY 2015 and Subsequent Years for CAHs that are not Meaningful EHR Users

Section 4102(b)(2) of the HITECH Act amends section 1814(l) of the Act to include an adjustment to a CAH's Medicare reimbursement for inpatient services if the CAH has not met the meaningful EHR user definition for an EHR reporting period. The adjustment will be made for a cost reporting period that begins in FY 2015, FY 2016, FY 2017, and each subsequent FY thereafter. Specifically, sections 1814(l)(4)(A) and (B) of the Act now provide that, if a CAH has not demonstrated meaningful use of CEHRT for an applicable reporting period, then for a

cost reporting period that begins in FY 2015, its reimbursement will be reduced from 101 percent of its reasonable costs to 100.66 percent. For a cost reporting period beginning in FY 2016, its reimbursement will be reduced to 100.33 percent of its reasonable costs. For a cost reporting period beginning in FY 2017 and each subsequent FY, its reimbursement will be reduced to 100 percent of reasonable costs.

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

a. Applicable Reduction of Reasonable Cost Payment Reduction in FY 2015 and Subsequent Years for CAHs that are not Meaningful EHR Users

In the Stage1 final rule (75 FR 44564), we finalized the regulations regarding the CAH adjustment at §495.106(e) and §413.70(a)(6).

b. EHR Reporting Period for Determining Whether a CAH is Subject to the Applicable Reduction of Reasonable Cost Payment in FY 2015 and Subsequent Years

For CAHs we proposed an EHR reporting period that is aligned with the payment adjustment year. For example, if a CAH is not a meaningful EHR user in FY 2015, then its Medicare reimbursement will be reduced to 100.66 percent for its cost reporting period that begins in FY 2015. This differs from what was proposed for eligible hospitals: an EHR reporting period prior to the payment adjustment year. We stated in the proposed rule that we believed the Medicare cost report process would allow us to make the CAH reduction for the cost reporting period that begins in the payment adjustment year, with minimal disruptions to the

CAH's cash flow and minimal administrative burden on the Medicare contractors as discussed later.

CAHs are required to file an annual Medicare cost report that is typically for a consecutive 12-month period. The cost report reflects the inpatient statistical and financial data that forms the basis of the CAH's Medicare reimbursement. Interim Medicare payments may be made to the CAH during the cost reporting period based on the previous year's data. Cost reports are filed with the CAH's Medicare contractor after the close of the cost reporting period and the data on the cost report are subject to reconciliation and a settlement process prior to a final Medicare payment being made.

We proposed to amend the definition of the EHR reporting period that will apply for purposes of payment adjustments under §495.4. For CAHs this will be the full Federal fiscal year that is the same as the payment adjustment year (unless a CAH is in its first year of demonstrating meaningful use, in which case a continuous 90-day reporting period within the payment adjustment year will apply). The adjustment would then apply based upon the cost reporting period that begins in the payment adjustment year (that is, FY 2015 and thereafter). Thus, if a CAH is not a meaningful user for FY 2015, and thereafter, then the adjustment would be applied to the CAH's reasonable costs incurred in a cost reporting period that begins in that affected FY as described in §413.70(a)(6)(i).

We proposed to require CAHs to submit their attestations on meaningful use by November 30th of the following FY. For example, if a CAH is attesting that it was a meaningful EHR user for FY 2015, the attestation must be submitted no later than November 30, 2015. Such an attestation (or lack thereof) will then affect interim payments to the CAH made after December 1st of the applicable FY. If the cost reporting period ends prior to December 1st of the

applicable FY then any applicable payment adjustment will be made through the cost report settlement process.

All comments received on this provision were in support. We thank commenters for their support and finalize as proposed for the reasons outlined in the proposed rule.

c. Exception to the Application of Reasonable Cost Payment Reductions to CAHs in FY 2015 and Subsequent FYs

As discussed previously, CAHs may receive exceptions from the payment adjustments for significant hardship. While our current regulations, in §413.70(a)(6)(ii) and (iii) contain this hardship provision we proposed revising these regulations to align them with the exceptions being proposed for EPs and subsection (d) hospitals. As with EPs and subsection (d) hospitals we proposed that CAHs could apply for an exception on the basis of lack of sufficient Internet connectivity. Applications will be required to demonstrate insufficient Internet connectivity to comply with the meaningful use objectives requiring internet connectivity (that is, summary of care documents, electronic prescribing, making health information available online, and submission of public health information) and insurmountable barriers to obtaining such internet connectivity. As CAHs will have an EHR reporting period aligned with the payment adjustment year, we proposed that the insufficient Internet connectivity will need to be demonstrated for each applicable payment adjustment year. For example, as proposed, to avoid a payment adjustment for cost reporting periods that begin during FY 2015, the hardship would need to be demonstrated for FY 2015. For each year subsequent to FY 2015, the basis for an exception would continue to be for the hardship in the FY in which the affected cost reporting period begins. As stated in §413.70(a)(6)(iii), any exception granted may not exceed 5 years. After 5 years, the exception will expire and the appropriate adjustment will apply if the CAH has not

become a meaningful EHR user for the appropriate EHR reporting period.

Comment: Commenters have suggested that it is inappropriate to base the Internet connectivity exception on the same year that a CAH is expected to demonstrate meaningful use. They assert that it is impractical for a CAH to achieve sufficient internet connectivity and meet meaningful use all in 1 year. A few commenters recommended a 2-year prospective exception for Internet connectivity as used for the EPs and inpatient PPS hospitals.

Response: We agree with commenters that established sufficient Internet connectivity and meaningful use in the same year is not feasible. However, since the payment adjustment year is aligned with the CAH's EHR period, we believe that using a 2-year lookback period similar to EPs and eligible hospitals is inappropriate for CAHs. Therefore, we will base the insufficient internet access exception on the cost reporting period that begins prior to or during the payment adjustment year. For FY 2015,the CAH must submit the application by November 30, 2015, but eligibility for this exception would be based on the information for any 90-day period within the cost reporting period that begins prior to or during the payment adjustment year.

After consideration of the comments, we are revising this exception to base it on any 90-day period within the cost reporting period that begins prior to or during the payment adjustment year.

As with new EPs and new eligible hospitals, we proposed an exception for a new CAH for a limited period of time after it has begun services. We proposed to allow an exception for 1 year after they accept their first patient. For example, a CAH that is established in FY 2015 would be exempt from the penalty through its cost reporting period ending at least 1 year after the CAH accepts its first patient. If the CAH is established March 15, 2015 and its first cost

reporting period is less than 12 months (for example, from March 15 through June 30, 2015), the exception would exist for both the short cost reporting period and the following 12-month cost reporting period lasting from July 1, 2015 through June 30, 2016. However, the new CAH would be required to submit its attestation that it was a meaningful EHR user for FY 2016 no later than November 30, 2016, in order to avoid being subject to the payment adjustment for the cost reporting period that begins in FY 2016 (in the previous example from July 1, 2016 through June 30, 2017).

We stated in the proposed rule that in proposing such an exception for newly established CAHs, it is important to ensure that the exception is not available to CAHs that have already been in operation in one form or another, perhaps under a different ownership or merely in a different location, and thus have in fact had an opportunity to demonstrate meaningful use of EHR technology. Therefore, we proposed that for the purposes of qualifying for this exception, a new CAH means a CAH that has operated (under previous or present ownership) for less than 1 year.

We stated in the proposed rule that in some cases an eligible hospital may convert to a CAH. An eligible hospital is a subsection (d) hospital that is a meaningful user and is paid under the inpatient hospital prospective payment systems as described in subpart A of Part 412 of the regulations. In these cases, eligible hospitals were able to qualify for purposes of the EHR hospital incentive payments by establishing meaningful use, and (as discussed previously) are also subject to a payment adjustment provision in FY 2015 and subsequent years if they fail to demonstrate meaningful use of EHR technology during an applicable reporting period. Therefore, we proposed not to treat a CAH that has converted from an eligible hospital as a newly established CAH for the purposes of this exception.

On the other hand, we stated in the proposed rule that other types of hospitals such as long-term care hospitals, psychiatric hospitals, and inpatient rehabilitation facilities are not subsection (d) hospitals. These other types of hospitals do not meet the definition of an "eligible hospital" for purposes of the Medicare EHR hospital incentive payments and the application of the proposed hospital market basket adjustment in FY 2015 and subsequent years under section 1886(n)(6)(B) of the Act. In some instances, a CAH may be converted from one of these types of hospitals. In that case, the CAH would not have had an opportunity to demonstrate meaningful use, and it is therefore appropriate to treat them as newly established CAHs if they convert from one of these other types of hospitals to a CAH for purposes of determining whether they should qualify for an exception from the application of the adjustment in FY 2015 and subsequent years. Thus, we proposed to consider a CAH that converts from one of these other types of hospitals to be a newly established CAH for the purposes of qualifying for this proposed exception from the application of the adjustment in FY 2015 and subsequent years.

In summary, we proposed for purposes of qualifying for the exception to revise §413.70(a)(6)(ii) to state that a newly established CAH means a CAH that has operated (under previous or present ownership) for less than 1 year. We also proposed to revise §413.70(a)(6)(ii) to state that the following CAHs are not newly established CAHs for purposes of this exception:

- A CAH that builds new or replacement facilities at the same or another location even if coincidental with a change of ownership, a change in management, or a lease arrangement.
- A CAH that closes and subsequently reopens.
- A CAH that has been in operation for more than 1 year but has participated in the Medicare program for less than 1 year.
- A CAH that has been converted from an eligible subsection (d) hospital.

Comment: Identical to the concerns raised for subsection (d) hospitals, several comments stated that the new CAH exception for at least 1 full year cost reporting period be triggered not by when the hospital accepts its first patient, but rather when it accepts its first Medicare-covered patient.

Response: We agree with the commenters and revise the exception for new CAHs to be for at least 1 full year cost reporting period after they accept their first Medicare-covered patient. This change renders our third criteria (a CAH that has been in operation for more than 2 years but has participated in the Medicare program for less than 2 years) for not considering a CAH new moot as the exception is now based on the admission of the first Medicare-covered patient, which we believe is sufficiently analogous to starting participation in the Medicare program to allow us to remove this criteria.

After consideration of comments, we are revising this exception to base it on the point when the CAH accepts their first Medicare patient.

Finally, we proposed an additional exception in this final rule for extreme circumstances that make it impossible for a CAH to demonstrate meaningful use requirements through no fault of its own during the reporting period. Such circumstances might include: a CAH is closed; a natural disaster in which an EHR system is destroyed; EHR vendor going out of business; and similar circumstances. Because exceptions on extreme, uncontrollable circumstances must be evaluated on a case-by-case basis, we believe that it is appropriate to require CAHs to qualify for the exception through an application process.

Comment: Commenters supported this exception in principle. However, many commenters requested various circumstances be added to the list of example circumstances. This list is nearly entirely identical to that for EPs and subsection (d) hospitals as described

earlier.

Response: We used the same evaluation criteria we used for EPs and came to the same conclusion to add two examples. First, a CAH whose CEHRT (complete or modular) loses its certification either through revocation or because the vendor did not upgrade their CEHRT to the latest requirements; and second, a CAH suffering severe financial distress resulting in a bankruptcy or restructuring of debt

As described previously, we are finalizing the policy to align a CAH's payment adjustment year with the applicable EHR reporting period. A CAH must submit their meaningful use attestation for a specific EHR reporting period no later than 60 days after the close of the EHR reporting period (no later than November 30th of the year) otherwise the payment penalty could be applied to the CAH's cost reporting period that begins in that payment adjustment year. We proposed to require a CAH to submit an application for an exception, as described previously, to its Medicare contractor by the same November 30th date that the meaningful use attestation is due. Therefore, we proposed that a CAH will be subject to the payment adjustment if it has not submitted its meaningful use attestation (or its attestation has been denied) and has not submitted an application for an exception by November 30th of the subsequent EHR reporting period. If a CAH's request for an exception is not granted by the Medicare contractor then we proposed that the payment adjustment will be applied. We stated in the proposed rule that if a CAH anticipates submitting an exception application we recommend that the CAH communicate with its Medicare contractor to determine the necessary supporting documentation to submit by the November 30th due date.

After consideration of public comments, we are finalizing these application deadlines exception as proposed.

Table 18, summarizes the timeline for CAHs to avoid the applicable payment adjustment by demonstrating meaningful use or qualifying for an exception from the application of the adjustment.

Comment: Commenters provided the same suggestions for additional exceptions for CAHs that they did for eligible hospitals.

Response: As we stated in our response to similar comments submitted for eligible hospitals these additional exceptions could have been suggested as examples for the exception for extreme circumstances. We encourage hospitals in these situations to utilize the extreme circumstances exception. We believe these exceptions are too subjective to be finalized as new exceptions as suggested by commenters.

TABLE 18: TIMELINE FOR CAHs TO AVOID PAYMENT ADJUSTMENT

CAH with Cost Reporting Period Beginning During Payment Adjustment Year:	Demonstrate MU For EHR Reporting Period:	OR	For a CAH demonstrating MU for the first time, a Continuous 90-Day Reporting Period Ending No Later Than:	OR	Apply for an Exception No Later Than:
FY 2015	FY 2015(with submission no later than November 30, 2015)		September 30, 2015 (with submission no later than November 30, 2015)		November 30, 2015
FY 2016	FY 2016 (with submission no later than November 30, 2016)		September 30, 2016 (with submission no later than November 30, 2016)		November 30, 2016
FY 2017	FY 2017 (with submission no later than November 30, 2017)		September 30, 2017 (with submission no later than November 30, 2017)		November 30, 2017
FY 2018	FY 2018 (with submission no later than November 30, 2018)		September 30, 2018 (with submission no later than November 30, 2018)		November 30, 2018
FY 2019	FY 2019 (with submission no later than November 30, 2019)		September 30, 2019 (with submission no later than November 30, 2019)		November 30, 2019

Notes: (FY refers to the Federal fiscal year October 1 to September 30. For example, FY 2015 is October 1, 2014 to September 30, 2015.)
The timelines for FY 2020 and subsequent fiscal years follow the same pattern.

TABLE 19: PERIOD HARDSHIP MUST BE SHOWN WITH APPLICATION DATE FOR CAHs

Exception	Period of Consideration for Exception	**Submit Application** For FY2015 No later than
Insufficient Internet access – CAHs	Demonstrate insufficient internet access for any 90 day period within the cost reporting period that begins prior to or during the payment adjustment year	Nov 30, 2015
New CAHl	New CAH granted an exception for one full cost reporting period after they admit their first Medicare patient	Guidance to be issued following publication of the final rule
Extreme Circumstances outside of the CAH's Control	Oct 1 through Sept 30 of the payment adjustment year	Nov 30, 2015

5. Administrative Review Process of Certain Electronic Health Record Incentive Program Determinations

In the Stage 2 proposed rule we proposed an administrative appeals process would apply to both Stage 1 and Stage 2 of meaningful use. We also posted guidance on the CMS website, http://www.cms.gov/qualitymeasures/05_ehrincentiveprogramappeals.asp, in the interim between the publication of this proposed rule and the publication of the final rule. We sought public comments both on the guidance and the proposed rule.

We proposed to limit permissible appeals to the following three types of appeals:

- Eligibility Appeals
- Meaningful Use Appeals
- Incentive Payment Appeals We also proposed certain filing and other deadlines for such administrative appeals. We refer readers to our proposed rule at (77 FR 13779 through 13780) for a full explanation of these proposals.

We received several comments on our appeals proposals, which are discussed in this section of the preamble. However, after review of the public comments and the appeals filed as of the writing of this final rule, we believe the administrative review process is primarily procedural and does not need to be specified in regulation. The appeals process we proposed

essentially constituted an agency reconsideration of certain types of determinations regarding eligibility for the program, meaningful use, or incentive payment amounts. We believe such an informal reconsideration process may be included in procedural guidance, rather than in our regulations. Therefore, our administrative appeals process will be included on our website at www.cms.gov/EHRIncentivePrograms.

We recognize that there is a procedural appeals process currently in effect, and in all cases, we will require that requests for appeals, all filings, and all supporting documentation and data be submitted through a mechanism and in a manner specified by us. We expect all providers to exhaust this administrative review process prior to seeking review in Federal Court.

As we stated in the proposed rule, we also note that the HITECH Act prohibits both administrative and judicial review of the standards and method used to determine eligibility and payment (including those governing meaningful use) (see 42 CFR 413.70(a)(7), 495.106(f), 495.110, 495.212). Our limited appeal process would not provide administrative review of these areas; but rather would involve cases of individual applicability; that is, where a provider is challenging not the standards and methods themselves, but whether the provider met the regulatory standards and methods promulgated by CMS in its rules.

While we are not finalizing regulations on appeals, we respond to comments we received on our proposals.

Comment: Several commenters requested CMS make more explicit information available to providers on the documentation that should be available in the event of an audit.

Response: In the event of an audit, at a minimum, providers should have available electronic or paper documentation that supports providers' completion of the Attestation Module responses, including the specific information that supports each measure. In addition, providers

should have documentation to support the submission of CQMs, including the specific information that supports each measure. Providers should also maintain documentation to support their incentive payment calculations, for example data to support amounts included on their cost report, which are used in the calculation. As indicated in the Stage 1 final rule, providers should keep documentation for at least 6 years following the date of attestation.

Comment: A commenter noted that states may need to change their audit procedures or State Medicaid Health Information Technology (HIT) Plans (SMHPs) regarding audit and appeals by CMS for demonstrating meaningful use.

Response: We proposed that states would have an option to have CMS audit and conduct appeals of eligible hospitals' meaningful use. We finalize that proposal in our Medicaid regulations at §495.332. We agree that SMHPs regarding audit and appeals may need revising. We are working closely with states to align principles regarding both audit and appeals process for both the Medicare and Medicaid EHR Incentive Programs. We intend to give states both technical support and program information to ensure consistency in the application of those audit and appeals principles.

Comment: A number of commenters asked for the addition of appeal categories beyond those we proposed. Several commenters requested CMS implement an appeals process for penalties and hardship exemptions. One commenter requested more comprehensive language to better define the requirements and circumstances under which appeals may be heard and acted upon. Another commenter requested CMS institute an appeals process relating to MACs' decisions regarding reasonable costs and determining incentive payments for CAHs.

Response: We appreciate the number of commenters that requested additional appeal categories. Since the writing and publication of the Stage 1 final rule, we have had the

opportunity to review a number of appeals, and we note that many of these appeals do not necessarily fit easily into the categories we proposed. Based on the comments we received and the information we have regarding appeals that have already been filed, we are concerned that finalizing the categories we proposed for appeals could negatively impact providers and potentially add unnecessary burden and complexity. We are also concerned that specifying these categories could limit the flexibility we might otherwise have in addressing new or unanticipated appeal categories in the future, or in adding greater detail regarding the scope and requirements of particular types of appeals. For example, a number of the appeals we have received are related neither to eligibility, meaningful use, or incentive payments directly, but instead address registration or attestation system changes that we are currently in the process of implementing for providers' benefit. Because of these concerns, we decline to finalize the categories of appeals as proposed and intend to issue guidance regarding types or categories of appeals and accompanying requirements on our website at www.cms.gov/EHRIncentivePrograms.

As stated earlier, the HITECH Act prohibits both administrative and judicial review of the standards and methods used to determine eligibility and payment (including those governing meaningful use) (see 42 CFR 413.70(a)(7), 495.106(f), 495.110, 495.212). Any procedures would not allow administrative appeals of these issues. As for reasonable costs reported by CAHs, we already stated in the Stage 1 final rule that a CAH "may appeal the statistical and financial amounts from the Medicare cost report used to determine the CAH incentive payment," but that the CAH "would utilize the current provider appeal process pursuant to section 1878 of the Act." (75 FR 44464)

Finally, we note that there will not be appeal reconsiderations of hardship exception or payment adjustment determinations. As specified section at II.D.2.c. of this final rule, the

granting of a hardship exception will be through an application process, and we expect providers to make a full declaration of all relevant information at the time of filing of that application. We are concerned that there would not be adequate time to process hardship exception applications, render determinations, and also process appeals of those redeterminations. Therefore, we decline to allow appeal reconsiderations of hardship exception determinations. We note that the HITECH Act prohibits both administrative and judicial review of the standards and methods used to determine payment adjustments, including hardship exceptions to those payment adjustments.

Comment: A number of commenters noted concerns regarding the timelines proposed for filing appeals and forwarding documentation.

Response: We appreciate the many comments regarding the proposed timelines for appeals. However, we are not finalizing our appeal regulations in this final rule. We intend to issue guidance regarding timelines for types or categories of appeals on our website at www.cms.gov/EHRIncentivePrograms.

E. Medicare Advantage Organization Incentive Payments

1. Definitions (§495.200)

We proposed to add definitions of the terms "Adverse eligibility determination," "Adverse payment determination" and "MA payment adjustment year." We also proposed to add a definition for the term "Potentially qualifying MA-EPs and potentially qualifying MA-affiliated eligible hospitals," to cross reference the existing definition at §495.202(a)(4).

We proposed to clarify the application of "hospital-based EP" as that term is used in paragraph 5 of the definition of "qualifying MA-EP" in §495.200, to make clear that the calculation is not based on FFS-covered professional services, but rather on MA plan enrollees. Otherwise, qualifying MA-EPs who provide at least 80 percent of their covered professional services to MA plan enrollees of a qualifying MA organization might be considered "hospital based" solely on the basis of 90 percent of their FFS-covered professional services being provided in a hospital setting. We provided an example of a qualifying MA-EP that might bill FFS 10 times over a year for emergency room services provided to various Medicare patients. Although the vast majority of the MA-EP's covered services were reimbursed under his or her arrangement with a qualifying MA organization, 100 percent (or 10) of the MA-EP's FFS-covered services would have been for hospital-based services, which would prohibit the MA organization from receiving reimbursement under the MA EHR incentive program for the MA-EP. We do not believe that we should exclude MA-EPs from the MA EHR Incentive Program due to only a few FFS claims. Therefore, we are clarifying the definition of "qualifying MA-EP" to state that for purposes of the MA EHR Incentive Program, a hospital-based MA-EP provides 90 percent or more of his or her covered professional services in a hospital setting to MA plan enrollees of the qualifying MA organization.

We did not receive any comments on these provisions and we are finalizing them as proposed with the exception of the definitions of the terms "Adverse eligibility determination," and "Adverse payment determination." As we explain later in this preamble discussion, we do not believe formal regulations for an informal reconsideration procedural rule are necessary and therefore, we are not finalizing these two definitions in our regulations.

2. Identification of Qualifying MA Organizations, MA-EPs, and MA-Affiliated Eligible Hospitals (§495.202)

We proposed a technical change to §495.202(b)(1) to require that the qualifying MA organization identify those MA-EPs and MA-affiliated eligible hospitals that the qualifying MA organization believes would be meaningful users of CEHRT during the reporting period, when a qualifying MA organization intends to claim an incentive payment for a given qualifying MA-EP or MA-affiliated eligible hospital.

We also proposed an amendment to §495.202(b)(2) to reflect current policy that qualifying MA organizations must report the CMS Certification Number (CCN) for qualifying MA-affiliated eligible hospitals. We explained that as the program matures, it is necessary to report this detail to effectively administer the program. We are adopting this change in this final rule (§495.202(b)(2)).

We proposed a new §495.202(b)(3) to establish a reporting requirement to identify qualifying MA-EPs who have furnished more than 50 percent of their covered Medicare professional services to MA enrollees of the qualifying MA organization in a designated geographic Health Professional Shortage Area (HPSA) during the reporting period. We also proposed to redesignate the current §495.202(b)(3) as (b)(4), and revised the introductory language in (b)(2) to reflect this redesignation.

We also proposed to require MA organizations to identify qualifying MA-EPs or MA-affiliated eligible hospitals within 2 months of the close of the payment year (rather than within 60 days) (previously §495.202(b)(3), now newly redesignated §495.202(b)(4)). We explained that this change would be consistent with the Medicare FFS EHR Incentive Program, but in nonleap years this would reduce the time for reporting revenue amounts to CMS for qualifying MA-EPs from 60 days to 59 days. We proposed conforming amendments to §495.204(b)(2) and §495.210(b) and (c).

We also explained that because the redesignated §495.202 (b)(4) relates to both the payment phase and the payment adjustment phase of the program, we are adding the word "qualifying" to the text of the regulation. Therefore, we explained, this regulation applies to both qualifying MA-EPs and MA-affiliated eligible hospitals (both payment and payment adjustment phases of the program) and potentially qualifying MA-EPs and MA-affiliated eligible hospitals (only the payment adjustment phase of the program).

We proposed to redesignate the current §495.202(b)(4) as §495.202(b)(5), and to require a qualifying MA organization to identify the MA-EPs and MA-affiliated eligible hospitals that it believes would be both "qualifying" and "potentially qualifying." To calculate the payment adjustment, we explained that we will need to know how many qualifying MA-EPs and MA-affiliated eligible hospitals are, and are not, meaningful users. We also proposed to correct a cross-reference.

We did not receive any comments on these provisions and we are finalizing them as proposed.

3. Incentive Payments to Qualifying MA Organizations for Qualifying MA-EPs and Qualifying MA-Affiliated Eligible Hospitals (§495.204)

a. Amount Payable to a Qualifying MA Organization for its Qualifying MA-EPs

In §495.204(b), we proposed to clarify that methods relating to overhead costs may be submitted for MA-EPs regardless of whether the MA-EPs are salaried or paid in another fashion, such as on a capitated basis.

As stated previously, we also proposed to require MA organizations, to submit revenue amounts relating to their qualifying MA-EPs within 2 months of the close of the payment year, (rather than within 60 days).

b. Increase in Incentive Payment for MA-EPs Who Predominantly Furnish Services in a Geographic Health Professional Shortage Area (HPSA)

In a new §495.204(e) (we proposed to redesignate the current paragraph (e) as paragraph (f)), we proposed to add a provision clarifying the currently existing policy governing whether a qualifying MA organization is entitled to a HPSA increase for a given qualifying MA-EP. We explained that section 1848(o)(1)(B)(iv) of the Act, which is currently in effect, and as applied to the MA program, provides a 10-percent increase in the maximum incentive payment available for MA-EPs that predominantly furnish covered professional services during the MA EHR payment year in a geographic HPSA. We explained that consistent with the Medicare FFS EHR Incentive Program, we interpreted the term "predominantly" to mean more than 50 percent. For the MA EHR Incentive Program, we proposed to determine eligibility for the geographic HPSA increase on whether the qualifying MA-EP predominantly provided services to MA plan enrollees of the qualifying MA organization in a HPSA during the applicable MA EHR payment year.

Further, we explained that it is worth noting that an MA organization does not automatically receive a HPSA bonus merely because its qualifying MA-EPs predominantly served a geographic HPSA. We stated that in order for the MA organization to receive the 10 percent increase, the MA-EP needs to provide at least 10 percent or more of Medicare Part B covered professional services to MA plan enrollees of the qualifying MA organization. In other words, to qualify for the HPSA bonus an MA-EP needs to provide more than $24,000 of Medicare Part B covered professional services to MA plan enrollees of the qualifying MA organization. The MA-EP needs to provide up to $26,400 in covered services to earn the maximum HPSA-enhanced bonus of $19,800 if the first payment year is 2011 or 2012. Thus, for MA-EPs who predominantly furnish services in a geographic HPSA, the "incentive payment limit" in §495.102(b) would be $19,800, instead of $18,000, if the first MA EHR payment year for the MA organization with respect to the MA-EP is 2011 or 2012. If an MA organization could show that an MA-EP predominantly served beneficiaries in a HPSA during the payment year and that that MA-EP provided, for example, for the 2011 payment year, at least $26,400 in Part B professional services to MA plan enrollees of the MA organization during the payment year, we stated that the MA organization could receive the entire $19,800 incentive payment for that MA-EP. If the MA-EP provided less than $26,400 in Part B professional services, the potential incentive payment for that MA-EP for that MA organization would be less than $19,800 for the payment year. We proposed a conforming amendment in §495.202(b)(2)(ii) to require MA organizations to notify CMS whether the qualifying MA-EP predominantly provided covered services to MA plan enrollees in a HPSA.

We added a new paragraph (5) to redesignated paragraph (f). This new paragraph (5) clarifies that we would recoup the EHR incentive payment if one of the following entities fails to

comply with an audit request to produce documents or data needed to audit the validity of an EHR incentive payment: -- (1) a qualifying MA-EP, (2) an entity that employs a qualifying MA-EP (or in which a qualifying MA-EP had a partnership interest), (3) an MA-affiliated eligible hospital, or (4) any other party contracting with the qualifying MA organization. We explained that we already have the authority to do this under the current §495.204(e)(4), (to be redesignated as (f)(4)); however, we proposed to amend the regulations to specifically address what would happen in the case of a failure to produce documents or data related to an audit request.

We added a new paragraph (g) to §495.204 to clarify the current policy that in the unlikely event we paid a qualifying MA organization for a qualifying MA-EP, and it was later determined that the MA-EP-- (1) was entitled to a full incentive payment under the Medicare FFS EHR Incentive Program; or (2) had received payment under the Medicaid EHR Incentive Program, we would recover the funds paid to the qualifying MA organization for such an MA-EP from the MA organization. (We stated that the former case would be in the unlikely event an MA-EP appeared to have earned an EHR incentive of less than the full amount under FFS, and then later was determined to have earned the full amount under FFS. In accordance with duplicate payment avoidance provisions in section 1853(l)(3)(B) of the Act and implementing regulations at §495.208, we would recover the MA EHR incentive payment since a full FFS EHR payment was due.) If the organization still had an MA contract, we would recoup the amount from the MA organization's monthly payment under section 1853(a)(1)(A) of the Act. If the organization no longer had an MA contract, we would recoup any amounts through other means, such as formal collection. We stated that since duplicate and overpayments are prohibited by statute (sections 1853(l)(3)(B), 1853(m)(3)(B), and 1903(t)(2) of the Act), we

believe that this policy must apply to all years of the program, beginning with payment year 2011. Thus, we would recover overpaid MA EHR incentive payments for all MA EHR payment years, including payment year 2011.

We also clarified that, in accordance with statutory requirements, if it is determined that an MA organization received an incentive payment for an MA-affiliated eligible hospital that also received a payment under the Medicare FFS EHR Incentive program or that otherwise should not have received such payment, we would similarly recover the funds paid to the qualifying MA organization for such MA-affiliated eligible hospital from either the MA organization's monthly payment under section 1853(a)(1)(A) of the Act, from the MA-affiliated eligible hospital's CMS payment through the typical process for recouping Medicare funds from a "subsection (d)" hospital, or through other means such as a collection process, as necessary. As with EPs, as the statute prohibits us from making duplicate and overpayments, we explained that this policy does not constitute a new rule and must apply to all years of the program, beginning with payment year 2011.

We did not receive any comments on these provisions and are finalizing them as proposed.

4. Avoiding Duplicate Payments

We stated that qualifying MA-EPs are eligible for the Medicare FFS EHR incentive payment if they meet certain requirements under that program. However, we also stated that an EHR incentive payment is only allowed from one program. We believe that the requirement that MA organizations notify MA-EPs that the MA organization intended to claim them for the MA EHR Incentive Program would minimize misunderstandings among MA-EPs (particularly if they expected to receive an incentive payment under the Medicare FFS Incentive Program). We

stated that it was important for MA-EPs to understand certain aspects of the program such as when a qualifying MA organization claimed an MA-EP under the MA EHR Incentive Program and the MA-EP was not entitled to a full FFS EHR Incentive payment, the MA organization claim would prevent a partial payment under the Medicare FFS EHR Incentive Program from being paid directly to the MA-EP.

We proposed to require each qualifying MA organization to attest that it notified the MA-EPs it intends to claim. We proposed to require that this attestation be submitted along with the MA organization's meaningful use attestation for the MA EHR payment year for which the MA organization is seeking payment.

Therefore, we proposed to revise §495.208 by adding-- (1) a new paragraph (a) that requires a qualifying MA organization to notify MA-EPs when the MA organization intends to claim them for the MA EHR Incentive Program prior to making its attestation of meaningful use to CMS; (2) a new paragraph (b) that requires a qualifying MA organization to notify MA-EPs when it is claiming them, that the MA-EPs may still receive an incentive payment under the Medicare FFS or Medicaid EHR Incentive Program, if certain requirements are met; and (3) a new paragraph (c) that requires a qualifying MA organization to attest to CMS that these notification requirements have been satisfied by the MA organization. We also proposed to redesignate the current paragraphs (a) through (c) of §495.208 as (d) through (f), respectively.

As discussed previously, in §495.210, we proposed to change the requirement that MA organizations attest to meaningful use within 60 days after the close of the MA EHR payment year for both MA-EPs and MA-affiliated eligible hospitals, to a requirement to do so within 2 months in order provide consistency between the Medicare FFS and MA EHR Incentive Programs.

Comment: A commenter requested that CMS confirm that MA organization reporting to CMS under HEDIS, HOS, and CAHPS will continue to apply for purposes of the MA EHR Incentive Payment Program during Stage 2. The commenter questioned if MA organizations, for both qualifying MA-EPs and MA-affiliated eligible hospitals, will be permitted to continue to submit HEDIS, HOS, and CAHPS data in lieu of CQMs during Stage 2.

Response: We are confirming that during Stage 2 and subsequent stages of MA EHR Program implementation, we will continue to require qualifying MA organizations to successfully report HEDIS, HOS, and CAHPS measures in lieu of CQMs for purposes of meaningful use reporting for qualifying MA-EPs and MA-affiliated eligible hospitals.

After review of the public comments received, we are finalizing these provisions as proposed.

5. Payment Adjustments Effective for 2015 and Subsequent MA Payment Adjustment Years (§495.211).

In the proposed rule we explained that beginning in 2015, the law provides for adjustments to monthly MA payments under sections 1853(l)(4) and 1853(m)(4) of the Act if a qualifying MA organization's potentially qualifying MA-EPs or MA-affiliated eligible hospitals (or both) are not meaningful users of certified EHR technology. We proposed to add a definition of "MA Payment Adjustment Year" to the definitions in §495.200. The definition was needed in part because the payment adjustment phase of the MA EHR program continued indefinitely – beyond the last year for which MA EHR incentive payments could be made to qualifying MA organizations. Additionally, since we proposed to operationalize MA EHR payment adjustments in a different manner than under the FFS Medicare program, we believed a definition was warranted.

We proposed that an MA organization would have to had at least initiated participation in the incentive payment phase of the program from 2011 through 2014 for MA-EPs or through 2015 for MA-affiliated eligible hospitals, to have its Part C payment under section 1853(a)(1)(A) of the Act adjusted during the payment adjustment phase of the program, and would have to continue to qualify for participation in the program as a "qualifying MA organization" as defined for purposes of this program. The imposition of a payment adjustment is also conditioned on the qualifying MA organization having potentially qualifying MA-EPs and MA-affiliated eligible hospitals for the respective payment adjustment years. We took this approach because we believed that it would be impossible to verify that a given MA organization is, in fact, a qualifying MA organization with potentially qualifying MA-EPs and MA-affiliated eligible hospitals, unless the MA organization had first demonstrated that it met these requirements through receipt of MA EHR incentive payments for at least one of the MA EHR payment years as defined for purposes of this program. We noted that although MA EHR payment years for both MA-EPs and MA-affiliated eligible hospitals could theoretically continue through 2016, the last first MA EHR payment year for which an MA organization could receive an EHR incentive payment is 2014 for MA-EPs, and 2015 for MA-affiliated hospitals.

Furthermore, we believe that payment adjustments under section 1853 of the Act would have limited applicability in the MA EHR Incentive Program because the HITECH Act limited the type of organization that would qualify as a "qualifying MA organization" for purposes of the MA EHR Incentive Program in both phases of the program (the phase of the program during which we make incentive payments, and the phase of the program when we adjust payments under sections 1853(l)(4) and 1853(m)(4) of the Act). We stated that section 1853(l)(5) of the Act limits which MA organizations may participate by defining the term "qualifying MA

organization." We explained that a "qualifying MA organization" must be organized as a health maintenance organization (HMO), as defined in section 2791(b)(3) of the Public Health Service (PHS) Act (42 U.S.C. 1395w-23(l)(5)). The PHS Act further defines an HMO as a "federally qualified HMO, an organization recognized under state law as an HMO, or a similar organization regulated under state law for solvency in the same manner and to the same extent as such an HMO." (See 42 U.S.C. 300gg-91). We explained that an MA organization participating in Medicare Part C might not be a federally qualified HMO, nor an organization recognized under state law as an HMO, nor a similar organization regulated under state law for solvency in the same manner and to the same extent as such an HMO. We noted that organizations that do not meet the PHS definition of "HMO" may not receive an incentive payment, nor would they be eligible to have their Part C payment adjusted for having potentially qualifying MA-EPs or MA-affiliated eligible hospitals that do not successfully demonstrate meaningful use of certified EHR technology.

Secondly, section 1853(l)(2) of the Act requires that MA-EPs be as described in that paragraph. We stated that the vast majority of MA organizations do not employ their physicians; nor do they use physicians who work for, or who are partners of, an entity that contracts nearly exclusively with the MA organization (as set out in the definition of a "Qualifying MA-EP" in §495.200).

Thirdly, section 1853(m)(2) of the Act requires that a qualifying MA organization have common corporate governance with a hospital in order for it to be considered an MA-affiliated eligible hospital, and we did not expect many qualifying MA organizations to meet this test.

We explained that the current §495.202(b)(4) (which we proposed to redesignate as §495.202(b)(5)) requires all qualifying MA organizations that have potentially qualifying

MA-EPs or MA-affiliated eligible hospitals that are not meaningful users to initially report that fact to us beginning in June of MA plan year 2015. We proposed that this reporting requirement would include only qualifying MA organizations that participated in and received MA EHR incentive payments.

Further, we discussed that there may be MA organizations that participated in the incentive payment phase of the program, but then ceased being qualifying MA organizations, or that no longer have any qualifying MA-EPs or MA-affiliated eligible hospitals. We provided an example of a qualifying MA organization that contracts with a specific entity to deliver physicians' services during the payment phase of the EHR Incentive Program, but then the entity changes, or the MA organization loses its contract with the entity. We explained that such changes could cause the MA organization's MA EPs to no longer meet the 80/80/20 rule due to loss of the contract, or the entity might begin contracting with additional MA organizations. (See §495.200, for the definition of "Qualifying MA-EP.") Therefore, we explained, the MA organization would not necessarily have its monthly payment adjusted because it might no longer meet the basic requirements under which MA EHR incentive payments were made to it.

Therefore, we proposed to adjust payments, beginning for payment adjustment year 2015, only for qualifying MA organizations that received MA EHR payments and that had potentially qualifying MA-EPs or MA-affiliated eligible hospitals that were not meaningful EHR users. We proposed to rely on the existing self-reporting requirement in redesignated §495.202(b)(5) and subsequent audits to ensure compliance.

Comment: A commenter recommended that CMS apply MA payment adjustments to qualifying MA organizations only for the category of MA provider (that is, MA-EP versus MA-affiliated hospital) for which it claimed and received MA EHR incentive payments. For

example, if a qualifying MA organization claimed incentive payments during the payment phase of the program only for MA-EPs and not for any MA-affiliated eligible hospitals, then the MA organization should only be required to report on qualifying and potentially qualifying MA-EPs during the adjustment phase of the program, and should not be subject to payment adjustments for MA-affiliated hospitals.

Response: We agree with the commenter that we will apply payment adjustments only to qualifying MA organizations for the category (or categories) of MA provider (either MA-EP, MA-affiliated eligible hospital, or both) for which it claimed and received MA EHR incentive payments. To the same extent that qualifying MA organizations have identified themselves and their qualifying MA-EPs and/or MA-affiliated eligible hospitals during the payment phase of the MA EHR Incentive Program, we expect them to continue to identify themselves and their MA-EPs and MA-affiliated hospitals during the adjustment phase of the program. We are taking this approach because we believe it would be impossible to verify that a given qualifying MA organization has potentially qualifying MA-EPs or MA-affiliated eligible hospitals, unless it had first identified those providers to us. We have modified §495.211(c) to clarify that MA EHR payment adjustments with respect to MA-affiliated hospitals will only apply to qualifying MA organizations that previously received incentive payments under the MA EHR Incentive Program for MA-affiliated hospitals, and similarly, that MA EHR payment adjustments with respect to MA-EPs will only apply to qualifying MA organizations that previously received incentive payments under the MA EHR Incentive Program for MA-EPs.

We proposed to collect payment adjustments made under sections 1853(l)(4) and 1853(m)(4) of the Act after meaningful use attestations have been made. Final attestations of meaningful use occur after the end of an EHR reporting period, which for MA-EPs would run

concurrent with the payment adjustment year. In the case of potentially qualifying MA-affiliated eligible hospitals, attestations of meaningful use would occur by the end of November after the EHR reporting period. As noted previously, we proposed to amend §495.202(b) to indicate that in addition to initial identification of potentially qualifying MA-EPs and MA-affiliated eligible hospitals that are not meaningful users (as required by redesignated §495.202(b)(5)), qualifying MA organizations would also need to finally identify such MA-EPs and MA-affiliated eligible hospitals within 2 months of the close of the applicable EHR reporting period. Final identification by qualifying MA organizations of potentially qualifying MA-EPs and/or MA-affiliated eligible hospitals that are not meaningful users would then result in application of a payment adjustment by CMS. On the other hand, final identification of all qualifying MA-EPs and/or MA-affiliated eligible hospitals as meaningful users would obviate an adjustment. We stated that, through audit, we would verify the accuracy of an applicable MA organization's assertions or nonreporting.

We proposed to adjust one or more of the qualifying MA organization's monthly MA payments made under section 1853(a)(1)(A) of the Act after the qualifying MA organization attested to the percent of hospitals and professionals that either were, or were not, meaningful users of certified EHR technology. We stated that, to the extent a formerly qualifying MA organization did not report under §495.202(b)(4) or (5), we would verify, upon audit, the accuracy of the applicable MA organization's nondisclosure of such qualifying and potentially qualifying users.

Under our proposed approach, the adjustment would be calculated based on Part C payment data made under section 1853(a)(1)(A) of the Act for the payment adjustment year. We stated that since an MA-affiliated eligible hospital must attest to meaningful use by November

30th, we could use the Part C payment information in effect at the time of the attestation to calculate the payment adjustment for a specific potentially qualifying MA-affiliated eligible hospital with respect to a specific MA organization. Although we expected (and preferred) to make an adjustment to a single MA monthly payment totaling the adjustment for the year, we requested comment on whether more than one monthly payment should be adjusted. We stated that one possible approach would be to make this decision on a case-by-case basis depending upon a given qualifying MA organization's situation (for example, payment adjustment amount versus MA organization monthly payment).

For payment adjustments based on potentially qualifying MA-EPs that are not meaningful users of certified EHR technology, we also proposed to calculate the adjustment based on the Part C payment made under section 1853(a)(1)(A) of the Act for the payment adjustment year. Because attestations of meaningful use for qualifying MA-EPs occur in February of the calendar year following the EHR reporting year, we noted that we could calculate the payment adjustment based on the prior MA payment year's payment, and that we could apply that adjustment to one or more of the prospective Part C payments. While we preferred to make an adjustment to one MA prospective payment for the full amount of the payment adjustment when possible, we solicited comment on whether we should make adjustments over several months or in a single month (for the entire adjustment amount), when possible. We received no comments on this proposal and therefore we are adopting the policy of collecting payment adjustments as quickly as possible in a single month, when possible.

Thus, adjustments for MA payment adjustment year 2015 would be based on MA payment data under section 1853(a)(1)(A) of the Act. However, while the payment adjustment for the 2015 payment adjustment year would be collected as soon as possible, we stated that this

might not be until CY 2016 through an adjustment to the MA organization's MA capitation payment or payments under section 1853(a)(1)(A) of the Act.

We stated that proposed §495.211(c) made clear that the potentially qualifying MA-EP and MA-affiliated eligible hospital payment adjustments would be calculated separately, and that each adjustment was applied to the qualifying MA organization's monthly payment under section 1853(a)(1)(A) of the Act. As discussed previously, we are modifying §495.211(c) to clarify that MA EHR payment adjustments for MA-affiliated hospitals only apply to qualifying MA organizations that previously received incentive payments under the MA EHR Incentive Program for MA-affiliated hospitals, and that payment adjustments for MA-EPs only apply to qualifying MA organizations that previously received incentive payments under the MA EHR Incentive Program for MA-EPs.

Proposed paragraphs (a) through (c) would apply to adjustments based on both potentially qualifying and qualifying MA-EPs and MA-affiliated eligible hospitals that were not meaningful EHR users. Proposed paragraph (d) would apply only to adjustments based on potentially qualifying and qualifying MA-EPs that were not meaningful users of certified EHR technology. We also stated that paragraph (d) makes it clear that if a potentially qualifying MA-EP was not a meaningful user of CEHRT in payment adjustment year 2015 (and subsequent payment adjustment years), the qualifying MA organization's monthly Part C payment would be adjusted accordingly.

During the payment phase of the MA EHR Incentive Program qualifying MA organizations attest to meaningful use for each qualifying MA-EP and MA-affiliated eligible hospital they claimed. We also stated that during the payment adjustment phase of the program, we would need to know the percentage of both qualifying and potentially qualifying MA-EPs

and MA-affiliated eligible hospitals that were not meaningful users of certified EHR technology. This percentage could be derived by taking the total number of the qualifying MA organization's qualifying and potentially qualifying MA-EPs, or MA-affiliated eligible hospitals, and identifying the portion of those MA-EPs or MA-affiliated hospitals that were not meaningful EHR users. We would use this percentage to make the adjustment proportional to the percent that were not meaningful users for a given adjustment year and qualifying MA organization.

Moreover, in determining the proportion of potentially qualifying MA-EPs and potentially qualifying MA-affiliated eligible hospitals (those that were not meaningful users), we would exclude EPs and hospitals that were neither qualifying nor potentially qualifying in accordance with the definition of "qualifying" and "potentially qualifying MA-EPs" and "MA-affiliated eligible hospitals" in §495.200. Thus, an MA-EP that was a hospital-based EP would not be a qualifying or potentially qualifying MA-EP since such an EP did not meet item (5) of the definition of qualifying MA-EP in §495.200 and thus would not be used in our computation of the proportion of MA-EPs for purposes of applying the payment adjustment. We proposed the following formula to apply the payment adjustments proposed in §495.211(d)(2) to MA-EPs:

[the total number of potentially qualifying MA-EPs**]/[(**the total number of potentially qualifying MA-EPs) + (the total number of qualifying MA-EPs)**]**.

Similarly, the formula we proposed for purposes of applying payment adjustments in §495.211(e)(2)(iii) with respect to MA-affiliated hospitals was:

[the total number of potentially qualifying MA-affiliated eligible hospitals**]/[(**the total number of potentially qualifying MA-affiliated eligible hospitals) + (the total number of qualifying MA-affiliated eligible hospitals)**]**.

Keeping in mind that redesignated §495.202(b)(4) and (5) required qualifying MA organizations to identify potentially qualifying MA-EPs and potentially qualifying MA-affiliated eligible hospitals and to provide other information beginning for plan year 2015, we solicited comment on the question of whether, in the payment adjustment phase of this program, qualifying MA organizations with potentially qualifying MA-EPs and MA-affiliated eligible hospitals should-- (1) still be required to attest to the meaningful use objectives and measures; or (2) instead be required only to report the percent of MA-EPs and MA-affiliated eligible hospitals that are not meaningful users of certified EHR technology. We suggested that commenters take into account that MA-affiliated eligible hospitals would still be required to perform a reporting function on behalf of their MA-affiliated organization in the National Level Repository (NLR), and that they were generally bound to "subsection (d)" hospital reporting requirements of the NLR. Thus, we were primarily interested in comments related to MA-EPs.

We explained that while we wished to minimize burden, we were also concerned with our ability to audit the information reported to ensure compliance with MA program requirements. Having received no comments on this provision, we therefore adopt a final requirement to use only percentage-based reporting and, require MA organizations to retain and produce data and records necessary to substantiate their submissions, including evidence of meaningful use by those MA-EPs and MA-affiliated eligible hospitals so reported.

We proposed that payment adjustments for MA-EPs would be calculated by multiplying: (1) the percent established under §495.211(d)(4) (which, in accordance with the statute, increases the adjustment amount up until 2017 and potentially beyond); with (2) the Medicare Physician Expenditure Proportion; and (3) by the percent of the qualifying MA organization's qualifying and potentially qualifying MA-EPs that were not meaningful users. We explained that

section 1853(l)(4)(B)(i) of the Act requires MA payments to be reduced using the "percentage points" reduction of section 1848(a)(7)(A)(ii) of the Act. As section 1848(a)(7)(A)(ii) of the Act is "subject to clause (iii)," and as clause (iii) of that same provision requires payment adjustments to increase when the proportion of EPs who are meaningful EHR users is less than 75 percent, we proposed to apply a similar policy for the MA program. Specifically, we proposed that if the proportion of MA-EPs of a qualifying MA organization did not meet the 75 percent threshold (as determined in proposed §495.211(d)(2)) in 2018 and subsequent years, the percentage reduction could increase to 4 percent in 2018, and 5 percent in 2019 and subsequent years. We did not propose a possible 2 percent reduction for 2015 (consistent with the Medicare FFS EHR Incentive Program when an EP is subject to an adjustment in 2014 under the e-prescribing program), because MA organizations are not independently subject to e-prescribing payment adjustments.

We proposed that the Medicare Physician Expenditure Proportion for a year would be the Secretary's estimate of expenditures under Parts A and B not attributable to Part C that are attributable to expenditures for physician services. While we proposed a uniform portion for all MA organizations, we also proposed to adjust the proportion on a more individual basis to account for the fact that qualifying MA organizations may contract with a large number of EPs that are neither qualifying nor potentially qualifying. We explained that this individualized policy was based on the statutory language in section 1853(l)(1) of the Act, which states that the provisions of section 1848(a)(7) of the Act (that is, the payment adjustments) apply "with respect to" the EPs "described in paragraph (2)" of section 1853(l) of the Act. As section 1853(l)(2) of the Act creates several additional requirements for MA-EPs (that is, that they be employed by the qualifying MA organization, that they meet the 80/80/20 requirements, and so on), we proposed

adjusting the Physician Expenditure Proportion to recognize that many EPs may not qualify as MA-EPs, regardless of meaningful use. Thus, we proposed to adjust each MA organization's Physician Expenditure Proportion to recognize that not all of the EPs would meet the technical (nonmeaningful use) requirements to be potentially qualifying or qualifying MA-EPs. Without our proposed adjustment, a small sample size of MA-EPs could magnify the reduction amount during the payment adjustment phase of the program, because the actions of a limited set of qualifying and potentially qualifying MA-EPs (and whether they meaningfully used certified EHR technology) would determine whether all of an MA organization's physician expenditure proportion was reduced.

We provided an example of our proposed MA payment adjustment for adjustment year 2015 as follows:

Assume the hypothetical Medicare Physician Expenditure Proportion, adjusted as described previously, is 10 percent for 2015;

The qualifying MA organization's percent of qualifying and potentially qualifying MA-EPs that are not meaningful users is 15 percent for 2015; and

The monthly payment in 2015 for the given qualifying MA organization is $10,000,000.

The proposed formula would read as follows:

0.01 (the payment adjustment for 2015) X 0.1 (the hypothetical Medicare Physician Expenditure Proportion) X 0.15 (the percentage of qualifying and potentially qualifying MA-EPs that are not meaningful EHR users) X $10,000,000 (monthly Part C payment) X 12 (number of months in the MA payment year) = $18,000 for the entire year, or $1,500 a month. We proposed that this adjustment would then be collected

against one or more of the qualifying MA organization's payments under section 1853(a)(1)(A) of the Act.

In proposed §495.211(e), we set out a formula for payment adjustments based on potentially qualifying MA-affiliated eligible hospitals that are not meaningful users of certified EHR technology.

We proposed an adjustment equal to the product of the following:

- Monthly Part C payment for the payment adjustment year;
- The percentage point reduction that applies to FFS hospitals as a result of section 1886(b)(3)(B)(ix)(I) of the Act;
- The Medicare hospital expenditure proportion, adjusted in the same manner as the Physician Expenditure Proportion to recognize that not all hospitals are necessarily qualifying or potentially qualifying MA-affiliated eligible hospitals; and
- The percentage of qualifying and potentially qualifying MA-affiliated eligible hospitals of a given qualifying MA organization that are not meaningful users of certified EHR technology.

We proposed that the percentage point reduction of the first bullet (that is, the reduction that applies as a result of section 1886(b)(3)(B)(ix)(I) of the Act) would be based on the point reduction that results when three-fourths of the otherwise applicable percentage increase for the fiscal year was reduced by 33 1/3 percent for FY 2015, 66 2/3 percent for FY 2016, and 100 percent for FY 2017 and subsequent fiscal years. We stated this had the result of decreasing the otherwise applicable market basket update by one-fourth (for 2015), one-half (for 2016), and three-fourths (for 2017 and subsequent payment adjustment years).

We stated that the Medicare Hospital Expenditure Proportion for a year was the Secretary's estimate of expenditures under Medicare Parts A and B that were not attributable to Part C, that were attributable to expenditures for inpatient hospital services. As mentioned previously, we proposed that this proportion reflects only the MA-affiliated eligible hospitals that were either qualifying or potentially qualifying MA-affiliated eligible hospitals.

We also proposed to use the market basket percentage increase that would otherwise apply to "subsection (d)" hospitals for an MA payment adjustment year. We provided the following hypothetical example. The market basket percentage increase for FY 2015 was hypothetically 4 percent. Three-quarters of one-third of 4 percent would be 1 percent. The hypothetical Medicare Hospital Expenditure proportion for the year was 15 percent, and one of two of the relevant MA-affiliated eligible hospitals was not a meaningful EHR user for the applicable period (FY 2015). The monthly payment to the MA organization in 2015 was $10,000,000 a month.

The calculation would be as follows:

0.01 (the market basket percentage point reduction) X 0.15 (the Medicare Hospital Expenditure Proportion) X 0.5 (percent of the qualifying MA organization's qualifying and potentially qualifying MA-affiliated eligible hospitals that are not meaningful users) X $10,000,000 (monthly Part C payment) X 12 (number of months in the MA payment year) = $90,000 for the year, or $7,500 a month. The payment adjustment would be applied on either a monthly basis, or in one adjustment. As stated previously, we requested comment on this aspect of the final rule.

Comment: A commenter stated that the formula for computing the Medicare Physician Expenditure Proportion percent in §495.211(d)(3)(ii) was not clear on whether physicians who

saw no Medicare patient at all would be excluded from the expenditure proportion calculation (for example, most pediatricians), and whether a distinction would be made between services provided by MA-EPs and potential MA-EPs of the organization, and other physicians and the services they provide. The commenter explained that under the model of reimbursement for physician services it uses, the ability to track Part A and Part B costs to individual physicians was limited. The commenter proposed an alternate method for computing the Medicare Physician Expenditure Proportion based on what it called a "uniform distribution model as a proxy for the adjustment to the MPEP percent."

Response: We believe it is unnecessary to specifically exclude physicians, such as pediatricians, who see no Medicare patients from the Medicare Physician Expenditure Proportion calculation. Expenditures that are provided by EPs that are neither qualifying nor potentially qualifying MA-EPs are already adjusted out. This would be true in two ways for physicians, such as pediatricians, who see no Medicare patients. First, these physicians would not meet item (2) of the definition of a "qualifying MA-EP" in §495.200, since these physicians do not provide "at least 80 percent" of their Medicare-covered professional services to enrollees of the qualifying MA organization. Since they provide no Medicare-covered professional services to enrollees of the qualifying MA organization, they do not meet the "80 percent" requirement. Second, the Physician Expenditure Proportion is based only on Medicare expenditures for physician services (that is, the proportion of expenditures under Parts A and B not attributable to Part C that are attributable to expenditures for physician's services). Physician expenditures for non-Medicare services (like most services of a pediatrician) do not count in the calculation. Finally, we do not believe an alternative method of computing the Medicare Physician Expenditure Proportion is necessary and therefore are not considering the alternate approach

proposed by this commenter in this final rule. It should be noted that tracking Part B costs to individual MA-EPs (physicians) is a critical part of determining the incentive payment due a qualifying MA organization (see 42 CFR 495.204(ff)). To the extent methodologies for estimating the portion of MA-EP compensation that is attributable to Part B professional services are used during the payment phase of the MA EHR Incentive Program, we believe these methodologies can also be successfully used during the adjustment phase of the Program.

Comment: A commenter questioned if section 3401 of the Affordable Care Act market basket update adjustment due to changes in economy-wide productivity for FY 2012 and each subsequent fiscal year would be included, or if any other adjustment would be included in the market basket update rate used in the penalty adjustment formula.

Response: Section 1853(m)(4)(B)(i) of the Act directs us to use the "number of the percentage point reduction effected under section 1886(b)(3)(B)(ix)(I) for the period." That reduction is based off of a starting point of the applicable percentage increase otherwise applicable under clause (i), while mandating that this be "determined without regard to clause (viii), (xi) or (xii)" of section 1886(b)(3)(B) of the Act. Thus, the starting point for determining the percentage points by which the update is reduced is the applicable percentage increase in clause (i) of section 1886(b)(3)(B) of Act, before it has been further reduced for productivity (under clause (xi) for other statutory reductions (in clause (xii)), or for failure to report on certain measures (under clause (viii)). Currently, the applicable percentage increase in clause (i), before the other reductions have been made, is the market basket percentage increase for hospitals in all areas. Thus, such a market basket increase will be our starting point, and the percentage points by which that increase is reduced solely due to the application of EHR Program adjustments will be the point reduction we use in the MA formula.

Comment: A commenter proposed an alternate method for computing the Medicare Hospital Expenditure Proportion based on what they believe is "consistent with fee-for-service hospital penalties."

Response: We believe our proposed method is consistent with the method the Medicare fee-for-service program will use to implement EHR adjustments for "subsection (d)" hospitals.

Comment: One commenter expressed concern that CMS had proposed that payment adjustments would be based on an earlier payment period.

Response: We believe the commenter is confused, as we did not propose a prior EHR reporting period for the MA program.

We received no other comments on this section of the proposed rule. After consideration of the public comments received, we are finalizing these provisions as proposed with the one modification noted to §495.211(c).

6. Reconsideration Process for MA Organizations

We proposed a reconsideration process in new section, §495.213. We did not receive any comments on the proposed process. However, for the reasons stated in section II.D.5 of this final rule, we do not believe formal regulations for an informal reconsideration procedural rule are necessary and therefore we are not including this new section in this final rule.

As noted in the proposed rule and as required by statute, our administrative reconsideration process would not permit administrative review of the standards and methods used to determine eligibility and payment (see sections 1853(l)(8) and (m)(6) of the Act, and §495.212 of the regulations). However, it would allow a reconsideration of the application of such standards and methods, in certain circumstances.

F. Revisions and Clarifications to the Medicaid EHR Incentive Program

Unless otherwise specified, the changes discussed in this section of the rule will take effect upon publication of this final rule.

1. Net Average Allowable Costs

In this final rule, we are formalizing through rulemaking the guidance that was shared with state Medicaid Directors in a letter on April 8, 2011 (available at: http://www.cms.gov/smdl/downloads/SMD11002.pdf). These technical changes are required to implement section 205(e) of the Medicare and Medicaid Extenders Act of 2010 (Extenders Act, Pub. L. 111-309). The Extenders Act, enacted on December 15, 2010, amended sections 1903(t)(3)(E) and 1903(t)(6)(B) of the Act. The amended sections change the requirements for an EP to demonstrate the "net average allowable costs," the contributions from other sources, and the 15 percent provider contribution requirements to participate in the Medicaid EHR Incentive Payment Program. The Extenders Act provided that an EP has met this responsibility, as long as the incentive payment is not in excess of 85 percent of the net average allowable cost ($21,250 for first year payments).

Before the Extenders Act, Medicaid EPs who wanted to participate in the EHR Incentive Payment Program were required to provide documentation of certain costs related to acquiring and implementing certified EHR technology. The Extenders Act amended the relevant statute by allowing for providers to simply document and attest that they have adopted, implemented, upgraded, or meaningfully used certified EHR technology, while allowing us to set these average costs.

As a result, rather than requiring each EP to calculate the payments received from outside sources, each will use the average costs and contribution amount we established. After

conducting a meta-analysis of existing data of an EP's costs to adopt, implement, or upgrade certified EHR technology, we determined that average contributions from outside sources should not exceed $29,000. The documentation originally required by an EP to demonstrate that he or she contributed 15 percent (for example, $3,750 for year 1) of the "net average allowable costs" is also no longer needed. The Act now provides that an EP has met this responsibility as long as the incentive payment is not in excess of 85 percent of the net average allowable cost ($21,250). Given that this change is already in effect, we proposed to remove from the required content in the state Medicaid HIT Plan, the requirement that states describe the process in place to ensure that Medicaid EHR incentive payments are not paid at amounts higher than 85 percent of the net average allowable cost of certified EHR technology, as described in §495.332.

We received no comments on our proposal to codify this already-existing policy, and we are finalizing our proposals without modification.

TABLE E1: DETERMINATION OF NET AVERAGE ALLOWABLE COSTS FOR THE FIRST PAYMENT YEAR

First Year Variables[1]	Amounts	Prior to Extenders Act Changes	Currently
Average Allowable Costs	$54,000	Determined through a CMS meta-analysis, described in both the proposed rule (75 FR 1844) and the final rule (75 FR 44314).	No change.
Contributions from Other Sources	Does not exceed $29,000	Subtracted from Average Allowable Costs to reach "Net" Average Allowable Costs. An EP was required to show documentation of all contributions from certain other sources.	No documentation is needed. We have determined that average contributions do not exceed $29,000.
Capped Amount of "Net" Average Allowable Costs	$25,000	Capped by statute and designated in CMS final rule.	No change.
Contribution from the EP	$3,750	An EP was required to demonstrate that he or she had contributed at least 15 percent of the net average allowable costs towards a certified EHR.	No documentation needed. Determined to have been met by virtue of EP receiving no more than $21,250 in the first payment year.
Incentive payment[2]	$21,250	85 percent of the Net Average Allowable Costs; determined through statute. An EP could receive less than this amount if he or she had contributions from other sources exceeding $29,000.	All EPs will receive the maximum incentive payment of $21,250, as all EPs will be determined to have contributions from other sources under $29,000.

[1] These same concepts (but not figures) apply to the second through sixth years, integrating the figures from the Stage1final rule. Ultimately, the incentive paid in the second through sixth years is still the statutory maximum of $8,500.

[2] This figure is further reduced to two-thirds for pediatricians qualifying with reduced Medicaid patient volumes. This is described at 42 CFR 495.310.

2. Definition of Adopt, Implement Upgrade

We are adding clarifying language that maintains our policy that to qualify for an AIU payment, a provider must adopt, implement or upgrade to certified EHR technology that would allow that provider to qualify as a meaningful user. Our regulation has always defined certified EHR technology by reference to the ONC definition at 45 CFR 170.102, and ONC's definition of certified EHR technology has consistently required the technology to support meaningful use. While ONC is changing the definition of certified EHR technology, we do not believe this change would allow a provider to receive an incentive for technology that could not support meaningful use (that is for purchasing only "Base EHR" technology). Nevertheless, in order to be absolutely clear in our regulations, we are amending them to ensure that providers do not receive Medicaid incentives for adopting technology that would not allow them to demonstrate meaningful use.

3. Eligibility Requirements for Children's Hospitals

We proposed to revise the definition of a children's hospital in §495.302 to also include any separately certified hospital, either freestanding or hospital within hospital that predominately treats individuals under 21 years of age; and does not have a CMS certification number (CCN) because they do not serve any Medicare beneficiaries but has been provided an alternative number by CMS for purposes of enrollment in the Medicaid EHR Incentive Program. We will provide future guidance on how to obtain these alternative numbers.

The only comments we received on this proposal were favorable. We are finalizing these policies as proposed. Guidance to these hospitals and the states on enumeration and determining eligibility is also forthcoming.

4. Medicaid Professionals Program Eligibility

Section 1903(t) of the Act authorizes Medicaid payments to encourage the adoption and use of certified EHR technology, and places Medicaid patient volume requirements on EPs to qualify for such payments under the Medicaid program. Patient volume requirements ensure that Medicaid funding is used to encourage the adoption and use of technology specifically to benefit the care of Medicaid populations. Therefore, we proposed that at least one of the clinical locations used for the calculation of an EP's patient volume have CEHRT during the payment year for which the EP is attesting to adoption, implementation or upgrade or meaningful use. This will ensure that Medicaid funding goes to EPs using CEHRT to improve Medicaid patients' care.

The only comments that we received on this proposal were in support of the proposal. For the reasons explained in the proposed rule, we are finalizing this policy as proposed. We have amended §495.304 and §495.332 accordingly.

a. Calculating Patient Volume Requirements

We proposed to revise §495.306 (c) to allow states the option for their providers to calculate total Medicaid encounters or total needy individual patient encounters in any representative, continuous 90-day period in the 12 months preceding the EP or eligible hospital's attestation. This option will be in addition to the current regulatory language that bases patient volume on the prior calendar or fiscal year. We believe this adjustment will provide greater flexibility in eligible providers' patient volume calculations.

Likewise, we proposed to revise §495.306(d)(1)(i)(A) to allow for the calculation of the total Medicaid patients assigned to the EP's panel in any representative, continuous 90-day period in either the preceding calendar year, as is currently permitted, or in the 12 months

preceding the EPs' attestation, when at least one Medicaid encounter took place with the Medicaid patient in the 24 months prior to the beginning of the 90-day period. We also proposed to revise §495.306 (d)(1)(ii)(A) accordingly, so that the numerator and denominator are using equivalent periods. We proposed conforming changes to §495.306(d)(2)(i) and (ii) for needy individual patient volume. We proposed changing the period during which the encounter must take place from 12 months to 24 months to account for new clinical guidelines from the U.S. Preventive Health Services Task Force that allow greater spacing between some wellness visits. Therefore, in order for a patient to be considered "active" on a provider's panel, we proposed 24 months is more appropriate. This change is also in order to be consistent with the proposed Stage 2 meaningful use measure for patient reminders sent to "active patients."

The only comments we received on this proposal were supportive. For the reasons explained in the proposed rule, we are finalizing this policy as proposed. We note that as explained in the proposed rule, this will be an option for states to implement at their discretion. States must seek prior approval from CMS via an amendment to their state Medicaid HIT Plan before implementing this change.

We also proposed to expand the definition of "encounter" to include any service rendered on any one day to an individual enrolled in a Medicaid program. We explained that such a definition will ensure that patients enrolled in a Medicaid program are counted, even if the Medicaid program did not pay for the service (because, for example, a third party payer paid for the item or service, or the service is not covered under Medicaid). We also explained that the definition would include encounters for patients who are Title XIX eligible and who meet the definition of "optional targeted low income children" under section 1905(u)(2) of the Act. Thus, individuals in Title XXI-funded Medicaid expansions (but not separate CHIPs) could be counted

in providers' patient volume calculations. We stated that this approach is consistent with existing policies that provide Title XIX protections to children enrolled in Title XXI-funded Medicaid expansions.

In the proposed rule, we noted that as of 2010, 33 states have Title XXI Medicaid expansions via approved state plan amendments. Therefore, under our proposed policy, providers in those states would be able to include encounters with individuals in such expansions in their patient volume calculation for purposes of this program. In 2010, over 2.1 million children were covered in Medicaid expansion programs. We stated that our proposed change would likely increase the number of eligible providers who qualify for the Medicaid EHR Incentive Program, particularly those serving children because it allows states to create a larger base of Medicaid patients to be counted toward the patient volume requirements than existed under the Stage 1 rule.

Comment: Some commenters were concerned about verifying patient volume requirements for patients seen for a service where Medicaid did not pay for all or part of the service. Commenters asked CMS to clarify the prepayment audit expectations of states with this broader definition.

Response: This final rule does not change states' obligations to complete due diligence to verify all eligibility criteria, including patient volume. Existing subregulatory guidance is available to states to assist in developing audit processes. We encourage states to take advantage of those materials, guidance, and technical assistance resources that we have made available to support their auditing activities.

Comment: Commenters, while supportive of these changes, inquired whether these changes would be retroactive and affect payments already disbursed. They asked, for example,

whether EPs who attested to Medicare for CY 2011 would be able to refund Medicare incentive payments and qualify for the Medicaid payment; or whether pediatricians who received the incentive for a patient volume of 20 percent would be able to receive a replacement payment associated with the 30 percent patient volume.

Response*:* These changes are not retroactive. Patient volume requirements for 2011 and 2012 are not affected by these changes. Eligibility for the program is determined at the time of attestation and prior to payment. States should implement this new definition of an encounter no later than 6 months after this rule is published and only for providers attesting for the 2013 program year and subsequent program years. In no event will this definition apply to attestations for the 2012 program year.

Comment: Commenters also inquired whether these new eligibility changes meant that an EP or eligible hospital denied an incentive payment because of failure to satisfy patient volume requirements could reapply in the same program year.

Response*:* As explained in our response to the previous comment, these changes would not be retroactive. Existing rules permit an EP or eligible hospital to reapply if they fail to meet the requirements for an incentive payment. If a provider fails to meet the requirements in 2013 before their state has implemented this change, they may then reapply after the change is made to their state's systems. Additionally, an EP or eligible hospital denied eligibility in a previous year is always permitted to reapply for a subsequent year (subject to rules for EPs switching programs as explained in §495.10).

For the reasons explained in the proposed rule, and because this change will help more Medicaid providers qualify for the program, we are finalizing this policy as proposed. The expanded definition of encounter will include individuals enrolled in Medicaid who had a

billable service on any one day during the 90-day patient volume timeframe.

In our proposed rule, we also clarified that we understand that multiple providers may submit an encounter for the same individual. For example, it may be common for a PA or NP to provide care to a patient, then a physician to also see, or invoice for services to that patient. We explained that it is acceptable in these and similar circumstances to count the same encounter for multiple providers for purposes of calculating each provider's patient volume when the encounters take place within the scope of practice. We did not receive any comments on this clarification and retain it for the final rule.

b. Practices Predominantly

Similar to our proposed revisions for patient volume, we proposed to revise the definition of "practices predominantly" at §495.302 in order to provide more flexibility for eligible professionals and states. A state could choose to allow EPs to use either: (1) the most recent calendar year; or (2) the most recent 12 months prior to attestation. Also, as with the previously noted patient volume changes, these "practices predominantly" changes are not retroactive. Patient volume requirements for 2011 and 2012 are not affected by these changes. States should implement this new definition of an encounter no later than 6 months after this rule is published and only for providers attesting to meeting program requirements for the 2013 program year and subsequent program years. In no event will this definition apply to attestations for the 2012 program year.

Comment: Some commenters -- commenting on the patient volume changes in §495.306, the "practice predominantly" changes in §495.302, and the revised definition of encounter -- expressed concerns about the system challenges associated with such changes. They requested that CMS consider the burden on state systems to implement these changes.

Response*:* We recognize that system changes must be considered when enacting or revising policies. However, we note that much of what we have proposed would be optional for states, while some would be required. We believe our final rule strikes a balance between optional and required policies for states, and providing 6 months to make systems changes balances implementation timelines with the overall goal to promote EHR adoption through the Medicaid EHR Incentive Program. We note that states receive 90 percent Federal matching funds for administrative costs associated with the EHR Incentive Program.

Comment*:* Although we did not make any proposals on the subject, some commenters requested a more prescriptive definition of pediatrician be provided to the states that includes pediatric ophthalmologists.

Response*:* We did not make any proposals on the definition of pediatrician. This final rule does not change the previous flexibility that states had to define pediatrician. In some states, pediatric ophthalmologists are eligible for the program, but that is entirely dependent on how the state has chosen to define pediatrician. This suggestion is also outside the scope of this rulemaking.

After consideration of the public comments received, we are finalizing the revised definition of "practices predominantly" at §495.302 as proposed; this revised definition is applicable to providers attesting to meeting program requirements for the 2013 program year and subsequent program years.

5. Medicaid Hospital Incentive Payment Calculation

a. Discharge Related Amount

In order to ensure that Medicaid regulations are consistent with Medicare, we proposed that the Medicaid calculation should be consistent with the Medicare calculation found

in §495.104(c)(2). Our current regulations at §495.310(g)(1)(i)(B) require the use of the "12-month period selected by the state, but ending in the Federal fiscal year before the hospital's fiscal year that serves as the first payment year." We also published a tip sheet with additional guidance on the Medicaid hospital incentive payment calculation, which can be found at: (https://www.cms.gov/MLNProducts/downloads/Medicaid_Hosp_Incentive_Payments_Tip_Sheets.pdf). However, some hospitals may not have a full 12 months of data ending with the Federal fiscal year immediately preceding the first payment year, or they may have a slightly older 12-month period that could be used. Therefore, we have revised our regulations at §495.310(g)(1)(i)(B) to allow states to use, for the purpose of calculating the discharge related amount, and other determinations (such as inpatient bed days), the most recent continuous 12-month period for which data are available prior to the payment year. If such 12-month period is a cost report, it should be one, single 12-month cost reporting period (and not a consolidation of two separate cost reporting periods). If it is an alternative source different from the cost report, we will rely on the state to ensure that the source is an appropriate source, and that the period is a continuous 12 months, and that the state is using the most recent data that are available. States should implement these changes only for hospitals that begin participation in the program starting in federal fiscal year 2013 or subsequent federal fiscal years. Hospitals that began participation before federal fiscal year 2013 must use discharge data from the hospital fiscal year that ends during the federal fiscal year prior to the hospital fiscal year that serves as the first payment year.

Comment: Commenters were concerned that hospitals may not have a full 12 months of data available ending with the Federal fiscal year immediately preceding the first payment year, thus restricting hospitals participation in the program.

Response: We appreciate the commenters concern; however, the change in regulatory language does not require hospitals to use data immediately preceding the first payment year, but rather the most recent 12 consecutive months of data available to the hospital prior to the payment year. The intent of this regulatory change was to encourage timely participation in the program. For the base year, the former policy required hospitals to initiate participation using a 12-month period ending in the Federal fiscal year before the hospital's fiscal year that serves as the first payment year. In recognition of this challenge, we are changing the regulation at §495.310(g)(1)(i)(B) to allow hospitals to use, for purposes of determining the base year for the Medicaid incentive payment calculation, the most recent continuous 12-month period for which data are available prior to the payment year. Only those hospitals that begin participation in program year 2013 and beyond will be affected by this change. Hospitals that began participation in the program before 2013 will not have to adjust previous calculations.

Comment: A commenter suggested that "the most recent data that are available" is ambiguous. Hospital cost report data are subject to significant audit and adjustments subsequent to their submission to the state, so the definition of "available" has a large impact on the reliability of the data used to calculate the incentive payment amount. The commenter noted that the state and CMS have a strong interest in ensuring that the data used to calculate the hospital incentive payment is accurate, defensible, and final, and the use of data that are not properly audited would create a significant potential for issuing incentive payments that would later need to be adjusted. The commenter suggested that CMS clarify "the most recent data that are available" means the most recent data that, in the judgment of the state, are properly audited and finalized.

Response: We appreciate the commenters concern; however, we do not agree that the

data needs to be audited and finalized in order to be used for the incentive payment calculation. It is our expectation that the hospital incentive payment is calculated using the most accurate data available at the time of calculation and it is the responsibility of the state to make the determination of which source is most accurate. We do not restrict data sources, as we believe the states are best positioned to balance the accuracy and timeliness of the data available. Medicare pays hospitals using preliminary, filed, cost report data and reconciles payment when the data is audited and finalized. Similarly, we allow states to adjust calculations and reconcile payments when audited and finalized data are available. State policy changes or proposals regarding reconciliation of hospital incentive payments must be reflected in the state' Medicaid Health Information Technology Plan (SMHP) and must be reviewed and approved by CMS.

b. Acute Care Inpatient Bed Days and Discharges for the Medicaid Share and Discharge-Related Amount

In order to ensure that the regulations accurately reflect our current policy, we proposed to amend the hospital payment regulations at §495.310(g)(1)(i)(B) and (g)(2) to recognize that only acute-care discharges and bed-days are included in our calculations. We currently require that only discharges from the acute care part of the hospital may be counted in both the discharge-related amount and the Medicaid share. For example, in response to a frequently asked question (https://questions.cms.gov, FAQ #2991), we explained that nursery days and nursery discharges (for newborns) could not be counted in both the Medicare and Medicaid EHR incentive programs. We stated: "[N]ursery days and discharges are not included in inpatient bed-day or discharge counts in calculating hospital incentives. . . because they are not considered acute inpatient services based on the level of care provided during a normal nursery stay."

Such regulatory amendments do not represent a change in policy but rather a clarification

of existing policy. The Medicaid share will count only those days that will count as inpatient-bed days for Medicare purposes under section 1886(n)(2)(D) of the Act. (See 75 FR 44498). In addition, in determining the overall EHR amount, section 1903(t)(5)(B) of the Act requires the use of applicable amounts specified in section 1886(n)(2)(A) of the Act.

Comment: A commenter expressed concern with the perceived removal of newborn nursery days from the hospital calculation. The commenter stated that this would create a disadvantage for some hospitals.

Response: We wish to be clear our policy on nursery days is not a new policy or a proposed change. The change in regulatory language on the use of acute inpatient bed days is to ensure that our regulation text clearly reflects our existing policy. The requirement to exclude non-acute inpatient bed days from the incentive payment calculation is consistent with both the Medicare and Medicaid regulations under Stage 1, as stated in our frequently asked questions (available at https://questions.cms.gov, FAQ# 2991). In that FAQ, we explain that the Medicaid payment to hospitals is based largely on the method that applies to Medicare incentive payments. Because such nursery discharges and bed days would not be included in the Medicare calculation, and because the Medicaid statute incorporates Medicare concepts, they also would not be counted in the Medicaid formula. We are simply adding additional language to clarify that all bed days and discharges used in the calculation are strictly limited to the acute-inpatient portion of the hospital. All hospitals will continue to exclude nonacute bed days and discharges from the hospital incentive calculation.

Comment: A commenter suggested that CMS clarify and inform states and providers that neonatal intensive care days are considered acute, and should be included in the Medicaid hospital incentive payment calculation.

Response: We appreciate the commenter's suggestion and recognize that neonatal intensive care days are considered acute inpatient services that should be included in the hospital incentive calculation.

c. Hospitals Switching States

There may be a situation where a hospital changes participation in one state Medicaid EHR incentive program to participation in another state. We are clarifying that in no case will a hospital receive more than the aggregate incentive amount calculated by the state from which the hospital initiated participation in the program. Section 495.310(e) requires a hospital to choose only one state per payment year from which to receive an incentive payment. Additionally, §495.310(f)(2) states that in no case can total incentives received by a hospital exceed the aggregate EHR incentive amount, as calculated in §495.310(g).

In this scenario, both states will be required to work together to determine the remaining payments due to the hospital based on the aggregate incentive amount and incentive amounts already paid. The hospital will then assume the second state's payment cycle, less the money paid from the first state. States should consult with CMS before addressing this specific scenario.

We did not receive any comments and we are finalizing these provisions as proposed for the reasons provided in the proposed rule.

6. Hospital Demonstrations of Meaningful Use - Auditing and Appeals

We proposed revisions to §495.312 under which states would have the option for CMS to conduct audits and handle any subsequent appeals of whether eligible hospitals are meaningful EHR users, on the state's behalf. (We note that the preamble text (at 77 FR 13788) did not reflect the proposed regulations.) We also proposed revisions to the SMHP requirements in

§495.332 by adding a new paragraph (g) that would allow the state, at the state's option, to include a signed agreement if the state has opted for CMS to conduct such audits and appeals. Under these proposals, the state electing the option would be required to (1) designate CMS to conduct all audits and appeals of eligible hospitals' meaningful use attestations; (2) be bound by the audit and appeal findings; (3) perform any necessary recoupments arising from the audits; and (4) be liable for any FFP granted the state to pay eligible hospitals that, upon audit (and any subsequent appeal) are determined not to have been meaningful EHR users. Finally, we proposed to revise our regulations at §495.370 to make clear that results of any adverse CMS audits (for states that have made the election) would be subject to the CMS administrative appeals process and not the state appeals process.

Most hospitals are eligible for both Medicare and Medicaid incentive payments, submit attestations on meaningful use to us under the Medicare attestation system, and, if successful, under the authority of section 1903(t)(8) of the Act, are deemed to have met the meaningful use requirements for Medicaid. Thus, we believe the revisions that were included in our proposed regulation text would provide states with the option to alleviate their burden to develop an audit process for hospitals and then perform audits on hospitals' meaningful use attestations. Because the regulation text made the CMS audits and appeals a state option, no state would be required to delegate the responsibility to CMS.

As discussed in the proposed rule preamble, many states indicated an interest in having CMS audit all hospitals' meaningful use attestations, and a majority of states have two or fewer Medicaid-only hospitals applying for incentive payments. Therefore, a state option for CMS to conduct audits and appeals will leverage the resources already devoted to auditing the vast majority of hospitals that are eligible for both incentive programs while retaining state flexibility

to perform their own meaningful use audits and appeals for the Medicaid-only hospitals in states that choose to do so. (In cases where a state has made the election, meaningful use attestation data collected by states for the Medicaid-only eligible hospitals would be shared with our auditors to enable this process).

As discussed in the proposed rule, we note that this policy does not extend to Medicaid eligible professionals, given the anticipated large number of Medicaid eligible professionals demonstrating meaningful use solely under the Medicaid program. In addition, states that opt for CMS to conduct audits and appeals will remain responsible for auditing all other aspects of eligibility for both EPs and eligible hospitals for incentive payments, including, but not limited to-- (1) adopt, implement or upgrade; (2) patient volume; (3) average stay length; and (4) calculation of payment amounts. States will also remain responsible for auditing EPs for compliance with meaningful use of certified EHR technology.

We did not receive any comments on either the preamble or the regulation text, and we are finalizing the proposed regulations for the reasons discussed previously.

7. State Flexibility for Stage 2 of Meaningful Use

We proposed to offer states flexibility with the public health measures in Stage 2, similar to that of Stage 1, subject to the same conditions and standards as the Stage 1 flexibility policy. This applies to the public health measures as well as the measure to generate lists of specific conditions to use for quality improvement, reduction of disparities, research or outreach. In addition, we proposed that whether moved to the core or left in the menu, states could also 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 ONC EHR certification criteria as finalized for Stage 2 of meaningful use.

We did not receive any comments on this policy. Although §495.316(d)(2) already contains provisions for state flexibility, there are new public health measure for Stage 2 of meaningful use and some of the descriptions are changing slightly for Stage 2. Therefore, in this final rule, we have amended § 495.316(d)(2) to ensure that the objectives for which states will have flexibility are adequately represented for both Stage 1 and Stage 2.

8. State Medicaid Health Information Technology Plan (SMHP) and Implementation Advance Planning Document (IAPD)

a. Frequency of Health Information Technology (HIT) Implementation Advanced Planning Document (IAPD) Updates

We proposed to revise §495.342 regarding the frequency of HIT IAPD updates. Rather than requiring each state to submit an annual HIT IAPD within 60 days from the HIT IAPD approved anniversary date, we proposed to require that a state's annual IAPD (also known as an IAPD Update (IAPD-U)) be submitted a minimum of 12 months from the date of the last CMS approved HIT IAPD. For example, if the initial HIT IAPD or previous IAPD-U was approved by CMS effective July 25, 2011, the state must submit their next HIT IAPD-U on or before July 25, 2012. Therefore, annual IAPD updates are required only if the state has not submitted an IAPD-U in the past 12 months, rather than on a fixed annual basis as currently reflected in §495.342. We did not propose to change the requirements of the circumstances of "as needed" IAPD updates as defined by §495.340.

Comment: Comments received on the change to the annual HIT IAPD submission deadline requirements were supportive of the change and the idea of reducing the administrative burden on states. A commenter requested that the phrase, "minimum of 12 months" be changed to "maximum of 12 months."

Response: We believe that a better solution would be to remove the word "minimum" from the text so it reads, "Each state is required to submit the HIT IAPD Updates 12 months from the date of the last CMS approved HIT IAPD and must contain the following." This more accurately describes the intent to clarify the timeline in which the state must submit the annual HIT IAPD. Therefore, §495.342 is revised accordingly.

b. Requirements of States Transitioning from HIT Planning Advanced Planning Documents (P-APDs) to HIT IAPDs

We proposed the following process for states that have an approved HIT P-APD and are ready to submit a HIT IAPD for review and approval. We do not allow states to have more than one HIT Advance Planning Document (APD) open at a time. If planning activities from the HIT P-APD have been completed, in their HIT IAPD the state should explain in a narrative format that all planning activities have been completed and the planning advanced planning document can be closed out. If there are HIT planning activities that the state determines will continue during the implementation period, these planning activities must be included as line items within the HIT IAPD budget.

We did not receive any comments on this discussion of the process states should use. We will use the previously-described process for states transitioning from a HIT P-APD to a HIT IAPD.

III. Waiver of Delayed Effective Date

We ordinarily provide a 60-day delay in the effective date of the provisions of a major rule in accordance with the Administrative Procedure Act (APA) (5 U.S.C. 553(d), which requires a 30-day delayed effective date, and the Congressional Review Act (5 U.S.C. 801(a)(3), which requires a 60-day delayed effective date for major rules. However, we can waive the delay in effective date if the Secretary finds, for good cause, that such delay is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons in the rule issued under 5 U.S.C. 553(d)(3) and 5 U.S.C. 808(2).

The Secretary finds that good cause exists to make certain regulatory provisions effective upon publication in the **Federal Register**.

Our revisions to §495.6(f) and (g) change certain criteria for meaningful use beginning with FY 2013. Some eligible hospitals and CAHs will begin their EHR reporting period using the criteria under §495.6(f) and (g) beginning October 1, 2012. All of these changes are optional and are meant to provide greater flexibility in meeting these criteria. Because these revisions relieve a restriction on eligible hospitals and CAHs, a waiver of the delayed effective date is in order. It is both unnecessary to delay the effective date, and in the public's best interest to waive the delay in effective date for these changes. Furthermore, ensuring that these provisions are effective beginning with FY 2013 would mitigate any disadvantage experienced by eligible hospitals and CAHs beginning their EHR reporting periods at the beginning of the fiscal year, because it would allow them to use these revised criteria at the beginning of such period. Our revisions to §495.6(f) include eliminating the reporting of clinical quality measures as a separate objective of meaningful use and instead including this reporting requirement as part of the definition of "meaningful EHR user" under §495.4. Accordingly, the delayed effective date must

also be waived with regard to the definition of "meaningful EHR user" under §495.4 and the revisions to §495.8. To allow these provisions to take effect with the beginning of FY 2013, it is impracticable to delay the effective date, which would occur after the beginning of the fiscal year.

We have also made a technical correction to §495.102(c) so that it correctly reflects the policy we adopted in the Stage 1 final rule for EPs who predominantly furnish services in a geographic HPSA. This change is technical in nature and merely codifies our existing policy. Retaining current regulatory language would allow an error to persist. Therefore, it is unnecessary, impracticable, and contrary to the public interest to delay the effective date of this codification.

We are also waiving the delay in effective date for all of the changes we are making to subpart D of part 495. Some of these changes either codify or more clearly specify already existing policy (deletions of §495.310(a)(1)(ii), §495.310(a)(2)(ii), and §495.332(d)(9) to reflect the existing policy on net average allowable cost under the Medicare and Medicaid Extenders Act of 2010; changes to §495.310(g) to clarify that the rules are for "acute-care inpatient discharges" and "acute care inpatient bed-days"; changes to §495.310 to clarify policy on hospitals switching states). Therefore, it is unnecessary, impracticable, and contrary to the public interest to delay the effective date of these provisions as they are already in effect as CMS policies.

Others of these changes merely provide states or eligible providers with additional flexibility to adopt policies that will be of benefit to the states or providers, thus relieving a restriction (§495.302 change in definition for children’s hospital and practices predominantly; §495.304 regarding allowing EPs and eligible hospitals to include individuals enrolled in a

Medicaid program in 2013; changes to §495.306 regarding additional flexibility for determining patient volume in 2013; changes to §495.312 and §495.332(c) and (g) and §495.370 regarding additional options for states in conducting audits and appeals of eligible hospitals' meaningful use; and changes to §495.342 adding flexibility on submission of the HIT IAPD). These changes will be in the public interest of states or eligible providers or both, because they provide additional flexibility allowing states to relieve their burdens, or allowing additional providers to qualify for Medicaid incentives under the program. It is important that these changes be in place as soon as possible, and especially as of October 1, 2012 for eligible hospitals beginning their fiscal years. Therefore, a waiver in the delay in the effective date is both impracticable and contrary to the public interest, and the Secretary finds good cause not to delay the effective date of these provisions.

The final change to subpart D (in §495.304(f) and §495.332(b)(6)) applies to EPs, who will not begin payment year 2013 until the beginning of the calendar year in any case. However, in the interest of ensuring that states have a reasonable opportunity to amend their SMHPs and to ensure consistency in effective date for the entire subpart it is in the public interest to waive the delay in effective date for these changes as well. Again, the effect on EPs would not take place until January of 2013 in any case – well after a 60-day delay has occurred.

For all these reasons, we believe that a 60-day delay in the effective date of the previously discussed provisions would be unnecessary, impracticable, and contrary to the public interest. Therefore, we find good cause for waiving the 60-day delay in the effective date for these provisions and making the provisions effective upon publication.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-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 fairly evaluate 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 we believe are subject to the PRA and collection of information requirements (ICRs) as a result of this final rule. This analysis finalizes our projections which were proposed in the March 7, 2012 **Federal Register** (77 FR 13790 through 13800) in which we proposed a revision to the existing PRA package approved under OMB control number 0938-1158. The projected numbers of EPs, eligible hospitals, CAHs, MA organizations, MA EPs, and MA-affiliated hospitals are based on the numbers used in the impact analysis assumptions as well as estimated federal costs and savings in section V. of this final rule. The actual burden will remain constant for all of Stage 2 as EPs, eligible hospitals, and CAHs will only need to attest that they have successfully demonstrated meaningful use one time per year. The only variable from year to year in Stage 2 will be the number of respondents, as

noted in the impact analysis assumptions. For the purposes of this analysis, we are focusing only on 2014, the first year in which a provider may participate in Stage 2 of the Medicare EHR Incentive Program. We do not believe the burden for EPs, eligible hospitals, and CAHs participating in Stage 1 prior to 2014 will be different from the agency information collection activities (75 FR 65354) based on this final rule. Beginning in 2012, Medicare EPs, eligible hospitals, and CAHs have the option to electronically report their clinical quality measures through the respective electronic reporting pilots. The burden for the EP pilot is discussed in the CY 2012 Medicare PFS final rule with comment period (76 FR 73450 through 73451). For eligible hospitals and CAHs, the burden is discussed in the CY 2012 OPPS final rule with comment period (76 FR 74489 through 74492).

A. ICR Regarding Demonstration of Meaningful Use Criteria (§495.6 and §495.8)

In §495.6 of the proposed rule, we proposed that to successfully demonstrate meaningful use of CEHRT for Stage 2, 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 §495.6. In §495.8, we proposed that a provider must also successfully report the clinical quality measures selected by CMS to CMS or the states, as applicable. We assumed that the CEHRT adopted by the provider would capture many of the objectives and associated measures and generate automated numerator and denominator information where required, or generate automated summary reports. We also expect that the provider would enable the functionality required to complete the objectives and associated measures that require the provider to attest that they have done so.

We proposed that EPs would be required to report on a total of 17 core objectives and associated measures, 3 of 5 menu set objectives and associated measures, and 12 ambulatory clinical quality measures. We estimated the total average annual cost burden for all 198,912 nonhospital-based EPs who may attest in 2014 to be $186,098,885 (198,912 EPs x 10 hours 24 minutes x $89.96 (mean hourly rate for physicians based on May 2010 Bureau of Labor Statistics (BLS data)). We proposed that eligible hospitals and CAHs would be required to report on a total of 16 core objectives and associated measures, 2 of the 4 menu set objectives and associated measures, and 24 clinical quality measures. We estimated the total 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 would be $2,375,564 (4,993 eligible hospitals and CAHs × $62.23 (12 hours 14 minutes × $62.23 (mean hourly rate for lawyers based on May 2010 BLS) data)).

Comment: A commenter suggested CMS account for website responsiveness when estimating the burden for providers as they enter attestation data. The commenter noted that the website would take several minutes after entering data until the next page would become available.

Response: We cannot forecast technical difficulties with our websites, but strive to maintain a high level of responsiveness.

Comment: Some commenters suggested CMS underestimated the amount of time it takes providers to attest that they have successfully demonstrated meaningful use. They noted that providers see attestation as more than just reporting their data at the end of the reporting period, rather, a process that is continuously monitored throughout that time. Others noted that the operational burden that providers encounter on a per-patient basis will increase significantly in

Stage 2.

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 individual providers' workflows or training needs to participate in these programs.

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.

In this final there, there are 13 core objectives and up to 3 menu set objectives that will require an EP to enter numerators and denominators during attestation. Eligible hospitals and CAHs will have to attest they have met 10 core objectives and 3 menu set 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 CEHRT. 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 their 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 3 core objectives and up to 3 menu set objectives that will require a "yes" or "no" response

during attestation. For eligible hospitals and CAHs, there are 5 core objectives and that will require a "yes" or "no" response during attestation and no such menu set objectives. We expect that it will take a provider or their designee 1 minute to attest to each objective that requires a "yes" or "no" response.

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

Table 20 lists those objectives and associated measures for EPs, eligible hospitals and CAHs. We estimate the core set of objectives and associated measures will take an EP 8 hours and 13 minutes to complete, and will take an eligible hospital or CAH 7 hours and 45 minutes to complete. For EPs, we estimate the completion of 3 menu set objectives and associated measures will take between 3 minutes and 30 minutes to complete, depending on the combination of objectives they choose to attest to. We estimate the selection, preparation, and electronic submission of the 9 ambulatory clinical quality measures will take EPs 1 hour and 30 minutes. We estimate it will take eligible hospitals and CAHs 30 minutes to attest to the 3 menu set objectives they choose. For eligible hospitals and CAHs, we estimate the selection, preparation, and electronic submission of 16 required clinical quality measures will take 2 hours and 40 minutes.

TABLE 20: BURDEN ESTIMATES

Eligible Professionals	Eligible Hospitals and CAHs	Stage 2 Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
CORE SET				
Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines.	Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines.	More than 60% of medication, 30% of laboratory, and 30% of radiology orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE.	10 minutes	10 minutes
Generate and transmit permissible prescriptions electronically (eRx).		More than 50% of all permissible prescriptions, or all prescriptions written by the EP and queried for a drug formulary and transmitted electronically using CEHRT.	10 minutes	
Record the following demographics · Preferred language · Sex · Race · Ethnicity · Date of birth	Record the following demographics · Preferred language · Sex · Race · Ethnicity · Date of birth · Date and preliminary cause of death in the event of mortality in the eligible hospital or CAH	More than 80% of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have demographics recorded as structured data.	10 minutes	10 minutes
Record and chart changes in vital signs: · Height/length · Weight · Blood pressure (age 3 and over) · Calculate and display BMI · Plot and display growth charts for patients 0-20 years, including BMI	Record and chart changes in vital signs: · Height/length · Weight · Blood pressure (age 3 and over) · Calculate and display BMI · Plot and display growth charts for patients 0-20 years, including BMI	More than 80% of all unique patients 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 blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data.	10 minutes	10 minutes

Eligible Professionals	Eligible Hospitals and CAHs	Stage 2 Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
Record smoking status for patients 13 years old or older.	Record smoking status for patients 13 years old or older.	More than 80% of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) have smoking status recorded as structured data.	10 minutes	10 minutes
Use clinical decision support to improve performance on high-priority health conditions.	Use clinical decision support to improve performance on high-priority health conditions.	1. Implement five clinical decision support interventions related to four or more clinical quality measures at a relevant point in care for the entire EHR reporting period. Absent four clinical quality measures related to an EP, eligible hospital or CAH's scope of practice or patient population, the clinical decision support interventions must be related to improving healthcare efficiency. 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.	1 minute	1 minute
Incorporate clinical lab-test results as structured data.	Incorporate clinical lab-test results as structured data	More than 55% of all clinical lab tests results ordered by the EP or by authorized providers of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period whose results are either in a positive/negative affirmation or numerical format are incorporated in CEHRT as structured data.	10 minutes	10 minutes

Eligible Professionals	Eligible Hospitals and CAHs	Stage 2 Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach	Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach.	Generate at least one report listing patients of the EP, eligible hospital or CAH with a specific condition.	1 minute	1 minute
Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care and send these patients the reminder, per patient preference.		More than 10% of all unique patients who have had two or more office visits with the EP within the 24 months before the beginning of the EHR reporting period were sent a reminder, per patient preference when available.	10 minutes	
	Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR).	More than 10% 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 for which all doses are tracked using eMAR.		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% of all unique patients seen by the EP during the EHR reporting period are provided timely (within 4 business days after the information is available to the EP) online access to their health information subject to the EP's discretion to withhold certain information. 2. More than 5% of all unique patients seen by the EP during the EHR reporting period (or their authorized representatives) view, download, or transmit to a third party their health information.	10 minutes	

Eligible Professionals	Eligible Hospitals and CAHs	Stage 2 Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
	Provide patients the ability to view online, download, and transmit information about a hospital admission.	1. More than 50% of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH have their information available online within 36 hours of discharge 2. More than 5% of all patients (or their authorized representatives) who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH view, download or transmit to a third party their information during the reporting period.		10 minutes
Provide clinical summaries for patients for each office visit.		Clinical summaries provided to patients or patient-authorized representatives within 1 business day for more than 50% of office visits.	10 minutes	
Use CEHRT to identify patient-specific education resources and provide those resources to the patient.	Use CEHRT to identify patient-specific education resources and provide those resources to the patient.	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. 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	10 minutes
Use secure electronic messaging to communicate with patients on relevant health information.		A secure message was sent using the electronic messaging function of CEHRT by more than 5% of unique patients (or their authorized representatives) seen by the EP during the EHR reporting period	10 minutes	

Eligible Professionals	Eligible Hospitals and CAHs	Stage 2 Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
The EP who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.	The eligible hospital or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.	The EP, eligible hospital or CAH performs medication reconciliation for more than 50% of transitions of care in which the patient is transitioned into the care of the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23).	10 minutes	10 minutes

Eligible Professionals	Eligible Hospitals and CAHs	Stage 2 Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
The EP who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care provides a summary care record for each transition of care or referral.	The eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care provides a summary care record for each transition of care or referral.	1. The EP, eligible hospital, or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50% of transitions of care and referrals. 2. The EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 10% of such transitions and referrals either (a) electronically transmitted using CEHRT to a recipient or (b) where the recipient receives the summary of care record via exchange facilitated by an organization that is a NwHIN Exchange participant or in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network. 3. An EP, eligible hospital or CAH must satisfy one of the two following criteria: (A) conducts one or more successful electronic exchanges of a summary of care document, as part of which is counted in "measure 2" (for EPs the measure at §495.6(j)(14)(ii)(B) and for eligible hospitals and CAHs the measure at §495.6(l)(11)(ii)(B)) with a recipient who has EHR technology that was developed designed by a different EHR technology developer than the sender's EHR technology certified to 45 CFR 170.314(b)(2).	10 minutes	10 minutes

Eligible Professionals	Eligible Hospitals and CAHs	Stage 2 Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.	Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.	Successful ongoing submission of electronic immunization data from CEHRT to an immunization registry or immunization information system for the entire EHR reporting period.	1 minute	1 minute
	Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice.	Successful ongoing submission of electronic reportable laboratory results from CEHRT to public health agencies for the entire EHR reporting period.		1 minute
	Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice.	Successful ongoing submission of electronic syndromic surveillance data from CEHRT to a public health agency for the entire EHR reporting period.		1 minute
Protect electronic health information created or maintained by the CEHRT through the implementation of appropriate technical capabilities.	Protect electronic health information 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 encryption/security 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
Core Set Burden			8 hours 13 minutes	7 hours 45 minutes
MENU SET				

Eligible Professionals	Eligible Hospitals and CAHs	Stage 2 Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
	Record whether a patient 65 years old or older has an advance directive.	More than 50% of all unique patients 65 years old or older admitted to the eligible hospital's or CAH's inpatient department (POS 21) during the EHR reporting period have an indication of an advance directive status recorded as structured data.		10 minutes
Imaging results consisting of the image itself and any explanation or other accompanying information are accessible through CEHRT.	Imaging results consisting of the image itself and any explanation or other accompanying information are accessible through CEHRT.	More than 10% of all tests whose result is one or moreimages ordered by the EP or by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 and 23) during the EHR reporting period are accessible through CEHRT.	10 minutes	10 minutes
Record patient family health history as structured data.	Record patient family health history as structured data.	More than 20% of all unique patients seen by the EP or admitted to the eligible hospital or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have a structured data entry for one or more first-degree relatives.	10 minutes	10 minutes
	Generate and transmit permissible discharge prescriptions electronically (eRx).	More than 10% of hospital discharge medication orders for permissible prescriptions (for new, changed, and refilled prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.		10 minutes

Eligible Professionals	Eligible Hospitals and CAHs	Stage 2 Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
Record electronic notes in patient records.	Record electronic notes in patient records.	Enter at least one electronic progress note created, edited, and signed by an eligible professional for more than 30 percent of unique patients with at least one office visit during the EHR reporting period. Enter at least one electronic progress note created, edited and signed by an authorized provider of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) for more than 30 percent of unique patients admitted to the eligible hospital or CAH's inpatient or emergency department during the EHR reporting period. Electronic progress notes must be text-searchable. Nonsearchable, notes do not qualify, but this does not mean that all of the content has to be character text. Drawings and other content can be included with searchable notes under this measure.	10 minutes	10 minutes
	Provide structured electronic lab results to ambulatory providers.	Hospital labs send structured electronic clinical lab results to the ordering provider for more than 20% of electronic lab orders received.		10 minutes
Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice		Successful ongoing submission of electronic syndromic surveillance data from CEHRT to a public health agency for the entire EHR reporting period.	1 minute	

Eligible Professionals	Eligible Hospitals and CAHs	Stage 2 Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
Capability to identify and report cancer cases to a public health central cancer registry, except where prohibited, and in accordance with applicable law and practice.		Successful ongoing submission of cancer case information from CEHRT to a public health central cancer registry for the entire EHR reporting period.	1 minute	
Capability to identify and report specific cases to a specialized registry (other than a cancer registry), except where prohibited, and in accordance with applicable law and practice.		Successful ongoing submission of specific case information from CEHRT to a specialized registry for the entire EHR reporting period.	1 minute	
Menu Set Least Burdensome Criteria			3 minutes	
Menu Set Most Burdensome Criteria			30 minutes	30 minutes
Time to Attest and Report Clinical Quality Measures			1 hour 30 minutes	2 hours 40 minutes
Total - Core Set (including CQMs) + Least Burdensome Menu Set Criteria			9 hours 46 minutes	
Total - Core Set (including CQMs) + Most Burdensome Menu Set Criteria			10 hours 13 minutes	10 hours 55 minutes

First, we will discuss the burden associated with the EP attestation to meeting the core meaningful use objectives and associated measures. We estimate that it will take no longer than 8 hours and 13 minutes to attest that during the EHR reporting period, they used the CEHRT, specify the EHR technology used, and satisfy each of the applicable core objectives and associated measures. We estimate it will take an EP 30 minutes if they choose to submit the most burdensome objectives and associated measures from the menu set. If an EP chooses to attest to the least burdensome menu set objectives and associated measures, we estimate this will take approximately 3 minutes. We also estimate that it will take an EP an additional 1 hour and 30 minutes to select, prepare, and electronically submit the ambulatory clinical quality measures. The total burden hours for an EP to attest to the most burdensome criteria previously specified is 10 hours and 13 minutes. The total burden hours for an EP to attest to the least burdensome criteria previously specified is 9 hours and 46 minutes. We estimate that there could be approximately 537,600 nonhospital-based Medicare and Medicaid EPs in 2014. We anticipate approximately 37 percent (198,912) of these EPs may attest to the information previously specified (after registration and completion of Stage 1) in CY 2014 to receive an incentive payment. We estimate the burden for the approximately 13,000 MA EPs in the MAO burden section. We estimate the total burden associated with these requirements for an EP is 10 hours and 13 minutes (8 hours 13 minutes + 30 minutes + 1 hour 30 minutes). The total estimated annual cost burden for all EPs to attest to EHR technology, meaningful use core set and most burdensome menu set criteria, and electronically submit the ambulatory clinical quality measures is $182,877,942(198,912 EPs x 10 hours 13 minutes x $89.96 (mean hourly rate for physicians based on May 2010 Bureau of Labor Statistics (BLS) data)). We estimate the total burden associated with these requirements for an EP is 9 hours and 46 minutes (8 hours 13 minutes +

3 minutes + 1 hour 30 minutes). The total estimated cost burden for all EPs to attest to EHR technology, meaningful use core set and least burdensome menu set criteria, and electronically submit the ambulatory clinical quality measures is $174,825,587 (198,912 EPs x 9 hours 46 minutes x $89.96 (mean hourly rate for physicians based on May 2010 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 7 hours and 45 minutes to attest that during the EHR reporting period, they used the CEHRT, specify the EHR technology used, and satisfied each of the applicable core objectives and associated measures. We estimate it will take an eligible hospital or CAH 30 minutes to choose and submit the objectives and associated measures from the menu set. We also estimate that it will take an eligible hospital or CAH an additional 2 hours and 40 minutes to select, prepare, and electronically submit the clinical quality measures. Therefore, the total burden hours for an eligible hospital or CAH to attest to the aforementioned criteria is 10 hours, 55 minutes. We estimate that there are about 4,993 eligible hospitals and CAHs (3,573 acute care hospitals, 1,325 CAHs, 84 children's hospitals, and 11 cancer hospitals) that may attest to the aforementioned criteria (after registration and completion of Stage 1) in FY 2014 to receive an incentive payment. We estimate the burden for the 30 MA-affiliated hospitals in section III.B. of this final rule. We estimate the total burden associated with these requirements for an eligible hospital or CAH is 10 hours and 55 minutes (7 hours 45 minutes + 30 minutes + 2 hours 40 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 is $2,069,061 (4,993 eligible hospitals and CAHs x $62.23 (11 hours 4 minutes x $62.23 (mean hourly rate for

lawyers based on May 2010 BLS) data)).

B. 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 in Stage 2, because-- (1) qualifying MA organizations do not have to report the ambulatory clinical quality measures for their qualifying MA EPs; and (2) 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 en 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 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 eligible professionals, but non-clinical staff. We believe that the individual gathering the information could be equivalent to a GS 9, step 1, 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, or approximately $59.00/hour. Therefore, for the approximately 13,000 potentially qualifying MA EPs, we believe it will cost the participating qualifying MA organizations approximately $435,500 annually to make the attestations ([9,750 hours x $25.00]+[3,250 hours x $59.00]).

Furthermore, MA-affiliated eligible hospitals will be able to complete the attestations

slightly faster than eligible hospitals because MA-affiliated eligible hospitals do not have to report the hospital clinical quality measures. While it is estimated that it will take an eligible hospital or CAH approximately between 16 hours, 24 minutes and 16 hours, 33 minutes to attest to the applicable meaningful use objectives and associated measures, 8 of those hours are attributed to reporting clinical quality measures, which MA organizations do not have to report. Therefore, we estimate that it will take between 8 hours, 24 minutes and 8 hours, 33 minutes (which on average is 8 hours 29 minutes) for an MA organization's MA-affiliated eligible hospitals to make the attestations. We believe that the individual gathering the information could be equivalent to a GS 9, step 1, 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, or approximately $59.00/hour. We believe that the person gathering the information could dedicate 7 of the estimated hours to gathering the information, and the individual certifying could take 1 hour and 29 minutes of the estimated time. Therefore, for the approximately 30 potentially qualifying MA-affiliated eligible hospitals, we believe it will cost the participating qualifying MA organizations in the aggregate approximately $7,870 annually to successfully attest ([210 hrs x $25.00]+[44 hrs x $59.00]).

We did not receive any comments and we are finalizing these estimates as proposed.

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

The burden associated with this section is the time and effort associated with completing the single provider election repository and each state's process for the administration of the Medicaid incentive payments, including tracking of attestations and oversight; the submission of the state Medicaid HIT Plan and the additional planning and implementation documents;

enrollment or reenrollment of providers, and collection and submission of the data for providers to demonstrate that they have adopted, implemented, or upgraded CEHRT or that they are meaningful users of such technology. We believe the burden associated with these requirements has already been accounted for in our discussion of the burden for §495.316 in the Stage 1 final rule. However, we proposed to revise 42 CFR 495 regarding the frequency of HIT IAPD updates. Rather than requiring each state to submit an annual HIT IAPD within 60 days from the HIT IAPD approved anniversary date, we proposed to require that a state's annual IAPD or IAPD Update (IAPD-U) be submitted at a minimum of 12 months from the date of the last CMS approval. We are finalizing our proposed revision to 42 CFR 495; therefore, annual IAPD updates are only required if a state has not submitted an IAPD-U in the past 12 months, which will create less of a burden on the states. We expect that it will take a state 70 hours to update an annual IAPD. We believe that the requirement for states to agree to have CMS conduct audits and appeals for hospitals for meaningful use will reduce state burden, as they will not conduct their own audits. Also, the alternatives for calculating patient volume will alleviate state burden as patient volume will be more easily calculated.

We did not receive any comments and we are finalizing these estimates as proposed.

TABLE 21: ESTIMATED ANNUAL REPORTING AND RECORDKEEPING REQUIREMENTS

Reg Section	OMB Control No.	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Cost ($)
§495.6 - EHR Technology Used, Core Set Objectives/Measures (EPs)	???-New	198,912	198,912	8.22	1,635,057	$89.96	$147,089,695.33
§495.6 - Menu Set Objectives/Measures (EPs) HIGH	???-New	198,912	198,912	0.50	99,456	$89.96	$8,947,061.76
§495.6 - Menu Set Objectives/Measures (EPs) LOW	???-New	198,912	198,912	0.05	9,946	$89.96	$894,706.18
§495.6 - Menu Set Objectives/Measures (EPs) AVERAGE	???-New	198,912	198,912	0.28	54,701	$89.96	$4,920,883.97
§495.8 - CQMs for EPs	???-New	198,912	198,912	1.50	298,368	$89.96	$26,841,185.28
§495.6 - EHR Technology Used, Core Set Objectives/Measures (hospitals/CAHs)	???-New	2,696	2,696	7.75	20,894	$62.23	$1,300,233.62
§495.6 - Menu Set Objectives/Measures (hospitals/CAHs)	???-New	2,696	2,696	0.50	1,348	$89.96	$121,266.08
§495.8 - CQMs for hospitals/CAHs	???-New	2,696	2,696	2.67	7,198	$89.96	$647,560.87
§495.210 - Gather information for attestation (MA EPs)	???-New	13,000	13,000	0.75	9,750	$25.00	$243,750.00
§495.210 - Attesting on behalf of MA EPs	???-New	13,000	13,000	0.25	3,250	$59.00	$191,750.00
§495.210 - Total cost of attestation for Stage 2 (MA EPs)	???-New	13,000	13,000	1.00	13,000	n/a	$435,500.00
§495.210 - Gather information for attestation (MA-affiliated hospitals)	???-New	30	30	7.00	210	$25.00	$5,250.00
§495.210 - Attesting on behalf of MA-affiliated hospitals	???-New	30	30	1.48	44	$59.00	$2,619.60
§495.210 - Total cost of attestation for Stage 2 (MA-affiliated hospitals)	???-New	30	30	8.48	254	n/a	$7,869.60

Reg Section	OMB Control No.	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Cost ($)
§495.342 - 1. Frequency of Health Information Technology (HIT) Implementation Advanced Planning Document (IAPD) Updates	???-New	56	56	70.00	3,920	$56.24	$220,460.80
Burden Total for 2014					**2,034,740.16**		**$181,584,656**

Note: All nonwhole numbers in this table are rounded to 2 decimal places.

If you would like to comment on these information collection and recordkeeping requirements, submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, [CMS-0044-F]

Fax: (202) 395-6974; or

Email: OIRA_submission@omb.eop.gov

V. Regulatory Impact Analysis

A. Statement of Need

This final rule will implement the provisions of the ARRA that provide incentive payments to EPs, eligible hospitals, and CAHs participating in Medicare and Medicaid programs that adopt and meaningfully use CEHRT. The final rule specifies applicable criteria for earning incentives and avoiding payment adjustments.

B. Overall Impact

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

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This final rule 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 that to the best of our ability presents the costs and benefits of the final rule.

As noted in section I. of this final rule, this final rule is one of two coordinated rules related to the adoption and meaningful use of CEHRT. The other is ONC's final rule, titled "Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology" published elsewhere in this **Federal Register**. This analysis focuses on the impact associated with Stage 1 meaningful use participation in 2014, Stage 2 requirements for meaningful use, the changes in quality measures that will take effect beginning in 2014, and other changes in the Medicare and Medicaid EHR Incentive Programs.

A number of factors will affect the adoption of EHR systems and demonstration of meaningful use. Many of these factors are addressed in this analysis and in the provisions of the final rule titled "Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology" published elsewhere in this **Federal Register**. Readers should understand that these forecasts are also subject to substantial uncertainty since demonstration of meaningful use will depend not only on the standards and requirements for FYs 2014 and 2015 for eligible hospitals and CYs 2014 and 2015 for EPs, but on future rulemakings issued by the HHS.

The Act 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 CEHRT. Payment adjustments are incorporated into the Medicare 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 disadvantaged 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 incentives 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.

One legislative uncertainty arises because under current law, physicians are scheduled for payment reductions under the sustainable growth rate (SGR) formula for determining Medicare payments. The current override of SGR payment reductions prevents any further reductions of Medicare physician payments throughout the rest of 2012. Any payment reductions implemented in CY 2013 and subsequent calendar years could cause major changes in physician behavior, enrollee care, and other Medicare provider payments, but the specific nature of these changes is exceptionally uncertain. Under a current law scenario, the EHR incentives or payment adjustments will exert only a minor influence on physician behavior relative to any large payment reductions. However, the Congress has legislatively avoided physician payment reductions for each year since 2002.

All of these factors taken together make it difficult to predict with precision the timing or rates of adoption and ultimately meaningful use. Further, new data regarding rates of adoption or costs of implementation is just starting to emerge. Because of this continued uncertainty, these estimates for adoption rates should be used with caution. Our estimate of meaningful use demonstration assumes that by 2019 nearly 100 percent of hospitals and nearly 70 percent of EPs will be meaningful users. This estimate is based on the substantial economic incentives created by the combined direct and indirect factors affecting providers.

Data from the EHR Incentive Program to date has shown that about 12 percent of EPs and 8 percent of hospitals received incentive payments in 2011, the first year. This may be because providers have taken a "wait and see approach" in the first year of implementation or that they have had problems receiving certified systems. Two thousand eleven was the first year of the program and saw initially slow, but rapidly accelerating, growth in qualification for and payment of meaningful use incentives. Given that this is very early data, and given the differences between Stage 1 and Stage 2 requirements, this data only indicates preliminary penetration rates.

Overall, we expect spending under the EHR incentive program for transfer payments to Medicare and Medicaid providers between 2014 and 2019 to be $15.4 billion (these estimates include payment adjustments for Medicare providers who do not achieve meaningful use in 2015 and subsequent years in the amount of $2.1 billion). 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 also that adopting entities will achieve dollar savings at least equal to their total costs, and that there will be additional benefits to society. We believe that implementation costs are significant for each participating entity because providers must purchase CEHRT to qualify as meaningful users of EHRs. However, we believe that providers who have already purchased CEHRT and participated in Stage 1 of meaningful use will experience significantly lower costs for participation in the program. We continue to believe that the short-term costs to demonstrate meaningful use of CEHRT are 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 to the best of our ability presents the costs and benefits of this final rule.

Previously, the Stage 2 proposed rule and the Stage 1 final rule impact analyses showed two plausible scenarios for program costs. In this RIA, we are showing a scenario based on the FY 2013 Mid-Session Review of the President's budget. The estimates are based on the limited actual historical data that is now available for the EHR Incentive Programs. The new projections differ somewhat from the two scenarios presented previously. The major reasons for the differences are different assumed penetration rates based on more recent data and analysis, and revised assumptions as to the timing of payments in relation to when meaningful use is achieved based on the actual experience of the programs to date. When compared with the two illustrations from the Stage 2 proposed rule and Stage 1 final rule, the penetration rates for the current estimates are generally closer to those in the high cost scenario. In general, the actual program experience, which is included in the new estimates, showed somewhat lower payments early in the first year, and somewhat higher payments towards the end of the first year than assumed in the two previously-used scenarios. The accounting statement numbers under the 7-percent discount for the two scenarios from the previous estimates were $706 million and $2,346 million. The current accounting statement number under the 7-percent discount is $2,558 million. The current projections, while based on more up-to-date information, are still very uncertain and actual future outcomes are likely to differ somewhat from these projections.

Comment: A commenter suggested that the impact analysis should only address Stage 2 of the EHR Incentive Programs.

Response: Although we considered the idea of only addressing Stage 2 in this impact analysis, we do not believe that such an analysis would provide a comprehensive impact of this final rule. This final rule establishes not only Stage 2 criteria but also changes to Stage 1 criteria and both payment adjustments and hardship exceptions that could affect providers at all stages of

meaningful use. In addition, providers in all payment years will be at differing stages of meaningful use, and any impact analysis that focused on a single stage would not accurately capture the costs and benefits that accrue from all providers who are participating in the EHR Incentive Programs during a given payment year. Therefore, we include all providers in this impact analysis.

C. Anticipated Effects

The objective of the remainder of this 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 industry for implementation of this technology.

1. Overall Effects

a. Regulatory Flexibility Analysis and Small Entities

The Regulatory Flexibility Act (RFA) requires agencies to prepare a Final 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 million and $34 million in annual revenues. For the purposes of the RFA, essentially all non-profit organizations are considered small entities, regardless of size. Individuals and states are not included in the definition of a small entity. Since the vast majority of Medicare providers (well over 90 percent) are small entities within the RFA's definitions, it is the normal practice of HHS simply to assume that all affected providers are "small" under the RFA. In this case, most EPs, eligible hospitals, and CAHs are either nonprofit or meet the SBA's size standard for small business. We also believe

that the effects of the incentives program on many and probably most of these affected entities will be economically significant. Accordingly, this RIA section, in conjunction with the remainder of the preamble, constitutes the required Regulatory Flexibility Analysis. 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 will make it attractive to virtually all eligible entities. Furthermore, entities that do not demonstrate meaningful use of EHR technology for an applicable reporting period will be subject to significant Medicare payment reductions beginning with 2015. The anticipation of 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 they currently have could be upgraded to meet the criteria for certified EHR technology 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 noncertified 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.

The most recent data available suggests that more providers have adopted EHR technology since the publication of the Stage 1 final rule. A 2011 survey conducted by the ONC and the AHA found that the percentage of U.S. hospitals which had adopted EHRs doubled from 16 to 35 percent between 2009 and 2011. In November 2011, a CDC survey found the percentage of physicians who adopted basic EHRs in their practice had doubled from 17 to

34 percent between 2008 and 2011, with the percent of primary care doctors using this technology nearly doubling from 20 to 39 percent. While these numbers are encouraging, they are still low relative to the overall population of providers. The majority of EPs still need to purchase certified EHR technology, implement this new technology, and train their staff on its use. The costs for implementation and complying with the criteria of meaningful use could lead to higher operational expenses. However, we believe that the combination of payment incentives and long-term overall gains in efficiency will compensate for the initial expenditures.

(1) Number of Small Entities

In total, we estimate that there are approximately 624,000 healthcare organizations (EPs, practices, eligible hospitals or CAHs) that will be affected by the incentive program. These include hospitals and physician practices as well as doctors of medicine or osteopathy, dental surgery or dental medicine, podiatric medicine, optometry or a chiropractor. Additionally, as many as 47,000 nonphysician practitioners (such as certified nurse-midwives, etc) will be eligible to receive the Medicaid incentive payments.

Of the 624,000 healthcare organizations we estimate will be affected by the incentive program, we estimate that 94.71 percent will be EPs, 0.8 percent will be hospitals, and 4.47 percent will be MA organization physicians or hospitals. We further estimate that EPs will 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). In the paper, Evidence on the Costs and Benefits of Health Information Technology, May 2008, in attempting to estimate the total cost of implementing health IT systems in office-based medical practices, recognized the complicating factors of EHR types, available features, and differences in characteristics of the practices that are adopting them. The CBO estimated a cost range of

$25,000 to $45,000 per physician. 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 to achieve meaningful use. We estimate $1 million for maintenance, upgrades, and training each year.

(2) Conclusion

As discussed later in this analysis, we believe that there are many positive effects of adopting EHR on health care providers, quite apart from the incentive payments to be provided under this rule. While economically significant, we do not believe that the net effect on individual providers will be negative over time except in very rare cases. Accordingly, we believe that the object of the RFA to minimize burden on small entities is met by this rule.

b. Small Rural Hospitals

Section 1102(b) of the Act requires us to prepare a 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. This final rule 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 certified EHR technology by the applicable reporting period. As stated previously, we have determined that this final rule 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 will arise from the implementation of certified EHR technology in a rural eligible hospital will 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, we have statutory authority to make case-by-case exceptions for significant hardship, and proposed certain case-by-case applications that may be made when there are barriers to internet connectivity that will impact health information exchange.

c. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates will require spending in any 1 year $100 million in 1995 dollars, updated annually for inflation. In 2012, that threshold is approximately $139 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 imposes no substantial mandates on states. This program is voluntary for states and states offer the incentives at their option. The State role in the incentive program is essentially to administer the Medicaid incentive program. While this entails certain procedural responsibilities, these do not involve substantial State expense. In general, each State Medicaid Agency that participates in the incentive program will be required to invest in systems and technology to comply. States will have to identify and educate providers, evaluate their attestations and pay the incentive. However, the Federal government will fund 90 percent of the State's related administrative costs, providing controls on the total State outlay.

The investments needed to meet the meaningful use standards 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 will have a negative impact on providers that fail to meaningfully use certified EHR technology for the applicable 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 $139 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.

d. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This final rule 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 this final rule does add a new business requirement for states, because of the existing systems that will need to be modified to track and report on the new meaningful use requirements for provider attestations. We are providing 90 percent 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.

2. Effects on Eligible Professionals, Eligible Hospitals, and CAHs

a. Background and Assumptions

The principal costs of this final rule are the additional expenditures that will be undertaken by eligible entities in order to obtain the Medicare and Medicaid incentive payments to adopt, implement or upgrade and/or demonstrate 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 somewhat uncertain for several reasons: (1) 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 reporting period; (2) the Stage 1 and Stage 2 criteria for the demonstration of meaningful use of CEHRT has been finalized, but will change in Stage 3 and over time; and (3) the impact of the financial incentives and payment adjustments on the rate of adoption of certified EHR technology by EPs, eligible hospitals, and CAHs is difficult to predict based on the information we have currently collected. The net costs and savings shown for this program represent a possible scenario and actual impacts could differ substantially.

Based on input from a number of internal and external sources, including the Government Accountability Office (GAO) and CBO, we estimated the numbers of EPs and eligible hospitals, including CAHs under Medicare, Medicaid, and MA and used them throughout the analysis.

- About 568,900 Medicare FFS EPs in 2014 (some of whom will also be Medicaid EPs).
- About 14 percent of the total EPs are hospital-based Medicare EPs, and are not eligible for the program. This leaves approximately 491,000 nonhospital-based Medicare EPs in 2014.

● About 20 percent of the nonhospital-based Medicare EPs (approximately 98,200 Medicare EPs in 2014) are also eligible for Medicaid (meet the 30 percent Medicaid patient volume criteria), but can only be paid under one program. We assume that any EP in this situation will choose to receive the Medicaid incentive payment, because it is larger.

● About 46,600 non-Medicare eligible EPs (such as dentists, pediatricians, and eligible nonphysicians such as certified nurse-midwives, nurse practitioners and physicians assistants) will be eligible to receive the Medicaid incentive payments.

● 4,993 eligible hospitals comprised of the following:

++ 3,573 acute care hospitals.

++ 1,325 CAHs

++ 84 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.

● 12 MA organizations (about 28,000 EPs, and 29 hospitals) will be eligible for incentive payments.

b. Industry Costs and Adoption Rates

In the Stage 1 final rule (75 FR 44545 through 44547), we estimated the impact on healthcare providers using information from the same four studies cited previously in this final rule. Based on these studies and current average costs for available certified EHR technology 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, the range is from $1 million to $100 million. Although reports vary widely, we anticipate that the average will be $5 million to achieve meaningful use, because providers who will like to 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 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. 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. These estimates are similar to estimates made in the Stage 1 final rule. 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.

Comment: Some commenters suggested that specific costs and financial gains for each provider be recorded as part of attestation to inform the overall impact analysis. Another commenter suggested that the analysis should include costs associated with unintended consequences of the regulation, such as the loss of revenue to providers through the elimination of unnecessary or duplicative tests and the resistance of the market to improving patient care under such circumstances. The commenter also suggested that the impact analysis should be stratified according to primary care and specialty providers.

Response: Although we agree that a system that records the specific costs and benefits for each provider would yield a more accurate financial analysis, we believe that such a requirement would place a significant burden on providers and potentially limit participation in the EHR Incentive Programs. We also do not believe that there is an accurate method to calculate the loss of revenue due to the elimination of unnecessary or duplicative tests or market resistance to improving patient care. The reduction of costs while improving patient care is one of the goals of the EHR Incentive Programs, and we do not believe that these reductions should be classified as negative impacts for the healthcare system as they would also lead to lower overall health care costs. Nor do we believe it is possible for us to proactively estimate such savings at this time. Because both primary-care and specialty providers receive the same incentive payment amounts under this program, we do not believe there is a benefit to stratifying the impact analysis in this way.

d. Costs of EHR Adoption for Eligible Hospitals

AHA conducts annual surveys that among other measures, track hospital spending. This data reflects the latest figures from the 2008 AHA Survey. Costs at these levels of adoption were

significantly higher in 2008 than in previous years. This may better reflect the costs of implementing additional functionalities. The range in yearly information technology spending among hospitals is large, from $36,000 to over $32 million based on the AHA data. EHR system costs specifically were reported by experts to run as high as $20 million to $100 million. HHS discussions with experts led to cost ranges for adoption that varied by hospital size and level of EHR system sophistication. Research to date has shown that adoption of comprehensive EHR systems is limited. In the aforementioned AHA study, 1.5 percent of these organizations had comprehensive systems, which were defined as hospital-wide clinical documentation of cases, test results, prescription and test ordering, plus support for decision-making that included treatment guidelines. Some 10.9 percent have a basic system that does not include physician and nursing notes, and can only be used in one area of the hospital. Applying a similar standard to the 2008 AHA data, results in roughly 3 to 4 percent of hospitals having comprehensive systems and 12 to 13 percent having basic systems. According to hospital CEOs, the main barrier to adoption is the cost of the systems, and the lack of capital. Hospitals have been concerned that they will not be able to recoup their investment, and they are already operating on limited margins. Because uptake of advanced systems is low, it is difficult to get a solid average estimate for implementation and maintenance costs that can be applied across the industry. In addition, we recognize that there are additional industry costs associated with adoption and implementation of EHR technology that are not captured in our estimates that eligible entities will incur. Because the impact of those activities, such as reduced staff productivity related to learning how to use the EHR technology, the need to add additional staff to work with HIT issues, and administrative costs related to reporting are unknown at this time and difficult to quantify.

Comment: Some commenters suggested that overall IT operating costs should be included as part of the analysis. These commenters also suggested that estimates for costs related to staff training were too low and should include time and resources devoted to understanding the EHR Incentive Programs regulations. Other commenters suggested that costs associated with the time and resources related to registration and attestation should be included as part of the analysis. Finally, some commenters suggested that costs associated with EHR products, consultants, and trained IT professionals have increased since the start of the EHR Incentive Programs and should be reflected in the analysis.

Response: As noted in this impact analysis, we based cost estimates for IT on peer-reviewed studies of EHR and health IT costs. These cost estimates included maintenance and operating costs specific to EHRs and staff training. There are many aspects of IT operating costs that are not directly related to the maintenance or operation of CEHRT, and we do not believe it would be appropriate to include those costs as part of the impact analysis of this regulation. We are not aware of any new data that suggests an overall increase in the costs of CEHRT or related implementation and maintenance costs since the start of the EHR Incentive Programs, and in many cases we believe that the product and maintenance costs of CEHRT can be significantly lower than our estimates. Therefore, we are continuing to use the estimates we proposed for this impact analysis. We also do not believe it is appropriate to include additional costs related to registration and attestation, as the cost for dedicating resources to these activities is addressed earlier in this final rule in our discussion of information collection requirements.

3. Medicare Incentive Program Costs

a. Medicare Eligible Professionals (EPs)

We continue the method of cost estimation we used to determine the estimated costs of

the Medicare incentives for EPs in our Stage 1 final rule (75 FR 44549). In order to determine estimated costs, we first needed to determine the EPs with Medicare claims. Then, we calculated that about 14 percent of those EPs are hospital based according to the definition in §495.4 (finalized in our Stage 1 final rule), and therefore, do not qualify for incentive payments. This percent of EPs was subtracted from the total number of EPs who have claims with Medicare. These numbers were tabulated from Medicare claims data.

In the Stage 1 final rule, we also estimated that about 20 percent of EPs that were not hospital based will qualify for Medicaid incentive payments and will choose that program because the payments are higher. Current program data does not provide additional evidence regarding this, so we continued to use the 20 percent estimation in the current projections. Of the remaining EPs, we estimated the percentage which will be meaningful users each calendar year. As discussed previously, our estimates for the number of EPs that will successfully demonstrate meaningful use of CEHRT are uncertain. The percentage of Medicare EPs who will satisfy the criteria for demonstrating meaningful use of CEHRT and will qualify for incentive payments is a key, but a highly uncertain factor. Accordingly, the estimated number of nonhospital based Medicare EPs who will demonstrate meaningful use of CEHRT over the period CYs 2014 through 2019 is as shown in Table 22.

TABLE 22: MEDICARE EPs DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY

	Calendar Year					
	2014	**2015**	**2016**	**2017**	**2018**	**2019**
EPs who have claims with Medicare (thousands)	568.9	574.8	580.8	586.8	592.7	598.6
Nonhospital Based EPs (thousands)	491.0	496.1	501.3	506.4	511.5	516.7
EPs that are both Medicare and Medicaid EPs (thousands)	98.2	99.2	100.3	101.3	102.3	103.3
Percent of EPs who are Meaningful Users	37	46	52	57	62	67

	Calendar Year					
	2014	**2015**	**2016**	**2017**	**2018**	**2019**
Meaningful Users (thousands)	147.1	184.2	206.5	229.3	252.5	276.1

Our estimates of the incentive payments and payment adjustment savings are presented in Table 23. These payments reflect the Medicare and Medicaid incentive payments and payment adjustments included in 42 CFR Part 495 of our regulations. They reflect our assumptions about the proportion of EPs who will demonstrate meaningful use of CEHRT. These assumptions were developed based on a review of the studies presented in the Stage 1 impact analysis.

Specifically, our assumptions are based on literature estimating current rates of physician EHR adoption and rates of diffusion of EHRs and similar technologies. There are a number of studies that have attempted to measure the rate of adoption of electronic medical records (EMR) among physicians prior to the enactment of the HITECH Act (see, for example, Funky and Taylor (2005) The State and Pattern of Health Information Technology Adoption. RAND Monograph MG-409. Santa Monica: The RAND Corporation; Ford, E.W., Menachemi, N., Peterson, L.T., Huerta, T.R. (2009) "Resistance is Futile: But it is Slowing the Pace of EHR Adoption Nonetheless" Journal of the American Informatics Association 16(3): 274-281). More recently, there is also some data available to suggest that more providers have adopted EHR technology since the start of the EHR Incentive Programs. The 2011 ONC-AHA survey cited earlier found that the percentage of U.S. hospitals which had adopted EHRs increased from 16 to 35 percent between 2009 and 2011. In November 2011**,** the CDC survey cited earlier found the percentage of physicians who adopted basic (EHRs in their practice had doubled from 17 to 34 percent between 2008 and 2011. These survey results are in line with the estimated rate of EHR adoption presented in the Stage 1 impact analysis, but they constitute a relatively small sample on which to base new estimates. Therefore we maintain the estimates that were based on

the study with the most rigorous definition, though we note again that neither the Stage 1 nor the Stage 2 meaningful use criteria are equivalent to a fully functional system as defined in this study. (DesRoches, CM, Campbell, EG, Rao, SR et al (2008) "Electronic Health Records in Ambulatory Care-A National Survey of Physicians" New England Journal of Medicine 359(1): 50-60. In addition, we note that the final penetration rates used in the initial estimates were developed in consensus with industry experts relying on the studies. Actual adoption trends could be different from these assumptions, given the elements of uncertainty we describe throughout this analysis.

Estimated net costs of the Medicare EP portion of the HITECH Act are shown in Table 23.

TABLE 23: ESTIMATED COSTS (+) AND SAVINGS (–) FOR MEDICARE EPs DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY (IN BILLIONS)

Fiscal Year	Incentive Payments	Payment Adjustment Receipts	Benefit Payments	Net Total
2014	$1.9	—	—	$1.9
2015	$2.0	–$0.1	—	$1.9
2016	$0.8	–$0.1	—	$0.6
2017	$0.3	–$0.2	—	$0.1
2018	—	–$0.2	—	–$0.2
2019	—	–$0.2	—	–$0.2

b. Medicare Eligible Hospitals and CAHs

In brief, the estimates of hospital adoption were developed by calculating projected incentive payments (which are driven by discharges), comparing them to projected costs of attaining meaningful use, and then making assumptions about how rapidly hospitals will adopt given the fraction of their costs that were covered.

Specifically, the first step in preparing estimates of Medicare program costs for eligible hospitals was to determine the amount of Medicare incentive payments that each hospital in the country could potentially receive under the statutory formula, based on its discharge numbers (total patients and Medicare patients). The total incentive payments potentially payable over a 4-year period vary significantly by hospitals' inpatient caseloads, ranging from a low of about $11,000 to a high of $12.9 million, with the median being $3.8 million. The potential Medicare incentive payments for each eligible hospital were compared with the hospital's expected cost of purchasing and operating certified EHR technology. Costs of adoption for each hospital were estimated using data from the 2009 AHA survey and IT supplement. Estimated costs varied by size of hospital and by the likely status of EHR adoption in that class of hospitals. Hospitals were grouped first by size (CAHs, non-CAH hospitals under 400 beds, and hospitals with 400 or more beds) because EHR adoption costs do vary by size: namely, larger hospitals with more diverse service offerings and large physician staffs generally implement more customized systems than smaller hospitals that might purchase off-the-shelf products. We then calculated the proportion of hospitals within each class that were at one of three levels of EHR adoption: (1) hospitals which had already implemented relatively advanced systems that included CPOE systems for medications; (2) hospitals which had implemented more basic systems through which lab results could be shared, but not CPOE for medications; and (3) hospitals starting from

a base level with neither CPOE or lab reporting. The CPOE for medication standard was chosen for this estimate because expert input indicated that the CPOE standard in the final meaningful use definition will be the hardest one for hospitals to meet. Table 24 provides these proportions.

TABLE 24: HOSPITAL IT CAPABILITIES BY HOSPITAL SIZE

	Levels of Adoption							
	Any CPOE Meds		Lab Results		Neither		Total	
Hospital Size	Number of Hospitals	Percentage	Number of Hospitals	Percentage	Number of Hospitals	Percentage	Number of Hospitals	Percentage
CAHs	169	22%	390	51%	210	27%	769	23%
Small/Medium	834	37%	1,051	47%	348	16%	2,233	67%
Large (400+beds)	200	56%	145	41%	10	3%	355	10%
Total	1203	36%	1586	47%	568	17%	3,357	100%

We then calculated the costs of moving from these stages to meaningful use for each class of hospital, assuming that even for hospitals with CPOE systems they will incur additional costs of at least 10 percent of their IT budgets. These costs were based on cross-sectional data from the AHA survey and thus do not likely represent the true costs of implementing systems. This data reflects the latest figures from the 2009 AHA Survey. Costs at these levels of adoption were significantly higher than in previous years. This may better reflect the costs of implementing additional functionalities. We have also updated the number of discharges using the most recent cost report data available. The payment incentives available to hospitals under the Medicare and Medicaid programs are included in our regulations at 42 CFR part 495. We estimate that there are 12 MAOs that might be eligible to participate in the incentive program. Those plans have 29 eligible hospitals. The costs for the MA program have been included in the overall Medicare estimates.

Our estimated net costs for section 4102 of the HITECH Act are shown in Table 25: Estimated costs (+) and savings (–) for eligible hospitals adopting certified EHRs. This

provision is estimated to increase Medicare hospital expenditures by a net total of $5.3 billion during FYs 2014 through 2019.

TABLE 25: ESTIMATED COSTS (+) AND SAVINGS (–) FOR MEDICARE ELIGIBLE HOSPITALS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY (IN BILLIONS)

Fiscal Year	Incentive Payments	Payment Adjustment Receipts	Benefit Payments	Net Total
2014	$2.1	—	([1])	$2.1
2015	$2.2	-$0.4	([1])	$1.8
2016	$1.7	-$0.5	([1])	$1.2
2017	$0.5	-$0.3	([1])	$0.2
2018	—	-$0.1	([1])	-$0.1
2019	—	—	([1])	([1])

[1] Savings of less than $50 million.

Based on the comparison of Medicare incentive payments and implementation/operating costs for each eligible hospital (described previously), we made the assumptions shown in Tables 25, related to the prevalence of CEHRT for FYs 2014 through 2018. These assumptions are consistent with the actual program data for 2011. As indicated, eligible hospitals that could cover the full cost of an EHR system through Medicare incentive payments were assumed to implement them relatively rapidly, and vice versa. In other words, eligible hospitals will have an incentive to purchase and implement an EHR system if they perceive that a large portion of the costs will be covered by the incentive payments. Table 26 shows the assumptions that were used.

TABLE 26: ASSUMED PROPORTION OF ELIGIBLE HOSPITALS WITH CERTIFIED EHR TECHNOLOGY, BY PERCENTAGE OF SYSTEM COST COVERED BY MEDICARE INCENTIVE PAYMENTS

Fiscal Year	Incentive Payments as Percentage of EHR Technology Cost				
	100+%	75-100%	50-75%	25-50%	0-25%
2014	1.0	0.95	0.85	0.5	0.3

Fiscal Year	Incentive Payments as Percentage of EHR Technology Cost				
	100+%	75-100%	50-75%	25-50%	0-25%
2015	1.0	1.0	0.95	0.75	0.5
2016	1.0	1.0	1.0	0.9	0.75
2017	1.0	1.0	1.0	1.0	0.9
2018	1.0	1.0	1.0	1.0	1.0

For instance, 95 percent of eligible hospitals whose incentive payments will cover between 75 percent and 100 percent of the cost of a certified EHR system were assumed to have a certified system in FY 2014. All such hospitals were assumed to have a certified EHR system in FY 2015 and thereafter.

High rates of EHR adoption are anticipated in the years leading up to FY 2015 due to the payment adjustments that will be imposed on eligible hospitals. However, we know from industry experts that issues surrounding the capacity of vendors and expert consultants to support implementation, issues of access to capital, and competing priorities in responding to payer demand will limit the number of hospitals that can adopt advanced systems in the short term. Therefore, we cannot be certain of the adoption rate for hospitals due to these factors and others previously outlined in this preamble.

For large, organized facilities such as hospitals, we believe that the revenue losses caused by these payment adjustments will be a substantial incentive to adopt certified EHR technology, even in instances where the Medicare incentive payments will cover only a portion of the costs of purchasing, installing, populating, and operating the EHR system. Based on the assumptions about incentive payments as percentages of EHR technology costs in Table 26, we estimated that the great majority of eligible hospitals will qualify for at least a portion of the Medicare incentive payments that they could potentially receive, and only a modest number will incur payment adjustments. Nearly all eligible hospitals are projected to have implemented CEHRT by FY

2019. Table 27 shows our estimated percentages of the total potential incentive payments associated with eligible hospitals that could demonstrate meaningful use of EHR systems. Also shown are the estimated percentages of potential incentives that will actually be paid each year.

TABLE 27: ESTIMATED PERCENTAGE OF MEDICARE INCENTIVES WHICH COULD BE PAID FOR MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY ASSOCIATED WITH ELIGIBLE HOSPITALS AND ESTIMATED PERCENTAGE PAYABLE IN YEAR

Fiscal Year	Percent Associated with Eligible Hospitals	Percent Payable in Year
2014	66.1%	66.1%
2015	80.2%	72.2%
2016	91.3%	48.8%
2017	97. 7%	—
2018	100.0%	—

For instance in FY 2014, 66.1 percent of the total amount of incentive payments which could be payable in that year will be for eligible hospitals who have demonstrated meaningful use of CEHRT and therefore will be paid. In FY 2015, 80.2 percent of the total amount of incentive payments which could be payable will be for hospitals who have certified EHR systems, but some of those eligible hospitals will have already received 4 years of incentive payments, and therefore 72.2 percent of all possible incentive payments actually paid in that year.

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 nonqualifying 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 are discussed under "general considerations" at the end of 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.

c. Critical Access Hospitals (CAHs)

We estimate that there are 1,325 CAHs eligible to receive EHR incentive payments. In the Stage 1 impact analysis, we estimated that the 22 percent of CAHs with relatively advanced EHR systems will achieve meaningful use before 2016 given on the financial assistance available under HITECH for Regional Extension Centers, whose priorities include assisting CAHs in EHR adoption. We also estimated that most of the remaining CAHs that had already adopted some kind of EHR system at that time (51 percent of CAHs) will also achieve meaningful use by 2016. Current program payment data, as well as current data from the Regional Extension Centers, provides some more information for us to alter these estimates. Our new estimates regarding the incentives that will be paid to CAHs are incorporated into the overall Medicare and Medicaid program costs.

4. Medicaid Incentive Program Costs

Under section 4201 of the HITECH Act, states can voluntarily participate in the Medicaid incentive payment program. However, as of the writing of this final rule 48 states are already participating in the Medicaid incentive payment program and the remaining states have indicated they will begin participation in 2012. Therefore we anticipate that all states will be participating by 2014, as we estimated in the Stage 1 impact analysis. The payment incentives available to EPs and hospitals under the Medicaid programs 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 hospital and EP. Table 28 shows our estimates for the net Medicaid costs for eligible hospitals and EPs.

TABLE 28: ESTIMATED FEDERAL COSTS (+) AND SAVINGS (–) UNDER MEDICAID (IN BILLIONS)

Fiscal Year	Incentive Payments		Benefit Payments	Net Total
	Hospitals	Eligible Professionals		
2014	0.6	0.5	([1])	1.1
2015	0.4	0.8	([1])	1.2
2016	0.5	0.8	([1])	1.2
2017	0.5	0.7	([1])	1.2
2018	0.1	0.7	([1])	0.8
2019	0.0	0.5	([1])	0.5

[1] Savings of less than $50 million.

a. Medicaid EPs

To determine the Medicaid EP incentive payments, we first determined the number of qualifying EPs. As indicated previously, we assumed that 20 percent of the nonhospital-based Medicare EPs will meet the requirements for Medicaid incentive payments (30 percent of patient volume from Medicaid). All of these EPs were assumed to choose the Medicaid incentive payments, as they are larger. In addition, the total number of Medicaid EPs was adjusted to include EPs who qualify for the Medicaid incentive payments but not for the Medicare incentive payments, such as most pediatricians, dentists, certified nurse-midwives, nurse practitioners, and physicians assistants. As noted previously, there is much uncertainty about the rates of demonstration of meaningful use that will be achieved. Our estimates are listed in Table 29.

TABLE 29: ASSUMED NUMBER OF NONHOSPITAL BASED MEDICAID EPS WHO WILL BE MEANINGFUL USERS OF CERTIFIED EHR TECHNOLOGY (ALL POPULATION FIGURES ARE IN THOUSANDS)

		Calendar Year					
		2014	2015	2016	2017	2018	2019
	EPs who have claims with Medicare	568.9	574.8	580.8	586.8	592.7	598.6
	Nonhospital –based EPs	491.0	496.1	501.3	506.4	511.5	516.7
A	EPs who meet the Medicaid patient volume threshold	98.2	99.2	100.3	101.3	102.3	103.3

		Calendar Year					
		2014	**2015**	**2016**	**2017**	**2018**	**2019**
B	Medicaid[1] only EPs	46.6	47.4	48.1	48.9	49.7	50.4
	Total Medicaid EPs (A + B)	144.8	146.6	148.4	150.2	152.0	153.8
	Percent of EPs receiving incentive payment during year	49.2%	58.8%	64.0%	52.9%	29.5%	22.6%
	Number of EPs receiving incentive payment during year	71.2	86.3	95.0	79.4	44.8	34.8
	Percent of EPs who have ever received incentive payment	49.2%	58.8%	64.0%	68.9%	73.5%	77.9%
	Number of EPs who have ever received incentive payment	71.2	86.3	95.0	103.4	111.7	119.8

It should be noted that since the Medicaid EHR incentive payment program provides that a Medicaid EP can receive an incentive payment in their first year because he or she has demonstrated a meaningful use or because he or she has adopted, implemented, or upgraded certified EHR technology, these participation rates include not only meaningful users but eligible providers implementing CEHRT as well.

b. Medicaid Hospitals

Medicaid incentive payments to most acute-care hospitals were estimated using the same adoption assumptions and method as described previously for Medicare eligible hospitals and shown in Table 30. Because hospitals' Medicare and Medicaid patient loads differ, we separately calculated the range of percentage of total potential incentives that could be associated with qualifying hospitals, year by year, and the corresponding actual percentages payable each year. Acute care hospitals may qualify to receive both the Medicare and Medicaid incentive payments.

As stated previously, the estimated eligible hospital incentive payments were calculated based on the hospitals' qualifying status and individual incentive amounts payable under the statutory formula. The estimated savings in Medicaid benefit expenditures resulting from the use of CEHRT are discussed under "general considerations." Since we were using Medicare cost report 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 nonchildren's hospitals.

TABLE 30: ESTIMATED PERCENTAGE OF POTENTIAL MEDICAID INCENTIVES ASSOCIATED WITH ELIGIBLE HOSPITALS AND ESTIMATED PERCENTAGE PAYABLE EACH YEAR

Fiscal Year	Percent Associated with Eligible Hospitals	Percent Payable in Year
2014	67.5%	59.3%
2015	81.1%	37.9%
2016	91.8%	33.7%
2017	97.7%	24.3%
2018	100.0%	10.7%
2019	100.0%	0.0%

5. Benefits for all EPs and all Eligible Hospitals

In this final rule we have not quantified the overall benefits to the industry, nor to eligible hospitals or EPs in the Medicare, Medicaid, or MA programs. Although information on the costs and benefits of adopting systems that specifically meet the requirements for the EHR Incentive Programs (for example, certified EHR technology) has not yet been collected, and although some studies question the benefits of health information technology, a 2011 study completed by ONC (Buntin et al. 2011 "The Benefits of Health Information Technology: A Review of the Recent Literature Shows Predominantly Positive Results" Health Affairs.) found that 92 percent of 154 articles published from July 2007 up to February 2010 reached conclusions that showed the overall positive effects of health information technology on key aspects of care, including quality and efficiency of health care. Among the positive results highlighted in these articles were decreases in patient mortality, reductions in staffing needs, correlation of clinical decision support to reduced transfusion and costs, reduction in complications for patients in hospitals with more advanced health IT, and a reduction in costs for hospitals with less advanced health IT. Another study, at one hospital emergency room in Delaware, showed the ability to download and

create a file with a patient's medical history saved the ER $545 per use, mostly in reduced waiting times. A pilot study of ambulatory practices found a positive ROI within 16 months and annual savings thereafter (Greiger, et al. 2007, A Pilot Study to Document the Return on Investment for Implementing an Ambulatory Electronic Health Record at an Academic Medical Center http://www.journalacs.org/article/S1072-7515%2807%2900390-0/abstract - article-footnote-1s.) A study that compared the productivity of 75 providers within a large urban primary care practice over a 4 year period showed increases in productivity of 1.7 percent per month per provider after EHR adoption (DeLeon et al. 2010, "The business end of health information technology. Can a fully integrated electronic health record increase provider productivity in a large community practice?" J Med Pract Manage). Some vendors have estimated that EHRs could result in cost savings of between $100 and $200 per patient per year. At the time of the writing of this final rule, there was only limited information on participation in the EHR Incentive Programs and on adoption of Certified EHR Technology. As participation and adoption increases, there will be more opportunities to capture and report on cost savings and benefits. A number of relevant studies are required in the HITECH Act for this specific purpose, and the results will be made public, as they are available.

6. Benefits to Society

According to the recent CBO study "Evidence on the Costs and Benefits of Health Information Technology" (http://www.cbo.gov//ftpdocs/91xx/doc9168/05-20-HealthIT.pdf) when used effectively, EHRs can enable providers to deliver health care more efficiently. For example, the study states that EHRs can reduce the duplication of diagnostic tests, prompt providers to prescribe cost-effective generic medications, remind patients about preventive care reduce unnecessary office visits and assist in managing complex care. This is consistent with the

findings in the ONC study cited previously. Further, the CBO report claims that there is a potential to gain both internal and external savings from widespread adoption of health IT, noting that internal savings will likely be in the reductions in the cost of providing care, and that external savings could accrue to the health insurance plan or even the patient, such as the ability to exchange information more efficiently. However, it is important to note that the CBO identifies the highest gains accruing to large provider systems and groups and claims that office-based physicians may not realize similar benefits from purchasing health IT products. At this time, there is limited data regarding the efficacy of health IT for smaller practices and groups, and the CBO report notes that this is a potential area of research and analysis that remains unexamined. The benefits resulting specifically from this final rule 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.

Since the CBO study, there has been additional research that has emerged documenting the association of EHRs with improved outcomes among diabetics (Hunt, JS et al. (2009) "The impact of a physician-directed health information technology system on diabetes outcomes in primary care: a pre- and post-implementation study" Informatics in Primary Care 17(3):165-74; Pollard, C et al. (2009) "Electronic patient registries improve diabetes care and clinical outcomes in rural community health centers" Journal of Rural Health 25(1):77-84) and trauma patients (Deckelbaum, D. et al. (2009) "Electronic medical records and mortality in trauma patients "The Journal of Trauma: Injury, Infection, and Critical Care 67(3): 634-636), enhanced efficiencies in ambulatory care settings (Chen, C et al. (2009) "The Kaiser Permanente Electronic Health Record: Transforming and Streamlining Modalities Of Care."Health Affairs 28(2):323-333),

and improved outcomes and lower costs in hospitals (Amarasingham, R. et al. (2009) "Clinical information technologies and inpatient outcomes: a multiple hospital study" Archives of Internal Medicine 169(2):108–14). However, data relating specifically to the EHR Incentive Programs is limited at this time.

7. General Considerations

The estimates for the HITECH Act provisions were based on the economic assumptions underlying the President's 2013 Budget. Under the statute, Medicare incentive payments for CEHRT are excluded from the determination of MA capitation benchmarks. As noted previously, there is considerable uncertainty about the rate at which eligible hospitals, CAHs and EPs are adopting EHRs and other HIT. Nonetheless, we believe that the Medicare incentive payments and the prospect of significant payment adjustments for not demonstrating meaningful use will result in the great majority of hospitals implementing CEHRT in the early years of the Medicare EHR incentive program. We expect that a steadily growing proportion of practices will implement CEHRT over the next 10 years, even in the absence of the Medicare incentives. Actual future Medicare and Medicaid costs for eligible hospital and EP incentives will depend in part on the standards developed and applied for assessing meaningful use of certified EHR technology. We are administering the requirements in such a way as to encourage adoption of CEHRT and facilitate qualification for incentive payments, and expect to adopt progressively demanding standards at each stage year. Certified EHR technology has the potential to help reduce medical costs through efficiency improvements, such as prompter treatments, avoidance of duplicate or otherwise unnecessary services, and reduced administrative costs (once systems are in place), with most of these savings being realized by the providers rather than by Medicare or Medicaid. To the extent that this technology will have a net positive effect on efficiency, then

more rapid adoption of such EHR systems will achieve these efficiencies sooner than will otherwise occur, without the EHR incentives. As noted, the possible efficiency savings from the adoption of EHR is expected to be realized by the providers rather than the payers. We expect a negligible impact on benefit payments to hospitals and EPs from Medicare and Medicaid as a result of the implementation of EHR technology.

In the process of preparing the estimates for this rule, we consulted with and/or relied on internal CMS sources, as well as the following sources:

- Congressional Budget Office (staff and publications).
- American Medical Association (staff and unpublished data).
- American Hospital Association.
- Actuarial Research Corporation.
- CMS Statistics 2011.
- RAND Health studies on:

++ "The State and Pattern of Health Information Technology Adoption"(Fonkych & Taylor, 2005);

++ "Extrapolating Evidence of Health Information Technology Savings and Costs"(Girosi, Meili, & Scoville, 2005); and

++ "The Diffusion and Value of Healthcare Information Technology"(Bower, 2005).

- Kaiser Permanente (staff and publications).
- Miscellaneous other sources (Health Affairs, American Enterprise Institute, ONC survey, Journal of Medical Practice Management, news articles and perspectives).

As noted at the beginning of this analysis, it is difficult to predict the actual impacts of the HITECH Act with much 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.

8. Summary

The total cost to the Medicare and Medicaid programs between 2014 and 2019 is estimated to be $15.4 billion in transfers. We do not estimate total costs to the provider industry, but rather provide a possible per EP and per eligible hospital outlay for implementation and maintenance.

TABLE 31: 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	
2014	$2.1	$1.9	$0.6	$0.5	$5.1
2015	$1.8	$1.9	$0.4	$0.8	$4.9
2016	$1.2	$0.6	$0.5	$0.8	$3.1
2017	$0.2	$0.1	$0.5	$0.7	$1.5
2018	-$0.1	-$0.2	$0.1	$0.7	$0.5
2019	_	-$0.2	$0.0	$0.5	$0.3

9. Explanation of Benefits and Savings Calculations

In our analysis, we assume that benefits to the program will accrue in the form of savings to Medicare, through the Medicare payment adjustments. Expected qualitative benefits, such as improved quality of care, better health outcomes, and the like, are unable to be quantified at this time.

D. Accounting Statement

Whenever a rule is considered a significant rule under Executive Order 12866, we are required to develop an accounting statement indicating the classification of the expenditures associated with the provisions of this final rule. Monetary annualized benefits and nonbudgetary costs are presented as discounted flows using 3 percent and 7 percent factors. Additional

expenditures that will be undertaken by eligible entities in order to obtain the Medicare and Medicaid incentive payments to adopt and demonstrate meaningful use of certified EHR technology, and to avoid the Medicare payment adjustments that will ensue if they fail to do so are noted by a placeholder in the accounting statement. 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.

Expected qualitative benefits include improved quality of care, better health outcomes, reduced errors and the like. Private industry costs will 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.

TABLE 32: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES CYs 2014 THROUGH 2019 (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**
		Low Estimate	**High Estimate**		
Annualized Monetized Costs to Private Industry Associated with Reporting Requirements	2014	$178.0	$186.1	7%	CY 2014
		$178.0	$186.1	3%	
Qualitative--Other private industry costs associated with the adoption of EHR technology.	These costs will 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	2014	$2,558		7%	CYs 2014-2019
		$2,441		3%	
From Whom To Whom?	Federal Government to Medicare- and Medicaid-eligible professionals and hospitals				

E. Conclusion

The previous analysis, together with the remainder of this preamble, provides an RIA. We believe there are many positive effects of adopting EHR on health care providers, quite apart from the incentive payments to be provided under this rule. We believe there are benefits that can be obtained by eligible hospitals and EPs, including: reductions in medical recordkeeping costs, reductions in repeat tests, decreases in length of stay, and reduced errors. When used effectively, EHRs can enable providers to deliver health care more efficiently. For example, 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. We also believe that internal savings will likely come through the reductions in the cost of providing care. While economically significant, we do not believe that the net effect on individual providers will be negative over time except in very rare cases. Accordingly, we believe that the RFA objective to minimize burden on small entities is met by this final rule.

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

List of Subjects

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, 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 set forth 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).

Subpart D—Basic Method for Determining Prospective Payment Federal Rates for Inpatient Operating Costs

2. Section 412.64 is amended as follows:

A. Revising paragraph (d)(3) introductory text.

B. Adding paragraphs (d)(4) and (5).

The revision and addition read as follows:

§412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.

* * * * *

(d) * * *

(3) Beginning fiscal year 2015, in the case of a "subsection (d) hospital," as defined under section 1886(d)(1)(B) of the Act, that is not a meaningful electronic health record (EHR) user as defined in part 495 of this chapter for the applicable EHR reporting period and does not receive an exception, three-fourths of the applicable percentage change specified in paragraph (d)(1) of this section is reduced—

* * * * *

(4) Exception. (i) General rules. The Secretary may, on a case-by-case basis, exempt

an eligible hospital that is not a qualifying eligible hospital from the application of the reduction under paragraph (d)(3) of this section if the Secretary determines that compliance with the requirement for being a meaningful EHR user would result in a significant hardship for the eligible hospital.

(ii) To be considered for an exception, a hospital must submit an application, in the manner specified by CMS, demonstrating that it meets one or more than one of the criteria specified in this paragraph (d)(4) of this section. These types of exceptions are subject to annual renewal, but in no case may a hospital be granted this type of exception for more than 5 years. (See §495.4 for definitions of payment adjustment year, EHR reporting period, and meaningful EHR user.)

(A) During any 90-day period from the beginning of the fiscal year that is 2 years before the payment adjustment year to April 1 of the year before the payment adjustment year, the hospital was located in an area without sufficient Internet access to comply with the meaningful use objectives requiring internet connectivity, and faced insurmountable barriers to obtaining such internet connectivity. Applications requesting this exception must be submitted by April 1 of the year before the applicable payment adjustment year.

(B)(1) During the fiscal year that is 2 fiscal years before the payment adjustment year, the hospital that has previously demonstrated meaningful use faces extreme and uncontrollable circumstances that prevent it from becoming a meaningful EHR user. Applications requesting this exception must be submitted by April 1 of the year before the applicable payment adjustment year.

(2) During the fiscal year preceding the payment adjustment year, the hospital that has not previously demonstrated meaningful use faces extreme and uncontrollable circumstances that

prevent it from becoming a meaningful EHR user. Applications requesting this exception must be submitted by April 1 of the year before the applicable payment adjustment year.

(C) The hospital is new in the payment adjustment year, and has not previously operated (under previous or present ownership). This exception expires beginning with the first Federal fiscal year that begins on or after the hospital has had at least one 12-month (or longer) cost reporting period after they accept their first Medicare covered patient. For purposes of this exception, the following hospitals are not considered new hospitals:

(1) A hospital that builds new or replacement facilities at the same or another location even if coincidental with a change of ownership, a change in management, or a lease arrangement.

(2) A hospital that closes and subsequently reopens.

(3) A hospital that changes its status from a CAH to a hospital that is subject to the Medicare hospital inpatient prospective payment systems.

(5) A State in which hospitals are paid for services under section 1814(b)(3) of the Act must--

(i) Adjust the payments to each eligible hospital in the State that is not a meaningful EHR user in a manner that is designed to result in an aggregate reduction in payments to hospitals in the State that is equivalent to the aggregate reduction that would have occurred if payments had been reduced to each eligible hospital in the State in a manner comparable to the reduction under paragraph (d)(3) of this section; and

(ii) Provide to the Secretary, by January 1, 2013, a report on the method that it proposes to employ in order to make the requisite payment adjustment described in paragraph (d)(5)(i) of this section.

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

3. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Public Law 106-133 (113 Stat. 1501A–332).

4. Section 413.70 is amended by revising paragraphs (a)(6)(i) introductory text, (a)(6)(ii), and (a)(6)(iii) to read as follows:

§413.70 Payment for services of a CAH.

(a) * * *

(6)(i) For cost reporting periods beginning in or after FY 2015, if a CAH is not a qualifying CAH for the applicable EHR reporting period, as defined in §495.4 and §495.106(a) of this chapter, then notwithstanding the percentage applicable in paragraph (a)(1) of this section, the reasonable costs of the CAH in providing CAH services to its inpatients are adjusted by the following applicable percentage:

* * * * *

(ii) The Secretary may on a case-by-case basis, exempt a CAH that is not a qualifying CAH from the application of the payment adjustment under paragraph (a)(6)(i) of this section if the Secretary determines that compliance with the requirement for being a meaningful user would result in a significant hardship for the CAH. In order to be

considered for an exception, a CAH must submit an application demonstrating that it meets one or more of the criteria specified in this paragraph (a)(6) for the applicable payment adjustment year no later than November 30 after the close of the applicable EHR reporting period. The Secretary may grant an exception for one or more of the following:

(A) During any 90-day period from the beginning of the cost reporting period that begins in the fiscal year before the payment adjustment year to November 30 after the end of the payment adjustment year, the hospital was located in an area without sufficient Internet access to comply with the meaningful use objectives requiring internet connectivity, and faced insurmountable barriers to obtaining such internet connectivity.

(B) A CAH that faces extreme and uncontrollable circumstances that prevent it from becoming a meaningful EHR user during the payment adjustment year.

(C) The CAH is new in the payment adjustment year and has not previously operated (under previous or present ownership). This exception expires beginning with the first Federal fiscal year that begins on or after the hospital has had at least one 12-month (or longer) cost reporting period after they accept their first Medicare-covered patient. For the purposes of this exception, the following CAHs are not considered new CAHs:

(1) A CAH that builds new or replacement facilities at the same or another location even if coincidental with a change of ownership, a change in management, or a lease arrangement.

(2) A CAH that closes and subsequently reopens.

(3) A CAH that has been converted from an eligible hospital as defined at §495.4

of this chapter.

(iii) Exceptions granted under paragraph (a)(6)(ii) of this section are subject to annual renewal, but in no case may a CAH be granted such an exception for more than 5 years.

* * * * *

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

5. 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).

Subpart A—General Provisions

6. Section 495.4 is amended as follows:

A. Revising the definition of "EHR reporting period".

B. Adding the definition of "EHR reporting period for a payment adjustment year" in alphabetical order.

C. Revising the definition of "Hospital-based EP".

D. Revising paragraphs (1) and (3) of the definition of "Meaningful EHR user".

E. Adding the definition of "Payment adjustment year" in alphabetical order.

The revisions and additions read as follows:

§495.4 Definitions.

* * * * *

EHR reporting period. Except with respect to payment adjustment years, EHR reporting period means either of the following:

(1) For an eligible EP--

(i) 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;

(ii) Except as specified in paragraphs (1)(iii) and (1)(iv) of this definition, 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.

(iii) For an EP seeking to demonstrate he or she is a meaningful EHR user for the Medicare EHR incentive program for CY 2014, any of the following 3-month periods:

(A) January 1, 2014 through – March 31, 2014.

(B) April 1, 2014 through June 30, 2014.

(C) July 1, 2014 through September 30, 2014.

(D) October 1, 2014 through December 31, 2014.

(iv) For an EP seeking to demonstrate he or she is a meaningful EHR user for the Medicaid EHR incentive program for CY 2014any continuous 90-day period within CY 2014.

(2) For an eligible hospital or CAH--

(i) 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 Federal fiscal year;

(ii) Except as specified in paragraph (2)(iii) of this definition, 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 Federal fiscal year.

(iii) For an eligible hospital or CAH seeking to demonstrate it is a meaningful EHR user for FY 2014, any of the following 3-month periods:

(A) October 1, 2013 through December 31, 2013.

(B) January 1, 2014 through March 31, 2014.

(C) April 1, 2014 through June 30, 2014.

(D) July 1, 2014 through September 30, 2014.

EHR reporting period for a payment adjustment year. For a payment adjustment year, the EHR reporting period means the following:

(1) For an EP--

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

(B) The special EHR reporting period for CY 2014 (specified in paragraph (1)(iii) or (1)(iv) of this definition, as applicable) of the definition of "EHR Reporting Period" that occurs within the calendar year that is 2 years before the payment adjustment year and is only for EHR reporting periods in CY 2014.

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

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

(B) Under this exception, the provider must successfully register for and attest to meaningful use no later than the date October 1 of the year before the payment adjustment year.

(2) For an eligible hospital--

(i)(A) Except as provided in paragraphs (2)(i)(B), (ii), and (iii) of this definition, the

Federal fiscal year that is 2 years before the payment adjustment year.

(B) The special EHR reporting period for FY 2014 (defined in paragraph (2)(iii) of the definition "EHR Reporting Period") that occurs within the fiscal year that is 2 years before the payment adjustment year and is only for EHR reporting periods in fiscal year 2014.

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

(iii)(A) If in the Federal fiscal year that is 2 years before the payment adjustment year and for all prior Federal fiscal years the eligible hospital has not successfully demonstrated it is a meaningful EHR user, then any continuous 90-day period that both begins in the Federal fiscal year that is 1 year before the payment adjustment year and ends at least 3 months before the end of such prior Federal fiscal year.

(B) Under this exception, the eligible hospital must successfully register for and attest to meaningful use no later than July 1 of the year before the payment adjustment year.

(3) For a CAH—

(i) Except as provided in paragraph (3)(ii) of this definition, the Federal fiscal year that is the payment adjustment year.

(ii) If the CAH is demonstrating it is a meaningful EHR user for the first time in the payment adjustment year, any continuous 90-day period within the Federal fiscal year that is the payment adjustment year.

* * * * *

Hospital-based EP. Unless it meets the requirements of §495.5 of this part, a hospital-based EP means an EP who furnishes 90 percent or more of his or her covered

professional services in sites of service identified by the codes used in the HIPAA standard transaction as an inpatient hospital or emergency room setting in the year preceding the payment year, or in the case of a payment adjustment year, in either of the 2 years before such payment adjustment year.

(1) For Medicare, this is calculated based on--

(i) The FFY preceding the payment year; and

(ii) For the payment adjustments, on the--

(A) FFY preceding the payment adjustment year; or

(B) FFY 2 years before the payment adjustment year.

(2) For Medicaid, it is at the State's discretion if the data is gathered on the Federal fiscal year or calendar year preceding the payment year.

* * * * *

Meaningful EHR user * * *

(1) Subject to paragraph (3) of this definition, an EP, eligible hospital or CAH that, for an EHR reporting period for a payment year or payment adjustment year, demonstrates in accordance with §495.8 meaningful use of Certified EHR Technology by meeting the applicable objectives and associated measures under §495.6 and successfully reporting the clinical quality measures selected by CMS to CMS or the States, as applicable, in the form and manner specified by CMS or the States, as applicable; and

* * * * *

(3) To be considered a meaningful EHR user, at least 50 percent of an EP's patient encounters during an EHR reporting period for a payment year (or, in the case of a payment adjustment year, during an applicable EHR reporting period for such payment adjustment year)

must occur at a practice/location or practices/locations equipped with Certified EHR Technology.

* * * * *

Payment adjustment year means either of the following:

(1) For an EP, a calendar year beginning with CY 2015.

(2) For a CAH or an eligible hospital, a Federal fiscal year beginning with FY 2015.

* * * * *

7. Section 495.5 is added to read as follows:

§495.5 Requirements for EPs seeking to reverse a hospital-based determination under §495.4.

(a) Exception for certain EPs. Beginning with payment year 2013, an EP who meets the definition of hospital-based EP specified in §495.4 but who can demonstrate to CMS that the EP funds the acquisition, implementation, and maintenance of Certified EHR Technology, including supporting hardware and interfaces needed for meaningful use without reimbursement from an eligible hospital or CAH, and uses such Certified EHR Technology in the inpatient or emergency department of a hospital (instead of the hospital's Certified EHR Technology), may be determined by CMS to be a nonhospital-based EP.

(b) Process for determining a nonhospital-based EP. When an EP registers for a given payment year they should receive a determination of whether they have been determined "hospital-based."

(1) An EP determined "hospital-based," but who wishes to be determined nonhospital-based as specified in paragraph (a) of section, may use an administrative process to provide documentation and seek a nonhospital-based determination. Such administrative process

will be available throughout the incentive payment year and including the 2 months following the incentive payment year in which the EP may attest to being a meaningful EHR user.

(2) If an EP is determined nonhospital-based under paragraph (a) of this section, to be considered nonhospital-based for subsequent payment years, the EP must attest in such payment year (or by the time the EP must attest it is a meaningful EHR user for such year) that the EP continues to meet the criteria of paragraph (a) of this section.

(c) Requirements for nonhospital-based EPs. An EP determined nonhospital-based must--

(1) Continue to meet all applicable requirements to receive an incentive payment, including meeting all requirements for meaningful use; and

(2) Demonstrate meaningful use using all encounters at all locations equipped with Certified EHR Technology, including those in the inpatient and emergency departments of the hospital.

8. Section 495.6 is amended as follows:

A. Redesignating paragraph (a)(2)(ii) as paragraph (a)(2)(ii)(A).

B. Adding paragraph (a)(2)(ii)(B).

C. Redesignating paragraph (b)(2)(ii) as paragraph (b)(2)(ii)(A).

D. Adding paragraph (b)(2)(ii)(B).

E. In paragraphs (c) introductory text and (c)(1), the references "paragraphs (d) through (g)" are removed and the references "paragraphs (d) through (m)" is added in their place.

F. Redesignating paragraph (d)(1)(ii) as paragraph (d)(1)(ii)(A).

G. Adding paragraph (d)(1)(ii)(B).

H. Redesignating paragraph (d)(4)(iii) as paragraph (d)(4)(iii)(A).

I. Adding a paragraph (d)(4)(iii)(B).

J. Redesignating paragraph (d)(8)(i)(E) as paragraph (d)(8)(i)(E)(1).

K. Adding paragraphs (d)(8)(i)(E)(2) and (3).

L. Redesignating paragraph (d)(8)(ii) as paragraph (d)(8)(ii)(A).

M. Adding paragraphs (d)(8)(ii)(B) and (C).

N. Redesignating paragraph (d)(8)(iii) as paragraph (d)(8)(iii)(A).

O. Adding paragraphs (d)(8)(iii)(B) and (C).

P. Redesignating paragraph (d)(10)(i) as paragraph (d)(10)(i)(A).

Q. Adding paragraph (d)(10)(i)(B).

R. Redesignating paragraph (d)(10)(ii) as paragraph (d)(10)(ii)(A).

S. Adding a paragraph (d)(10)(ii)(B).

T. Redesignating paragraph (d)(12)(i) as paragraph (d)(12)(i)(A).

U. Adding a paragraph (d)(12)(i)(B).

V. Redesignating paragraph (d)(12)(ii) as paragraph (d)(12)(ii)(A).

W. Adding a paragraph (d)(12)(ii)(B).

X. Redesignating paragraph (d)(12)(iii) as paragraph (d)(12)(iii)(A).

Y. Adding a paragraph (d)(12)(iii)(B).

Z. Redesignating paragraph (d)(14)(i) as paragraph (d)(14)(i)(A).

AA. Adding a paragraph (d)(14)(i)(B).

BB. Redesignating paragraph (d)(14)(ii) as paragraph (d)(14)(ii)(A).

CC. Adding a paragraph (d)(14)(ii)(B).

DD. In paragraph (e) introductory text--

i. Removing the colon and adding a period in its place.

ii. Adding a sentence at the end of the paragraph.

EE. Redesignating paragraph (e)(5)(i) as paragraph (e)(5)(i)(A).

FF. Adding a paragraph (e)(5)(i)(B).

GG. Redesignating paragraph (e)(5)(ii) as paragraph (e)(5)(ii)(A).

HH. Adding paragraph (e)(5)(ii)(B).

II. Redesignating paragraph (e)(9)(i) as (e)(9)(i)(A).

JJ. Adding paragraph (e)(9)(i)(B).

KK. Redesignating paragraph (e)(10)(i) as (e)(10)(i)(A).

LL. Adding paragraph (e)(10)(i)(B).

MM. Redesignating paragraph (f)(1)(ii) as paragraph (f)(1)(ii)(A).

NN. Adding paragraphs (f)(1)(ii)(B) and (C).

OO. Redesignating paragraph (f)(7)(i)(E) as paragraph (f)(7)(i)(E)(1).

PP. Adding a paragraphs (f)(7)(i)(E)(2) and (3).

QQ. Redesignating paragraph (f)(7)(ii) as (f)(7)(ii)(A).

RR. Adding paragraphs (f)(7)(ii)(B) and (C).

SS. Redesignating paragraph (f)(9)(i) as paragraph (f)(9)(i)(A).

TT. Adding a paragraph (f)(9)(i)(B).

UU. Redesignating paragraph (f)(9)(ii) as paragraph (f)(9)(ii)(A).

VV. Adding a paragraph (f)(9)(ii)(B).

WW. Redesignating paragraphs (f)(11)(i) and (ii) as paragraphs (f)(11)(i)(A) and (ii)(A), respectively.

XX. Adding paragraphs (f)(11)(i)(B) and (ii)(B).

YY. Redesignating paragraph (f)(12)(i) as paragraph (f)(12)(i)(A).

ZZ. Adding a paragraph (f)(12)(i)(B).

AAA. Redesignating paragraph (f)(12)(ii) as paragraph (f)(12)(ii)(A).

BBB. Adding a paragraph (f)(12)(ii)(B).

CCC. Redesignating paragraph (f)(12)(iii) as paragraph (f)(12)(iii)(A).

DDD. Adding a paragraph (f)(12)(iii)(B).

EEE. Redesignating paragraph (f)(13)(i) as paragraph (f)(13)(i)(A).

FFF. Adding a paragraph (f)(13)(i)(B).

GGG. Redesignating paragraph (f)(13)(ii) as paragraph (f)(13)(ii)(A).

HHH. Adding a paragraph (f)(13)(ii)(B).

III. In paragraph (g) introductory text--

i. Removing the colon and adding a period in its place.

ii. Adding a sentence at the end of the paragraph.

JJJ. Redesignating paragraph (g)(8)(i) as paragraph (g)(8)(i)(A).

KKK. Adding a paragraph (g)(8)(i)(B).

LLL. Redesignating paragraph (g)(9)(i) as paragraph (g)(9)(i)(A).

MMM. Adding a paragraph (g)(9)(i)(B).

NNN. Redesignating paragraph (g)(10)(i) as paragraph (g)(10)(i)(A).

OOO. Adding a paragraph (g)(10)(i)(B).

PPP. Revising paragraphs (h) and (i).

QQQ. Adding new paragraphs (j) through (m).

The additions and revisions read as follows:

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

* * * * *

(a) * * *

(2) * * *

(ii) * * *

(B) Beginning 2014, an exclusion does not reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply in paragraph (e) of this section unless five or more objectives can be excluded. An EP must meet five of the objectives and associated measures specified in paragraph (e) of this section, one of which must be either paragraph (e)(9) or (10) of this section, unless the EP has an exclusion from five or more objectives specified in paragraph (e) of this section, in which case the EP must meet all remaining objectives and associated measures in paragraph (e) of this section.

* * * * *

(b) * * *

(2) * * *

(ii) * * *

(B) Beginning 2014, an exclusion does not reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply in paragraph (g) of this section. Eligible hospitals or CAHs must meet five of the objectives and associated measures specified in paragraph (g) of this section, one which must be specified in paragraph (g)(8), (9), or (10) of this section.

* * * * *

(d) * * *

(1) * * *

(ii) * * *

(B) Subject to paragraph (c) of this section, more than 30 percent of medication orders created by the EP during the EHR reporting period are recorded using computerized provider order entry, or the measure specified in paragraph (d)(1)(ii)(A) of this section.

* * * * *

(4) * * *

(iii) * * *

(B) Beginning 2013, any EP who 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/her EHR reporting period, or the exclusion specified in (d)(4)(iii)(A) of this section.

* * * * *

(8)(i) * * *

(E) * * *

(2) For 2013, plot and display growth charts for patients 0-20 years, including body mass index, or paragraph (d)(8)(i)(E)(1) of this section.

(3) Beginning 2014, plot and display growth charts for patients 0-20 years, including body mass index.

(ii) * * *

(B) For 2013-- (1) Subject to paragraph (c) of this section, more than 50 percent of all unique patients seen by the EP during the EHR reporting period have blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data; or

(2) The measure specified in paragraph (d)(8)(ii)(A) of this section.

(C) Beginning 2014, only the measure specified in paragraph (d)(8)(ii)(B)(1) of this section.

(iii) * * *

(B) For 2013, either of the following:

(1) The exclusion specified in paragraph (d)(8)(iii)(A) of this section.

(2) The exclusion for an EP who--

(i) Sees no patients 3 years or older is excluded from recording blood pressure;

(ii) Believes that all three vital signs of height/length, weight, and blood pressure have no relevance to their scope of practice is excluded from recording them;

(iii) Believes that height/length and weight are relevant to their scope of practice, but blood pressure is not, is excluded from recording blood pressure; or

(iv) Believes that blood pressure is relevant to their scope of practice, but height/length and weight are not, is excluded from recording height/length and weight.

(C) Beginning 2014, only the exclusion specified in paragraph (d)(8)(iii)(B)(2) of this section.

* * * * *

(10)(i) * * *

(B) Beginning 2013, this objective is reflected in the definition of a meaningful EHR user in §495.4 and is no longer listed as an objective in this paragraph (d).

(ii) * * *

(B) Beginning 2013, this measure is reflected in the definition of a meaningful EHR user in §495.4 and no longer listed as a measure in this paragraph (d).

* * * * *

(12)(i) * * *

(B) Beginning 2014, 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.

(ii) * * *

(B) Beginning 2014, subject to paragraph (c) of this section, more than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely (available to the patient 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.

(iii) * * *

(B) Beginning 2014, any EP who neither orders nor creates any of the information listed for inclusion as part of this measure.

* * * * *

(14)(i) * * *

(B) Beginning 2013, this objective is no longer required as part of the core set.

(ii) * * *

(B) Beginning 2013, this measure is no longer required as part of the core set.

* * * * *

(e) * * * Beginning 2014, an EP must meet five of the following objectives and associated measures, one of which must be either paragraph (e)(9) or (10) of this section unless the EP has an exclusion from five or more objectives in this paragraph (e), in which case the EP must meet all remaining objectives and associated measures in paragraph (e) of this section.

* * * * *

(5)(i) * * *

(B) Beginning 2014, this objective is no longer included in the menu set.

(ii) * * *

(B) Beginning 2014, this measure is no longer included in the menu set.

* * * * *

(9)(i) * * *

(B) Beginning 2013, capability to submit electronic data to immunization registries or immunization information systems and actual submission except where prohibited and according to applicable law and practice.

* * * * *

(10)(i) * * *

(B) Beginning 2013, capability to submit electronic syndromic surveillance data to public health agencies and actual submission except where prohibited and according to applicable law and practice.

* * * * *

(f) * * *

(1) * * *

(ii) * * *

(B) Subject to paragraph (c) of this section, 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, or the measure specified in paragraph (f)(1)(ii)(A) of this section.

* * * * *

(7) * * *

(i) * * *

(E) * * *

(2) For 2013, plot and display growth charts for patients 0-20 years, including body mass index, or paragraph (f)(7)(i)(E)(1) of this section.

(3) Beginning 2014, plot and display growth charts for patients 0-20 years, including body mass index.

(ii) * * *

(B) For 2013-- (1) Subject to paragraph (c) of this section, more than 50 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 have blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data; or

(2) The measure specified in paragraph (f)(7)(ii)(A) of this section.

(C) Beginning 2014, only the measure specified in paragraph (f)(7)(ii)(B)(1) of this section.

* * * * *

(9) * * *

(i) * * *

(B) Beginning 2013, this objective is reflected in the definition of a meaningful EHR user in §495.4 and no longer listed as an objective in this paragraph (f).

(ii) * * *

(B) Beginning 2013, this measure is reflected in the definition of a meaningful EHR user in §495.4 and no longer listed as a measure in this paragraph (f).

* * * * *

(11) * * *

(i) * * *

(B) Beginning 2014, this objective is no longer required as part of the core set.

(ii) * * *

(B) Beginning 2014, this measure is no longer required as part of the core set.

(12) * * *

(i) * * *

(B) Beginning 2014, provide patients the ability to view online, download, and transmit information about a hospital admission.

(ii) * * *

(B) Beginning 2014, subject to paragraph (c) of this section, 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.

(iii) * * *

(B) Beginning 2014, this exclusion is no longer available.

* * * * *

(13) * * *

(i) * * *

(B) Beginning 2013, this objective is no longer required as part of the core set.

(ii) * * *

(B) Beginning 2013, this measure is no longer required as part of the core set.

* * * * *

(g) * * * Beginning 2014, eligible hospitals or CAHs must meet five of the following objectives and associated measures, one which must be specified in paragraph (g)(8), (9), or (10) of this section:

* * * * *

(8)(i) * * *

(B) Beginning 2013, Capability to submit electronic data to immunization registries or immunization information systems and actual submission except where prohibited and according to applicable law and practice.

(9)(i) * * *

(B) Beginning 2013, capability to submit electronic data on reportable (as required by State or local law) lab results to public health agencies and actual submission except where prohibited according to applicable law and practice.

(10)(i) * * *

(B) Beginning 2013, capability to submit electronic syndromic surveillance data to public health agencies and actual submission except where prohibited and according to applicable law and practice.

* * * * *

(h) Stage 2 criteria for EPs. (1) General rule regarding Stage 2 criteria for meaningful use for EPs. Except as specified in paragraph (h)(2) of this section, EPs must meet all objectives and associated measures of the Stage 2 criteria specified in paragraph (j) of this section and 3 objectives of the EP's choice from paragraph (k) of this section to meet the definition of a

meaningful EHR user.

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

(A) Must ensure that the objective in paragraph (j) or (k) of this section includes an option for the EP to attest that the objective is not applicable.

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

(C) Attests.

(ii)(A) An exclusion will reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply in paragraph (j) of this section. For example, an EP that has an exclusion from one of the objectives in paragraph (j) of this section must meet 16 objectives from such paragraph to meet the definition of a meaningful EHR user.

(B) An exclusion does not reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply in paragraph (k) of this section unless four or more exclusions apply. For example, an EP that has an exclusion for one of the objectives in paragraph (k) of this section must meet three of the five nonexcluded objectives from such paragraph to meet the definition of a meaningful EHR user. If an EP has an exclusion for four of the objectives in paragraph (k) of this section, then he or she must meet the remaining two nonexcluded objectives from such paragraph to meet the definition of a meaningful EHR user.

(i) Stage 2 criteria for eligible hospitals and CAHs. (1) General rule regarding Stage 2 criteria for meaningful use for eligible hospitals or CAHs. Except as specified in paragraph (i)(2) of this section, eligible hospitals and CAHs must meet all objectives and associated measures of the Stage 2 criteria specified in paragraph (l) of this section and three objectives of

the eligible hospital's or CAH's choice from paragraph (m) of this section to meet the definition of a meaningful EHR user.

(2) Exclusions for nonapplicable objectives. (i) An eligible hospital or CAH may exclude a particular objective that includes an option for exclusion contained in paragraphs (l) or (m) of this section, if the hospital meets all of the following requirements:

(A) The hospital meets the criteria in the applicable objective that would permit an exclusion.

(B) The hospital so attests.

(ii)(A) An exclusion will reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply in paragraph (l) of this section. For example, an eligible hospital that has an exclusion from 1 of the objectives in paragraph (l) of this section must meet 15 objectives from such paragraph to meet the definition of a meaningful EHR user.

(B) An exclusion does not reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply in paragraph (m) of this section. For example, an eligible hospital that has an exclusion for one of the objectives in paragraph (m) of this section must meet three of the five nonexcluded objectives from such paragraph to meet the definition of a meaningful EHR user.

(j) Stage 2 core criteria for EPs. An EP must satisfy the following objectives and associated measures, except those objectives and associated measures for which an EP qualifies for an exclusion under paragraph (h)(2) of this section specified in this paragraph (j).

(1)(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) Measures. Subject to paragraph (c) of this section--

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

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

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

(iii) Exclusions in accordance with paragraph (h)(2) of this section. (A) For the measure specified in paragraph (j)(1)(ii)(A) of this section, any EP who writes fewer than 100 medication orders during the EHR reporting period.

(B) For the measure specified in paragraph (j)(1)(ii)(B) of this section, any EP who writes fewer than 100 laboratory orders during the EHR reporting period.

(C) For the measure specified in paragraph (j)(1)(ii)(C), any EP who writes fewer than 100 radiology orders during the EHR reporting period.

(2)(i) Objective. Generate and transmit permissible prescriptions electronically (eRx).

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

(iii) Exclusion in accordance with paragraph (h)(2) of this section. Any EP who--

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

(B) 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.

(3)(i) Objective. Record all of the following demographics:

(A) Preferred language.

(B) Sex.

(C) Race.

(D) Ethnicity.

(E) Date of birth.

(ii) Measure. More than 80 percent of all unique patients seen by the EP during the EHR reporting period have demographics recorded as structured data.

(4)(i) Objective. Record and chart changes in the following vital signs:

(A) Height/Length.

(B) Weight.

(C) Blood pressure (ages 3 and over).

(D) Calculate and display body mass index (BMI).

(E) Plot and display growth charts for patients 0 - 20 years, including body mass index.

(ii) Measure. Subject to paragraph (c) of this section, more than 80 percent of all unique patients seen by the EP during the EHR reporting period have blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data.

(iii) Exclusion in accordance with paragraph (h)(2) of this section. Any EP who--

(A) Sees no patients 3 years or older is excluded from recording blood pressure;

(B) Believes that all three vital signs of height/length, weight, and blood pressure have no relevance to their scope of practice is excluded from recording them;

(C) Believes that height/length and weight are relevant to their scope of practice, but blood pressure is not, is excluded from recording blood pressure; or

(D) Believes that blood pressure is relevant to their scope of practice, but height/length and weight are not, is excluded from recording height/length and weight.

(5)(i) Objective. Record smoking status for patients 13 years old or older.

(ii) Measure. Subject to paragraph (c) of this section, more than 80 percent of all unique patients 13 years old or older seen by the EP during the EHR reporting period have smoking status recorded as structured data.

(iii) Exclusion in accordance with paragraph (h)(2) of this section. Any EP who sees no patients 13 years old or older.

(6)(i) Objective. Use clinical decision support to improve performance on high priority health conditions.

(ii) Measures. (A) 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

(B) The EP has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

(iii) Exclusion in accordance with paragraph (h)(2) of this section for paragraph (j)(6)(ii)(B) of this section. An EP who writes fewer than 100 medication orders during the EHR reporting period.

(7)(i) Objective. Incorporate clinical lab test results into Certified EHR Technology as structured data.

(ii) Measure. Subject to paragraph (c) of this section, more than 55 percent of all clinical

lab tests results ordered by the EP during the EHR reporting period whose results are either in a positive/negative affirmation or numerical format are incorporated in Certified EHR Technology as structured data.

(iii) Exclusion in accordance with paragraph (h)(2) of this section. Any EP who orders no lab tests whose results are either in a positive/negative affirmation or numerical format during the EHR reporting period.

(8)(i) Objective. Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach.

(ii) Measure. Generate at least one report listing patients of the EP with a specific condition.

(9)(i) Objective. Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care and send these patients the reminder, per patient preference.

(ii) Measure. Subject to paragraph (c) of this section, more than 10 percent of all unique patients who have had two or more office visits with the EP within the 24 months before the beginning of the EHR reporting period were sent a reminder, per patient preference when available.

(iii) Exclusion in accordance with paragraph (h)(2) of this section. Any EP who has had no office visits in the 24 months before the beginning of the EHR reporting period.

(10)(i) 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.

(ii) Measures. (A) More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely (available to the patient 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; and

(B) More than 5 percent of all unique patients seen by the EP during the EHR reporting period (or their authorized representatives) view, download or transmit to a third party their health information.

(iii) Exclusion in accordance with paragraph (h)(2) of this section. Any EP who--

(A) Neither orders nor creates any of the information listed for inclusion as part of the measures in paragraphs (j)(10)(ii)(A) and (B) of this section, except for "Patient name" and "Provider's name and office contact information," is excluded from both paragraphs (j)(10)(ii)(A) and (B) of this section; 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 3Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period is excluded from paragraph (j)(10)(ii)(B) of this section.

(11)(i) Objective. Provide clinical summaries for patients for each office visit.

(ii) Measure. Subject to paragraph (c) of this section, clinical summaries provided to patients or patient-authorized representatives within 1 business day for more than 50 percent of office visits.

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

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

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

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

(13)(i) Objective. 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.

(ii) Measure. Subject to paragraph (c) 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.

(iii) Exclusion in accordance with paragraph (h)(2) of this section. Any EP who was not the recipient of any transitions of care during the EHR reporting period.

(14)(i) Objective. 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.

(ii) Measures. (A) Subject to paragraph (c) of this section, the EP that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50 percent of transitions of care and referrals;

(B) Subject to paragraph (c) of this section, the EP that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 10 percent of such transitions and referrals either--

(1) Electronically transmitted using Certified EHR Technology to a recipient; or

(2) Where the recipient receives the summary of care record via exchange facilitated by

an organization that is a NwHIN Exchange participant or in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network, and

(C) Subject to paragraph (c) of this section an EP must satisfy one of the following:

(1) Conducts one or more successful electronic exchanges of a summary of care record meeting the measure specified in paragraph (j)(14)(ii)(B) of this section with a recipient using technology to receive the summary of care record that was designed by a different EHR developer than the sender's EHR technology certified at 45 CFR 107.314(b)(2); or

(2) Conducts one or more successful tests with the CMS designated test EHR during the EHR reporting period.

(iii) Exclusion in accordance with paragraph (h)(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.

(15)(i) Objective. Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.

(ii) Measure. Successful ongoing submission of electronic immunization data from Certified EHR Technology to an immunization registry or immunization information system for the entire EHR reporting period.

(iii) Exclusion in accordance with paragraph (h)(2) of this section. Any EP that meets one or more of the following criteria:

(A) Does not administer any of the 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.

(B) Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required for Certified EHR Technology at the start of his or her EHR reporting period.

(C) Operates in a jurisdiction where no immunization registry or immunization information system provides information timely on capability to receive immunization data.

(D) Operates in a jurisdiction for which no immunization registry or immunization information system that is capable of accepting the specific standards required by Certified EHR Technology at the start of his or her EHR reporting period can enroll additional EPs.

(16)(i) Objective. Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

(ii) Measure. Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the encryption/security of data stored in Certified EHR Technology in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the EP's risk management process.

(17)(i) Objective. Use secure electronic messaging to communicate with patients on relevant health information.

(ii) Measure. A secure message was sent using the electronic messaging function of Certified EHR Technology by more than 5 percent of unique patients (or their authorized representatives) seen by the EP during the EHR reporting period.

(iii) Exclusion in accordance with paragraph (h)(2) of this section. Any EP who meets one or more of the following criteria:

(A) Has no office visits during the EHR reporting period.

(B) 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 3Mbps broadband availability according to the latest information available from the FCC on the first day of their EHR reporting period.

(k) Stage 2 menu set criteria for EPs. An EP must meet 3 of the following objectives and associated measures, unless the EP has an exclusion from 4 or more objectives in this paragraph (k) of this section, in which case the EP must meet all remaining objectives and associated measures.

(1)(i) Objective. Imaging results consisting of the image itself and any explanation or other accompanying information are accessible through Certified EHR Technology.

(ii) Measure. Subject to paragraph (c) of this section, more than 10 percent of all tests whose result is one or more images ordered by the EP during the EHR reporting period are accessible through Certified EHR Technology.

(iii) Exclusion in accordance with paragraph (h)(2) of this section. Any EP who meets one or more of the following criteria.

(A) Orders less than 100 tests whose result is an image during the EHR reporting period.

(B) Has no access to electronic imaging results at the start of the EHR reporting period.

(2)(i) Objective. Record patient family health history as structured data.

(ii) Measure. More than 20 percent of all unique patients seen by the EP during the EHR reporting period have a structured data entry for one or more first-degree relatives.

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

(3)(i) Objective. Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice.

(ii) Measure. Successful ongoing submission of electronic syndromic surveillance data from Certified EHR Technology to a public health agency for the entire EHR reporting period.

(iii) Exclusion in accordance with paragraph (h)(2) of this section. Any EP that meets one or more of the following criteria:

(A) Is not in a category of providers who collect ambulatory syndromic surveillance information on their patients during the EHR reporting period.

(B) Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required for Certified EHR Technology at the start of their EHR reporting period.

(C) Operates in a jurisdiction where no public health agency provides information timely on capability to receive syndromic surveillance data.

(D) Operates in a jurisdiction for which no public health agency that is capable of accepting the specific standards required by Certified EHR Technology at the start of their EHR reporting period can enroll additional EPs.

(4)(i) Objective. Capability to identify and report cancer cases to a public health central cancer registry, except where prohibited, and in accordance with applicable law and practice.

(ii) Measure. Successful ongoing submission of cancer case information from Certified EHR Technology to a public health central cancer registry for the entire EHR reporting period.

(iii) Exclusion in accordance with paragraph (h)(2) of this section. Any EP who meets one or more of the following--

(A) Does not diagnose or directly treat cancer.

(B) Operates in a jurisdiction for which no public health agency is capable of receiving electronic cancer case information in the specific standards required for Certified EHR Technology at the start of their EHR reporting period.

(C) Operates in a jurisdiction where no public health agency provides information timely on capability to receive electronic cancer case information.

(D) Operates in a jurisdiction for which no public health agency that is capable of receiving electronic cancer case information in the specific standards required for Certified EHR Technology at the beginning of their EHR reporting period can enroll additional EPs.

(5)(i) Objective. Capability to identify and report specific cases to a specialized registry (other than a cancer registry), except where prohibited, and in accordance with applicable law and practice.

(ii) Measure. Successful ongoing submission of specific case information from Certified EHR Technology to a specialized registry for the entire EHR reporting period.

(iii) Exclusion in accordance with paragraph (h)(2) of this section. Any EP who meets one or more of the following criteria:

(A) Does not diagnose or directly treat any disease associated with a specialized registry sponsored by a national specialty society for which the EP is eligible, or the public health agencies in their jurisdiction;

(B) Operates in a jurisdiction for which no specialized registry sponsored by a public health agency or by a national specialty society for which the EP is eligible is capable of receiving electronic specific case information in the specific standards required by Certified EHR Technology at the beginning of their EHR reporting period;

(C) Operates in a jurisdiction where no public health agency or national specialty society for which the EP is eligible provides information timely on capability to receive information into their specialized registries; or

(D) Operates in a jurisdiction for which no specialized registry sponsored by a public health agency or by a national specialty society for which the EP is eligible that is capable of receiving electronic specific case information in the specific standards required by Certified EHR Technology at the beginning of his or her EHR reporting period can enroll additional EPs.

(6)(i) Objective. Record electronic notes in patient records.

(ii) Measure. Enter at least one electronic progress note created, edited, and signed by an EP for more than 30 percent of unique patients with at least one office visit during the EHR reporting period. The text of the electronic note must be text-searchable and may contain drawings and other content.

(l) Stage 2 core criteria for eligible hospitals or CAHs. An eligible hospital or CAH must meet the following objectives and associated measures except those objectives and associated measures for which an eligible hospital or CAH qualifies for an exclusion under paragraph (i)(2) of this section.

(1)(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) Measures. Subject to paragraph (c) of this section, more than--

(A) Sixty 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,

(B) Thirty 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

(C) Thirty 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.

(2)(i) Objective. Record all of the following demographics:

(A) Preferred language.

(B) Sex.

(C) Race.

(D) Ethnicity.

(E) Date of birth.

(F) Date and preliminary cause of death in the event of mortality in the eligible hospital or CAH.

(ii) Measure. More than 80 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 have demographics recorded as structured data.

(3)(i) Objective. Record and chart changes in the following vital signs:

(A) Height/Length.

(B) Weight.

(C) Blood pressure (ages 3 and over).

(D) Calculate and display body mass index (BMI).

(E) Plot and display growth charts for patients 0 - 20 years, including body mass index.

(ii) Measure: Subject to paragraph (c) of this section, more than 80 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 have blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data.

(4)(i) Objective. Record smoking status for patients 13 years old or older.

(ii) Measure. Subject to paragraph (c) of this section, more than 80 percent of all unique patients 13 years old or older admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have smoking status recorded as structured data.

(iii) Exclusion in accordance with paragraph (i)(2) of this section. Any eligible hospital or CAH that admits no patients 13 years old or older to their inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

(5)(i) Objective. Use clinical decision support to improve performance on high priority health conditions.

(ii) Measures. (A) 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

(B) 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.

(6)(i) Objective. Incorporate clinical lab test results into Certified EHR Technology as structured data.

(ii) Measure. More than 55 percent of all clinical lab tests results ordered by authorized providers of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period whose results are either in a positive/negative affirmation or numerical format are incorporated in Certified EHR Technology as structured data.

(7)(i) Objective. Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research or outreach.

(ii) Measure. Generate at least one report listing patients of the eligible hospital or CAH with a specific condition.

(8)(i) Objective. Provide patients the ability to view online, download, and transmit information about a hospital admission.

(ii) Measures. (A) 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; and

(B) More than 5 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH (or their authorized representative) view, download or transmit to a third party their information during the EHR reporting period.

(iii) Exclusion in accordance with paragraph (i)(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 3Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period is excluded from paragraph (l)(8)(ii)(B) of this section.

(9)(i) Objective. Use clinically relevant information from Certified EHR Technology to

identify patient-specific education resources and provide those resources to the patient.

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

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

(ii) Measure. Subject to paragraph (c) 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).

(11)(i) Objective. The eligible hospital or CAH that 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.

(ii) Measures. (A) Subject to paragraph (c) in this section, the eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50 percent of transitions of care and referrals,

(B) Subject to paragraph (c) in this section, the eligible hospital or CAH that transitions their patient to another setting of care or provider of care provides a summary of care record for more than 10 percent of such transitions and referrals either--

(1) Electronically transmitted using Certified EHR Technology to a recipient; or

(2) Where the recipient receives the summary of care record via exchange facilitated by an organization that is a NwHIN Exchange participant or in a manner that is consistent with the

governance mechanism ONC establishes for the nationwide health information network; and

(C) Subject to paragraph (c) of this section an eligible hospital or CAH must satisfy one of the following:

(1) Conducts one or more successful electronic exchanges of a summary of care record meeting the measure specified in paragraph (l)(11)(ii)(B) of this section with a recipient using technology to receive the summary of care record that was designed by a different EHR developer than the sender's EHR technology certified at 45 CFR 107.314(b)(2); or

(2) Conducts one or more successful tests with the CMS designated test EHR during the EHR reporting period.

(12)(i) Objective. Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.

(ii) Measure. Successful ongoing submission of electronic immunization data from Certified EHR Technology to an immunization registry or immunization information system for the entire EHR reporting period.

(iii) Exclusion in accordance with paragraph (i)(2) of this section. Any eligible hospital or CAH that meets one or more of the following criteria:

(A) The eligible hospital or CAH does not administer any of the 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.

(B) The eligible hospital or CAH operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required for Certified EHR Technology at the start of their EHR reporting period.

(C) The eligible hospital or CAH operates in a jurisdiction where no immunization registry or immunization information system provides information timely on capability to receive immunization data.

(D) Operates in a jurisdiction for which no immunization registry or immunization information system that is capable of accepting the specific standards required by Certified EHR Technology at the start of their EHR reporting period can enroll additional eligible hospitals or CAHs.

(13)(i) Objective. Capability to submit electronic reportable laboratory results to public health agencies, where except where prohibited, and in accordance with applicable law and practice.

(ii) Measure. Successful ongoing submission of electronic reportable laboratory results from Certified EHR Technology to a public health agency for the entire EHR reporting period.

(iii) Exclusion in accordance with paragraph (i)(2) of this section. Any eligible hospital or CAH that meets one or more of the following criteria:

(A) Operates in a jurisdiction for which no public health agency is capable of receiving electronic reportable laboratory results in the specific standards required for Certified EHR Technology at the start of their EHR reporting period.

(B) Operates in a jurisdiction for which no public health agency provides information timely on capability to receive electronic reportable laboratory results.

(C) Operates in a jurisdiction for which no public health agency that is capable of accepting the specific standards required by Certified EHR Technology at the start of their EHR reporting period can enroll additional eligible hospitals or CAHs.

(14)(i) Objective. Capability to submit electronic syndromic surveillance data to public

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

(ii) Measure. Successful ongoing submission of electronic syndromic surveillance data from Certified EHR Technology to a public health agency for the entire EHR reporting period.

(iii) Exclusion in accordance with paragraph (i)(2) of this section. Any eligible hospital or CAH that meets one or more of the following criteria:

(A) Does not have an emergency or urgent care department.

(B) Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required for Certified EHR Technology at the start of their EHR reporting period or can enroll additional eligible hospitals or CAHs.

(C) Operates in a jurisdiction for which no public health agency provides information timely on capability to receive syndromic surveillance data.

(D) Operates in a jurisdiction for which no public health agency that is capable of accepting the specific standards required by Certified EHR Technology at the start of their EHR reporting period can enroll additional eligible hospitals or CAHs.

(15)(i) Objective. Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

(ii) Measure. Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the encryption/security of data stored in Certified EHR Technology in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the eligible hospital's or CAH's risk management process.

(16)(i) Objective. Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR).

(ii) Measure. Subject to paragraph (c) of this section, more than 10 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 for which all doses are tracked using eMAR.

(iii) Exclusion in accordance with paragraph (i)(2) of this section. Any eligible hospital or CAH with an average daily inpatient census of fewer than 10 patients.

(m) Stage 2 menu set criteria for eligible hospitals or CAHs. An eligible hospital or CAH must meet the measure criteria for three of the following objectives and associated measures.

(1)(i) Objective. Record whether a patient 65 years old or older has an advance directive.

(ii) Measure. Subject to paragraph (c) of this section, more than 50 percent of all unique patients 65 years old or older admitted to the eligible hospital's or CAH's inpatient department (POS 21) during the EHR reporting period have an indication of an advance directive status recorded as structured data.

(iii) Exclusion in accordance with paragraph (i)(2) of this section. Any eligible hospital or CAH that admits no patients age 65 years old or older during the EHR reporting period.

(2)(i) Objective. Imaging results consisting of the image itself and any explanation or other accompanying information are accessible through Certified EHR Technology.

(ii) Measure. Subject to paragraph (c) of this section, more than 10 percent of all tests

whose result is an image ordered by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period are accessible through Certified EHR Technology.

(3)(i) Objective. Record patient family health history as structured data.

(ii) Measure. More than 20 percent of all unique patients admitted to the eligible hospital or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have a structured data entry for one or more first-degree relatives.

(4)(i) Objective. Generate and transmit permissible discharge prescriptions electronically (eRx).

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

(iii) Exclusion in accordance with paragraph (i)(2) 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 its EHR reporting period.

(5)(i) Objective. Record electronic notes in patient records.

(ii) Measure: Enter at least one electronic progress note created, edited and signed by an authorized provider of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) for more than 30 percent of unique patients admitted to the eligible hospital or CAH's inpatient or emergency department during the EHR reporting period. The text of the electronic note must be text-searchable and may contain drawings and other content.

(6)(i) Objective. Provide structured electronic lab results to ambulatory providers.

(ii) Measure. Hospital labs send structured electronic clinical lab results to the ordering provider for more than 20 percent of electronic lab orders received.

9. Section 495.8 is amended as follows:

A. Revising paragraph (a)(2)(i)(B) and (a)(2)(ii).

B. Revising paragraphs (b)(2)(i)(B) and (b)(2)(ii).

§495.8 Demonstration of meaningful use criteria.

(a) * * *

(2) * * *

(i) * * *

(B) Satisfied the required objectives and associated measures under §495.6 for the EP's stage of meaningful use.

* * * * *

(ii) Reporting clinical quality information. Successfully report the clinical quality measures selected by CMS to CMS or the States, as applicable, in the form and manner specified by CMS or the States, as applicable.

* * * * *

(b) * * *

(2) * * *

(i) * * *

(B) Satisfied the required objectives and associated measures under §495.6 for the eligible hospital or CAH's stage of meaningful use.

* * * * *

(ii) Reporting clinical quality information. Successfully report the clinical quality measures selected by CMS to CMS or the States, as applicable, in the form and manner specified by CMS or the States, as applicable.

* * * * *

§495.10 [Amended]

10. In §495.10, paragraph (a)(3) is amended by removing the phrase "Business address and" and adding in its place the phrase "Business address, business email address, and".

11. Section 495.100 is amended by revising the definitions of "Qualifying CAH," "Qualifying eligible professional (qualifying EP)," and "Qualifying hospital" to read as follows:

§495.100 Definitions.

* * * * *

Qualifying CAH means a CAH that is a meaningful EHR user for the EHR reporting period applicable to a payment year or payment adjustment year in which a cost reporting period begins.

Qualifying eligible professional (qualifying EP) means an EP who is a meaningful EHR user for the EHR reporting period applicable to a payment or payment adjustment year and who is not a hospital-based EP, as determined for that payment or payment adjustment year.

Qualifying hospital means an eligible hospital that is a meaningful EHR user for the EHR reporting period applicable to a payment or payment adjustment year.

10. Section 495.102 is amended as follows:

A. Revising paragraphs (c), (d)(1), and (d)(2)(iii).

B. Adding paragraph (d)(2)(iv).

C. Revising paragraph (d)(3).

D. Adding paragraphs (d)(4) and (5).

The revisions and additions read as follows:

§495.102 Incentive payments to EPs.

* * * * *

(c) Increase in incentive payment limit for EPs who predominantly furnish services in a geographic HPSA. In the case of a qualifying EP who furnishes more than 50 percent of his or her covered professional services during the payment year in a geographic HPSA that is designated as of December 31 of the prior year, the incentive payment limit determined under paragraph (b) of this section is to be increased by 10 percent.

(d) Payment adjustment effective in CY 2015 and subsequent years for nonqualifying EPs.

(1)(i) Subject to paragraphs (d)(3) and (4) of this section, beginning 2015, for covered professional services furnished by an EP who is not hospital-based, and who is not a qualifying EP by virtue of not being a meaningful EHR user (for the EHR reporting period applicable to the payment adjustment year), the payment amount for such services is equal to the product of the applicable percent specified in paragraph (d)(2) of this section and the Medicare physician fee schedule amount for such services.

(2) * * *

(iii) For 2017, 97 percent.

(iv) For 2018 and subsequent years, 97 percent, except as provided in paragraph (d)(3) of this section.

(3) Decrease in applicable percent in certain circumstances. If, beginning CY 2018 and for each subsequent year, the Secretary finds that the proportion of EPs who are meaningful EHR users is less than 75 percent, the applicable percent must be decreased by 1 percentage point for

EPs from the applicable percent in the preceding year, but in no case will the applicable percent be less than 95 percent.

(4) Exceptions. The Secretary may, on a case-by-case basis, exempt an EP from the application of the payment adjustment under paragraph (d)(1) of this section if the Secretary determines that compliance with the requirement for being a meaningful EHR user would result in a significant hardship for the EP. To be considered for an exception, an EP must submit, in the manner specified by CMS, an application demonstrating that it meets one or more of the criteria in this paragraph (d)(4) unless otherwise specified in the criteria. The Secretary's determination to grant an EP an exemption may be renewed on an annual basis, provided that in no case may an EP be granted an exemption for more than 5 years.

(i) During any 90-day period from the beginning of the year that is 2 years before the payment adjustment year to July 1 of the year preceding the payment adjustment year, the EP was located in an area without sufficient Internet access to comply with the meaningful use objectives requiring internet connectivity, and faced insurmountable barriers to obtaining such internet connectivity. Applications requesting this exception must be submitted no later than July 1 of the year before the applicable payment adjustment year.

(ii) The EP has been practicing for less than 2 years.

(iii)(A) During the calendar year that is 2 calendar years before the payment adjustment year, the EP that has previously demonstrated meaningful use faces extreme and uncontrollable circumstances that prevent it from becoming a meaningful EHR user. Applications requesting this exception must be submitted no later than July 1 of the year before the applicable payment adjustment year.

(B) During the calendar year preceding the payment adjustment year, the EP that has not

previously demonstrated meaningful use faces extreme and uncontrollable circumstances that prevent it from becoming a meaningful EHR user. Applications requesting this exception must be submitted by July 1 of the year before the applicable payment adjustment year.

(iv) An EP may request an exception through an application submitted by July 1 of the year before the applicable payment adjustment year due to difficulty in meeting meaningful use based on any one of the following during the period that begins 2 calendar years before the payment adjustment year through the application deadline:

(A) The EP practices at multiple locations and can demonstrate inability to control the availability of Certified EHR Technology at one such practice location or a combination of practice locations , and where the location or locations constitute more than 50 percent of their patient encounters.

(B) The EP can demonstrate difficulty in meeting meaningful use on the basis of lack of face-to-face or telemedicine interaction with patients and lack of need for follow up with patients.

(C) The EP 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. Such an EP may be deemed to qualify for this exception, subject to the 5-year limit that applies to all exceptions under this paragraph.

(5) Payment adjustments not applicable to hospital-based EPs. No payment adjustment under paragraphs (d)(1) through (3) of this section may be made in the case of a hospital-based eligible professional, as defined in §495.4.

§495.106 [Amended]

12. In §495.106, paragraph (e) is amended by removing the phrase "for a payment year"

and adding the phrase "for a payment adjustment year" in its place.

13. Section 495.200 is amended by--

A. Adding definitions for "MA payment adjustment year," and "Potentially qualifying MA EPs and potentially qualifying MA-affiliated eligible hospitals" in alphabetical order.

B. Revising paragraph (5) of the definition of "Qualifying MA EP".

The additions and revision read as follows:

§495.200 Definitions.

* * * * *

MA payment adjustment year means--(1) For qualifying MA organizations that receive an MA EHR incentive payment for at least 1 payment year, calendar years beginning with CY 2015.

(2) For MA-affiliated eligible hospitals, the applicable EHR reporting period for purposes of determining whether the MA organization is subject to a payment adjustment is the federal fiscal year ending in the MA payment adjustment year.

(3) For MA EPs, the applicable EHR reporting period for purposes of determining whether the MA organization is subject to a payment adjustment is the calendar year concurrent with the payment adjustment year.

* * * * *

Potentially qualifying MA EPs and potentially qualifying MA-affiliated eligible hospitals are defined for purposes of this subpart in §495.202(a)(4).

* * * * *

Qualifying MA EP * * *

(5) Is not a "hospital-based EP" (as defined in §495.4 of this part) and in determining whether 90 percent or more of his or her covered professional services were furnished in a hospital setting, only covered professional services furnished to MA plan enrollees of the qualifying MA organization, in lieu of FFS patients, will be considered.

* * * * *

14. Section 495.202 is amended as follows:

A. Revising paragraph (b)(1).

B. In paragraph (b)(2) introductory text, removing the cross-reference "(b)(3)" and adding the cross-reference "(4)" in its place.

C. Revising paragraph (b)(2)(iii).

D. Redesignating paragraphs (b)(3) and (4) as paragraphs (b)(4) and (5).

E. Adding a new paragraph (b)(3).

F. Revising newly redesignated paragraph (b)(4).

G. Revising newly redesignated paragraphs (b)(5)(i) and (ii).

The addition and revisions read as follows:

§495.202 Identification of qualifying MA organizations, MA-EPs and MA-affiliated eligible hospitals.

* * * * *

(b) * * *

(1) A qualifying MA organization, as part of its initial bid starting with plan year 2012, must make a preliminary identification of MA EPs and MA-affiliated eligible hospitals that the MA organization believes will be qualifying MA EPs and MA-affiliated eligible hospitals for which the organization is seeking incentive payments for the current plan year.

(2) * * *

(iii) NPI or CCN.

* * * * *

(3) When reporting under either paragraph (b)(1) or (4) of this section for purposes of receiving an incentive payment, a qualifying MA organization must also indicate whether more than 50 percent of the covered Medicare professional services being furnished by a qualifying MA EP to MA plan enrollees of the MA organization are being furnished in a designated geographic HPSA (as defined in §495.100 of this part).

(4) Final identification of qualifying and potentially qualifying, as applicable, MA EPs and MA-affiliated eligible hospitals must be made within 2 months of the close of the payment year or the EHR reporting period that applies to the payment adjustment year as defined in §495.200.

(5) * * *

(i) Identify all MA EPs and MA-affiliated eligible hospitals of the MA organization that the MA organization believes will be either qualifying or potentially qualifying;

(ii) Include information specified in paragraph (b)(2)(i) through (iii) of this section for each professional or hospital; and

* * * * *

15. Section 495.204 is amended as follows:

A. Revising the section heading.

B. Revising paragraphs (b)(2) and (b)(4) introductory text, and (b)(4)(i) and (ii).

C. Redesignating paragraph (e) as paragraph (f).

D. Adding new paragraphs (e), (f)(5), and (g).

The revisions and additions read as follows:

§495.204 Incentive payments to qualifying MA organizations for qualifying MA-EPs and qualifying MA-affiliated eligible hospitals.

* * * * *

(b) * * *

(2) The qualifying MA organization must report to CMS within 2 months of the close of the calendar year, the aggregate annual amount of revenue attributable to providing services that would otherwise be covered as professional services under Part B received by each qualifying MA EP for enrollees in MA plans of the MA organization in the payment year.

* * * * *

(4) CMS requires the qualifying MA organization to develop a methodological proposal for estimating the portion of each qualifying MA EP's salary or revenue attributable to providing services that would otherwise be covered as professional services under Part B to MA plan enrollees of the MA organization in the payment year. The methodological proposal--

(i) Must be approved by CMS; and

(ii) May include an additional amount related to overhead, where appropriate, estimated to account for the MA-enrollee related Part B practice costs of the qualifying MA EP.

* * * * *

(e) Potential increase in incentive payment for furnishing services in a geographic HPSA. In the case of a qualifying MA EP who furnishes more than 50 percent of his or her covered professional services to MA plan enrollees of the qualifying MA organization during a payment year in a geographic HPSA, the maximum amounts referred to in paragraph (b)(3) of this section are increased by 10 percent.

(f) * * *

(5) If an MA EP, or entity that employs an MA EP, or in which an MA EP has a partnership interest, MA-affiliated eligible hospital, or other party contracting with the MA organization, fails to comply with an audit request to produce applicable documents or data, CMS recoups all or a portion of the incentive payment, based on the lack of applicable documents or data.

(g) Coordination of payment with FFS or Medicaid EHR incentive programs. (1) If, after payment is made to an MA organization for an MA EP, it is determined that the MA EP is eligible for the full incentive payment under the Medicare FFS EHR Incentive Program or has received a payment under the Medicaid EHR Incentive Program, CMS recoups amounts applicable to the given MA EP from the MA organization's monthly MA payment, or otherwise recoups the applicable amounts.

(2) If, after payment is made to an MA organization for an MA-affiliated eligible hospital, it is determined that the hospital is ineligible for the incentive payment under the MA EHR Incentive Program, or has received a payment under the Medicare FFS EHR Incentive Program, or if it is determined that all or part of the payment should not have been made on behalf of the MA-affiliated eligible hospital, CMS recoups amounts applicable to the given MA-affiliated eligible hospital from the MA organization's monthly MA payment, or otherwise recoups the applicable amounts.

16. Section 495.208 is amended as follows:

A. Redesignating paragraphs (a) through (c) as paragraphs (d) through (f).

B. Adding new paragraphs (a) through (c).

The additions read as follows:

§495.208 Avoiding duplicate payment.

(a) CMS requires a qualifying MA organization that registers MA EPs for the purpose of participating in the MA EHR Incentive Program to notify each of the MA EPs for which it is claiming an incentive payment that the MA organization intends to claim, or has claimed, the MA EP for the current plan year under the MA EHR Incentive Program.

(b) The notice must make clear that the MA EP may still directly receive an EHR incentive payment if the MA EP is entitled to a full incentive payment under the FFS portion of the EHR Incentive Program, or if the MA EP registered to participate under the Medicaid portion of the EHR Incentive Program and is entitled to payment under that program - in both of which cases no payment would be made for the EP under the MA EHR incentive program.

(c) An attestation by the qualifying MA organization that the qualifying MA organization provided notice to its MA EPs in accordance with this section must be required at the time that meaningful use attestations are due with respect to MA EPs for the payment year.

* * * * *

17. Section 495.210 is amended by revising paragraphs (b) and (c) to read as follows:

§495.210 Meaningful EHR user attestation

* * * * *

(b) Qualifying MA organizations are required to attest within 2 months after the close of a calendar year whether each qualifying MA EP is a meaningful EHR user.

(c) Qualifying MA organizations are required to attest within 2 months after close of the FY whether each qualifying MA-affiliated eligible hospital is a meaningful EHR user.

18. Add §495.211 to subpart C to read as follows:

§495.211 Payment adjustments effective for 2015 and subsequent MA payment years with

respect to MA EPs and MA-affiliated eligible hospitals.

(a) In general. Beginning for MA payment adjustment year 2015, payment adjustments set forth in this section are made to prospective payments (issued under section 1853(a)(1)(A) of the Act) of qualifying MA organizations that previously received incentive payments under the MA EHR Incentive Program, if all or a portion of the MA-EPs and MA-affiliated eligible hospitals that would meet the definition of qualifying MA-EPs or qualifying MA-affiliated eligible hospitals (but for their demonstration of meaningful use) are not meaningful EHR users.

(b) Adjustment based on payment adjustment year. The payment adjustment is calculated based on the payment adjustment year.

(c) Separate application of adjustments for MA EPs and MA-affiliated eligible hospitals. The payment adjustments identified in paragraphs (d) and (e) of this section are applied separately. Paragraph (d) of this section applies only to qualifying MA organizations that received payment for any MA payment year for qualifying MA EPs under §495.204. Paragraph (e) of this section applies only to qualifying MA organizations that received payment for any MA payment year for qualifying MA-affiliated eligible hospitals under §495.204.

(d) Payment adjustments effective for 2015 and subsequent years with respect to MA EPs. (1) For payment adjustment year 2015, and subsequent payment adjustment years, if a qualifying MA EP is not a meaningful EHR user during the payment adjustment year, CMS--

(i) Determines a payment adjustment based on data from the payment adjustment year; and

(ii) Collects the payment adjustment owed by adjusting a subsequent year's prospective payment or payments (issued under section 1853(a)(1)(A) of the Act), or by otherwise collecting

the payment adjustment, if, in the year of collection, the MA organization does not have an MA contract with CMS.

(2) Beginning for payment adjustment year 2015, a qualifying MA organization that previously received incentive payments must, for each payment adjustment year, report to CMS the following:

[the total number of potentially qualifying MA EPs**]/[**(the total number of potentially qualifying MA EPs) + (the total number of qualifying MA EPs)**]**.

(3) The monthly prospective payment amount paid under section 1853(a)(1)(A) of the Act for the payment adjustment year is adjusted by the product of--

(i) The percent calculated in accordance with paragraph (d)(2) of this section;

(ii) The Medicare Physician Expenditure Proportion percent, which is CMS's estimate of proportion of expenditures under Parts A and B that are not attributable to Part C that are attributable to expenditures for physicians' services, adjusted for the proportion of expenditures that are provided by EPs that are neither qualifying nor potentially qualifying MA EPs with respect to a qualifying MA organization; and

(iii) The applicable percent identified in paragraph (d)(4) of this section.

(4) Applicable percent. The applicable percent is as follows:

(i) For 2015, 1 percent;

(ii) For 2016, 2 percent;

(iii) For 2017, 3 percent.

(iv) For 2018, 3 percent, except, in the case described in paragraph (d)(4)(vi) of this section, 4 percent.

(v) For 2019 and each subsequent year, 3 percent, except, in the case described in paragraph (d)(4)(vi) of this section, the percent from the prior year plus 1 percent. In no case will the applicable percent be higher than 5 percent.

(vi) Beginning with payment adjustment year 2018, if the percentage in paragraph (d)(2) of this section is more than 25 percent, the applicable percent is increased in accordance with paragraphs (d)(4)(iv) and (v) of this section.

(e) Payment adjustments effective for 2015 and subsequent years with respect to MA-affiliated eligible hospitals. (1)(i) The payment adjustment set forth in this paragraph (e) applies if a qualifying MA organization that previously received an incentive payment (or a potentially qualifying MA-affiliated eligible hospital on behalf of its qualifying MA organization) attests that a qualifying MA-affiliated eligible hospital is not a meaningful EHR user for a payment adjustment year.

(ii) The payment adjustment is calculated by multiplying the qualifying MA organization's monthly prospective payment for the payment adjustment year under section 1853(a)(1)(A) of the Act by the percent set forth in paragraph (e)(2) of this section.

(2) The percent set forth in this paragraph (e) is the product of--

(i) The percentage point reduction to the applicable percentage increase in the market basket index for the relevant Federal fiscal year as a result of §412.64(d)(3) of this chapter;

(ii) The Medicare Hospital Expenditure Proportion percent specified in paragraph (e)(3) of this section; and

(iii) The percent of qualifying and potentially qualifying MA-affiliated eligible hospitals that are not meaningful EHR users. Qualifying MA organizations are required to report to CMS

[the number of potentially qualifying MA-affiliated eligible hospitals**]/[(**the total number of potentially qualifying MA-affiliated eligible hospitals) + (the total number of qualifying MA-affiliated eligible hospitals)**]**.

(3) The Medicare Hospital Expenditure Proportion for a year is the Secretary's estimate of expenditures under Parts A and B that are not attributable to Part C, that are attributable to expenditures for inpatient hospital services, adjusted for the proportion of expenditures that are provided by hospitals that are neither qualifying nor potentially qualifying MA-affiliated eligible hospitals with respect to a qualifying MA organization.

19. Section 495.302 is amended as follows:

A. In the definition of "Adopt, implement or upgrade," by revising paragraph (1).

B. In the definition of "Children's hospital," by revising paragraph (1), redesignating paragraph (2) as paragraph (3), and adding a new paragraph (2).

C. In the definition of "Practices predominantly," by removing the phrase "in the most recent calendar year" and adding the phrase "(within the most recent calendar year or, as an optional State alternative beginning for payment year 2013, within the 12-month period preceding attestation)".

The revisions and addition read as follows:

§495.302 Definitions.

* * * * *

Adopt, implement or upgrade * * *

(1) Acquire, purchase, or secure access to certified EHR technology capable of meeting meaningful use requirements;

* * * * *

Children's hospital * * *

(1) Has a CMS certification number (CCN), (previously known as the Medicare provider number), that has the last 4 digits in the series 3300-3399; or

(2) Does not have a CCN but has been provided an alternative number by CMS for purposes of enrollment in the Medicaid EHR Incentive Program as a children's hospital and;

* * * * *

20. Section 495.304 is amended as follows:

A. In paragraphs (c)(1) and (2), by removing the phrase "individuals receiving Medicaid" and adding the phrase " individuals enrolled in a Medicaid program" in its place.

B. Adding paragraph (f).

The addition reads as follows:

§495.304 Medicaid provider scope and eligibility.

* * * * *

(f) Further patient volume requirements for the Medicaid EP. For payment year 2013 and all subsequent payment years, at least one clinical location used in the calculation of patient volume must have Certified EHR Technology--

(1) During the payment year for which the EP attests to having adopted, implemented or upgraded Certified EHR Technology (for the first payment year); or

(2) During the payment year for which the EP attests it is a meaningful EHR user.

21. Section 495.306 is amended as follows;

A. Revising paragraphs (b), (c)(1)(i), (c)(2)(i), (c)(3)(i), (d)(1)(i)(A), (d)(1)(ii)(A), (d)(2)(i)(A), (d)(2)(ii)(A), and (e)(1) introductory text.

B. In paragraph (e)(1)(i), by removing "; or" and adding a period in its place.

C. Adding paragraph (e)(1)(iii).

D. Revising paragraph (e)(2)(i) introductory text.

E. In paragraph (e)(2)(i)(A), by removing "; or" and adding a period in its place.

F. Adding paragraph (e)(2)(i)(C).

G. Revising paragraph (e)(2)(ii) introductory text.

H. In paragraph (e)(2)(ii)(A), by removing "; or" and adding a period in its place.

I. Adding paragraph (e)(2)(ii)(C).

J. Revising paragraph (e)(3) introductory text.

K. In paragraphs (e)(3)(i) and (ii), by removing the semicolon and adding a period in its place.

L. In paragraph (e)(3)(iii), by removing "; or" and adding a period in its place.

M. Redesignating paragraphs (e)(3)(iii) and (e)(3)(iv) as paragraphs (e)(3)(iv) and (e)(3)(v).

N. Adding a new paragraph (e)(3)(iii).

The revisions and additions read as follows:

§495.306 Establishing patient volume.

* * * * *

(b) State option(s) through SMHP. (1) A State must submit through the SMHP the option or options it has selected for measuring patient volume.

(2)(i) A State must select the method described in either paragraph (c) or paragraph (d) of this section (or both methods).

(ii) Under paragraphs (c)(1)(i), (c)(2)(i), (c)(3)(i), (d)(1)(i), and (d)(2)(i) of this section, States may choose whether to allow eligible providers to calculate total Medicaid or total needy

individual patient encounters in any representative continuous 90-day period in the 12 months preceding the EP or eligible hospital's attestation or based upon a representative, continuous 90-day period in the calendar year preceding the payment year for which the EP or eligible hospital is attesting.

(3) In addition, or as an alternative to the method selected in paragraph (b)(2) of this section, a State may select the method described in paragraph (g) of this section.

(c) * * *

(1) * * *

(i) The total Medicaid patient encounters in any representative, continuous 90-day period in the calendar year preceding the EP's payment year, or in the 12 months before the EP's attestation; by

* * * * *

(2) * * *

(i) The total Medicaid encounters in any representative, continuous 90-day period in the fiscal year preceding the hospitals' payment year or in the 12 months before the hospital's attestation; by

* * * * *

(3) * * *

(i) The total needy individual patient encounters in any representative, continuous 90-day period in the calendar year preceding the EP's payment year, or in the 12 months before the EP's attestation; by

* * * * *

(d) * * *

(1) * * *

(i)(A) The total Medicaid patients assigned to the EP's panel in any representative, continuous 90-day period in either the calendar year preceding the EP's payment year, or the 12 months before the EP's attestation when at least one Medicaid encounter took place with the individual in the 24 months before the beginning of the 90-day period; plus

* * * * *

(ii)(A) The total patients assigned to the provider in that same 90-day period with at least one encounter taking place with the patient during the 24 months before the beginning of the 90-day period; plus

* * * * *

(2) * * *

(i)(A) The total Needy Individual patients assigned to the EP's panel in any representative, continuous 90-day period in the either the calendar year preceding the EP's payment year, or the 12 months before the EP's attestation when at least one Needy Individual encounter took place with the individual in the 24 months before the beginning of the same 90-day period; plus

* * * * *

(ii)(A) The total patients assigned to the provider in that same 90-day period with at least one encounter taking place with the patient during the 24 months before the beginning of the 90-day period, plus

* * * * *

(e) * * *

(1) A Medicaid encounter means services rendered to an individual on any one day

where:

* * * * *

(iii) The individual was enrolled in a Medicaid program (or a Medicaid demonstration project approved under section 1115 of the Act) at the time the billable service was provided.

(2) * * *

(i) A Medicaid encounter means services rendered to an individual per inpatient discharge when any of the following occur:

* * * * *

(C) The individual was enrolled in a Medicaid program (or a Medicaid demonstration project approved under section 1115 of the Act) at the time the billable service was provided.

(ii) A Medicaid encounter means services rendered in an emergency department on any 1 day if any of the following occur:

* * * * *

(C) The individual was enrolled in a Medicaid program (or a Medicaid demonstration project approved under section 1115 of the Act) at the time the billable service was provided.

(3) For purposes of calculating needy individual patient volume, a needy patient encounter means services rendered to an individual on any 1 day if any of the following occur:

* * * * *

(iii) The individual was enrolled in a Medicaid program (or a Medicaid demonstration project approved under section 1115 of the Act) at the time the billable service was provided.

* * * * *

22. Section 495.310 is amended as follows:

A. Removing and reserving paragraphs (a)(1)(ii) and (a)(2)(ii).

B. Adding paragraph (f)(8).

C. Revising paragraph (g)(1)(i)(B) introductory text.

D. In paragraphs (g)(1)(i)(B)(1) through (g)(1)(i)(B)(3), by removing the term "discharge" wherever it appears and adding the term "acute-care inpatient discharge" in its place.

E. In paragraph (g)(1)(i)(C), by removing the term "discharges" and adding the term "acute-care inpatient discharges" in its place.

F. In paragraphs (g)(2)(i)(A) and (B), (g)(2)(ii)(A), and (g)(2)(iii), by removing the phrase "inpatient-bed-days" wherever it appears and adding the phrase "acute care inpatient-bed-days" in its place.

The addition and revision read as follows:

§495.310 Medicaid provider incentive payments.

* * * * *

(f) * * *

(8) The aggregate EHR hospital incentive amount calculated under paragraph (g) of this section is determined by the State from which the eligible hospital receives its first payment year incentive. If a hospital receives incentive payments from other States in subsequent years, total incentive payments received over all payment years of the program can be no greater than the aggregate EHR incentive amount calculated by the initial State.

(g) * * *

(1) * * *

(i) * * *

(B) The discharge-related amount for the most recent continuous 12-month period selected by the State, but ending before the federal fiscal year that serves as the first payment

year. The discharge-related amount is the sum of the following, with acute-care inpatient discharges over the 12-month period and based upon the total acute-care inpatient discharges for the eligible hospital (regardless of any source of payment):

* * * * *

23. Section 495.312 is amended by revising paragraph (c) to read as follows:

§495.312 Process for payments.

* * * * *

(c) State's role. (1) Except as specified in paragraph (c)(2) of this section, the State determines the provider's eligibility for the EHR incentive payment under subparts A and D of this part and approves, processes, and makes timely payments using a process approved by CMS.

(2) At the State's option, CMS conducts the audits and handles any subsequent appeals, of whether eligible hospitals are meaningful EHR users on the States' behalf.

* * * * *

24. Section 495.316 is amended by revising paragraph (d)(2) to read as follows:

§495.316 State monitoring and reporting regarding activities required to receive an incentive payment.

* * * * *

(d) * * *

(2)(i) Subject to §495.332, the State may propose a revised definition for Stage 1 of meaningful use of certified EHR technology, subject to CMS prior approval, but only with respect to the following objectives:

(A) Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research or outreach.

(B) Capability to submit electronic data to immunization registries or immunization information systems and actual submission except where prohibited, and according to applicable law and practice.

(C) Capability to submit electronic data on reportable (as required by State or local law) lab results to public health agencies and actual submission except where prohibited according to applicable law and practice.

(D) Capability to submit electronic syndromic surveillance data to public health agencies and actual submission except where prohibited and according to applicable law and practice.

(ii) Subject to §495.332, the State may propose a revised definition for Stage 2 of meaningful use of certified EHR technology, subject to CMS prior approval, but only with respect to the following objectives:

(A) Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach.

(B) Capability to submit electronic data to immunization registries or immunization information systems, except where prohibited, and in accordance with applicable law and practice.

(C) Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice.

(D) Capability to provide electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice.

(E) Capability to identify and report cancer cases to a public health central cancer registry, except where prohibited, and in accordance with applicable law and practice.

(F) Capability to identify and report specific cases to a specialized registry (other than a cancer registry), except where prohibited, and in accordance with applicable law and practice.

* * * * *

23. Section 495.332 is amended by:

A. Adding paragraph (b)(6).

B. Revising paragraph (c) introductory text.

C. Removing paragraph (d)(9).

D. Adding paragraph (g).

The additions and revisions read as follows:

§495.332 State Medicaid health information technology (HIT) plan requirements.

* * * * *

(b) * * *

(6) For ensuring that at least one clinical location used for the calculation of the EP's patient volume has Certified EHR Technology during the payment year for which the EP is attesting.

(c) Monitoring and validation. Subject to paragraph (g) of this section, for monitoring and validation of information States must include the following:

* * * * *

(g) Optional--signed agreement. At the State's option, the State may include a signed agreement indicating that the State does all of the following:

(1) Designates CMS to conduct all audits and appeals of eligible hospitals' meaningful use attestations.

(2) Is bound by the audit and appeal findings described in paragraph (g)(1) of this section.

(3) Performs any necessary recoupments if audits (and any subsequent appeals) described in paragraph (g)(1) of this section determine that an eligible hospital was not a meaningful EHR user.

(4) Is liable for any FFP granted to the State to pay eligible hospitals that, upon audit (and any subsequent appeal) are determined not to have been meaningful EHR users.

26. Section 495.342 is amended by revising the introductory text to read as follows:

§495.342 Annual HIT IAPD requirements.

Each State is required to submit the HIT IAPD Updates 12 months from the date of the last CMS approved HIT IAPD and must contain the following:

* * * * *

27. Section 495.370 is amended by adding paragraph (d) to read as follows:

§495.370 Appeals process for a Medicaid provider receiving electronic health record incentive payments.

* * * * *

(d) This section does not apply in the case that CMS conducts the audits and handles any subsequent appeals under §495.312(c)(2) of this part.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program) (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare--Hospital Insurance; and Program No. 93.774, Medicare--Supplementary Medical Insurance Program)

Dated: August 21, 2012

_____

Marilyn Tavenner,

Acting Administrator,

Centers for Medicare & Medicaid Services.

Approved: August 21, 2012

_____

Kathleen Sebelius,

Secretary,

Department of Health and Human Services.

BILLING CODE 4120-01-P

[FR Doc. 2012-21050 Filed 08/23/2012 at 2:30 pm; Publication Date: 09/04/2012]