This document is scheduled to be published in the
Federal Register on 03/07/2012 and available online at
http://federalregister.gov/a/2012-04443, and on **FDsys.gov**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, and 495

[CMS-0044-P]

RIN 0938-AQ84

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

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would specify 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 would specify 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 and other program participation requirements. This proposed rule would also revise certain Stage 1 criteria, as well as criteria that apply regardless of Stage, as finalized in the final rule titled Medicare and Medicaid Programs; Electronic Health Record Incentive Program published on July 28, 2010 in the **Federal Register**. The provisions included in the Medicaid section of this proposed rule (which relate to calculations of patient volume and hospital eligibility) would take effect shortly after finalization of this rule, not subject to the proposed 1 year delay for Stage 2 of meaningful use of certified EHR technology.

Changes to Stage 1 of meaningful use would take effect for 2013, but most would be optional until 2014.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on **[**OFR--insert date 60 days after date of publication in the **Federal Register]**.

ADDRESSES: In commenting, please refer to file code CMS-0044-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

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

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

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-0044-P,

P.O. Box 8013,

Baltimore, MD 21244-8013.

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

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

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-0044-P,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

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

a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW.,

Washington, DC 20201

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

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-1066 in advance to schedule your arrival with one of our staff members.

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

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

FOR FURTHER INFORMATION CONTACT:

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

Jessica Kahn, (410) 786-9361, for Medicaid Incentive Program issues.

James Slade, (410) 786-1073, or Matthew Guerand, (410) 786 1450, for Medicare Advantage issues.

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

Douglas Brown, (410) 786-0028, or Maria Durham, (410) 786-6978, for Clinical quality measures issues.

Lawrence Clark, (410) 786-5081, for Administrative appeals process issues.

SUPPLEMENTARY INFORMATION:

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

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

Acronyms

ARRA	American Recovery and Reinvestment Act of 2009
AAC	Average Allowable Cost (of certified EHR technology)
AIU	Adopt, Implement, Upgrade (certified EHR technology)
CAH	Critical Access Hospital
CAHPS	Consumer Assessment of Healthcare Providers and Systems
CCN	CMS Certification Number
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 Physician Order Entry
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
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 certified EHR technology)
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
PFFS	Private Fee-For-Service
PHO	Physician Hospital Organization
PHS	Public Health Service
PHSA	Public Health Service Act
PIHP	Prepaid Inpatient Health Plan
POS	Place of Service
PPO	Preferred Provider Organization
PQRI	Physician Quality Reporting Initiative
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. 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

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)

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. Proposed Clinical Quality Measures for Eligible Professionals

a. Statutory and Other Considerations

b. Clinical Quality Measures Proposed for Eligible Professionals for CY 2013

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

5. Proposed 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. Proposed Clinical Quality Measures for Eligible Hospitals and Critical Access Hospitals

a. Statutory and Other Considerations

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

7. Proposed 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 Certified EHR Technology

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

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. Payment Adjustment Not Applicable To Hospital-Based EPs

3. Incentive Market Basket Adjustment Effective In FY 2015 And Subsequent Years For Eligible Hospitals Who Are Not Meaningful EHR Users

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 to CAHs in FY 2015 and Subsequent FYs

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

a. Permissible Appeals

b. Filing Requirements

c. Preclusion of Administrative and Judicial Review

d. Inchoate Review

e. Informal Review Process Standards

(1) Request for Supporting Documentation

b. Informal Review Decision

3. Final Reconsideration

4. Exhaustion of Administrative Review

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 for Potentially Qualifying MA EPs and Potentially Qualifying MA-affiliated Eligible Hospitals (§495.211).

6. Appeals Process for MA Organizations

F. Proposed 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 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. Collection of Information Requirements

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

IV. Response to Comments

V. Regulatory Impact Analysis

A. Statement of Need

B. Overall Impact

C. Anticipated Effects

D. Accounting Statement

I. Executive Summary and Overview

A. Executive Summary

1. Purpose of Regulatory Action

a. Need for the Regulatory Action

In this proposed rule the Secretary of the Department of Health and Human Services (the Secretary) would specify Stage 2 criteria EPs, eligible hospitals, and CAHs must meet in order to qualify for an incentive payment, as well as introduce changes to the program timeline and detail payment adjustments. These proposed criteria were substantially adopted from the recommendations of the Health IT Policy Committee (HITPC), a Federal Advisory Committee that coordinates industry and provider input regarding the Medicare and Medicaid EHR Incentive Programs, as well as in consideration of current program data for the Medicare and Medicaid EHR Incentive Programs.

b. Legal Authority for the Regulatory Action

The American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111-5) amended Titles XVIII and XIX of the Social Security Act (the Act) to authorize incentive payments to eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs), and Medicare Advantage (MA) organizations to promote the adoption and meaningful use of certified electronic health record (EHR) technology.

Sections 1848(o), 1853(l) and (m), 1886(n), and 1814(l) of the Act provide the statutory basis for the Medicare incentive payments made to meaningful EHR users. These statutory provisions govern EPs, Medicare Advantage (MA) organizations (for certain qualifying EPs and hospitals that meaningfully use certified EHR technology), 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 certified EHR technology 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 statutory basis, 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 criteria, we finalized a separate set of core objectives and menu objectives for both EPs and eligible hospitals and CAHs. EPs

and hospitals must meet or qualify for an exclusion to all of the core objectives and 5 out of the 10 menu measures in order to qualify for an EHR incentive payment. In this proposed rule, we propose to maintain the same core-menu structure for the program for Stage 2. We propose that EPs must meet or qualify for an exclusion to 17 core objectives and 3 of 5 menu objectives. We propose that eligible hospitals and CAHs must meet or qualify for an exclusion to 16 core objectives and 2 of 4 menu objectives. Nearly all of the Stage 1 core and menu objectives would be retained for Stage 2. The "exchange of key clinical information" core objective from Stage 1 would be 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 would be removed because it would be replaced by an "electronic/online access" core objective. There are also multiple Stage 1 objectives that would be 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. For EPs, we propose a set of clinical quality measures beginning in 2014 that align with existing quality programs such as measures used for the Physician Quality Reporting System (PQRS), CMS Shared Savings Program, and National Council for Quality Assurance (NCQA) for medical home accreditation, as well as those proposed under Children's Health Insurance Program Reauthorization Act

(CHIPRA) and under ACA Section 2701. For eligible hospitals and CAHs, the set of CQMs we propose beginning in 2014 would align with the Hospital Inpatient Quality Reporting (HIQR) and the Joint Commission's hospital quality measures.

This proposed rule also outlines a process by which EPs, eligible hospitals, and CAHs would submit CQM data electronically, reducing the associated burden of reporting on quality measures for providers. We are soliciting public feedback on several mechanisms for electronic CQM reporting, including aggregate-level electronic reporting group reporting options; and through existing quality reporting systems. Within these mechanisms of reporting, we outline different approaches to CQM reporting that would require EPs to report 12 CQMs and eligible hospitals and CAHs to report 24 CQMs in total.

c. Payment Adjustments and Exceptions

Medicare payment adjustments are required by statute to take effect in 2015. We propose a process by which payment adjustment would be determined by a prior reporting period. Therefore, we propose that any successful meaningful user in 2013 would avoid payment adjustment in 2015. Also, any Medicare provider that first meets meaningful use in 2014 would avoid the penalty if they are able to demonstrate meaningful use at least 3 months prior to the end of the calendar or fiscal year (respectively) and meet the registration and attestation requirement by July 1, 2014 (eligible hospitals) or October 1, 2014 (EPs).

We also propose exceptions to these payment adjustments. This proposed rule outlines three categories of exceptions based on the lack of availability of internet access

or barriers to obtaining IT infrastructure, a time-limited exception for newly practicing EPs or new hospitals who would not otherwise be able to avoid payment adjustments, and unforeseen circumstances such as natural disasters that would be handled on a case-by-case basis. We also solicit comment on a fourth category of exception due to a combination of clinical features limiting a provider's interaction with patients and lack of control over the availability of Certified EHR technology at their practice locations..

d. Modifications to Medicaid EHR Incentive Program

We propose to expand the definition of what constitutes a Medicaid patient encounter, which is a required eligibility threshold for the Medicaid EHR Incentive Programs. We propose to include encounters for individuals enrolled in a Medicaid program, including Title XXI-funded Medicaid expansion encounters (but not separate CHIP programs. We also propose flexibility in the look-back period for patient volume to be over the 12 months preceding attestation, not tied to the prior calendar year.

We also propose to make 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.

e. Stage 2 Timeline Delay

Finally, we propose a minor delay of 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 for Medicare in 2011 would begin using Stage 2 criteria in 2013. This proposed rule delays the onset of those Stage 2 criteria until 2014, which we believe provides the needed time for vendors to develop Certified EHR Technology.

3. Summary of Costs and Benefits

This proposed 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 proposed rule. The total Federal cost of the Medicare and Medicaid EHR Incentive Programs is estimated to be $14.6 billion in transfers between 2014 and 2019. In this proposed rule we have not quantified the overall benefits to the industry, nor to eligible hospitals, or EPs 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.

Fiscal Year	**Medicare Eligible**		**Medicaid Eligible**		**Total**
	Hospitals	**Professionals**	**Hospitals**	**Professionals**	
2014	$1.3	$1.2	$0.4	$0.8	$3.7
2015	$1.2	$1.1	$0.5	$0.9	$3.7
2016	$0.6	$0.8	$0.9	$1.0	$3.3
2017	$0.0	$0.2	$1.0	$1.0	$2.2
2018	-$0.2	-$0.2	$0.6	$0.9	$1.1
2019	-$0.0	-$0.2	$0.1	$0.7	$0.6

Amounts are in 2012 billions

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 eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs), and Medicare Advantage (MA) Organizations to promote the adoption and meaningful use of certified electronic health record (EHR) technology. On July 28, 2010 we published in the **Federal Register** (75 FR 44313 through 44588) a final rule titled "Medicare and Medicaid Programs; Electronic Health Record Incentive Program," that specified the Stage 1 criteria EPs, eligible hospitals, and CAHs must meet in order to qualify for an incentive payment, calculation of the incentive payment amounts, and other program participation requirements (hereinafter referred to as the Stage 1 final rule). (For a full explanation of the amendments made by ARRA, see the final rule (75 FR 44316).) In that final rule, we also detailed that the Medicare and Medicaid EHR Incentive Programs would 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 Certified EHR Technology and the standards and certification criteria for Certified EHR Technology were coordinated. Current ONC regulations may be found at 45 CFR part 170. For Stage 2, CMS and ONC will again work together to align our regulations,

We urge those interested in this proposed rule to also review the ONC proposed rule on standards and implementation specifications for Certified EHR Technology. Readers may also visit http://healthit.hhs.gov and http://www.cms.hhs.gov/EHRincentiveprograms for more information on the efforts at the Department of Health and Human Services (HHS) to advance HIT initiatives.

II. Provisions of the Proposed Regulations

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

1. Uniform Definitions

In the Stage 1 final rule, we finalized many uniform definitions for the Medicare FFS, MA, and Medicaid EHR incentive programs. These definitions are set forth in part 495 subpart A of the regulations, and we are proposing to maintain most of these definitions, including, for example, "Certified EHR Technology," "Qualified EHR," "Payment Year," and "First, Second, Third, Fourth, Fifth, and Sixth Payment Year." We note that our definitions of "Certified EHR Technology" 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 proposed rule that is published elsewhere in this issue of the **Federal Register**. We are revising the descriptions of the EHR reporting period to clarify that for providers who are demonstrating meaningful for the first time their EHR reporting period is 90 days regardless of payment year. We propose 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, as discussed in section II.D. of this proposed rule.

2. Meaningful EHR User

We propose to include clinical quality measure reporting as part of the definition of "meaningful EHR user" instead of as a separate meaningful use objective under 42 CFR 495.6. This change is explained in section II.A.3.d. in the context of the proposed Stage 2 criteria for meaningful use.

The third paragraph of the definition of meaningful EHR user at 42 CFR 495.4 currently read as follows: "(3) To be considered a meaningful EHR user, at least 50 percent of an EP's patient encounters during the EHR reporting period during the payment year must occur at a practice/location or practices/locations equipped with certified EHR technology." We propose to revise the third paragraph of the definition of meaningful EHR user at 42 CFR 495.4 to 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 Certified EHR Technology." This change is to include the payment adjustment in this definition. Currently, it only refers to the incentives.

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, Congress identified the broad goal of expanding the use of EHRs through the concept of meaningful use. Section

1903(t)(6)(C) of the Act also requires that Medicaid providers adopt, implement, upgrade or meaningfully use Certified EHR Technology if they are to receive incentives under Title XIX. Certified EHR Technology 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, 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 rulemaking, 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 Certified EHR Technology 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 July 28, 2010, and this rule outlines our proposed Stage 2 approach. We currently anticipate at least one additional update, and anticipate updating the Stage 3 criteria with another proposed rule by early 2014. The stages represent an initial graduated approach to arriving at the ultimate goal.

- Stage 1: 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 Certified EHR Technology that will allow for continuous quality improvement and ease of information exchange. By having these functionalities in certified EHR technology 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 Certified EHR Technology. 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 proposing certain changes to the Stage 1 criteria in section II.B.3.b. of this proposed rule.

• Stage 2: Our Stage 2 goals, consistent with other provisions of Medicare and Medicaid law, 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 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. Stage 2 meaningful use requirements include 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 to support transitions in care across unaffiliated providers, settings and EHR systems. Increasingly robust expectations for health information exchange in Stage 2 and Stage 3 will support the goal that information follows the patient. In addition, as we forecasted in the Stage 1 final rule, we now consider nearly every objective that was optional for Stage 1 to be required in Stage 2, and we reevaluated the thresholds and exclusions of all the measures.

• 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, 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 (as described later in this section) 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 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 with our expected timeline for the stages of meaningful use.

TABLE 1: 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 are proposing changes to this timeline as well as its extension beyond 2014. Under the timeline used in the Stage 1 final rule (75 FR 44323), 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 or October 1, 2012, respectively. We anticipate publishing a final rule by summer 2012. The HIT Policy

Committee recommended we delay by 1 year the start of Stage 2 for providers who became meaningful EHR users in 2011. Stage 2 of meaningful use requires 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. We have heard similar concerns from other stakeholders and agree that, based on our proposed definition of meaningful use for Stage 2, providers could have difficulty implementing these changes in time. Therefore, we are proposing a 1-year extension of Stage 1 of meaningful use for providers who successfully demonstrated meaningful use for 2011. Our proposed timeline through 2021 is displayed in Table 2. We refer readers to II.D.2 of this proposed rule for a discussion of the applicable EHR reporting period that would be used to determine whether providers are subject to payment adjustments.

TABLE 2: 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

Please note 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. Medicaid EPs and eligible hospitals can receive a Medicaid EHR incentive payment for "adopting, implementing, and upgrading" (AIU) to Certified EHR

Technology for their first payment year, which is not reflected in Table 2. 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 there will be a Stage 4 of meaningful use, we expect to update this table in the rulemaking for Stage 3.

b. Changes to Stage 1 Criteria for Meaningful Use

We propose the following changes to the objectives and associated measures for Stage 1. As explained later in this proposed rule, most of these changes would be optional for Stage 1 in 2013 and would be required for Stage 1 beginning in 2014 (CY for EPs, FY for eligible hospitals/CAHs). We do not believe that this creates an additional hardship as providers would have the option of completing Stage 1 in the same manner in 2013 as in 2011 and 2012, and in fact, the changes we propose create flexibility for EPs, eligible hospitals, and CAHs seeking to achieve Stage 1 meaningful use objectives.

The current denominator for the CPOE objective measure for Stage 1 is the number of unique patients with at least one medication in their medication list seen by an EP or admitted to an eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period. We created this denominator in response to comments that our original Stage 1 proposed denominator for this measure, the number of orders for medications, is difficult to measure. Following publication of the final rule, we have received nearly unanimous feedback from providers that the

logical denominator for this measure is the number of orders for medications and that it is measurable. For more details please reference the discussion of the Stage 2 CPOE objective. Beginning in 2013 (CY for EPs, FY for eligible hospitals/CAHs), we propose to allow providers in Stage 1 to 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 proposed CPOE objective in the Stage 2 criteria section). A provider seeking to meet Stage 1 in 2013 could use either the current or the proposed alternative denominator to calculate the percentage for the CPOE measure.

Starting with the EHR reporting periods in FY/CY 2014, the proposed "alternative denominator" would be required for all providers in Stage 1 and Stage 2.

For the objective of record and chart changes in vital signs, our Stage 2 proposal 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). We propose an identical change to the Stage 1 exclusion as well, starting in CY 2013. We also propose 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 propose identical changes 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 would be an alternative in 2013 to the current Stage 1 requirements and would be required for Stage 1 beginning in 2014. We have found the

objective of "capability to exchange key clinical information" to be surprisingly difficult for providers to understand, which has made the objective considerably more difficult to achieve than we envisioned in the Stage 1 final rule. As the measure for this objective is simply a test with no associated requirement for follow-up submission, we are concerned the value of this objective is not sufficient to justify the burden of compliance. However, we also strongly believe that meaningful use of EHRs must ultimately involve real and ongoing electronic health information exchange to support care coordination, as the Stage 2 objectives on this subject (described below) make clear. We considered four options for this objective, and welcome comment on all four, that variously reduce or eliminate the burden of the objective or increase the value of the objective. The first option we considered is removal of this objective. This acknowledges our experience with Stage 1 and the limited benefit of just a test. The second option is to require that the test be successful. This would increase the value of the objective and eliminate a common question we receive on what happens if the test is unsuccessful. The third option is 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 from the menu set. This would eliminate the burden and complexity of the test, but preserve the domain of care coordination for Stage 1. The fourth option is 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. This would increase the benefit of the objective and reduce the complexity of the defining the parameters of the test, but potentially increases the real

burden of compliance significantly beyond what is currently included in Stage 1. We are proposing 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). In Stage 2, we propose to move to actual use cases of electronic exchange of health information as discussed later in this proposed rule, which would require significant testing in the years of Stage 1. We encourage comments on all four options and will evaluate them again in light of the public comment received.

We propose for Stage 2 a new method for making patient information available electronically, which would enable patients to view online and download their health information and hospital admission information. We discuss in the Stage 2 criteria section the proposed "view, download, and transmit" objectives for EPs and hospitals. Starting in 2014, Certified EHR Technology will no longer be certified to the Stage 1 EP and hospital core objectives of providing patients with electronic copies of their health information and discharge instructions upon request, nor will it support the Stage 1 EP menu objective of providing patients with timely electronic access to their health information. Therefore starting in 2014, for Stage 1, we propose to replace these objectives with the new "view online, download and transmit" objectives. We discuss these objectives further in our proposed Stage 2 criteria.

We are proposing a revised definition of a meaningful EHR user which would incorporate the requirement to submit clinical quality measures, as discussed in section II.A.2. of this proposed rule, and as such are removing the objective to submit clinical quality measures beginning in 2013 and the associated regulation text under 45 CFR

495.6 for Stage 1 to conform with this change in the definition of a meaningful EHR user.

For the Stage 1 public health objectives, beginning in 2013, we also propose to add "except where prohibited" to the regulation text, because we want 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).

TABLE 3: CHANGES TO STAGE 1

Stage 1 Objective	Proposed 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 Only (Optional)
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: Replacing the 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	2014 – Onward (Required)
Record and chart changes in vital signs	**Change: Addition of alternative age limitations** 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	2013 – Only (Optional)

Stage 1 Objective	Proposed Changes	Effective Year (CY/FY)
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)
Record and chart changes in vital signs	**Change: Age Limitations on Growth Charts 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 42 CFR 495.6**	2013 – Onward (Required)

Stage 1 Objective	Proposed Changes	Effective Year (CY/FY)
EP Objective: Provide patients with an electronic copy of their health information (including diagnostics test results, problem list, medication lists, medication allergies) upon request. Hospital Objective: Provide patients with an electronic copy of their discharge instructions and procedures 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, medication allergies) within 4business days of the information being available to the EP.	**Change: Replace these three 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 42 CFR 495.6	2013 – Onward (Required)

c. State Flexibility for Stage 2 of Meaningful Use

We propose 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, whether moved to the core or left 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 ONC EHR certification criteria as finalized for Stage 2 of meaningful use.

We solicit comment on extending State flexibility as described for Stage 2 of meaningful use and whether this remains a useful tool for State Medicaid agencies.

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

We are proposing 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 propose to follow that approach for our Stage 2 core set with two exceptions. We are proposing 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 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 are also proposing 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 are proposing 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 are proposing to eliminate certain Stage 1 objectives for Stage 2, such as the objective for testing the capability to exchange key clinical information. We are also proposing 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 would 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 are proposing a total of 17 core objectives and 5 menu objectives for EPs. We propose 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 1policy where an EP could reduce by the number of exclusions applicable to the EP the number of menu set objectives that the EP would otherwise need to meet. We received feedback on Stage 1 that we have received 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, so we are proposing 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 are proposing this change because we are concerned that under the current Stage 1 requirements 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 greater flexibility to do this in the selection of Stage 1 menu objectives through 2013, we believe 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 have provided exclusions for the Stage 2 menu objectives that we believe will 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 currently intend 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. 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. The same policy would also apply for the Stage 1 menu objectives for EPs beginning in 2014.

We propose a total of 16 core objectives and 4 menu objectives for eligible hospitals and CAHs for Stage 2. We propose 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. 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.

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

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 discuss the barriers and include exclusions in our descriptions of the individual objectives later. We are proposing 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 recognize that at the time of publication, our data (derived internally from attestations) only reflects the meaningful use attestation from Medicare providers. Before the publication of the final rule, we plan on adjusting the data on the successful attestations to date to reflect the experience of successful Medicaid meaningful EHR users. This may result in changes to our current assumptions based upon the data available at the time of the proposed rule, especially given the different eligible professional types in the Medicaid EHR Incentive Program. It may be that different eligible professional types may have different levels of success in meeting the meaningful use measure thresholds, given their scope of practice.

(2) EPs Practicing in Multiple Practices/Locations

We propose 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 Certified EHR Technology. 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 Certified EHR Technology. For

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 Certified EHR Technology 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 Certified EHR Technology 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 Certified EHR Technology 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.

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 have also received requests for clarification on what it means for a practice/location to be equipped with Certified EHR Technology. We define a practice/location as equipped with Certified EHR Technology if the record of the patient encounter that occurs at that practice/location is created and maintained in Certified EHR Technology. This can be accomplished in three ways: Certified EHR Technology could be permanently installed at the practice/location, the EP could bring Certified EHR Technology to the practice/location on a portable computing device, or the EP could access Certified EHR Technology 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 Certified EHR Technology at the practice/location and then later input that information into Certified EHR Technology that exists at a different practice/location, we do not believe this process takes advantage of the value Certified EHR Technology offers. We are proposing 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. There is no interaction. The determination of whether an EP is hospital-based or not occurs prior to the application of this policy, so only non-hospital 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).

(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 Certified EHR Technology, but including all patients in the denominators of other measures, to be complicated for providers to implement. We are proposing 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 Certified EHR

Technology, making this distinction no longer relevant.

We also continue our policy that EPs practicing in multiple locations do not have to include patients seen at practices/locations that are not equipped with Certified EHR Technology in the calculations of the meaningful use measures as long as the EP has 50 percent of their patient encounters during the EHR reporting period at locations equipped with Certified EHR Technology.

We are proposing new objectives that could increase reporting burden. To minimize the burden, we are proposing 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 wherever possible and if appropriate. To provide a check on the burden of reporting of meaningful use, we propose for Stage 2 to use 1 of 4 denominators for each of the measures associated with the meaningful use objectives. We focus on denominators because the action that moves something from the denominator to the numerator usually requires the use of Certified EHR Technology by the provider. These actions are easily tracked by the technology.

The four proposed 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.

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 would 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 would 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 would not be able to satisfy meaningful use, as they would 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.

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. Transitions of care are 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 proposed rule is

only intended to apply to the EHR Incentive Programs and is not applicable to other Federal regulations.)

The four proposed 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).
- Inpatient bed days.
- Transitions of care.

The explanation of "unique patients" and "transitions of care" in the preceding paragraph for EPs also applies for eligible hospitals and CAHs. 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).

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 would 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.

(4) Discussion of the Relationship of Meaningful Use to Certified EHR Technology

We propose to continue our policy of linking each meaningful use objective to certification criteria for Certified EHR Technology. 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. 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 Certified EHR Technology. For example, in e-Rx and public health reporting, Certified EHR Technology 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 despite these standards and capabilities such as contacting both parties and troubleshooting issues that may arise through the normal course of business.

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

We propose 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, meeting the criteria of the measure means that the provider has met the objective for Stage 2.

(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.

We propose to continue to define CPOE as entailing the provider's use of computer assistance to directly enter medical orders (for example, medications, consultations with other providers, laboratory services, imaging studies, and other auxiliary services) from a computer or mobile device. The order is then documented or captured in a digital, structured, and computable format for use in improving safety and efficiency of the ordering process.

CPOE improves quality and safety by allowing clinical decision support at the point of the order and therefore influences the initial order decision. CPOE improves safety and efficiency by automating aspects of the ordering process to reduce the

possibility of communication and other errors. Consistent with the recommendations of the HIT Policy Committee, we would 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 this is a logical step in the progression of meaningful use.

Our experience with Stage 1 of meaningful use demonstrated that our definition of CPOE in the Stage 1 final rule does not indicate when in the ordering process the CPOE function must be utilized. We provided guidance at: https://questions.cms.hhs.gov/app/answers/detail/a_id/10134/ on the Stage 1 criteria to say 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. Our experience shows that the limiting criterion is the first time the order becomes part of the patient's medical record rather than the limitation to licensed healthcare professionals entering the order. Our experience has also demonstrated that each provider must make the decision of whether the record of an order is part of the patient's medical record independently as the possible variations in process and record keeping are too numerous for a universal statement on when in the process an order becomes part of the patient's medical record. To further CPOE's ability to improve safety and efficiency and to provide greater clarity for Stage 2 of meaningful use, we are proposing to redefine the point in the ordering process when CPOE must be utilized. We propose that to be considered CPOE, the CPOE function must be utilized to create the first record of any type for the order. This

removes the possibility that a record of the order could be created prior to CPOE, but not be part of the patient's medical record. In a practice, this means the originating provider (the provider whose judgment creates the order) must personally use the CPOE function, verbally communicate the order to someone else who will use the CPOE function, or give an electronic or written order that must not be retained in any way once the CPOE function has been utilized. This is a meaningful use requirement and does not affect any other legal or regulatory requirements as to what constitutes a patient's health record or order. With this new proposal, we invite 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.

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.

Our experience with Stage 1 of meaningful use has shown that a denominator of all orders created by the EP or in the hospital would not be unduly burdensome for providers. Many providers have voluntarily provided information on the number of medication orders in their clinic or hospital. However, this does not guarantee such a denominator would be feasible for all providers. We believe the EHRs can calculate a denominator of all orders entered into the Certified EHR Technology, with the numerator limited to those entered into Certified EHR Technology using CPOE. Potentially, this would exclude those orders that are never entered into the Certified EHR Technology in any manner. The provider would be responsible for including those orders in their denominator. However, we believe that providers using Certified EHR Technology use it as the patient's medical record; therefore, an order not entered into Certified EHR Technology would be an order that is not entered into a patient's medical record. For this reason, we expect that orders given for patients that are never entered into the Certified EHR Technology to be few in number or non-existent. We encourage comments on whether a denominator other than number of medication, laboratory, and radiology orders created by the EP or in the hospital would be needed for EPs and/or hospitals. For example, the HIT Policy Committee recommended a denominator of "patients with at least one type of order." We are proposing, however, a different denominator for this measure, which we believe would be possible to collect given our experience in Stage 1 of meaningful use and a much more accurate measure of actual CPOE usage. The denominator of "patients with at least one type of order" is a proxy measure for the number of orders issued by the EP, eligible hospital or CAH. The accuracy of that proxy

is dependent on the frequency in which an encounter results in an order. For example, an EP whose scope of practice is such that they order a medication on nearly every encounter would have every encounter as an opportunity to move the patient from the denominator to a numerator. The 2005 National Ambulatory Medical Care Survey (referenced in the Stage 1 final rule, 75 FR 44333) found that 66 percent of office-based visits had any type of medication order. EPs whose office visits are consistent with the survey findings would have a third fewer opportunities to move the patient from the denominator to the numerator. We believe a direct measure of the number of orders is feasible and more accurate as it is not dependent on the frequency of orders. We encourage comments on whether the barriers to collecting information for our proposed denominator would be greater in a hospital or ambulatory setting. As we noted previously, the denominator used in Stage 1 (as well as the denominator recommended by the HIT Policy Committee) is much more representative of CPOE use in a hospital setting than an ambulatory setting, so these settings could require different denominators or measures. We request comment on different denominators or measures and encourage 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.

Based on our experience with attestation data from Stage 1, we continue to believe that the 60 percent threshold that we finalized previously for Stage 2 is appropriate. We also believe that this threshold translates to our new measure. The HIT Policy Committee recommended including laboratory and radiology orders in the

measure, but as "yes/no" attestations of one order being entered using CPOE rather than at the 60 percent threshold. We believe this is unnecessary given the advance of CPOE. In our discussions with EPs, eligible hospitals and CAHs we find that they do not roll out CPOE with only one order type, but rather include medications, laboratory and radiology/imaging orders as a package. We are also concerned 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. We welcome comment on whether laboratory and radiology orders are sufficiently different in the use of CPOE that they would require a different threshold and whether such a threshold should be a lower percentage or a yes/no attestation.

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

- Denominator*:* Number of medication, radiology, and 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 60 percent in order for an EP, eligible hospital or CAH to meet this measure.

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

To qualify for the exclusion, an EP's total number of medication, laboratory and radiology orders collectively must be less than 100. For example, an EP who writes 75

medication orders, 50 laboratory orders and no radiology orders during the EHR reporting period would not meet the exclusion.

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

For Stage 2, we are proposing 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 continue to believe 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 believe it is appropriate to include this functionality as part of the objective for using clinical decision support.

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

The use of electronic prescribing has several advantages over having the patient carry the prescription to the pharmacy or directly faxing a handwritten or typewritten prescription to the pharmacy. When the EP generates the prescription electronically, Certified EHR Technology 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 Certified EHR Technology 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 propose to continue to define prescription as the authorization by an EP to dispense a drug that would not be dispensed without such authorization. This includes authorization for refills of previously authorized drugs. We propose 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. However, as Stage 2 of meaningful use would not go into effect until 2014, it is possible that significant progress in the availability of products enabling the electronic prescribing of controlled substances may occur. We encourage comments addressing the current and expected availability of these products and whether the availability would be sufficient to include controlled substances in the Stage 2 measure for e-Rx or to warrant an additional measure for EPs to choose that would include controlled substance electronic prescriptions in the denominator.

We do not believe that OTC medicines will be routinely electronically prescribed and propose to continue to exclude them from the definition of a prescription. However, we encourage public comment on this assumption.

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 Certified EHR Technology 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 propose 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, the EP needs to use Certified EHR Technology 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 the standards included in certification of EHRs.

We received many inquiries as to the alignment with this objective and the eRx payment adjustment authorized by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). The HITECH Act phases out the adjustment starting in CY 2015 so alignment between the programs is no longer necessary. At the time of publication of this proposed rule, the determination for CY 2013 MIPPA eRx payment adjustment will have already occurred. For these reasons alignment with Stage 2 becomes a moot point.

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

In Stage 1 of meaningful use, we adopted a measure of more than 40 percent of all permissible prescriptions written by the EP are transmitted electronically using Certified EHR Technology. In the Stage 1 rule (75 FR 44338), we acknowledged that there were reasons why a patient may prefer a paper prescription. A patient could have this preference for any number of reasons such as the desire to shop for the best price (especially for patients in the Part D "donut hole"), the ability to obtain medications through the Department of Veterans Affairs, lack of finances, indecision about whether to

have the prescription filled locally or by mail order, and desire to use a manufacturer coupon to obtain a discount. We correspondingly lowered the threshold to 40 percent from 75 percent as proposed for Stage 1 to account for patient preference for a paper prescription. While pharmacy acceptance of electronic prescriptions continues to accelerate, these patient preferences remain creating a ceiling for this threshold on which there is limited data with which to estimate.

The HIT Policy Committee recommended an increase in the threshold of this measure from 40 percent to 50 percent. The average successful Medicare meaningful EHR user rate currently exceeds 50 percent demonstrating to us that 50 percent does not exceed the ceiling created by patient preferences. We also believe that providers participating in Stage 2 will already have significant experience with this objective and can meet an even higher threshold. Therefore we are proposing a threshold of 65 percent for this measure.

The ease with which an EP can meet this measure depends heavily on the availability of pharmacies in their local area that accept electronic prescriptions. We propose 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. For EP's practicing at multiple locations, they are eligible for the exclusion if any of their practice locations that are equipped with Certified EHR Technology 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 have considered instances where an EP may prescribe medications in a facility (such as a nursing home or ambulatory surgery center) where they are compelled to use the facility's ordering system, which may not be Certified EHR Technology. While we are not proposing exclusionary criteria related to this circumstance, we encourage comments on whether one is necessary or if the proposed 50 percent threshold is low enough to account for this situation.

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. We recognize that not all drug formularies are linked to all Certified EHR Technologies, so we are not requiring that the formulary be relevant for each patient. Therefore, the comparison could return a result of formulary unavailable for that patient and medication combination and still allow the EP to meet the measure of this objective. This modification of the measure replaces the Stage 1 menu objective of "Implement drug-formulary checks" and is intended to provide better integration guidance for both EPs and their supporting vendors.

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.

- Numerator: The number of prescriptions in the denominator generated, compared to a drug formulary and transmitted electronically.

- Threshold: The resulting percentage must be more than 65 percent in order for an EP to meet this measure.

Exclusions: Any EP who writes fewer than 100 prescriptions during the EHR reporting period or does not have a pharmacy within their organization and there are no pharmacies that accept electronic prescriptions within 25 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 are proposing 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 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 Certified EHR Technology. However, the continued demonstration of their meaningful use in Stage 2 is 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 are proposing 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." EPs and hospitals would have to ensure the accuracy of these fields when providing the summary of care, which we believe will 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 proposed rule published elsewhere in this issue of the **Federal Register**.

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.

The recording of demographic data benefits healthcare and population health. Gender, race, ethnicity, and age are all established risk factors for a large number of diseases and conditions. Having this information available to healthcare providers improves their ability to care for individual patients. This same information combined with preferred language and date and cause of death can create revealing data on the health of populations as small as the population treated by a single healthcare provider to

the national population. Health disparities can be identified and risk factors for disease and conditions can be identified and refined, among other uses for this data.

In order to obtain these benefits, especially for public health, it is important that information from different sources be comparable. For this reason, we propose to continue the use of the Office of Management and Budget (OMB) standards for race and ethnicity (http://www.whitehouse.gov/omb/inforeg_statpolicy/#dr). As outlined in the OMB policy, more detailed descriptions of race can be used, but ultimately would need to be mapped to 1 of the 5 races included in the OMB standards. Current OMB standards align race categories with every geographic location in the globe so there are not barriers to completing such mapping. We recognize that race is a social construct that varies across cultures and time which is why we fully support the use of other descriptions that can then be mapped using geography constructs to the OMB standards. There must also be the option for the selection of multiple races for a patient and an option for cases when a patient declines to provide the information.

The recording of the cause of death raised many questions from providers in Stage 1 of meaningful use. Some cases are referred to medical examiners to determine the official cause of death while others are not. Individual hospital policies and local/State laws and regulations vary. For purposes of meaningful use, we refer to the preliminary cause of death recorded by the hospital. This preliminary cause is not required to be amended due to additional information, but the hospital may amend the information if they want to maintain the most accurate information. The recording of the preliminary cause of death also does not have to occur within a specified timeframe from

the death. We believe these clarifications will enable hospitals to meet this measure, but we encourage comments on our description of recording the cause of death.

In addition, we encourage public comment on the burden and ability of including disability status for patients as part of the data collection for this objective. We believe that the recording of disability status for certain patients can improve care coordination, and so we are considering making the recording of disability status an option for providers. We seek comment on the burden incorporating such an option would impose on EHR vendors, as well as the burden that collection of this data might impose on EPs, eligible hospitals, and CAHs. In addition, we request public comment on --(1) how to define the concept "disability status" in this context; and (2) whether the option to collect disability status for patients should be captured under the objective to record demographics, or if another objective would be more appropriate.

We also seek comment on whether, we should also include the recording of gender identity and/or sexual orientation. T We encourage commenters to identify the benefits of inclusion and the applicability across providers.

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.

For Stage 1 of meaningful use, we adopted a measure of 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) have demographics recorded as structured data. We agree with the HIT Policy Committee recommendation to increase the threshold of

this measure and are proposing a more than 80 percent threshold for Stage 2 of meaningful use. Our experience with Stage 1 shows performance on this measure above 80 percent.

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'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 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 Certified EHR Technology 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 proposed 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.

Having accurate information on height/length (depending on a patient's age), weight, and blood pressure both on the current condition of the patient and changes over time provide context to a large number and great variety of clinical decisions. By capturing height, weight, and blood pressure in a structured format, EHRs can analyze and display the information without the need for intervention by the provider. The calculation of body mass index and plotting of growth charts are just two examples. The provider need not do anything to calculate BMI or plot a growth chart if height and weight are recorded as structured data because this functionality is included within Certified EHR Technology. Similarly, information on blood pressure provides many opportunities for clinical decision support and the identification of patient education materials. Again, these automated processes can be enabled within Certified EHR Technology simply by recording blood pressure as structured data.

We propose to continue our policy from Stage 1 that height/length, weight, and blood pressure do not each need to be updated by a provider at every patient encounter nor even once per patient seen during the EHR reporting period. For this objective, we are primarily concerned that some information is available to the EP, eligible hospital or CAH, who can then make the determination based on the patient's individual circumstances as to whether height/length, weight, and blood pressure need to be updated. The information can get into the patient's medical record as structured data in a number of ways. Some examples include entry by the EP, eligible hospital, or CAH,

entry by someone on the EP, eligible hospital, or CAH's staff, transfer of the information electronically or otherwise from another provider, or 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 hospital to determine what level of accuracy is needed for them to provide care to the patient and how best to obtain this information. Any method of obtaining height, weight or blood pressure is acceptable for purposes of this objective as long as the information is recorded as structured data.

We have received continuous feedback during Stage 1 of meaningful use on the appropriate age for collecting these vital signs. In particular, we have heard from numerous health care professionals and associations and the HIT Policy Committee recommended that height/length and weight should not be age-limited and that the limit for blood pressure should be raised to 3 years of age and older in order to align with guidelines and recommendations from other health care associations. We agree with this alignment and propose to remove the height/length and weight age limits and raise the blood pressure limit to 3 years of age and older, but we encourage public comment on the age limitations of vital signs. Age is determined based on the date when the patient is last seen by the EP or admitted to the inpatient or emergency department of the hospital during the EHR reporting period.

Because we propose to remove the age restrictions on recording height/length and weight, we also propose to remove the age restrictions on calculating and displaying BMI and growth charts.

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 included two exclusions for EPs for this measure in Stage 1 of meaningful use. The first is that EPs who do not see any patients 2 years old or older (proposed to be raised to 3 years old or older optionally in 2013 and permanently in 2014) are excluded from recording blood pressure. The second is for EPs who believe that all 3 vital signs of height/length, weight, and blood pressure have no relevance to their scope of practice. We received considerable feedback on Stage 1 that many EPs believe that while they may collect weight and blood pressure, they do not believe height/length is relevant to their scope of practice, or that blood pressure is relevant, but not height/length and weight, or some other combination.

Weight without height/length is not useful from a record keeping perspective. A 225 pound man who is 5'5" has different considerations than a 225 pound man who is 6'5". Therefore, we propose to keep the recording of height/length and weight as linked requirements. We believe there are situations where height/length and weight may be relevant, but blood pressure is not. We are less certain that there would be cases where blood pressure is relevant, but height/length and weight are not. We propose for Stage 2 to split the exclusion so that an EP can choose to record height/length and weight only and exclude blood pressure or record blood pressure only and exclude height/length and

weight. We encourage comments on this split and whether it should or should not go both ways.

For Stage 1 of meaningful use, we adopted a measure of 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) have vital signs recorded as structured data. We agree with the HIT Policy Committee recommendation to increase the threshold of this measure and are proposing a more than 80 percent threshold for Stage 2 of meaningful use. Our preliminary Stage 1 data shows that the recording of vital signs far exceeded the measure threshold of more than 50 percent, so we are proposing a threshold of 80 percent for this measure for Stage 2 of meaningful use. We will continue to monitor this Stage 1 data as we solicit public comment so that we can determine if the more than 80 percent threshold is appropriate for this measure.

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'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 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.

An 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. An 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.

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 do not propose rules on who may record smoking status or how often the record should be updated.

For Stage 2, we propose to limit this measure to those patients 13 years old and older (as we did in Stage 1). We have not observed any significant consensus around when it is appropriate to collect smoking status, regardless of the presence or absence of other risk factors. If commenters disagree with our age limitation, we encourage them to include their reasons for disagreement and any evidence that may be available as to improved consensus among healthcare providers on what age limit is appropriate.

In Stage 1 of meaningful use, we considered whether to expand the collection of information from smoking status to other forms of tobacco use. We continue to believe that there are insufficient electronic standards for collecting information on other types of tobacco use and that situations where a patient might use multiple types of tobacco would damage the standardized collection of smoking data, but we request comment on whether this is the case.

Finally, in Stage 1 of meaningful use, we considered whether to include second hand smoke information as part of this objective. We continue to believe that the level of complexity in introducing this requirement is beyond a reasonable expectation of meaningful use at this time. We believe it would be difficult to define what constitutes a level of exposure to trigger recording second hand smoke information. We encourage commenters to submit information to us that demonstrates consensus and/or standards around the collection of second hand smoking data that would provide the basis on which to create an additional tobacco-related measure that is applicable to all EPs and hospitals.

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 Stage 1 of meaningful use, we adopted a measure of more than 50 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) have smoking status recorded as structured data. As we discussed in the Stage 1 final rule

(75 FR 44344), there were many concerns by commenters over the appropriate age at which to inquire about smoking status. There were also considerable differences among commenters as to what the appropriate inquiry was and what it should have included. Because of these comments, we adopted 50 percent as the measure of this objective. The HIT Policy Committee recommended an increase in the threshold of this measure from more than 50 percent to more than 80 percent. Our preliminary Stage 1 data shows that the recording of smoking status far exceeded the measure threshold of more than 50 percent, so we are proposing a threshold of 80 percent for this measure for Stage 2 of meaningful use. We will continue to monitor this Stage 1 data as we solicit public comment so that we can determine if the more than 80 percent threshold is appropriate for this measure.

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.

Replaced EP Objective: Report ambulatory clinical quality measures to CMS or, in the case of Medicaid EPs, the States.

Replaced Eligible Hospital/CAH Objective: Report hospital clinical quality measures to CMS or, in the case of Medicaid eligible hospitals, the States.

In addition to the meaningful use core and menu objectives, EPs and hospitals are still required to report clinical quality measures to CMS or the States in order to demonstrate meaningful use of Certified EHR Technology. However, we propose to eliminate these objectives under 42 CFR 495.6 and instead include the reporting of clinical quality measures (CQMs) as part of the definition of "meaningful EHR user" under 42 CFR 495.4. For more information about the requirements for reporting clinical quality measures, see section II.B.3. of this proposed rule. As explained in that section, we are proposing to move to electronic reporting of clinical quality measure information. Because the core and menu objectives under §495.6 are reported through attestation, we believe it makes more sense to separate the reporting of CQMs from the other meaningful use objectives and measures for Stage 2.

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

Clinical decision support at the point of care is an area of health IT in which significant evidence exists for its substantial positive impact on the quality, safety, and efficiency of care delivery. In Stage 1, we specified that the clinical decision support rule should be relevant to the provider's specialty or related to a high clinical priority. We purposely used a description that would allow a provider significant leeway in

determining the clinical decision support interventions that are most relevant to their scope of practice and benefit their patients in the greatest way. Following the recommendations of the HIT Policy Committee, we are proposing to modify the objective for Stage 2 to using clinical decision support to improve performance on high-priority health conditions. We believe that it is best left to the provider's clinical discretion to determine which clinical decision support interventions would address high-priority conditions for their individual patient populations, but we are requiring as a measure of this objective that the clinical decision support intervention be related to 5 or more of the clinical quality measures on which EPs or hospitals would be expected to report. We define "related" to mean that the intervention's intent is to improve the performance of the EP, eligible hospital, or CAH on a given clinical quality measure. Because clinical quality measures focus on high-priority health conditions by definition, this alignment will ensure that clinical decision support is also focused on high-priority health conditions and improved performance in measurable quality areas.

For Stage 2, we are also proposing to make the Stage 1 objective for "Implement drug-drug and drug-allergy checks" one of the measures of this clinical decision support objective. We continue to believe 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 believe it is appropriate to include this functionality as part of this objective for using clinical decision support. Finally, we have replaced the term "clinical decision support rule" used in our Stage 1 rule with the term

"clinical decision support intervention" to better align with, and clearly allow for, the variety of decision support mechanisms available to help improve clinical performance and outcomes. This mirrors an identical change in the ONC Standards and Certification proposed rule.

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

1. Implement 5 clinical decision support interventions related to 5 or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period.

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.

The drug-drug and drug-allergy checks and the implementation of 5 clinical decision support interventions are separate measures for this objective. Therefore the EP or hospital must implement clinical decision support interventions in addition to drug-drug and drug-allergy interaction checks.

For Stage 2 based on the HIT Policy Committee recommendations, each clinical decision support intervention must enable the provider to review all of the following attributes of the intervention: developer of the intervention, bibliographic citation, funding source of the intervention, and release/revision date of the intervention. This will enable providers to review complete information including any potential conflict of interest for the decision support intervention(s), if they so choose. Certified EHR technology will

display these attributes allowing providers to review them. Such information may be valuable so that providers can understand whether the clinical evidence that the intervention represents is current, and whether the development of that intervention was sponsored by an organization that may have conflicting business interests including, but not limited to, a pharmaceutical company, pharmacy benefits management company, or device manufacturer. We believe that there may be cases in which such organizations will have interest in sponsoring clinical decision support interventions, and such interventions may very well be in the patient's best interest. Nonetheless, such sponsorship should be made transparent to the provider using the system.

In addition to the review of clinical decision support attributes, providers must implement the clinical decision support 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. Although we leave it to the provider's clinical discretion to determine the relevant point in patient care when such interventions will be most effective, the interventions must be presented through Certified EHR Technology to a licensed healthcare professional who can exercise clinical judgment about the decision support intervention before an action is taken on behalf of the patient.

Finally, we propose that clinical decision support intervention must be related to 5 or more of the clinical quality measures that we will finalize for EPs and hospitals and on which they will be expected to report. By relating clinical decision support interventions to one or more clinical quality measures, providers are necessarily focusing on high-priority health conditions, as required by the objective and recommended by the HIT

Policy Committee. Providers would implement 5 clinical decision support interventions that they believe will result in improvement in performance for 5 or more of the clinical quality measures on which they report. For example, EPs reporting on the clinical quality measure of "Preventive Care and Screening: Influenza Immunization for Patients 50 Years Old or Older" (NQF 0041, PQRI 110) could choose to implement a clinical decision support intervention that triggers an alert in Certified EHR Technology prompting a licensed healthcare professional to ask about influenza immunizations whenever a patient 50 years old or older presents for an office visit or other action that increases the likelihood that the patient receives an influenza immunization.

Please note that for Stage 2, we do not propose to require the provider to demonstrate actual improvement in performance on clinical quality measures. Rather, the provider must use the goal of improvement in performance for a clinical quality measure when the provider selects a clinical decision support intervention to implement. 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.

We do not believe that any EP, eligible hospital, or CAH would be in a situation where they could not implement five clinical decision support intervention as previously

described. Therefore, we do not propose any exclusions for this objective and its associated measure.

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 are not proposing 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. The HIT Policy Committee recommended that these objectives be combined with objectives for online viewing and downloading. We agree with the HIT Policy Committee and are replacing these Stage 1 objectives with proposed objectives and measures for Stage 2 that would enable patients to view online and download their health information and hospital admission information (discussed later in this rule). We believe 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.

Proposed EP Objective: Provide 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.

We also note 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.

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

Following the recommendation of the HIT Policy Committee, we propose to continue the 50 percent threshold from Stage 1. Although many EPs provide paper summaries as the patient leaves the office, we believe that a timeframe is still needed for those EPs who provide electronic summaries either as the provider's preferred method of distribution or to accommodate patient requests for electronic summaries. Because the clinical summary is intended to be a summary of clinical information relevant to an office visit, we agree with the HIT Policy Committee that 24 hours is a sufficient timeframe in which to provide this summary. We note that the vast majority of information required in the clinical summary should be immediately available upon completion of the office visit. Although we provided 3 business days to send the clinical summary in Stage 1, we now

believe that a faster exchange of information with patient is not only possible but also encourages better quality of care. However, we welcome comments on this timeframe. As in Stage 1, if a paper summary is mailed to the patient, the timeframe relates to when the summary is mailed and not when it is received by the patient.

Summaries of an office visit 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 results. When such information becomes available, the HIT Policy Committee recommended that the EP have 4 business days to make the information known to the patient. We concur that EPs should make this information known to the patient, but do not believe that a new clinical summary must be issued in every instance. For example, current common practice is for laboratory results to be delivered by phone. We are proposing another objective of meaningful use that would provide for online access to the latest health information, whereas this clinical summary objective focuses on a singular visit. We also are concerned with the practicality of measuring this aspect and cannot determine how we would assign a denominator to it. The EHR would have to be capable of recognizing that additional information is available, link such information to a specific office visit, time the provision of information to the patient, and create a record that the patient was notified. We believe that this is too burdensome. The clinical summary would include information on pending tests, and therefore, will alert patients that more information may soon be available if necessary. 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 is provided a clinical summary of their visit within 24 hours.
- 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.

We propose to require the following information 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 and any updates to it.
- Current medication list and any updates to it.
- Current medication allergy list and any updates to it.
- Procedures performed during the visit.
- Immunizations or medications administered during the visit.
- Vital signs and any updates.
- Laboratory test results.
- List of diagnostic tests pending.
- Clinical instructions.

- Future appointments.
- Referrals to other providers.
- Future scheduled tests.
- Demographics maintained by EP (gender, race, ethnicity, date of birth, preferred language). (New requirement for Stage 2.)
- Smoking status (New requirement for Stage 2.)
- Care plan field, including goals and instructions. (New requirement for Stage 2.)
- Recommended patient decision aids (if applicable to the visit). (New requirement for Stage 2.)

This is not intended to limit the information made available in the clinical summary by the EP. An EP can make available additional information and still meet the objective. The content of the care plan is dependent on the clinical context. We propose to describe a care plan as the structure used to define the management actions for the various conditions, problems, or issues. For purposes of meaningful use measurement, we propose that 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).

We encourage EPs to develop the most robust care plan that is warranted by the situation. We also welcome comments on both our description of a care plan and whether a description is necessary for purpose of meaningful use. When an office visit

lasts for several consecutive days and/or the patient is seen by multiple EPs during one office visit, a single consolidated summary at the end of the visit meets this objective. An example of a multiday office visit could be an evaluation one day, a diagnostic test the next and a follow-up treatment the next day based on the results of the test. Even in cases where multiple office visits occur under a global or bundled claim/fee, each visit results in an update to the status of the health of the patient and must be accompanied with a clinical summary.

We would also maintain several other policies from Stage 1. For purposes of meaningful use, an EP may withhold information from the clinical summary if they believe substantial harm may arise from its disclosure through an after-visit clinical summary. 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 can select any modality (for example, online, CD, USB) as their electronic option and does not have to accommodate requests for different modalities. We do not believe it would be appropriate for an EP to charge the patient a fee for providing the summary.

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.

Removed Objective: Capability to exchange key clinical information.

In Stage 2, we propose 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 believe that this actual use case is more beneficial and easier to understand. We also propose to remove this objective for Stage 1 as well, but consider other option. Please refer to the section titled "Changes to Stage 1"for details of the options considered. As we propose that the EHR reporting period for Stage 2 of meaningful use is the entire year, a prudent provider would 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 Certified EHR Technology through the implementation of appropriate technical capabilities.

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.

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.

This measure is the same as in Stage 1 except that we specifically address the encryption/security of data is that is stored in Certified EHR Technology (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 do not propose to change the HIPAA Security Rule requirements, or require any more than would be 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 propose this measure because the implementation of Certified EHR Technology 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.

We emphasize 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.

(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 propose 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 would remain in the menu set for Stage 2. As discussed later, we also propose to modify and combine some of these objectives and associated measures for Stage 2.

Consolidated Objective: Implement drug formulary checks.

For Stage 2, we are proposing 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.

Proposed Objective: Incorporate clinical lab-test results into Certified EHR Technology as structured data.

We believe that incorporating clinical lab-test results into Certified EHR Technology as structured data assists in the exchange of complete information between providers of care, facilitates the sharing of information with patients and their designated representatives, and contributes to the improvement of health care delivery to the patient. We encourage every EP, eligible hospital, and CAH to utilize electronic exchange of results with laboratories in accordance with the certification criteria in the ONC standards and certification proposed rule published elsewhere in this issue of the **Federal Register**. If results are not received through electronic exchange, then they are presumably received in another form (such as by fax, telephone call, mail) and would need to be incorporated into the patient's medical record in some way. We encourage the recording of results as structured data; however, there would be risk of recording the data twice (for example, scanning the faxed results and then entering the results as structured data). To reduce the risk of entry error, we highly encourage the electronic exchange of the results with the laboratory, instead of manual entry through typing, option selecting, scanning or other means.

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 Certified EHR Technology as structured data.

Although the HIT Policy Committee did not recommend an increase in the threshold for this measure, our initial data on Stage 1 of meaningful use shows high compliance with this measure for those providers individually selecting the objective from the menu set. Therefore we are proposing to increase the threshold of this objective to 55 percent for Stage 2.

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

- 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 whose results are expressed in a positive or negative affirmation or as a number which are incorporated in Certified EHR Technology 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 whose results are either in a positive/negative 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.

Reducing the risk of entry error is one of the primary reasons we lowered the measure threshold to 40 percent for Stage 1, during which providers are changing their workflow processes to accurately incorporate information into EHRs through either electronic exchange or manual entry. However, for this measure, we do not limit the EP, eligible hospital or CAH to only counting structured data received via electronic exchange, but count in the numerator all structured data. By entering these results into the patient's medical record as structured data, the EP, eligible hospital or CAH is accomplishing a task that must be performed regardless of whether the provider is attempting to demonstrate meaningful use or not. We believe that entering the data as structured data encourages future exchange of information. We have received inquiries on Stage 1 on how to account for laboratory tests that are ordered in a group or panel. The inquiries have highlighted several problems this creates for measurement (for example, EHR only counting a panel as one, but the results individually creating more than 100 percent performance, panels that include tests that are included in the measure and other tests that are not included in the measure, EHRs that count the entire panel if one test meets the numerator criteria). The measure in Stage 1 and Stage 2 counts lab tests individually, not as panels or groups in both the numerator and the denominator for

the very complications illustrated by the inquiries that occur when this is not done. However, we solicit comment on whether such individual accounting is infeasible. We note that this in no way precludes the use of grouping and panels when ordering labs. While we are not proposing to move beyond numeric and yes/no tests, we request comments on whether standards and other capabilities would allow us to expand the measure to all quantitative results (all results that can be compared on as a ratio or on a difference scale).

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

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 would 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 proposed rule published elsewhere in this issue of the **Federal Register**; not all capabilities and variables must be used for every list.

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

We propose 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 do 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 are also seeking comment on whether a measure that either increases the number and/or frequency of the patient lists would further the intent of this objective.

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

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.

In Stage 1, this objective was stated as "Send reminders to patients per patient preference for preventive/follow-up care." For Stage 2, the HIT Policy Committee recommended that clinically relevant information from Certified EHR Technology be used to identify patients to whom reminders of preventive/follow-up care would be most beneficial. We agree with this recommendation and are proposing to modify this objective for Stage 2 as "Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care." An EP should use clinically relevant information stored within the Certified EHR Technology 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.

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 propose 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 encourage 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 are proposing 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.

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 an office visit 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 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.

The goal of this objective is 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, this objective aligns with the Fair

Information Practice Principles (FIPPs),[1] in affording baseline privacy protections to individuals.[2] 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). 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 agree 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, the patient must be able to access this information on demand, such as through a patient portal or personal health record (PHR). 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

---

[1] 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 would 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 the framework on which much privacy policy would 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.

[2] 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[2] 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.

of their disability. Additionally, other health information may not be accessible. 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.

In the Stage 1 final rule (75 FR 44356), we indicated that information should be available to the patient through online access within 4 business days of the information being available to the EP through either the receipt of final lab results or a patient encounter that updates the EP's knowledge of the patient's health. For Stage 2, we propose to maintain the requirement of information being made available to the patient through online access within 4 business days of the information being available to the EP. To that end, we propose to continue the definition of business days as Monday through Friday excluding Federal or State holidays on which the EP or their administrative staff are unavailable. The HIT Policy Committee recommended that EPs be required to make information resulting from a patient encounter available within 24 hours instead of 4 business days. They also recommended continuing the 4 business day timeframe for updates following the receipt of new information. We believe that splitting the timeframes in this manner adds unnecessary complexity to this objective and associated measure. We believe that 4 business days remains a reasonable timeframe and limits the needs for updating. To the extent that Certified EHR Technologies enable a quicker posting time we expect that this will be workflow benefit to the providers and they will utilize this quicker time regardless of the threshold timeline in meaningful use.

Proposed EP Measures: We propose 2 measures for this objective, both of which must be satisfied in order to meet the objective:

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 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.

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 would be a download.

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 online.

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

To calculate the percentage of the second measure for patients or patient-authorized representatives to 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 or downloaded or transmitted to a third party the patient's health information.
- Threshold: The resulting percentage must be more than 10 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 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.

The thresholds of both of these measures must be reached in order for the EP to meet the objective. If the EP reaches one of these thresholds but not the other, then the EP will fail to meet this objective, unless the EP meets an applicable exclusion. An EP that conducts the 50 percent or more of his or her patient encounters in a county that does

not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude the second measure. According to the FCC at the time of formulation of this proposed rule, 370 counties in the United States have broadband penetration of less than 50 percent (www.broadband.gov). Further discussion of this exclusion can be found under the eligible hospital and CAH objective of "Provide patients the ability to view online, download, and transmit information about a hospital admission." We are also proposing that an EP who neither orders nor creates any of the information listed for inclusion as part of these measures may exclude both the first and second measures.

Consistent with the recommendations of the HIT Policy Committee, we are proposing a threshold of more than 10 percent for patients (or their authorized representatives) to view, download or transmit to a third party health information. An EP has any number of ways to make this information available online. The EP can host a patient portal, contract with a vendor to host a patient portal, connect with an online PHR or other means. As long as the patient can view, download, and transmit the information using a standard web browser and internet connection, the means is at the discretion of the EP. We note that this new measure does not focus solely on access and instead requires action by patients or their authorized representatives in order for the EP to meet it. A patient who views their information online, downloads it from the internet or uses the internet to transmit it to a third party would count for purposes of the numerator. While this is a departure from most meaningful use measures, which are dependent solely

on actions taken by the EP, we believe that requiring a measurement of patient use ensures that the EP will promote the availability and active use of electronic health information by the patient or their authorized representatives. Furthermore, we believe that accountable care should extend to meaningful use objectives that encourage patient and family engagement. We invite comment on this new measure and whether the 10 percent threshold is too high or too low given the patient's role in achieving it.

We define patient-authorized representative as any individual to whom the patient has granted access to their health information. Examples would include family members, an advocate for the patient, or other individual identified by the patient. A patient would have to affirmatively grant access to these representatives with the exception of minors for whom existing local, State or Federal law grants their parents or guardians access without the need for the minor to consent and individuals who are unable to provide consent and where the State appoints a guardian.

In order to make the information available to patients online consistent with the information provided during transitions of care, we are aligning the information required to meet this objective with the information provided in the summary of care record for each transition of care or referral. Therefore, 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.
- Problem list.

- Procedures.
- Laboratory test results.
- Medication list.
- Medication allergy list.
- Vital signs (height, weight, blood pressure, BMI, growth charts).
- Smoking status.
- Demographic information (preferred language, gender, race, ethnicity, date of birth).
- Care plan field, including goals and instructions, and
- Any additional known care team members beyond the referring or transitioning provider and the receiving provider.

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.

As stated in the Stage 1 final rule (75 FR 44356), we understand that there may be situations where a provider decides that online posting is not the best forum to communicate results. Within the confines of laws governing patient access to their medical records, we defer to an EP's judgment as to whether to hold information back in anticipation of an actual encounter or conversation between the EP or a member of their staff and the patient. Furthermore, for purposes of meeting this objective, an EP may

withhold information from being accessible electronically if its disclosure would cause substantial harm to the patient or another individual. Therefore, if in the EP's judgment substantial harm may arise from the disclosure of particular information, an EP may choose to withhold that particular information. Any such withholding would not affect the EP's ability to meet this measure as that information would not be included in the percentage calculation. However, we note that such withholding of information would not have any effect on a provider's obligations under 45 CFR 164.524 when an individual exercises his or her right of access to inspect and obtain a copy of protected health information about the individual in a designated record set. We do not believe there would be a circumstance where all information about an encounter would be withheld from the patient and therefore some information would be eligible for uploading for online access. If nothing else, information that the encounter occurred should be provided. This is a meaningful use provision, which does not override applicable federal, State or local laws regarding patient access to health information, including the requirements under the HIPAA Privacy Rule at 45 CFR 164.524.

As discussed earlier in this proposed rule, beginning in 2014, Certified EHR Technology will no longer be certified for the Stage 1 objectives of providing patients with an electronic copy of their health information upon request and providing patients with timely electronic access to their health information. This new "view and download" objective would replace those objectives, and we are proposing to include it in the core set for Stages 1 and 2 beginning in 2014." However, for Stage 1, we are only proposing the first measure of "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." Both measures would be required for Stage 2.

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

Providing clinically relevant education resources to patients is a priority for the meaningful use of Certified EHR Technology. Because of our experience with this objective in Stage 1, we are clarifying that while Certified EHR Technology 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 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 Certified EHR Technology (that is, specific patient characteristics are linked to specific consumer health content). The EP or hospital should utilize Certified EHR Technology in a manner where the technology suggests patient-specific educational resources based on the information stored in the Certified EHR Technology. 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 Certified EHR Technology 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 are proposing to remove the phrase "if appropriate" from the objective for Stage 2 because we do not believe that any EP or hospital would have difficulty identifying appropriate patient-specific education resources for the low percentage of patients required by the measure of this objective.

We also recognize 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 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. We are specifically inviting comments and seeking input on whether EPs and hospitals believe that patient-specific education resources at appropriate literacy levels and with appropriate cultural competencies could be successfully identified at this time through the use of Certified EHR Technology.

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 Stage 1, the measure of 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 are proposing this as a core objective for Stage 2, we have modified the measure for EPs to "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." We recognize 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 are proposing to alter the measure to account for office visits rather than unique patients seen by the EP. We are also proposing an exclusion for EPs who have no office visits in order to accommodate such EPs. The resources would have to be those identified by CEHRT. If resources are not identified by CEHRT and provided to the patient then it would not count in the numerator. We do not intend through this requirement to limit the education resources provided to patient to only those identified by CEHRT. We set the threshold at only ten 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 would need to be provided prior to the calculation and subsequent attestation to meaningful use.

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

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

- Numerator: Number of patients who had office visits during the EHR reporting period who were subsequently provided patient-specific education resources identified by 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.

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 Certified EHR Technology.

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

Our explanation of "patient-specific education resources identified by Certified EHR Technology" for the EP measure also applies for the hospital 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.

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.

We note 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. It is for the receiving provider that up-to-date medication information will be most crucial in order to make informed clinical judgments for patient care. We reiterate 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. For the purposes of this objective, we propose to maintain the definition of a transition of care as the movement of a patient from one setting of care (for example, a hospital, ambulatory primary care practice, ambulatory specialty care practice, long-term care, home health, rehabilitation facility) to another.

For Stage 2, we also propose to maintain the definition of 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. There are additional resources available that further define medication reconciliation that while not incorporated into meaningful use may be helpful for EPs, eligible hospitals, and CAHs. While we believe that an electronic exchange of information following the transition of care of a patient is the most efficient method of performing medication reconciliation, we also realize it is unlikely that an automated process within the EHR will fully supplant the medication reconciliation conducted between the provider and the patient. Therefore, the electronic exchange of information is not a requirement for medication reconciliation.

While the objective is to conduct medication reconciliation at all relevant encounters, determining which encounters are relevant beyond transitions of care is too subjective to be included in the measure.

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).

The HIT Policy Committee recommended maintaining this threshold at 50 percent. However, because this measure relates directly to the role of information exchange that we seek to promote through the meaningful use of Certified EHR Technology, we believe that a higher threshold for this measure is appropriate. Although the majority chose to defer this measure in Stage 1, the performance of both EPs and hospitals was well above the Stage 1 threshold. For these reasons we are proposing to raise the threshold of this measure to 65 percent for Stage 2..

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 65 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.

By guaranteeing 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.

The feedback we have received from providers who have met Stage 1 meaningful use requirements has convinced us that the exchange of key clinical information is most efficiently accomplished within the context of providing a summary of care record during transitions of care. Therefore, we are proposing to eliminate the 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.

In addition the HIT Policy Committee made two separate Stage 2 recommendations for EPs, eligible hospitals, and CAHs to record additional information--

- 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.

We believe that this information is best incorporated as required data within the summary of care record itself. Rather than implement two separate objectives and measures for these recommendations, we are establishing these as required fields along with the summary of care information listed later. The ONC proposed rule on standards and certification includes these as standard fields required to populate the summary of care document so Certified EHR Technology would be able to include this information. We also recognize that a "care plan" may require further definition. The content of the care plan is dependent on the clinical context. We propose to describe a care plan as the structure used to define the management actions for the various conditions, problems, or

issues. For purposes of meaningful use measurement we propose that 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).

We encourage EPs to develop the most robust care plan that is warranted by the situation. We also welcome comments on both our description of a care plan and whether a description is necessary for purpose of meaningful use.

All summary of care documents used to meet this objective must include the following:

- Patient name.
- Referring or transitioning provider's name and office contact information (EP only).
- Procedures.
- Relevant past diagnoses.
- Laboratory test results.
- Vital signs (height, weight, blood pressure, BMI, growth charts).
- Smoking status.
- Demographic information (preferred language, gender, race, ethnicity, date of birth).
- Care plan field, including goals and instructions, and

- Any additional known care team members beyond the referring or transitioning provider and the receiving provider.

In addition, eligible hospitals and CAHs would be required to include discharge instructions.

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:

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

We encourage all summary of care documents to contain the most recent and up-to-date information on all elements. In order for the summary of care document to count in the numerator of this objective, the EP or hospital must verify these three fields for problem list, medication list, and medication allergy list are not blank and include the most recent information known by the EP or hospital as of the time of generating the summary of care document. We define problem list as a list of current and active diagnoses. We solicit 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 define an up-to-date problem list as a list populated with the most recent diagnoses known by the EP or hospital. 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. 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."

We leave it to the provider's clinical judgment to identify any additional clinical information that would be relevant to include in the summary of care record.

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 Certified EHR Technology to a recipient with no organizational affiliation and using a different Certified EHR Technology vendor than the sender for more than 10 percent of transitions of care and referrals.

- Exclusion: Any EP who neither transfers a patient to another setting nor refers a patient to another provider during the EHR reporting period is excluded from both measures.

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 65 percent in order for an EP, eligible hospital, or CAH to meet this measure.

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 Certified EHR Technology would have access to the same information, so providing a clinical care summary for transfers within the hospital would not be necessary.

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 electronically transmitted using Certified EHR Technology to a recipient with no organizational affiliation and using a different Certified EHR Technology vendor than the sender.
- Threshold: The percentage must be more than 10 percent in order for an EP, eligible hospital or CAH to meet this measure.

For Stage 2, we are proposing 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 proposed 2014 Edition EHR certification criteria. Please see the ONC proposed rule published elsewhere in this issue of the **Federal Register** for more details.

These protocols will allow every provider with certified electronic health record technology 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 propose 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 a provider must use Certified EHR Technology 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 Certified EHR Technology 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.

We acknowledge 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. Thus, ONC requests comments on whether equivalent alternative transport standards exist to the ones ONC proposes to exclusively permit for certification. Comments on transports standards should be made to the ONC

proposed rule published elsewhere in this issue of the Federal register, while comments on the appropriateness of limiting this measure to only those standards finalized by ONC should be made to this rule. Note, 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. The required elements and standards of the summary of care document will be discussed in the ONC standards and certification proposed rule published elsewhere in this issue of the **Federal Register**. We are considering, in lieu of requiring solely the transmission capability and transport standard(s) included in a provider's Certified EHR Technology 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 request public comment on whether this additional flexibility should be added to our proposed numerator limitations.

Another potential concern could be 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 has 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 solicit 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 propose 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 Certified EHR Technology from the same EHR vendor.

We propose 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 believe that it is 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 recognize 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 solicit comment on the following concerns stakeholders may have relative to the numerator limitations we proposed previously.

We could see 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 that 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 recognize 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 recognize 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 seek 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 exclusions Certified EHR Technology 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, and ONC will seek comment in their proposed certification rule as to the feasibility of this reporting requirement for certified EHR technologies.

Despite the possible unintended consequences of the parameters we propose for the numerator, we believe that these limitations will help ensure that electronic health information exchange proceeds at the pace necessary to accomplish the goals of meaningful use. We encourage 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.

However, we note that electronic transmittal is not a requirement for the first measure to provide a summary of care record. For the first measure, where the electronic transmittal of the summary of care record is not a requirement but an option, a provider is permitted to generate an electronic or paper copy of the summary of care record using the Certified EHR Technology and to document that it was provided to the patient, receiving

provider or both. In this case, the use of physical media such as a CD-ROM, a USB or hard drive, or other formats could satisfy the measure of this objective.

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. We believe 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 encourage comment on whether there are significant barriers in addition to those discussed above to EPs meeting the 10 percent threshold for this measure.

In addition, the HIT Policy Committee recommended maintaining the 50 percent threshold from Stage 1. However, because this measure relates directly to the role of information exchange that we seek to promote through the meaningful use of Certified EHR Technology, we believe that a higher threshold for this measure is appropriate. Although the majority chose to defer this measure in Stage 1, the performance of both EPs and hospitals was well above the Stage 1 threshold. For these reasons we are proposing to raise the threshold of this measure to 65 percent for Stage 2.

The thresholds of both measures must be reached in order for the EP, eligible hospital, or CAH to meet the objective. If the EP, eligible hospital, or CAH reaches one of these thresholds but not the other, then the EP, eligible hospital, or CAH will fail to meet this objective.

(c) Public Health Objectives

Due to similar considerations among the public health objectives, we are discussing them together. Some Stage 2 public health objectives are in the core set while others are in the menu set. Each objective is identified as either core or menu in the below 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 where authorized, 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 are proposing the following requirements, which would apply to all of the public health objectives and measures. We propose that actual patient data is required for the meaningful use measures that include ongoing submission of patient data.

There are a growing number of public health agencies partnering 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 at:

https://questions.cms.hhs.gov/app/answers/detail/a_id/10764/kw/immunizations) we clarify that such arrangements with HIE organizations, if serving on the behalf of the public health agency 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 Certified EHR Technology 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.

- An eligible provider is required to utilize the transport method or methods supported by the public health agency in order to achieve meaningful use.
- Unlike in Stage 1, a failed submission would not meet the objective. An eligible provider must either have successful ongoing submission or meet exclusion criteria.
- We expect that CMS, CDC and public health agencies (PHA) 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 request comments on challenges to implementing this strategy.

We will accept a yes/no attestation and information indicating to which public health agency the public health data were submitted to support each of the public health meaningful use measures.

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 would not preempt otherwise applicable State or local laws that govern reporting. In the latter case, EPs, eligible hospitals and CAHs would be excluded from 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.

This objective is in the Stage 2 core set for EPs, eligible hospitals and CAHs. 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 Certified EHR Technology, 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 propose 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.

The HIT Policy Committee recommended making this a core objective for Stage 2 for EPs and hospitals, and we are adopting their recommendation. We agree that the bar for Stage 2 should move from simply testing the electronic submission of immunization data to ongoing submission. We also agree that given the focus on upgrading and enhancing immunization registries' capacity, under CDC's guidance, this measure is sufficiently achievable to warrant its inclusion in the core set of Stage 2 meaningful use measures. However, we specifically invite comment on the challenges that moving this objective from the menu set to the core set would present for EPs and hospitals.

We also propose to modify the Stage 1 objective to add "except where prohibited" because we want 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 is not required by either law or practice. There are a few instances where some EPs, eligible hospitals, and CAHs are not authorized or cannot submit 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).

Proposed 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.

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 the 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 receiving electronic immunization data in the specific for Certified EHR Technology at the start of their EHR reporting period; or (3) 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 Certified EHR Technology at the start of their EHR reporting period. For the second and third scenarios, there is no exclusion if an entity designated by the immunization registry can receive electronic immunization data submissions. For example, if the immunization registry cannot accept the data directly or in the version of HL7 used by the provider's Certified EHR Technology, but has designated a Health Information Exchange to do so on their behalf, the provider could not claim the 2nd or 3rd exclusions previously noted.

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.

This objective is in the Stage 2 core set for eligible hospitals and CAHs. The same rationale for the 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.

Proposed Eligible Hospital/CAH Measure: Successful ongoing submission of electronic reportable laboratory results from Certified EHR Technology to a public health agency for the entire EHR reporting period.

Please refer to the general public health discussion regarding use of intermediaries.

Exclusions: The eligible hospital or CAH operates in a jurisdiction for which no public health agency is capable of receiving electronic reportable laboratory results in the specific standards required by ONC for EHR certification at the start of the EHR reporting period.

Proposed Objective: Capability to submit electronic syndromic surveillance data to public health agencies except where prohibited, and in accordance with applicable law and practice.

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 Certified EHR Technology, either due to technical or resource readiness. Given public health IT infrastructure improvements and new implementation guidance, for Stage 2, we are proposing 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 proposed 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 providers, and there is no corresponding implementation guide at the time of this proposed rule. CDC is working with the syndromic surveillance community to develop a new implementation guide for ambulatory reporting of syndromic surveillance information, which it expects will be available in the fall of 2012. 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 are not proposing to adopt their recommendation for EPs. We specifically invite 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.

Proposed Measure: Successful ongoing submission of electronic syndromic surveillance data from Certified EHR Technology to a public health agency for the entire 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 (we expect that the CDC will be issuing (in Spring 2013) the CDC PHIN Messaging Guide for Ambulatory Syndromic Surveillance and we may relay on this guide to determine which categories of EPs would not collect such information); (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 ONC for EHR certification for 2014 at the start of their EHR reporting period; or (4) the EP, eligible hospital, or CAH operates in a jurisdiction for which no public health agency is capable of accepting the specific standards required for Certified EHR Technology at the start of their EHR reporting period. As was described under the immunization registry measure, the third and fourth exclusions do not apply if the public health agency has designated an HIE to collect this information on its behalf and that HIE can do so in the specific Stage 2 standards and/or the same standard as the provider's Certified EHR Technology. 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 would be open at all times.

(d) New Core and Menu Set Objectives and Measures for Stage 2

We are proposing 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 are proposing 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 these new menu set 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 Certified EHR Technology.

Making the image that results from diagnostic scans and accompanying information accessible through Certified EHR Technology 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.

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 Certified EHR Technology, but in absence of such exchange it is acceptable to manually add the image and accompanying information to Certified EHR Technology.

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 Certified EHR Technology.

For Stage 2, we do 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 Certified EHR Technology may be counted in the numerator of this measure. We define accessible as either incorporation of the image and accompanying information into Certified EHR Technology or an indication in Certified EHR Technology 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 Certified EHR Technology. Meaningful use does not 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 Certified EHR Technology. This link must conform to the certification requirements associated with this objective in the ONC rule. We encourage comments on the necessary level of specification and what those specifications should be to define accessible and what constitutes a direct link.

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

- Denominator: Number of scans and tests whose result is one or more image 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 Certified EHR Technology.
- Threshold: The resulting percentage must be more than 40 percent in order to meet this measure.

Exclusion: Any EP who does not perform diagnostic interpretation of scans or tests whose result is an image during the EHR reporting period.

We also solicit comments on a potential second measure for this objective that would encourage the exchange of imaging and results between providers. We are considering 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 Certified EHR Technology also be

exchanged with another provider of care. However, we are concerned that this extra measure may be difficult for some EPs to meet and might discourage a significant number of EPs from selecting this objective as part of their menu set. We also solicit comment on whether an exclusion for this second measure should be included for providers who do not typically exchange imaging scans and test results as a normal part of their workflow, and we encourage commenters to provide details about how such an exclusion might be included.

Proposed Objective: Record patient family health history as structured data

Family health history is a major risk indicator for a variety of chronic conditions for which effective screening and prevention tools are available. Certified EHR technology can use family health history, if captured as structured data, to inform clinical decision support, patient reminders, and patient education. Family health history would also benefit from greater interoperability made possible by EHRs. A family health history is unique to each patient and fairly static over time. Currently, every provider requests this information 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.

The HIT Policy Committee recommended delaying the inclusion of this objective until Stage 3 due to absence of available standards. However, we believe that standards supporting family health history are currently available. We are proposing this as a menu objective for Stage 2.

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.

For Stage 2, we do not propose to include the capability to exchange family health history electronically as part of the measure. We do not believe there is sufficient structured data capture of family health history to support such exchange. After Stage 2 increases the capture of family health history in EHRs, we will seek to include exchange with other providers and the patient in Stage 3.

We propose 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 note that this is a minimum and not a limitation on the health history that can be recorded. We invite comment on the utility of expanding this definition to capture risks associated with social and other environmental determinants.

We do 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.

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.

We are concerned that certain EPs may not be able to meet this measure either due to scope of practice constraints or lack of patient interaction. Therefore, we are proposing 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 would not have the face-to-face contact with patients necessary to obtain family health history information. We also believe that EPs who do not have office visits may be unable to obtain family health history information from referring physicians, which could prevent them from being able to meet the measure of this objective. While the exclusion does not relate directly to the denominator, it represents the barriers justifying the exclusion. Furthermore, all office visits would not require updates to family health history.

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.

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. 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 have included this objective to provide more flexibility in the menu objectives that EPs can choose. We believe that cancer reporting could provide many EPs with a meaningful use public health reporting option that is more aligned with their scope of practice.

We include "except where prohibited and in accordance with applicable law" 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.

Proposed EP Measure: Successful ongoing submission of cancer case information from Certified EHR Technology to a cancer registry for the entire EHR reporting period.

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; or (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 under Stage 2 at the beginning of their EHR reporting period.

An EP must either successfully submit or meet 1 of the exclusion criteria.

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.

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.

Proposed EP Measure: Successful ongoing submission of specific case information from Certified EHR Technology to a specialized registry for the entire EHR reporting period.

Exclusions: Any EP that meets at least 1of 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; or (2) the EP operates in a jurisdiction for which no registry is capable of receiving electronic specific case information in the specific standards required under Stage 2 at the beginning of their EHR reporting period.

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

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 are proposing this as a core objective for EPs for Stage 2. The additional time made available for Stage 2 implementation makes possible the inclusion of some new objectives in the core set. 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 seek comment on whether there may be special concerns with this objective in regards to behavioral health.

Proposed EP Measure: A secure message was sent using the electronic messaging function of Certified EHR Technology by more than 10 percent of unique patients seen by the EP during the EHR reporting period.

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

- Denominator: Number of unique patients seen by the EP during the EHR reporting period.
- Numerator: The number of patients in the denominator who send a secure electronic message to the EP using the electronic messaging function of Certified EHR Technology 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 no office visits during the EHR reporting period.

We note that this new measure requires action by patients in order for the EP to meet it. While this is a departure from most meaningful use measures, which are dependent solely on actions taken by the EP, we believe that requiring a measurement of patient use ensures that the EP will promote the availability and active use of secure electronic messaging by the patient. Furthermore, we believe that accountable care should extend to accountability for meaningful use objectives that encourage patient and family engagement. We invite comment on this new measure and whether EPs believe that the 10 percent threshold is too high or too low given the patient's role in achieving it.

We specify that the secure messages sent should contain relevant health information specific to the patient in order to meet the measure of this objective. We believe the 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, not because we believe that the messages sent by the patient to the healthcare provider do not need to contain relevant health information, but because we believe the provider is best equipped to determine whether such information is included. It would be too great a burden for the certified EHR technology, or the attestation process, to determine whether the information in the secure message has such information. We also note that 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 as a condition of meeting this measure.

To address some circumstances regarding scope of practice, we propose an exclusion to this objective for EPs who have no office visits during the EHR reporting period. Not having any office visits for an entire EHR reporting period indicates that there may not be a need for follow-up communication through secure electronic messaging.

Proposed Eligible Hospital/CAH Objective: Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (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 are proposing 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 propose to define eMAR as technology that automatically documents the administration of medication into Certified EHR Technology 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 proposed rule published elsewhere in this issue of the **Federal Register**.

By its very definition, eMAR occurs at the point of care so we do not propose additional qualifications on when it must be used or who must use it.

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.

This recommendation by the HIT Policy Committee was that the measure of this objective be that eMAR is implemented and in use for the entire EHR reporting period in at least one ward/unit of the hospital. However, we recognize that it may be difficult to provide a definition of ward or unit that is applicable for all eligible hospitals and CAHs. Therefore we are proposing a percentage-based measure that would be applicable to all medication orders created by authorized providers of an inpatient or emergency department. We believe the low threshold of 10 percent allows eligible hospitals and CAHs maximum flexibility in how they choose to implement eMAR. We note that this approach does not prevent an eligible hospital or CAH from implementing eMAR in a single ward or unit, provided that they are able to meet the 10 percent threshold from orders tracked through eMAR in that unit. Eligible hospitals and CAHs might also elect to implement eMAR more widely in order to better complement their current workflow.

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 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.

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

The use of electronic prescribing has several advantages over having the patient carry the prescription to the pharmacy or directly faxing a handwritten or typewritten prescription to the pharmacy. When the hospital generates the prescription electronically, Certified EHR Technology 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 Certified EHR Technology 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.

The HIT Policy Committee recommended the inclusion of eRx for hospitals for discharge medications. We agree that eRx has unique advantages for discharge medications versus medications dispensed within the hospital. Primarily the efficiency of

the transmission and the information it provides to the external pharmacy and/or third party to compare to other medication orders received for the patient.

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 Certified EHR Technology.

The HIT Policy Committee recommended that this measure be limited to new or changed prescriptions that were ordered during the course of treatment of the patient while in the hospital. The limitation is necessary because prescriptions that originate prior to the hospital stay, and that remain unchanged, would be within the purview of the original prescriber, and not hospital staff or attending physicians. We propose to include this limitation as we agree with the HIT Policy Committee that the hospital would not issue refills for medications they did not authorize or alter during their treatment of the patient. We ask that commenters consider whether a hospital issues refills to patients being discharged for medications the patient was taking when they arrived at the hospital and, if so, whether distinguishing those prescriptions from new or altered prescriptions is unnecessarily burdensome for the hospital.

As this would be a new menu objective for hospitals for Stage 2 and we continue to have concerns about the effect of patient preferences, we are proposing a threshold of 10 percent as recommended by the HIT Policy Committee. We do not believe that an exclusion based on the number of medications is necessary, as we cannot envision a hospital with fewer than 100 prescriptions, but we do propose an exclusion if there are no

pharmacies that accept electronic prescriptions within 25 miles of the hospital. A hospital with an internal pharmacy that can dispense these electronic prescriptions to patients after discharge could not qualify for this exclusion.

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. Not all drug formularies are linked to all Certified EHR Technologies, so we do not require that the formulary be one that is relevant for the particular patient. Therefore, the comparison could return a result of formulary unavailable for that patient and medication combination. This modification of the measure replaces the Stage 1 menu objective of "Implement drug-formulary checks" and is intended to provide better integration guidance both for the hospital and their supporting vendors. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- Denominator: Number of new or changed prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances for patients discharged during the EHR reporting period.
- Numerator: The number of prescriptions in the denominator generated, compared to 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 there are no pharmacies that accept electronic prescriptions within 25 miles 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.

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, this objective aligns with the FIPPs,[3] in affording baseline privacy protections to individuals. We believe that 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. Providers who are covered by civil rights laws must provide individuals

[3] Ibid.

with disabilities equal access to information and appropriate auxiliary aids and services as provided in the applicable statutes and regulations.

We propose this as a core objective for hospitals in Stage 2 with the following information that must be available as part of the objective:

- Admit and discharge date and location.
- Reason for hospitalization.
- Providers of care during hospitalization.
- Problem list maintained by the hospital on the patient.
- Relevant past diagnoses known by the hospital.
- Medication list maintained by the hospital on the patient (both current admission and historical).
- Medication allergy list maintained by the hospital on the patient (both current admission and historical).
- Vital signs at discharge.
- Laboratory test results (available at time of discharge).
- Care transition summary and plan for next provider of care (for transitions other than home).
- Discharge instructions for patient, and
- Demographics maintained by hospital (gender, race, ethnicity, date of birth, preferred language, smoking status).

This is not intended to limit the information made available by the hospital. A hospital can make available additional information and still align with the objective.

A hospital has any number of ways to make this information available online. The hospital can host a patient portal, contract with a vendor to host a patient portal, connect with an online PHR or other means. As long as the patient can view and download the information using a standard web browser and internet connection, the means is at the discretion of the hospital.

Proposed 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.

This objective replaces two Stage 1 objectives for providing patients electronic copies of their health information upon request and providing electronic copies of discharge instructions. In Stage 1 of meaningful use, there was a measure of 50 percent of patients requesting electronic copies (within 3 business days) and discharge instructions (at time of discharge) were provided to them. The creation of this Stage 2 combined objective creates different time constraints. The HIT Policy Committee recommended 36 hours from discharge as an appropriate time period to meet this measure. We see no compelling reason to alter this recommendation; however, we encourage comment on whether this is an appropriate time frame for this new measure.

The second measure represents a new concept for meaningful use criteria, because it measures the hospital based upon the actions of the patient. The HIT Policy Committee noted that providers would want flexibility with respect to the type of guidance provided to patients. In turn, the HIT Policy Committee recommended best practice guidance for providers, vendors, and software developments. We believe the hospital can sponsor education and awareness activities that result in patients viewing their information. Also, the low threshold of 10 percent recognizes that this kind of measure is in its earlier stages. A patient who views their information online, downloads it from the internet or uses the internet to transmit it to a third party would count for purposes of the numerator. However, we recognize, that in areas of the country where a significant section of the patient population does not have access to broadband internet, this measure may be significantly harder or impossible to achieve. For example, for a hospital in an area with 100 percent broadband availability, only 10 percent of the patient population must view the information. However, a hospital in an area with 30 percent broadband availability must essentially have a third of their patient population view the information. In addition, areas with high broadband penetration tend to correlate with more prolific users making it more likely that patients will view information online. There are 2 possible solutions to this disparity. The first is to exclude hospitals that operate in areas with below a certain threshold of broadband penetration. The second would be to change the measure to 10 percent of the broadband penetration. According to the FCC, 370 counties in the United States have broadband penetration of less than 50 percent (www.broadband.gov). Hospitals in areas of low broadband availability tend

to service large areas that may extend beyond the county in which the hospital is located. Under the first option we considered if the county in which the hospital is located has less than 50 percent 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, the hospital may exclude the second measure. Under the second option, the hospital would have to meet 10 percent of the broadband availability according to the FCC in the county in which they are located at the beginning of the EHR reporting period. For example, if the reported availability in a county on October 1 2014, for a hospital was 23 percent, the hospital's threshold for the second measure would be 2.3 percent. There are counties currently with zero percent availability. If there is a hospital in a county with zero percent availability, those hospitals would not have to meet the second measure. We propose to adopt the first method as we believe the second method is too complex to be a practical requirement. However, we welcome comments on both options as well as the correct threshold for the first option.

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

First Measure:

- 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.

Second Measure:

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

- Numerator: The number of patients in the denominator who view, download or transmit to a third party the information provided by the eligible hospital or CAH online during the EHR reporting period.

- 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 will be excluded from the second measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period is excluded from the second measure.

(e) Objective and Measure Carried Over Unmodified from Stage 1 Menu Set to Stage 2 Menu Set

Proposed Eligible Hospital/CAH Objective: Record whether a patient 65 years old or older has an advance directive.

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 Certified EHR Technology or link to an electronic copy of the advance directive. However, we propose to maintain this objective as part of the Menu Set and we are not proposing a copy or link to the advance directive for eligible hospitals and CAHs in Stage 2. 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 do not propose to adopt the HIT Policy Committee's recommendations to require this objective as a core measure, to store an electronic copy of the advance directive in the Certified EHR Technology, or to link to an electronic copy of the advance directive.

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 would not record this information under current standards of practice and would 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 would be excluded from the objective would be too cumbersome and still might not be comprehensive. Therefore, we are not proposing the recording of the existence of advance directives as an objective for EPs in Stage 2. However, we invite public comment on this decision and encourage 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.

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.

We propose that the measure of this objective would remain unmodified from Stage 1. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- 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.

Please note 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.

(f) Other HIT Policy Committee Recommended Objectives Not Proposed

We are not proposing these objectives for Stage 2 as explained at each objective, but we encourage comments on whether these objectives should be incorporated into Stage 2.

Hospital Objective: Provide structured electronic lab results to eligible professionals.

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 would need to be done so using the capabilities Certified EHR Technology. 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 Certified EHR Technology. To facilitate the ease with which this electronic exchange may take place, ONC has proposed that for certification, ambulatory EHR technology would need to be able to incorporate lab test results formatted in the same standard and implementation specifications to which inpatient EHR technology would

need to be certified as being able to create. However, we are not proposing this objective for a variety of reasons. While ONC is working to ease the barriers to this exchange through certification, this assumes that over 40 percent of the ordering providers would be utilizing Certified EHR Technology. Also, as discussed elsewhere, there is more to exchange than the established standards. Secondly, although hospital labs supply nearly half of all lab results to EPs, 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 are 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 focuses on the inpatient and emergency departments of a hospital. This objective is not related to these departments, in fact, it explicitly excludes services provided in these departments. We encourage comments on both the pros and cons of this objective and whether it should be considered for the final rule as recommended by the HIT Policy Committee.

The HIT Policy Committee recommended this as a core objective for Stage 2 for eligible hospitals.

EP Objective/Measure: Record patient preferences for communication medium for more than 20percent of all unique patients seen during the EHR reporting period.

We believe that this requirement is better incorporated with other objectives that require patient communication and is not necessary as a standalone objective.

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 believe that this requirement is better incorporated with other objectives that require summary of care documents and is not necessary as a standalone objective.

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 believe that this requirement is better incorporated with other objectives that require summary of care documents and is not necessary as a standalone objective.

Objective/Measure: Record electronic notes in patient records for more than 30 percent of office visits.

While we believe that medical evaluation entries by providers are an important component of patient records that can provide information not otherwise captured within standardized fields, we believe there is evidence to suggest that electronic notes are already widely used by providers of Certified EHR Technology and therefore do not need to be included as a meaningful use objective. For example, a 2008 survey of healthcare professionals indicated that 75 percent of respondents were already using an EHR for physician charting/documentation and 74 percent were already using the EHR for nursing charting/documentation (2008 HIMSS/HIMSS Analytics Ambulatory Healthcare IT Survey: http://www.himss.org/content/files/2008_HA_HIMSS_ambulatory_Survey.pdf). However, we note that ONC has included in its Stage 2 proposed rule certification

capabilities that require Certified EHR Technology to allow the inclusion of electronic notes that are text-searchable.

Table 4 provides a summary of stage 2 objectives and measures that we are proposing to adopt.

TABLE 4: STAGE 2 MEANINGFUL USE OBJECTIVES AND ASSOCIATED MEASURES SORTED BY CORE AND MENU SET

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 to create the first record of the order.	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.	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.
	Generate and transmit permissible prescriptions electronically (eRx)		More than 65 percent of all permissible prescriptions written by the EP are compared to at least one drug formulary and transmitted electronically using Certified EHR Technology.
	Record the following demographics • Preferred language • Gender • Race • Ethnicity • Date of birth	Record the following demographics • Preferred language • Gender • 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) 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) 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% 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 department (POS 21 or 23) 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 5 clinical decision support interventions related to 5 or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. 2. The EP, eligible hospital or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entre EHR reporting period.

Health Outcomes Policy Priority	Stage 2 Objectives		Stage 2 Measures
	Eligible Professionals	Eligible Hospitals and CAHs	
	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 or numerical format are incorporated in Certified EHR Technology as structured data
	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		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
		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 are tracked using eMAR..

Health Outcomes Policy Priority	Stage 2 Objectives		Stage 2 Measures
	Eligible Professionals	Eligible Hospitals and CAHs	
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 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
		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 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 reporting period
	Provide clinical summaries for patients for each office visit		Clinical summaries provided to patients within 24 hours for more than 50 percent of office visits.

Health Outcomes Policy Priority	Stage 2 Objectives		Stage 2 Measures
	Eligible Professionals	Eligible Hospitals and CAHs	
	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 Certified EHR Technology are provided to patients for more than 10 percent of all office visits by the EP. 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 10 percent of unique patients seen 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 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).

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 should provide 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 should provide 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 65 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 electronically transmits a summary of care record using certified EHR technology to a recipient with no organizational affiliation and using a different Certified EHR Technology vendor than the sender for more than 10 percent of transitions of care and referrals.
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
		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 as authorized.
		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

Health Outcomes Policy Priority	Stage 2 Objectives		Stage 2 Measures
	Eligible Professionals	Eligible Hospitals and CAHs	
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 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.
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 and information are accessible through Certified EHR Technology.	Imaging results and information are accessible through Certified EHR Technology.	More than 40 percent of all scans and tests whose result is an image 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 or changed prescriptions) are compared to at least one drug formulary and transmitted electronically using Certified EHR Technology
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 State cancer registry, except where prohibited, and in accordance with applicable law and practice.		Successful ongoing submission of cancer case information from Certified EHR Technology to a cancer registry for the entire EHR reporting period
	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

1. Time Periods for Reporting Clinical Quality Measures

This section clarifies the time periods as they relate to reporting clinical quality measures only. We are not proposing any changes to the time periods for reporting clinical quality measures. The EHR reporting period for clinical quality measures under the EHR Incentive Program is the period during which data collection or measurement for clinical quality measures occurs. The reporting period is consistent with our Stage 1 final rule (75 FR 44314) and will continue to track with the EHR reporting periods for the meaningful use criteria:

- Eligible Professionals (EPs): January 1 through December 31 (calendar year).
- Eligible Hospitals and Critical Access Hospitals (CAHs): October 1 through September 30 (Federal fiscal year).
- EPs, eligible hospitals, and CAHs in their first year of meaningful use for Stage 1, the EHR reporting period would be 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 the 90-day EHR reporting period ends at least three months before the end of the CY or FY, and that all submission is completed by October 1 or July 1, respectively. For an explanation of the applicable EHR reporting periods for determining the payment adjustments, please see section II.D. of this proposed rule.

TABLE 5: REPORTING ON CLINICAL QUALITY MEASURES USING CERTIFIED EHR TECHNOLOGY BY ELIGIBLE PROFESSIONALS, ELIGIBLE

HOSPITALS AND CRITICAL ACCESS HOSPITALS

Provider Type	Reporting Period for First Year of Meaningful Use (Stage 1)	Submission Period for First Year of Meaningful Use (Stage 1)	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	90 consecutive days	Anytime immediate following the end of the 90-day reporting period, but no later than February 28 of the following calendar year.	1 calendar year (January 1 - December 31)	2 months following the end of the EHR reporting period (January 1 - February 28)
Eligible Hospital/CAH	90 consecutive days	Anytime immediate following the end of the 90-day reporting period, but no later than November 30 of the following fiscal year.	1 fiscal year (October1 - September 30)	2 months following the end of the EHR reporting period (October 1 - November 30)

For example, for an EP, an EHR reporting period would be January 1, 2014 through December 31, 2014 and is the same as CY 2014. If the EP is in his or her first year of Stage 1, the EHR reporting period could be at the earliest from January 1, 2014 through March 31, 2014 and at the latest from October 3, 2014 through December 31, 2014. If the EP is demonstrating meaningful use for the first time in CY 2014, for purposes of avoiding the payment adjustment in CY 2015, the EHR reporting period must end by September 30, 2014.

For an eligible hospital or CAH, an EHR reporting period would be October 1, 2013 through September 30, 2014 and is the same as FY 2014. If the eligible hospital or CAH is in its first year of meaningful use for Stage 1, the EHR reporting period could be at the earliest from October 1, 2013 through December 29, 2013 and at the latest from July 3, 2014 through September 30, 2014. If an eligible hospital is demonstrating meaningful use for the first time in FY 2014, for purposes of avoiding the payment adjustment in FY 2015, the EHR reporting period must end by June 30, 2014.

For EPs, eligible hospitals, and CAHs, the submission period for clinical quality measure data to us generally would be 2 months immediately following the end of the EHR reporting period:

- Eligible Professionals: 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 could submit clinical quality measure data anytime after their respective 90-day EHR reporting period up to 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 clinical quality measure data no later than October 1 (for EPs) or July 1 (for eligible hospitals) of such preceding year.

Using the same examples for the EHR reporting periods previously for an EP, the submission period for CY 2014 would be January 1, 2015 through February 28, 2015. If the EP is in his or her first year of Stage 1, the submission period could begin at the earliest April 1, 2014 and would end February 28, 2015. However, if the EP is demonstrating meaningful use for the first time in CY 2014, for purposes of avoiding the payment adjustment in CY 2015, the clinical quality measure data must be submitted by October 1, 2014.

Using the same examples for the EHR reporting periods previously for an eligible hospital and CAH, the submission period for FY 2014 would be October 1, 2014 through November 30, 2014. If the eligible hospital and CAH is in its first year of Stage 1, the submission period could be begin at the earliest December 30, 2013 and would end November 30, 2014. However, if an eligible hospital is demonstrating meaningful use for the first time in FY 2014, for purposes of avoiding the payment adjustment in FY 2015, the clinical quality measure data must be submitted by July 1, 2014.

2. Certification Requirements for Clinical Quality Measures

The Office of the National Coordinator (ONC) sets the certification criteria for EHR technology, which for clinical quality measures are described in 45 CFR 170.314(c) in ONC's proposed rule published elsewhere in this issue of the **Federal Register**. Certified EHR Technology will be required for the reporting methods finalized from this proposed rule. This may include attestation, reporting under the PQRS EHR reporting option, the group reporting options for EPs, the aggregate portal-based reporting methods, and the finalized reporting method for eligible hospitals and CAHs. Readers should refer to ONC's proposed rule for an explanation of the definition of Certified EHR Technology that would apply beginning with 2014.

In addition, for attestation and the aggregate portal-based reporting methods for EPs, eligible hospitals and CAHs, Certified EHR Technology must be certified to "incorporate and calculate" in accordance with 45 CFR 170.314(c)(2) for each individual clinical quality measure that an EP, eligible hospital or CAH submits. EPs, eligible hospitals and CAHs must only submit clinical quality measures that their Certified EHR Technology is explicitly certified to calculate according to 45 CFR 170.314(c)(2) in ONC's proposed rule in order to meet the meaningful use requirement for reporting clinical quality measures. For example, if an EP's Certified EHR Technology is only certified to calculate clinical quality measures #1 through #12, and the EP submits clinical quality measures #1 through #11 and #37, the EP would not have met the meaningful use requirement for reporting clinical quality measures because his/her Certified EHR Technology was not certified to calculate clinical quality measure #37.

Likewise, for attestation and the aggregate portal-based reporting methods, Certified EHR Technology must be certified for "reporting" (please refer to the discussion of

45 CFR 170.314(c)(3) in ONC's proposed rule), which certifies the capability to create and transmit a standard aggregate XML-based file that can be electronically accepted by CMS.

3. Criteria for Selecting Clinical Quality Measures

We are soliciting comment on a wide ranging list of 125 potential measures for EPs and 49 potential measures for eligible hospitals and CAHs. We expect to finalize only a subset of these proposed measures.

We are committed to aligning quality measurement and reporting among our programs (for example, IQR, PQRS, CHIPRA, ACO programs). Our alignment efforts focus on several fronts including choosing the same measures for different program measure sets, standardizing measure development and specification processes across CMS programs, coordinating quality measurement stakeholder involvement efforts and opportunities for public input, and identifying ways to minimize multiple submission requirements and mechanisms. For example, we are working towards allowing CQM data submitted via certified EHRs by EPs and EHs/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 believe the alignment options for PQRS/EHR Incentive Program proposed in this rule are the first step towards such a vision. We are exploring how 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 ACA measure sets, etc). This would lessen provider burden and harmonize with our data exchange priorities, while also supporting our goal of the programs transforming our system to provide higher quality care, better health outcomes, and lower cost through improvement.

In addition to statutory requirements for EPs (section II.B.4.(a) of this proposed rule), eligible hospitals (section II.B.6.(a), of this proposed rule), and CAHs (section II.B.6.(a) of this proposed rule), we relied on the following criteria to select this initial list of proposed clinical quality measures for EPs, eligible hospitals, and CAHs:

- 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.

- Measures 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 Congress, "National Strategy for Quality Improvement in Health Care" (National Quality Strategy) (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). These include the following 6 priorities:

  ++ Making care safer by reducing harm caused in the delivery of care.

  ++ Ensuring that each person and family are engaged as partners in their care.

  ++ Promoting effective communication and coordination of care.

  ++ Promoting the most effective prevention and treatment practices for the leading

causes of mortality, starting with cardiovascular disease.

++ Working with communities to promote wide use of best practices to enable healthy living.

++ Making quality care more affordable for individuals, families, employers, and governments by developing and spreading new health care delivery models.

● Measures 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.

● Measures that address areas of care for different types of eligible professionals (for example, Medicare- and Medicaid-eligible physicians, and Medicaid-eligible nurse-practitioners, certified nurse-midwives, dentists, physician assistants).

In an effort to align the clinical quality measures used within the EHR Incentive Program with the goals of CMS and HHS, the National Quality Strategy, and the HITPC's recommendations, we have assessed all proposed measures against six domains based on the National Quality Strategy's six priorities, which were developed by the HITPC Workgroups, as follows:

● Patient and Family Engagement. These are measures 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 measures 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 measures 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 measures 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 measures that reflect efforts to significantly improve outcomes and reduce errors. These measures 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 measures that reflect clinical care processes closely linked to outcomes based on evidence and practice guidelines.

We welcome comments on these domains, and whether they will adequately align with and support the breadth of CMS and HHS activities to improve quality of care and health outcomes.

We also considered the recommendations of the Measure Applications Partnership

(MAP) for inclusion of clinical quality measures. 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 clinical quality measures that the MAP did not support. The MAP did not review the clinical quality measures for 2011 and 2012 that were previously adopted for the EHR Incentive Program in the Stage 1 final rule. We have included some of the clinical quality measures not supported by the MAP in Tables 8 (EPs) and 9 (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 included some measures to address specialty areas that may not have had applicable measures in the Stage 1 final rule.

We anticipate that only a subset of these measures will be finalized. When considering which measures to finalize, we will take into account public comment on the measures themselves and the priorities listed previously. We intend to prioritize measures that align with and support the measurement needs of CMS program activities related to quality of care, delivery system reform, and payment reform, especially:

- 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.

4. Measure Specification

We do not intend to use notice and comment rulemaking as a means to update or modify clinical quality measure specifications. A clinical quality measure that has completed the consensus process has a measure steward who has accepted responsibility for maintaining and updating the measure. In general, it is the role of the measure steward to make changes to a measure in terms of the initial patient population, numerator, denominator, and potential exclusions. We recognize that it may be necessary to update measure 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 measure, correcting faulty logic, adding or deleting codes as well as providing additional implementation guidance for a measure. These changes would be described in full through supplemental updates to the electronic specifications for EHR submission provided by CMS.

The complete measure 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 when considering the proposed clinical quality measures in this proposed rule, we would publish tables titled "Proposed Clinical Quality Measures for 2014 CMS EHR Incentive Programs for Eligible Professionals" and "Proposed Clinical Quality Measures for 2014 CMS EHR Incentive Programs for Eligible Hospitals and CAHs" on this website at or around the time of the publication of this proposed rule. These tables contain additional information for the EP, eligible hospital and CAH clinical quality

measures, respectively, which may not be found on the NQF website. Some of these measures are still being developed, therefore the additional descriptions provided in these tables may still change before the final rule is published. Public comments regarding these measures should be submitted using the same method required for all other comments related to this proposed rule. Please note that the titles and descriptions for the clinical quality measures included in these tables were updated by the measure stewards and therefore may not match the information provided on the NQF website. Measures that do not have an NQF number are not currently endorsed.

Measures would be tracked on a version basis as updates to those measures are made. We would require all EPs, eligible hospitals, and CAHs to submit the versions of the clinical quality measure as identified on our website, and they would need to include the version numbers when they report the measure. It is our intent to include the version numbers with our updates to the measure specifications.

Under certain circumstances, we believe it may be necessary to remove a clinical quality measure from the EHR Incentive Program between rulemaking cycles. When there is reason to believe that the continued collection of a measure as it is currently specified raises potential patient safety concerns and/or is no longer scientifically valid, it would be appropriate for us to take immediate action to remove the measure from the EHR Incentive Program and not wait for the rulemaking cycle. Likewise, if a clinical quality measure undergoes a substantive change by the measure steward between rulemaking cycles such that the measure's intent has changed, we would expect to remove the measure immediately from the EHR Incentive Program until the next rulemaking cycle when we could propose the revised measure for public comment. Under this policy, we would promptly remove such clinical quality measures from the set of measures

available for providers to report under the EHR Incentive Program, confirm the removal (or propose the revised measure) in the next EHR Incentive Program rulemaking cycle, and notify providers (EPs, eligible hospitals, and CAHs) and the public of our decision to remove the measure(s) through the usual communication channels (memos, email notification, website postings).

5. Proposed Clinical Quality Measures for Eligible Professionals

(a) Statutory and Other Considerations

Sections 1848(o)(2)(A)(iii) and 1903(t)(6)(C) of the Act provide for the reporting of clinical quality measures by EPs as part of demonstrating meaningful use of Certified EHR Technology. 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 Certified EHR Technology under Medicare and Medicaid. Therefore, to meet this requirement, we continue our practice from Stage 1 of proposing clinical quality measures that would apply for both the Medicare and Medicaid EHR Incentive Programs, as listed in sections II.B.4.(b). and II.B.4.(c). of this proposed rule.

Section 1848(o)(2)(B)(iii) of the Act requires that in selecting measures 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 Physician Quality Reporting System). Consistent with that requirement, we

are proposing to select clinical quality measures for EPs for the EHR Incentive Programs that align with other existing quality programs such as the Physician Quality Reporting System (PQRS) (76 FR 73026), the Medicare Shared Savings Program (76 FR 67802), measures used by the National Committee for Quality Assurance (NCQA) for medical home accreditation (http://ncqa.org), the Health Resources and Services Administration's (HRSA) Uniform Data System (UDS) (75 FR 73170), Children's Health Insurance Program Reauthorization Act (CHIPRA) (75 FR 44314), and the final Section 2701 adult measures under the Affordable Care Act (ACA) published in the Federal Register on January 4, 2012 (77 FR 286). When a measure is included in more than one CMS quality reporting program and is reported using Certified EHR Technology, we would seek to avoid requiring EPs to report the same clinical quality measure 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 clinical quality measures endorsed by the entity with a contract with the Secretary under section 1890(a) (namely, the National Quality Forum (NQF)). We are proposing clinical quality measures 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 measures for the EHR Incentive Programs. Measures listed in this proposed rule that do not have an NQF identifying number are not NQF endorsed, but are included in this proposed rule with the intent of eventually obtaining NQF endorsement of those measures determined to be critical to our program.

Per the preamble discussion in the Stage 1 final rule regarding measures gaps and Medicaid providers (75 FR 44506), we are proposing to increase the total number of clinical quality measures for EPs in order to cover areas noted by commenters such as behavioral health,

dental care, long-term care, special needs populations, and care coordination. The new measures we are proposing beginning with CY 2014 include new pediatric measures, an obstetric measure, behavioral/mental health measures, and measures related to HIV medical visits and antiretroviral therapy, as well as other measures that address National Quality Strategy goals.

We recognize that we do not have additional measures to propose beginning with CY 2014 in the areas of long-term and post-acute care. Since the publication of the Stage 1 final rule, we have partnered with the National Governor's Association to participate in a panel with long-term care and health information exchange experts to gain insight and consensus on possible clinical quality measures. At this time, however, no clinical quality measures for long-term and post-acute care have been identified as being ready (electronically specified) beginning with CY 2014. We expect to continue to develop or identify clinical quality measures for these areas with our partners and stakeholders for future years.

We are pleased to propose two oral health measures beginning with CY 2014. In the past year, we partnered with Agency for Healthcare Research and Quality (AHRQ) to solicit input from a technical expert panel to identify barriers to the adoption and use of health IT for oral health care providers. A final report titled "Quality Oral Health Care in Medicaid Through Health IT" is available at http://healthit.ahrq.gov/portal/server.pt/community/ahrq-fundedprojects/654/medicaid-schip/14760. CMS, the American Dental Association, and the Dental Quality Alliance have all strategized ways to encourage and support the use of EHRs for oral health providers. We expect to continue to develop or identify clinical quality measures for dental/oral health care with our partners and stakeholders that could be ready for future years.

(b) Proposed Clinical Quality Measures for Eligible Professionals for CY 2013

We propose that for the EHR reporting periods in CY 2013, EPs must submit data for the clinical quality measures that were finalized in the Stage 1 final rule for CYs 2011 and 2012 (75 FR 44398 through 44411, Tables 6 and 7). Updates to these clinical quality measures' electronic specifications are expected to be posted on the EHR Incentive Program website at least 6 months prior to the start of CY 2013 (https://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp). As required by the Stage 1 final rule, EPs must report on three core or alternate core measures, plus three additional measures. We refer readers to the discussion in the Stage 1 final rule for further explanation of the requirements for reporting those clinical quality measures (75 FR 44398 through 44411). The proposed reporting methods for EPs for CY 2013 are discussed in sections II.B.5.(a). and II.B.5.(b). of this proposed rule.

(c) Proposed Clinical Quality Measures for Eligible Professionals Beginning with CY 2014

We are proposing two reporting options that would begin in CY 2014 for Medicare and Medicaid EPs, as described below: Options 1 and 2. For Options 1, we are proposing the following two alternatives, but intend to finalize only a single method:

- Option 1a: EPs would report 12 clinical quality measures from those listed in Table 8, including at least 1 measure from each of the 6 domains.
- Option 1b: EPs would report 11 "core" clinical quality measures listed in Table 6 plus 1 "menu" clinical quality measure from Table 8.

We welcome comment regarding the advantages and disadvantages of Options 1a and 1b, including EP preference, the appropriateness of the domains, the number of clinical quality measures required, and the appropriate split between "core" and "menu" clinical quality measures. It is our intent to finalize the most operationally viable and appropriate option or

combination of options in our final rule. As an alternative to Options 1a or 1b, Medicare EPs who participate in both the Physician Quality Reporting System and the EHR Incentive Program may choose Option 2 , as described below (the Physician Quality Reporting System EHR Reporting Option).

We are proposing clinical quality measures in Table 8 that would apply to all EPs for the EHR reporting periods in CYs 2014 and 2015 (and potentially subsequent years), regardless of whether an EP is in Stage 1 or Stage 2 of meaningful use. For Medicaid EPs, the reporting method for clinical quality measures may vary by State. However, the set of clinical quality measures from which to select (Table 8) would be the same for both Medicaid EPs and Medicare EPs. Medicare EPs who are in their first year of Stage 1 of meaningful use may report clinical quality measures through attestation during the 2 months immediately following the end of the 90-day EHR reporting period as described in section II.B.1. of this proposed rule. Readers should refer to the discussion in the Stage 1 final rule for more information about reporting clinical quality measures through attestation (75 FR 44430 through 44431). We expect that by CY 2016, we will have engaged in another round of rulemaking for the EHR Incentive Programs. However, in the unlikely event such rulemaking does not occur, the clinical quality measures proposed for CYs 2014 and 2015 would continue to apply for the EHR reporting periods in CY 2016 and subsequent years. Therefore, we refer to clinical quality measures that apply "beginning with" or "beginning in" CY 2014.

- Option 1a: Select and submit 12 clinical quality measures from Table 8, including at least 1 measure from each of the 6 domains.

We are proposing that EPs must report 12 clinical quality measures from those listed in Table 8, which must include at least one measure from each of the following 6 domains, which are described in section II.B.3. of this proposed rule:

- Patient and Family Engagement.
- Patient Safety.
- Care Coordination.
- Population and Public Health.
- Efficient Use of Healthcare Resources.
- Clinical Process/Effectiveness.

EPs would select the clinical quality measures that best apply to their scope of practice and/or unique patient population. If an EP's Certified EHR Technology does not contain patient data for at least 12 clinical quality measures, then the EP must report the clinical quality measures for which there is patient data and report the remaining required clinical quality measures as "zero denominators" as displayed by the EPs Certified EHR Technology. If there are no clinical quality measures applicable to the EP's scope of practice or unique patient populations, EPs must still report 12 clinical quality measures even if zero is the result in either the numerator and/or the denominator of the measure. If all applicable clinical quality measures have a value of zero from their Certified EHR Technology, then EPs must report any 12 of the clinical quality measures. For this option, the clinical quality measures data would be submitted in an XML-based format on an aggregate basis reflective of all patients without regard to payer. One advantage of this approach is that EPs can choose measures that best fit their practice and patient populations. However, because of the large number of measures to choose from, this

approach would result in fewer EPs reporting on any given measure, and likely only a small sample of patient data represented in each measure.

- Option 1b: Submit 12 clinical quality measures composed of all 11 of the core clinical quality measures in Table 6 plus 1 menu clinical quality measure from Table 8.

We are considering a "core" clinical quality measure set that all EPs must report, which will reflect the national priorities outlined in section II.B.3. of this proposed rule. In addition to the core clinical quality measure set, we are considering a "menu" set from which EPs would select 1 clinical quality measure to report based on their respective scope of practice and/or unique patient population. One advantage of this approach is that quality data would be collected on a smaller set of measures, so the resulting data for each measure would represent a larger number of patients and therefore could be more accurate. However, this approach could mean that more measures are reported with zero denominators (if they are not applicable to certain practices or populations), making the data less comprehensive. The menu set would consist of the measures in Table 8 that are not part of the core clinical quality measure set. The core clinical quality measure set for EPs consists of the following measures in Table 6 (these clinical quality measures are also in Table 8):

TABLE 6: POTENTIAL CORE CLINICAL QUALITY MEASURE SET TO BE REPORTED BY ELIGIBLE PROFESSIONALS BEGINNING IN CY 2014

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Domain

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Domain
TBD	Title: Closing the referral loop: receipt of specialist report Description: Percentage of patients regardless of age with a referral from a primary care provider for whom a report from the provider to whom the patient was referred was received by the referring provider.	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	Care Coordination
TBD	Title: Functional status assessment for complex chronic conditions Description: Percentage of patients aged 65 years and older with heart failure and two or more high impact conditions 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	Patient and Family Engagement
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 during the measurement year.	NCQA Contact Information: www.ncqa.org	Clinical Process/ Effectiveness
NQF 0097	Title: Medication Reconciliation Description: Percentage of patients aged 65 years and older discharged from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) and seen within 60 days following discharge in the office by the physician providing on-going care who had a reconciliation of the discharge medications with the current medication list in the medical record documented.	AMA-PCPI Contact Information: cpe@ama-assn.org; National Committee for Quality Assurance (NCQA) Contact information: www.ncqa.org	Patient Safety
NQF 0418	Title: Screening for Clinical Depression Description: Percentage of patients aged 12 years and older screened for clinical depression using an age appropriate standardized tool and follow up plan documented.	CMS 1-888-734-6433 or http://questions.cms.hhs.gov/app/ask/p/21,26,1139	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	Population/ Public Health
TBD	Title: Preventive Care and Screening: Cholesterol – Fasting Low Density Lipoprotein (LDL) Test Performed AND Risk-Stratified Fasting LDL Description: Percentage of patients aged 20 through 79 years whose risk factors* have been assessed and a fasting LDL test has been performed. Percentage of patients aged 20 through 79 years who had a fasting LDL test performed and whose risk-stratified* fasting LDL is at or below the recommended LDL goal.	CMS 1-888-734-6433 or http://questions.cms.hhs.gov/app/ask/p/21,26,1139; QIP Contact Information: www.usqualitymeasures.org	Clinical Process/ Effectiveness

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Domain
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 transluminal coronary angioplasty (PTCA) from January 1-November 1 of the year prior to the measurement year, or who had a diagnosis of ischemic vascular disease (IVD) during the measurement year and the year prior to the measurement year and who had documentation of use of aspirin or another antithrombotic during the measurement year.	NCQA Contact Information: www.ncqa.org	Clinical Process/ Effectiveness
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 OB/GYN and who had evidence of body mass index (BMI) percentile documentation, counseling for nutrition and counseling for physical activity during the measurement year.	NCQA Contact information: www.ncqa.org	Population/ Public Health
NQF 0022	Title: Use of High-Risk Medications in the Elderly Description: Percentage of patients ages 65 years and older who received at least one high-risk medication. Percentage of patients 65 years of age and older who received at least two different high-risk medications.	NCQA Contact Information: www.ncqa.org	Patient Safety
TBD	Title: Adverse Drug Event (ADE) Prevention: Outpatient therapeutic drug monitoring Description: Percentage of patients 18 years of age and older receiving outpatient chronic medication therapy who had the appropriate therapeutic drug monitoring during the measurement year.	CMS 1-888-734-6433 or http://questions.cms.hhs.gov/app/ask/p/21,26,1139	Patient Safety

We selected these measures for the proposed core set based upon analysis of several factors that include: conditions that contribute the most to Medicare and Medicaid beneficiaries' morbidity and mortality; conditions that represent national public/population health priorities; conditions that are common to health disparities; those conditions that disproportionately drive healthcare costs that could improve with better quality measurement; measures that would enable CMS, States, and the provider community to measure quality of care in new dimensions with a stronger focus on parsimonious measurement; and those measures that include patient and/or caregiver engagement.

We request public comment on the core and menu set reporting schema described as well as the number and appropriateness of the core set listed in Table 6. We are considering that all identified core clinical quality measures must be reported by all EPs in addition to a menu set clinical quality measure. The policy on reporting "zeros" discussed previously under Option 1a would also apply for this core and menu option. In this option, an EP who does not report all of the identified core clinical quality measures, plus a menu set clinical quality measure, would have not met the requirements for submitting the clinical quality measures.

- Option 2: Submit and satisfactorily report clinical quality measures under the Physician Quality Reporting System's EHR Reporting Option.

We propose an alternative option for Medicare EPs who participate in both the Physician Quality Reporting System and the EHR Incentive Program. As an alternative to reporting the 12 clinical quality measures as described under Options 1a and 1b, and in order to streamline quality reporting options for participating providers, Medicare EPs who submit and satisfactorily report Physician Quality Reporting System clinical quality measures under the Physician Quality Reporting System's EHR reporting option using Certified EHR Technology would satisfy their clinical quality measures reporting requirement under the Medicare EHR Incentive Program. For more information about the requirements of the Physician Quality Reporting System, we refer readers to 42 CFR 414.90 and the CY 2012 Medicare Physician Fee Schedule final rule with comment period (76 FR 73314). EPs who choose this option to satisfy their clinical quality measures reporting obligation under the Medicare EHR Incentive Program would be required to comply with any changes to the requirements of the Physician Quality Reporting System that may apply in future years.

Table 7 lists the clinical quality measures that were finalized in the Stage 1 final rule (75 FR 44398 through 44408) that we are proposing to eliminate beginning with CY 2014.

TABLE 7: CLINICAL QUALITY MEASURES INCLUDED IN THE STAGE 1 FINAL RULE THAT ARE PROPOSED TO BE ELIMINATED BEGINNING IN CY 2014

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer* & Contact Information
NQF# 0013	Title: Hypertension: Blood Pressure Management Description: Percentage of patient visits aged 18 years and older with a diagnosis of hypertension who have been seen for at least 2 office visits, with blood pressure (BP) recorded	AMA-PCPI Contact Information: cpe@ama-assn.org
NQF# 0027	Title: Smoking and Tobacco Use Cessation, Medical assistance: a. Advising Smokers and Tobacco Users to Quit, b. Discussing Smoking and Tobacco Use Cessation Strategies	NCQA Contact Information: www.ncqa.org
NQF# 0084	Title: Heart Failure (HF): Warfarin Therapy Patients with Atrial Fibrillation Description: Percentage of all patients aged 18 years and older with a diagnosis of heart failure and paroxysmal or chronic atrial fibrillation who were prescribed warfarin therapy.	AMA-PCPI Contact Information: cpe@ama-assn.org

*AMA-PCPI = American Medical Association-Physician Consortium for Performance Improvement
NCQA = National Committee for Quality Assurance

Based in part on the feedback received throughout Stage 1, we propose to eliminate these three clinical quality measures beginning with CY 2014 for EPs at all Stages for the following reasons:

- NQF # 0013 – The measure steward did not submit this measure to the National Quality Forum for continued endorsement. We have included other measures that address high blood pressure and hypertension in the Table 8.
- NQF #0027 – We determined this measure is very similar to NQF #0028 a and b; therefore, to avoid duplication of measures, we propose to only retain NQF # 0028 a and b.

- NQF #0084 – The measure steward did not submit this measure to the National Quality Forum for continued endorsement. Additionally, CMS has decided to remove this measure because there are other FDA-approved anticoagulant therapies available in addition to Warfarin. We are proposing to replace this measure, pending availability of electronic specifications, with NQF #1525 – Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy.

Table 8 lists all of the clinical quality measures that we are considering for EPs to report for the EHR Incentive Programs beginning with CY 2014. However, we expect to finalize only a subset of these proposed measures based on public comment and the priorities listed in section II.B.3. of this proposed rule. The measures 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. Measures which are designated as "New" in the "New Measures" column were not finalized in the Stage 1 final rule. Please note that measures which are listed as also being part of the "ACO" program in the "Other Quality Programs that Use the Same Measure" column of Table 8 are Medicare Shared Savings Program measures. Some of the clinical quality measures in Table 8 will require the development of electronic specifications. Therefore, we propose to consider these measures for inclusion beginning with CY 2014 based on our expectation that their electronic specifications will be available at the time of or within a reasonable period after the publication of the final rule.

Additionally, some of these measures have not yet been submitted for consensus endorsement consideration or are currently under review for endorsement consideration by the National Quality Forum. We expect that any measure proposed in Table 8 for inclusion beginning with CY 2014 will be submitted for endorsement consideration by the measure

steward. The finalized list of measures that would apply for EPs beginning with CY 2014 will be published in the final rule. Because measure specifications may need to be updated more frequently than our expected rulemaking cycle would allow for, 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 expect to update specifications annually. All clinical quality measure specification updates, including a schedule for updates to electronic specifications, would be posted on the EHR Incentive Program website (https://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp), and we would notify the public of the posting.

TABLE 8: CLINICAL QUALITY MEASURES PROPOSED FOR MEDICARE AND MEDICAID ELIGIBLE PROFESSIONALS BEGINNING WITH CY 2014

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Other Quality Measure Programs that use the Same Measure**	New Measure	Domain
NQF 0001	Title: Asthma: Assessment of Asthma Control Description: Percentage of patients aged 5 through 50 years with a diagnosis of asthma who were evaluated at least once for asthma control (comprising asthma impairment and asthma risk).	American Medical Association-Physician Consortium for Performance Improvement (AMA-PCPI) Contact information: cpe@ama-assn.org	EHR PQRS		Clinical Process/ Effectiveness
NQF 0002	Title: Appropriate Testing for Children with Pharyngitis Description: Percentage of children 2-18 years of age who were diagnosed with pharyngitis, dispensed 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

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Other Quality Measure Programs that use the Same Measure**	New Measure	Domain
NQF 0004	Title: Initiation and Engagement of Alcohol and Other Drug Dependence Treatment: (a) Initiation, (b) Engagement Description: The percentage of adolescent and adult patients with a new episode of alcohol and other drug (AOD) dependence who initiate treatment through an inpatient AOD admission, outpatient visit, intensive outpatient encounter or partial hospitalization within 14 days of the diagnosis and 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 Accreditation		Clinical Process/ Effectiveness
NQF 0012	Title: Prenatal Care: Screening for Human Immunodeficiency Virus (HIV) Description: Percentage of patients, regardless of age, who gave birth during a 12-month period who were screened for HIV infection during the first or second prenatal care visit.	AMA-PCPI Contact Information: cpe@ama-assn.org	EHR PQRS		Population/ Public Health
NQF 0014	Title: Prenatal Care: Anti-D Immune Globulin Description: Percentage of D (Rh) negative, unsensitized patients, regardless of age, who gave birth during a 12-month period who received anti-D immune globulin at 26-30 weeks gestation.	AMA-PCPI Contact Information: cpe@ama-assn.org	EHR PQRS, NCQA-PCMH Accreditation		Patient Safety
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 during the measurement year.	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 ages 65 years and older who received at least one high-risk medication. Percentage of patients 65 years of age and older who received at least two different high-risk medications.	NCQA Contact Information: www.ncqa.org	PQRS	New	Patient Safety
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 OB/GYN and who had evidence of body mass index (BMI) percentile documentation, counseling for nutrition and counseling for physical activity during the measurement year.	NCQA Contact information: www.ncqa.org	EHR PQRS, UDS		Population/ Public Health

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Other Quality Measure Programs that use the Same Measure**	New Measure	Domain
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 Accreditation		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 Accreditation, UDS		Clinical Process/ Effectiveness
NQF 0033	Title: Chlamydia Screening in 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 year.	NCQA Contact Information: www.ncqa.org	EHR PQRS, CHIPRA, ACA 2701, HEDIS, State use, NCQA-PCMH Accreditation		Population/ Public Health
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 Accreditation		Clinical Process/ Effectiveness
NQF 0036	Title: Use of Appropriate Medications for Asthma Description: Percentage of patients 5 - 50 years of age who were identified as having persistent asthma and were appropriately prescribed medication during the measurement year. Report three age stratifications (5-11 years, 12-50 years, and total).	NCQA Contact Information: www.ncqa.org	EHR PQRS		Clinical Process/ Effectiveness

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Other Quality Measure Programs that use the Same Measure**	New Measure	Domain
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); two H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); two hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday. The measure calculates a rate for each vaccine and nine separate combination rates.	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 Accreditation		Clinical Process/ Effectiveness
NQF 0045	Title: Osteoporosis: Communication with the Physician Managing Ongoing Care Post-Fracture Description: Percentage of patients aged 50 years and older treated for a hip, spine, or distal radial fracture with documentation of communication with the physician managing the patient's on-going care that a fracture occurred and that the patient was or should be tested or treated for osteoporosis.	NCQA Contact Information: www.ncqa.org	PQRS, NCQA-PCMH Accreditation	New	Care Coordination
NQF 0046	Title: Osteoporosis: Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older Description: Percentage of female patients aged 65 years and older who have a central dual-energy X-ray absorptiometry measurement ordered or performed at least once since age 60 or pharmacologic therapy prescribed within 12 months.	NCQA Contact Information: www.ncqa.org	PQRS, NCQA-PCMH Accreditation	New	Clinical Process/ Effectiveness

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Other Quality Measure Programs that use the Same Measure**	New Measure	Domain
NQF 0047	Title: Asthma Pharmacologic Therapy for Persistent Asthma Description: Percentage of patients aged 5 through 50 years with a diagnosis of persistent asthma and at least one medical encounter for asthma during the measurement year who were prescribed long-term control medication.	AMA-PCPI Contact Information: cpe@ama-assn.org	EHR PQRS, UDS		Clinical Process/ Effectiveness
NQF 0048	Title: Osteoporosis: Management Following Fracture of Hip, Spine or Distal radius for Men and Women Aged 50 Years and Older Description: Percentage of patients aged 50 years or older with fracture of the hip, spine or distal radius that had a central dual-energy X-ray absorptiometry measurement ordered or performed or pharmacologic therapy prescribed.	NCQA Contact Information: www.ncqa.org	PQRS	New	Clinical Process/ Effectiveness
NQF 0050	Title: Osteoarthritis (OA): Function and Pain Assessment Description: Percentage of patient visits for patients aged 21 years and older with a diagnosis of OA with assessment for function and pain.	AMA-PCPI Contact Information: cpe@ama-assn.org	PQRS	New	Patient and Family Engagement
NQF 0051	Title: Osteoarthritis (OA): assessment for use of anti-inflammatory or analgesic over-the-counter (OTC) medications Description: Percentage of patient visits for patients aged 21 years and older with a diagnosis of OA with an assessment for use of anti-inflammatory or analgesic OTC medications.	AMA-PCPI Contact Information: cpe@ama-assn.org	PQRS	New	Clinical Process/ Effectiveness
NQF 0052	Title: Use of Imaging Studies for Low Back Pain Description: Percentage of patients with a primary diagnosis of low back pain who did not have an imaging study (plain x-ray, MRI, CT scan) within 28 days of 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 (type 1 or type 2) who had a retinal or dilated eye exam or a negative retinal exam (no evidence of retinopathy) by an eye care professional.	NCQA Contact Information: www.ncqa.org	EHR PQRS, Group Reporting PQRS		Clinical Process/ Effectiveness
NQF 0056	Title: Diabetes: Foot Exam Description: The percentage of patients aged 18 - 75 years with diabetes (type 1 or type 2) who had a foot exam (visual inspection, sensory exam with monofilament, or pulse exam).	NCQA Contact Information: www.ncqa.org	EHR PQRS, Group Reporting PQRS		Clinical Process/ Effectiveness

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Other Quality Measure Programs that use the Same Measure**	New Measure	Domain
NQF 0058	Title: Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis Description: Percentage of adults ages 18 through 64 years with a diagnosis of acute bronchitis who were not dispensed an antibiotic prescription on or within 3 days of the initial date of service.	NCQA Contact Information: www.ncqa.org	PQRS	New	Efficient Use of Healthcare Resources
NQF 0059	Title: Diabetes: Hemoglobin A1c Poor Control Description: Percentage of patients 18 - 75 years of age with diabetes (type 1 or type 2) who had hemoglobin A1c > 9.0%.	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 pediatric patients with diabetes with an HbA1c test in a 12-month measurement period.	NCQA Contact Information: www.ncqa.org		New	Clinical Process/ Effectiveness
NQF 0061	Title: Diabetes: Blood Pressure Management Description: Percentage of patients 18 - 75 years of age with diabetes (type 1 or type 2) who had blood pressure <140/90 mmHg.	NCQA Contact Information: www.ncqa.org	EHR PQRS, Group Reporting PQRS		Clinical Process/ Effectiveness
NQF 0062	Title: Diabetes: Urine Screening Description: Percentage of patients 18 - 75 years of age with diabetes (type 1 or type 2) who had a nephropathy screening test or evidence of nephropathy.	NCQA Contact Information: www.ncqa.org	EHR PQRS, Group Reporting PQRS		Clinical Process/ Effectiveness
NQF 0064	Title: Diabetes: Low Density Lipoprotein (LDL) Management and Control Description: Percentage of patients 18-75 years of age with diabetes (type 1 or type 2) who had LDL-C < 100 mg/dL.	NCQA Contact Information: www.ncqa.org	PQRS, Group Reporting PQRS		Clinical Process/ Effectiveness
NQF 0066	Title: Coronary Artery Disease (CAD): Angiotensin-converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy−Diabetes 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 diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) <40% who were prescribed ACE inhibitor or ARB therapy.	AMA-PCPI Contact Information: cpe@ama-assn.org	ACO, Group Reporting PQRS	New	Clinical Process/ Effectiveness
NQF 0067	Title: Coronary Artery Disease (CAD): Antiplatelet Therapy Description: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who were prescribed aspirin or clopidogrel.	AMA-PCPI Contact Information: cpe@ama-assn.org	EHR PQRS, Group Reporting PQRS		Clinical Process/ Effectiveness

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Other Quality Measure Programs that use the Same Measure**	New Measure	Domain
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 transluminal coronary angioplasty (PTCA) from January 1-November 1 of the year prior to the measurement year, or who had a diagnosis of ischemic vascular disease (IVD) during the measurement year and the year prior to the measurement year and who had documentation of use of aspirin or another antithrombotic during the measurement year.	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 who were given a diagnosis of URI and were not dispensed an antibiotic prescription on or three days after the episode date.	NCQA Contact Information: www.ncqa.org	PQRS, NCQA-PCMH Accreditation	New	Efficient Use of Healthcare Resources
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 Accreditation		Clinical Process/ Effectiveness
NQF 0073	Title: Ischemic Vascular Disease (IVD): Blood Pressure Management 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 transluminal coronary angioplasty (PTCA) from January 1- November 1 of the year prior to the measurement year, or who had a diagnosis of ischemic vascular disease (IVD) during the measurement year and the year prior to the measurement year and whose recent blood pressure is in control (<140/90 mmHg).	NCQA Contact Information: www.ncqa.org	EHR PQRS		Clinical Process/ Effectiveness

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Other Quality Measure Programs that use the Same Measure**	New Measure	Domain
NQF 0074	Title: Coronary Artery Disease (CAD): Lipid Control Description: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who have a LDL-C result <100mg/dL OR patients who have a LDL-C result ≥100mg/dL and have a documented plan of care to achieve LDL-C < 100mg/dL, including at a minimum the prescription of a statin.	AMA-PCPI Contact Information: cpe@ama-assn.org	PQRS, ACO, Group Reporting PQRS		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 transluminal angioplasty (PTCA) from January 1-November 1 of the year prior to the measurement year, or who had a diagnosis of ischemic vascular disease (IVD) during the measurement year and the year prior to the measurement year and who had a complete lipid profile performed during the measurement year and whose LDL-C<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 Accreditation		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

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Other Quality Measure Programs that use the Same Measure**	New Measure	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 0097	Title: Medication Reconciliation Description: Percentage of patients aged 65 years and older discharged from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) and seen within 60 days following discharge in the office by the physician providing on-going care who had a reconciliation of the discharge medications with the current medication list in the medical record documented.	AMA-PCPI Contact Information: cpe@ama-assn.org; NCQA Contact Information: www.ncqa.org	ACO, Group Reporting PQRS, NCQA-PCMH Accreditation	New	Patient Safety
NQF 0098	Title: Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Age 65 Years and Older Description: Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	NCQA Contact Information: www.ncqa.org	PQRS	New	Clinical Process/ Effectiveness

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Other Quality Measure Programs that use the Same Measure**	New Measure	Domain
NQF 0100	Title: Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older Description: Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	AMA-PCPI Contact Information: cpe@ama-assn.org; NCQA Contact Information: www.ncqa.org	PQRS	New	Patient and Family Engagement
NQF 0101	Title: Falls: Screening for Falls Risk Description: Percentage of patients aged 65 years and older who were screened for future fall risk (patients are considered at risk for future falls if they have had 2 or more falls in the past year or any fall with injury in the past year) at least once within 12 months.	AMA-PCPI Contact Information: cpe@ama-assn.org; NCQA Contact Information: www.ncqa.org	PQRS, ACO, Group Reporting PQRS	New	Patient Safety
NQF 0102	Title: Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy Description: Percentage of patients aged 18 years and older with a diagnosis of COPD and who have FEV1/FVC less than 70% and have symptoms who were prescribed an inhaled bronchodilator.	AMA-PCPI Contact Information: cpe@ama-assn.org	PQRS, Group Reporting PQRS	New	Clinical Process/ Effectiveness
NQF 0103	Title: Major Depressive Disorder (MDD): Diagnostic Evaluation Description: Percentage of patients aged 18 years and older with a new diagnosis or recurrent episode of MDD who met the DSM-IV criteria during the visit in which the new diagnosis or recurrent episode was identified during the measurement period.	AMA-PCPI Contact Information: cpe@ama-assn.org	PQRS	New	Clinical Process/ Effectiveness
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
NQF 0105	Title: Anti-depressant Medication Management: (a) Effective Acute Phase Treatment, (b)Effective Continuation Phase Treatment Description: The percentage of patients 18 years of age and older who were diagnosed with a new episode of major depression, treated with antidepressant medication, and who remained on an antidepressant medication treatment.	NCQA Contact Information: www.ncqa.org	EHR PQRS, HEDIS, State use, ACA 2701		Clinical Process/ Effectiveness

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Other Quality Measure Programs that use the Same Measure**	New Measure	Domain
NQF 0106	Title: Diagnosis of attention deficit hyperactivity disorder (ADHD) in primary care for school age children and adolescents Description: Percentage of patients newly diagnosed with ADHD whose medical record contains documentation of DSM-IV-TR or DSM-PC criteria.	Institute for Clinical Systems Improvement (ICSI) Contact Information: www.icsi.org		New	Care Coordination
NQF 0107	Title: Management of attention deficit hyperactivity disorder (ADHD) in primary care for school age children and adolescents Description: Percentage of patients treated with psychostimulant medication for the diagnosis of ADHD whose medical record contains documentation of a follow-up visit at least twice a year.	ICSI Contact Information: www.icsi.org		New	Clinical Process/ Effectiveness
NQF 0108	Title: ADHD: Follow-Up Care for Children Prescribed Attention-Deficit/Hyperactivity Disorder (ADHD) Medication Description: (a) Initiation Phase: Percentage of children 6 - 12 years of age as of the Index Prescription Episode Start Date with an ambulatory prescription dispensed for ADHD medication and who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. (b) Continuation and Maintenance (C&M) Phase: Percentage of children 6 - 12 years of age as of the Index Prescription Episode Start Date with an ambulatory prescription dispensed for ADHD medication who remained on the 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 Accreditation	New	Clinical Process/ Effectiveness

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Other Quality Measure Programs that use the Same Measure**	New Measure	Domain
NQF 0112	Title: Bipolar Disorder: Monitoring change in level-of-functioning Description: Percentage of patients aged 18 years and older with an initial diagnosis or new episode/presentation of bipolar disorder.	CQAIMH Contact Information: www.cqaimh.org; cqaimh@cqaimh.org		New	Clinical Process/ Effectiveness
NQF 0239	Title: Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (when indicated in ALL patients) Description: Percentage of patients aged 18 years and older undergoing procedures for which VTE prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	AMA-PCPI Contact Information: cpe@ama-assn.org	PQRS	New	Patient Safety
Formerly NQF 0246, no longer endorsed	Title: Stroke and Stroke Rehabilitation: Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) Reports Description: Percentage of final reports for CT or MRI studies of the brain performed either: · In the hospital within 24 hours of arrival, OR · In an outpatient imaging center to confirm initial diagnosis of stroke, transient ischemic attack (TIA) or intracranial hemorrhage. For patients aged 18 years and older with either a diagnosis of ischemic stroke, TIA or intracranial hemorrhage OR at least one documented symptom consistent with ischemic stroke, TIA or intracranial hemorrhage that includes documentation of the presence or absence of each of the following: hemorrhage, mass lesion and acute infarction.	AMA-PCPI Contact Information: cpe@ama-assn.org; NCQA Contact Information: www.ncqa.org	PQRS	New	Clinical Process/ Effectiveness
NQF 0271	Title: Perioperative Care: Discontinuation of Prophylactic Antibiotics (Non-Cardiac Procedures) Description: Percentage of non-cardiac surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics AND who received a prophylactic parenteral antibiotic, who have an order for discontinuation of prophylactic parenteral antibiotics within 24 hours of surgical end time.	AMA-PCPI Contact Information: cpe@ama-assn.org	PQRS, NCQA-PCMH Accreditation	New	Patient Safety

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Other Quality Measure Programs that use the Same Measure**	New Measure	Domain
NQF 0312	Title: Lower Back Pain: Repeat Imaging Studies Description: Percentage of patients with back pain who received inappropriate imaging studies in the absence of red flags or progressive symptoms (overuse measure, lower performance is better).	NCQA Contact Information: www.ncqa.org		New	Efficient Use of Healthcare Resources
NQF 0321	Title: Adult Kidney Disease: Peritoneal Dialysis Adequacy: Solute Description: Percentage of patients aged 18 years and older with a diagnosis of ESRD receiving peritoneal dialysis who have a Kt/V>= 1.7 per week measured once every 4 months.	AMA-PCPI Contact Information: cpe@ama-assn.org	PQRS	New	Care Coordination
NQF 0322	Title: Back Pain: Initial Visit Description: The percentage of patients with a diagnosis of back pain who have medical record documentation of all of the following on the date of the initial visit to the physician: 1. Pain assessment 2. Functional status 3. Patient history, including notation of presence or absence of "red flags" 4. Assessment of prior treatment and response, and 5. Employment status	NCQA Contact Information: www.ncqa.org	PQRS	New	Efficient Use of Healthcare Resources
NQF 0323	Title: Adult Kidney Disease: Hemodialysis Adequacy: Solute Description: Percentage of calendar months within a 12-month period during which patients aged 18 years and older with a diagnosis of end-stage renal disease (ESRD) receiving hemodialysis three times a week have a spKt/V≥1.2.	AMA-PCPI Contact Information: cpe@ama-assn.org	PQRS	New	Care Coordination
NQF 0382	Title: Oncology: Radiation Dose Limits to Normal Tissues Description: Percentage of patients, regardless of age, with a diagnosis of pancreatic or lung cancer receiving 3D conformal radiation therapy with documentation in medical record that radiation dose limits to normal tissues were established prior to the initiation of a course of 3D conformal radiation for a minimum of two tissues.	AMA-PCPI Contact Information: cpe@ama-assn.org;	PQRS	New	Patient Safety
NQF 0383	Title: Oncology: Measure Pair: Oncology: Medical and Radiation - Plan of Care for Pain Description: Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	AMA-PCPI Contact Information: cpe@ama-assn.org	PQRS	New	Patient and Family Engagement

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Other Quality Measure Programs that use the Same Measure**	New Measure	Domain
NQF 0384	Title: Oncology: Measure Pair: 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
NQF 0385	Title: Colon Cancer: Chemotherapy for Stage III Colon Cancer Patients Description: Percentage of patients aged 18 years and older with Stage IIIA through IIIC 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 0388	Title: Prostate Cancer: Three Dimensional (3D) Radiotherapy Description: Percentage of patients, regardless of age, with a diagnosis of clinically localized prostate cancer receiving external beam radiotherapy as a primary therapy to the prostate with or without nodal irradiation (no metastases; no salvage therapy) who receive three-dimensional conformal radiotherapy (3D-CRT) or intensity modulated radiation therapy (IMRT).	AMA-PCPI Contact Information: cpe@ama-assn.org	PQRS	New	Patient Safety

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Other Quality Measure Programs that use the Same Measure**	New Measure	Domain
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 0399	Title: Hepatitis C: Hepatitis A Vaccination in Patients with HCV Description: Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who have received at least one injection of hepatitis A vaccine, or who have documented immunity to hepatitis A.	AMA-PCPI Contact Information: cpe@ama-assn.org	PQRS, NCQA-PCMH Accreditation	New	Population/ Public Health
NQF 0400	Title: Hepatitis C: Hepatitis B Vaccination in Patients with HCV Description: Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who have received at least one injection of hepatitis B vaccine, or who have documented immunity to hepatitis B.	AMA-PCPI Contact Information: cpe@ama-assn.org	PQRS, NCQA-PCMH Accreditation	New	Population/ Public Health
NQF 0401	Title: Hepatitis C: Counseling Regarding Risk of Alcohol Consumption Description: Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who were counseled about the risks of alcohol use at least once within 12 months.	AMA-PCPI Contact Information: cpe@ama-assn.org	PQRS, NCQA-PCMH Accreditation	New	Clinical Process/ Effectiveness
NQF 0403	Title: Medical Visits Description: Percentage of patients regardless of age, with a diagnosis of HIV/AIDS with at least one medical visit in each 6 month period 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

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Other Quality Measure Programs that use the Same Measure**	New Measure	Domain
NQF 0405	Title: Pneumocystitis jiroveci pneumonia (PCP) Prophylaxis Description: Percentage of patients with 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 Accreditation	New	Clinical Process/ Effectiveness
NQF 0406	Title: Patients with HIV/AIDS Who Are Prescribed Potent Antiretroviral Therapy Description: Percentage of patients who were prescribed potent antiretroviral therapy.	AMA-PCPI Contact Information: cpe@ama-assn.org; NCQA Contact Information: www.ncqa.org	PQRS, NCQA-PCMH Accreditation	New	Clinical Process/ Effectiveness
NQF 0407	Title: HIV RNA control after six months of potent antiretroviral therapy Description: Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS who had at least two medical visits during the measurement year, with at least 60 days between each visit, who are receiving potent antiretroviral therapy, who have a viral load below limits of quantification after at least 6 months of potent antiretroviral therapy OR whose viral load is not below limits of quantification after at least 6 months of potent antiretroviral therapy and has a documented plan of care.	NCQA Contact Information: www.ncqa.org	PQRS	New	Clinical Process/ Effectiveness
NQF 0418	Title: Screening for Clinical Depression Description: Percentage of patients aged 12 years and older screened for clinical depression using an age appropriate standardized tool and follow up plan documented.	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	New	Population/ Public Health

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Other Quality Measure Programs that use the Same Measure**	New Measure	Domain
NQF 0419	Title: Documentation of Current Medications in the Medical Record Description: Percentage of specified visits as defined by the denominator criteria 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, vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route.	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, Group Reporting PQRS	New	Patient Safety
NQF 0421	Title: Adult Weight Screening and Follow-Up Description: Percentage of patients aged 18 years and older with a calculated body mass index (BMI) in the past six months or during the current visit documented in the medical record AND if the most recent BMI is outside of normal parameters, a follow-up plan is documented. 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 0507	Title: Radiology: Stenosis Measurement in Carotid Imaging Studies Description: Percentage of final reports for all patients, regardless of age, for carotid imaging studies (neck magnetic resonance angiography [MRA], neck computer tomography angiography [CTA], neck duplex ultrasound, carotid angiogram) performed that include direct or indirect reference to measurements of distal internal carotid diameter as the denominator for stenosis measurement.	AMA-PCPI Contact Information: cpe@ama-assn.org	PQRS	New	Clinical Process/ Effectiveness
NQF 0508	Title: Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Mammography Screening Description: Percentage of final reports for screening mammograms that are classified as "probably benign."	AMA-PCPI Contact Information: cpe@ama-assn.org	PQRS	New	Efficient Use of Healthcare Resources

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Other Quality Measure Programs that use the Same Measure**	New Measure	Domain
NQF 0510	Title: Radiology: Exposure Time Reported for Procedures Using Fluoroscopy Description: Percentage of final reports for procedures using fluoroscopy that include documentation of radiation exposure or exposure time.	AMA-PCPI Contact Information: cpe@ama-assn.org	PQRS	New	Patient Safety
NQF 0513	Title: Thorax CT: Use of Contrast Material Description: This measure calculates the percentage of thorax studies that are performed with and without contrast out of all thorax studies performed (those with contrast, those without contrast, and those with both).	CMS Contact Information: 1-888-734-6433 or http://questions.cms.hhs.gov/app/ask/p/21,26,1139		New	Efficient Use of Healthcare Resources
NQF 0519	Title: Diabetic Foot Care and Patient/Caregiver Education Implemented During Short Term Episodes of Care Description: Percentage of short term home health episodes of care during which diabetic foot care and education were included in the physician-ordered plan of care and implemented for patients with diabetes.	CMS Contact Information: 1-888-734-6433 or http://questions.cms.hhs.gov/app/ask/p/21,26,1139		New	Care Coordination
NQF 0561	Title: Melanoma: Coordination of Care Description: Percentage of patient visits, regardless of patient age, with a new occurrence of melanoma who have a treatment plan documented in the chart that was communicated to the physicians(s) providing continuing care within one month of diagnosis.	AMA-PCPI Contact Information: cpe@ama-assn.org; NCQA Contact Information: www.ncqa.org	PQRS	New	Care Coordination
NQF 0562	Title: Melanoma: Overutilization of Imaging Studies in Melanoma Description: Percentage of patients, regardless of age, with a current diagnosis of stage 0 through IIC melanoma or a history of melanoma of any stage, without signs or symptoms suggesting systemic spread, seen for an office visit during the one-year measurement period, for whom no diagnostic imaging studies were ordered.	AMA-PCPI Contact Information: cpe@ama-assn.org; NCQA Contact Information: www.ncqa.org	PQRS	New	Efficient Use of Healthcare Resources

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Other Quality Measure Programs that use the Same Measure**	New Measure	Domain
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 0575	Title: Diabetes: Hemoglobin A1c Control (<8.0%) Description: The percentage of patients 18-75 years of age with diabetes (type 1 or type 2) who had hemoglobin A1c <8.0%.	NCQA Contact Information: www.ncqa.org	EHR PQRS, Group Reporting PQRS, UDS		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
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

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Other Quality Measure Programs that use the Same Measure**	New Measure	Domain
NQF 0711	Title: Depression Remission at Six Months Description: Adult patients age 18 and older with major depression or dysthymia and an initial PHQ-9 score > 9 who demonstrate remission at six 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.	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
NQF 1335	Title: Children who have dental decay or cavities Description: Assesses if children aged 1-17 years have had tooth decay or cavities in the past 6 months.	Maternal and Child Health Bureau, Health Resources and Services Adminstration 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 documentation of a maternal depression screening for the mother.	NCQA Contact Information: www.ncqa.org		New	Population/ Public Health
NQF 1419	Title: Primary Caries Prevention Intervention as Part of Well/Ill Child Care as Offered by Primary Care Medical Providers Description: The measure will a) track the extent to which the PCMP or clinic (determined by the provider number used for billing) applies FV as part of the EPSDT examination and b) track the degree to which each billing entity's use of the EPSDT with FV codes increases from year to year (more children varnished and more children receiving FV four times a year according to ADA recommendations for high-risk children).	University of Minnesota Contact Information: www.umn.edu		New	Clinical Process/ Effectiveness

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Other Quality Measure Programs that use the Same Measure**	New Measure	Domain
NQF 1525	Title: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy Description: Percentage of patients aged 18 years and older with nonvalvular AF or atrial flutter at high risk for thromboembolism, according to CHADS2 risk stratification, who were prescribed warfarin or another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism during the 12-month reporting period.	AMA-PCPI Contact Information: cpe@ama-assn.org; American College of Cardiology Foundation (ACCF) www.cardiosource.org; American Heart Association (AHA) www.heart.org		New	Clinical Process/ Effectiveness
TBD	Title: Preventive Care and Screening: Cholesterol – Fasting Low Density Lipoprotein (LDL) Test Performed AND Risk-Stratified Fasting LDL Description: Percentage of patients aged 20 through 79 years whose risk factors* have been assessed and a fasting LDL test has been performed. Percentage of patients aged 20 through 79 years who had a fasting LDL test performed and whose risk-stratified* fasting LDL is at or below the recommended LDL 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: Falls: Risk Assessment for Falls Description: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	AMA-PCPI Contact Information: cpe@ama-assn.org; NCQA Contact Information: www.ncqa.org	PQRS	New	Patient Safety
TBD	Title: Falls: Plan of Care for Falls Description: Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	AMA-PCPI Contact Information: cpe@ama-assn.org; NCQA Contact Information: www.ncqa.org	PQRS	New	Patient Safety

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Other Quality Measure Programs that use the Same Measure**	New Measure	Domain
TBD	Title: Adult Kidney Disease: Blood Pressure Management Description: Percentage of patient visits for those patients aged 18 years and older with a diagnosis of CKD (stage 3, 4, or 5 not receiving RRT) and proteinuria with a blood pressure < 130/80 mmHg or ≥130/80 mmHg with documented plan of care.	AMA-PCPI Contact Information: cpe@ama-assn.org		New	Clinical Process/ Effectiveness
TBD	Title: Adult Kidney Disease: Patients on Erythropoiesis Stimulating Agent (ESA) - Hemoglobin Level > 12.0 g/dL Description: Percentage of calendar months within a 12-month period during which a hemoglobin (Hgb) level is measured for patients aged 18 years and older with a diagnosis of advanced CKD (stage 4 or 5, not receiving RRT) or end-stage renal disease (ESRD) (who are on hemodialysis or peritoneal dialysis) who are also receiving ESA therapy have a hemoglobin (Hgb) level > 12.0 g/dL.	AMA-PCPI Contact Information: cpe@ama-assn.org		New	Efficient Use of Healthcare Resources
TBD	Title: Chronic Wound Care: Use of wet to dry dressings in patients with chronic skin ulcers (overuse measure) Description: Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic skin ulcer without a prescription or recommendation to use wet to dry dressings.	AMA-PCPI Contact Information: cpe@ama-assn.org; NCQA Contact Information: www.ncqa.org	PQRS	New	Patient Safety
TBD	Title: Dementia: Staging of Dementia Description: Percentage of patients, regardless of age, with a diagnosis of dementia whose severity of dementia was classified as mild, moderate, or severe at least once within a 12 month period.	AMA-PCPI Contact Information: cpe@ama-assn.org	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: Dementia: Functional Status Assessment Description: Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of functional status is performed and the results reviewed at least once within a 12 month period.	AMA-PCPI Contact Information: cpe@ama-assn.org;	PQRS	New	Patient and Family Engagement

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Other Quality Measure Programs that use the Same Measure**	New Measure	Domain
TBD	Title: Dementia: Counseling Regarding Safety Concerns Description: Percentage of patients, regardless of age, with a diagnosis of dementia or their caregiver(s) who were counseled or referred for counseling regarding safety concerns within a 12 month period.	AMA-PCPI Contact Information: cpe@ama-assn.org	PQRS	New	Patient and Family Engagement
TBD	Title: Dementia: Counseling Regarding Risks of Driving Description: Percentage of patients, regardless of age, with a diagnosis of dementia or their caregiver(s) who were counseled regarding the risks of driving and the alternatives to driving at least once within a 12 month period.	AMA-PCPI Contact Information: cpe@ama-assn.org	PQRS	New	Patient Safety
TBD	Title: Dementia: Caregiver Education and Support Description: Percentage of patients, regardless of age, with a diagnosis of dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND referred to additional resources for support within a 12-month period.	AMA-PCPI Contact Information: cpe@ama-assn.org	PQRS	New	Patient and Family Engagement
TBD	Title: Chronic Wound Care: Patient education regarding long term compression therapy Description: Percentage of patients aged 18 years and older with a diagnosis of venous ulcer who received education regarding the need for long term compression therapy including interval replacement of compression stockings within the 12 month reporting period.	AMA-PCPI Contact Information: cpe@ama-assn.org; NCQA Contact Information: www.ncqa.org		New	Patient and Family Engagement
TBD	Title: Rheumatoid Arthritis (RA): Functional Status Assessment Description: Percentage of patients aged 18 years and older with a diagnosis of RA for whom a functional status assessment was performed at least once within 12 months.	AMA-PCPI Contact Information: cpe@ama-assn.org; NCQA Contact Information: www.ncqa.org	PQRS	New	Patient and Family Engagement
TBD	Title: Glaucoma Screening in Older Adults Description: Percentage of patients 65 years and older, without a prior diagnosis of glaucoma or glaucoma suspect, who received a glaucoma eye exam by an eye-care professional for early identification of glaucomatous conditions.	NCQA Contact Information: www.ncqa.org		New	Clinical Process/ Effectiveness

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Other Quality Measure Programs that use the Same Measure**	New Measure	Domain
TBD	Title: Chronic Wound Care: Patient Education regarding diabetic foot care. Description: Percentage of patients aged 18 years and older with a diagnosis of diabetes and foot ulcer who received education regarding appropriate foot care AND daily inspection of the feet within the 12 month reporting period.	AMA-PCPI Contact Information: cpe@ama-assn.org; NCQA Contact Information: www.ncqa.org		New	Patient and Family Engagement
TBD	Title: Hypertension: Improvement in blood pressure Description: Percentage of patients aged 18 years and older with 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 regardless of age with a referral from a primary care provider for whom a report from the provider to whom the patient was referred was received by the referring provider.	CMS 1-888-734-6433 or http://questions.cms.hhs.gov/app/ask/p/21,26,1139		New	Care Coordination
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 and two or more high impact conditions 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

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Steward & Contact Information	Other Quality Measure Programs that use the Same Measure**	New Measure	Domain
TBD	Title: Adverse Drug Event (ADE) Prevention: Outpatient therapeutic drug monitoring Description: Percentage of patients 18 years of age and older receiving outpatient chronic medication therapy who had the appropriate therapeutic drug monitoring during the measurement year.	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 Description: Percentage of patients aged 18 years and older who are screened for high blood pressure.	CMS 1-888-734-6433 or http://questions.cms.hhs.gov/app/ask/p/21,26,1139; QIP Contact Information: www.usqualitymeasures.org	PQRS, Group Reporting PQRS, ACO	New	Population/ Public Health
TBD	Title: Hypertension: Blood Pressure Management Description: Percentage of patients aged 18 years and older with a diagnosis of hypertension seen within a 12 month period with a blood pressure <140/90mmHg OR patients with a blood pressure ≥140/90mmHg and prescribed 2 or more anti-hypertensive medications during the most recent office visit.	AMA-PCPI Contact Information: cpe@ama-assn.org		New	Clinical Process/ Effectiveness

**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. Proposed Reporting Methods for Clinical Quality Measures for Eligible Professionals

(a) Proposed Reporting Methods for Medicaid EPs

For Medicaid EPs, 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 allow reporting through attestation. If a State does require such electronic reporting, the State is

responsible for sharing the details on the process with its provider community. We anticipate that whatever means States have deployed for capturing Stage 1 clinical quality measures 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, the States will establish the method and requirements, subject to CMS prior approval, for electronically reporting.

(b) Proposed Reporting Methods for Medicare EPs in CY 2013

In the CY 2012 Medicare Physician Fee Schedule final rule, we established a pilot program for Medicare EPs for CY 2012 that is intended to test and demonstrate our capacity to accept electronic reporting of Stage 1 clinical quality measure data (76 FR 73422 through 73425). The title of this pilot program is the Physician Quality Reporting System – Medicare EHR Incentive Pilot, and it capitalizes on existing quality measures reporting infrastructure. The EHR Incentive Program Registration and Attestation System is located at https://ehrincentives.cms.gov/hitech/login.action.

(c) Proposed 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 clinical quality measures selected by the Secretary "in a form and manner specified by the Secretary" as part of demonstrating meaningful use of Certified EHR Technology. As discussed in section II.B.4.b. of this proposed rule, Medicare EPs who are in their first year of Stage 1 may report clinical quality measures through attestation for a continuous 90-day EHR reporting period (for an explanation of reporting through attestation, see the discussion in the Stage 1 final rule (75 FR 44430 through 44431)).

Medicare EPs who choose to report 12 clinical quality measures as described in Options 1.a. and 1.b. in section II.B.4.c. of this proposed rule would submit through an aggregate

reporting method, which would require the EP to log into a CMS-designated portal. Once the EP has logged into the portal, they would be required to submit through an upload process, data produced as output from their Certified EHR Technology in an XML-based format specified by CMS.

We are considering an "interim submission" option for Medicare EPs who are in their first year of Stage 1 and who participate in the Physician Quality Reporting System. Under this option, EPs would submit the Physician Quality Reporting System clinical quality measures 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. The EP would report the remainder of his/her clinical quality measures data by the deadline specified for the Physician Quality Reporting System to meet the requirements of the Physician Quality Reporting System. We request public comment on this potential option. Medicare EPs who are beyond their first year of Stage 1 and who choose the Physician Quality Reporting System EHR reporting option (Option 2 in section II.B.4.(c). of this proposed rule) must report in the form and manner specified for the Physician Quality Reporting System (for more information on current reporting requirements, see the CY 2012 Medicare Physician Fee Schedule final rule with comment period (76 FR 73314)).

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

For Stage 1, EPs were required to report the clinical quality measures on an individual basis and did not have an option to report the measures 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 eligible professionals 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 are proposing three group reporting options to allow eligible professionals within a single group practice to report clinical quality measure data on a group level. All three methods would be available for Medicare EPs, while only the first one would be possible for Medicaid EPs, at States' discretion.

We are proposing each of these options as an alternative to reporting clinical quality measure data as an individual eligible professional under the proposed options and reporting methods discussed earlier in this rule. These group reporting options would only be available for reporting clinical quality measures 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 propose 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 clinical quality measures for the Medicare EHR Incentive Program. This group reporting option is only available for electronic reporting of clinical quality measures and is not available for those EPs in their first year of Stage 1. The clinical quality measures reported under this option would represent all EPs within the group. EPs who choose this group reporting option for clinical quality measures must still individually satisfy the objectives and associated measures for their respective stage of meaningful use. CMS proposes that States may also choose this option to accept group reporting for clinical quality measures, based upon a pre-determined definition of a "group practice," such as sharing one TIN.

- Medicare EPs participating in the Medicare Shared Savings Program and the testing of the Pioneer Accountable Care Organization (ACO) model who use Certified EHR Technology to submit ACO measures in accordance with the requirements of the Medicare Shared Savings Program would be considered to have satisfied their clinical quality measures reporting requirement as a group for the Medicare EHR Incentive Program. The Medicare Shared Savings Program does not require the use of Certified EHR Technology. However, all clinical quality measures data must be extracted from Certified EHR Technology in order for the EP to qualify for the Medicare EHR Incentive Program if an EP intends to use this group reporting option. EPs must still individually satisfy the objectives and associated measures for their respective stage of meaningful use, in addition to submitting clinical quality measures as part of an ACO. EPs who are part of an ACO but do not enter the data used for reporting the clinical quality measures (which excludes the survey tool or claims-based measures that are collected to calculate the quality performance score in the Medicare Shared Savings Program) into Certified EHR Technology would not be able to meet meaningful use requirements. (For more information about the requirements of the Medicare Shared Savings Program, see 42 CFR part 425 and the final rule published at 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 Shared Savings Program that may apply in the future. EPs must be part of a group practice (that is, two or more eligible professionals, 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 Physician Quality Reporting System clinical quality measures using Certified EHR Technology under the Physician Quality Reporting System Group Practice Reporting Option, would be considered to have satisfied their clinical

quality measures reporting requirement as a group for the Medicare EHR Incentive Program. For more information about the Physician Quality Reporting System Group Practice Reporting Option, see 42 CFR 414.90 and the CY 2012 Medicare Physician Fee Schedule final rule (76 FR 73314). EPs who use this group reporting option for the Medicare EHR Incentive Program would be required to comply with any changes to the Physician Quality Reporting System Group Practice Reporting Option that may apply in the future and must still individually satisfy the objectives and associated measures for their respective stage of meaningful use.

States would have the option to allow group reporting of clinical quality measures based upon the first option previously described, through an update to their State Medicaid HIT Plan, and would have to address how they would address the issue of EPs who switch group practices during an EHR reporting period.

7. Proposed Clinical Quality Measures 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 clinical quality measures by eligible hospitals and CAHs as part of demonstrating meaningful use of Certified EHR Technology. 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 clinical quality measures 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) (namely, the NQF). We are proposing clinical quality measures 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 measures for the EHR Incentive Programs. Measures listed in this proposed 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 Certified EHR Technology under Medicare and Medicaid. Therefore, to meet this requirement, we continue our practice from Stage 1 of proposing clinical quality measures that would apply for both the Medicare and Medicaid EHR Incentive Programs, as listed in sections II.B.6.(b). and II.B.6.(c). of this proposed rule.

In accordance with CMS and HHS quality goals as well as the HHS National Quality Strategy recommendations, the hospital clinical quality measures that we are proposing beginning with FY 2014 can be categorized into the following six domains, which are described in section II.B.3. of this proposed rule:

- Clinical Process/Effectiveness.
- Patient Safety.
- Care Coordination.
- Efficient Use of Healthcare Resources.
- Patient & Family Engagement.
- Population & Public Health.

The selection of clinical quality measures we are proposing 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 Program and Hospital Value-Based Purchasing Program, the National Quality Strategy, and other considerations discussed in sections II.B.6.(b). and II.B.6.(c). of this proposed rule. The proposed reporting methods for Medicare eligible hospitals and CAHs are described in sections II.B.7.(a). and II.B.7.(b). of this proposed rule. The proposed reporting methods for Medicaid-only eligible hospitals are described in section II.B.7.(c). of this 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 have analyzed the Hospital IQR Program, hospital measures used by State Medicaid agencies, and the Joint Commission's hospital quality measures when selecting the measures to be reported under the EHR Incentive Program. Furthermore, we have placed emphasis on those measures that are in line with the National Quality Strategy and the HITPC's recommendations.

(b) Proposed Clinical Quality Measures for Eligible Hospitals and CAHs for FY 2013

For the EHR reporting periods in FY 2013, we propose that the eligible hospitals and CAHs would be required to submit information on each of the 15 clinical quality measures that were finalized for FYs 2011 and 2012 in the Stage 1 final rule (75 FR 44418 through 44420, Table 10). We refer readers to the discussion in the Stage 1 final rule for further explanation of the requirements for reporting those clinical quality measures (75 FR 44411 through 44422).

(c) Clinical Quality Measures Proposed for Eligible Hospitals and CAHs Beginning with FY 2014

We are proposing to change the reporting requirement beginning with FY 2014 to require eligible hospitals and CAHs to report 24 clinical quality measures from a menu of 49 clinical quality measures, including at least 1 clinical quality measure from each of the 6 domains. The 49 clinical quality measures would include the current set of 15 clinical quality measures that were finalized for FYs 2011 and 2012 in the Stage 1 final rule as well as additional pediatric measures, an obstetric measure, and cardiac measures.

Our experience from Stage 1 in implementing the current set of 15 clinical quality measures in specialty and low volume eligible hospitals has 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 clinical quality measures for stroke and VTE. We are considering 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 measures. Hospitals that do not have enough cases to exceed the threshold would be exempt from reporting certain clinical quality measures. We solicit 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 clinical quality measures (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 "zeros" for the measures). We are also soliciting comment 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 more narrow patient base than acute care and critical access hospitals. Comments are solicited for application of the thresholds to Stage 1 of meaningful use in 2013, as the issue would be mitigated for Stages 1 and 2 by a beginning in 2014 proposed menu set of hospital clinical quality measures.

Aside from the previous threshold discussion, we are proposing clinical quality measures in Table 9 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. We propose that eligible hospitals and CAHs must report a total of 24 clinical quality measures from those listed in Table 9. Eligible hospitals and CAHs would have to select and report at least 1 measure from each of the following 6 domains:

- Patient and Family Engagement.
- Patient Safety.
- Care Coordination.
- Population and Public Health.
- Efficient Use of Healthcare Resources.
- Clinical Process/Effectiveness.

For the remaining clinical quality measures, eligible hospitals and CAHs would select and report the measures from Table 9 that best apply to their patient mix. We are soliciting comment on the number of measures and the appropriateness of the measures and domains for eligible hospitals and CAHs.

If an eligible hospital's or CAH's Certified EHR Technology does not contain patient data for at least 24 measures, including a minimum of at least 1 from each domain, then the eligible hospital or CAH must report the measures for which there is patient data and report the remaining required measures as "zero denominators" through the form and manner specified by the Secretary. In the unlikely event that there are no measures applicable to the eligible hospital's or CAH's patient mix, eligible hospitals or CAHs must still report 24 measures even if zero is the result in either the numerator or the denominator of the measure. If all measures have a value of zero from their Certified EHR Technology, then eligible hospitals or CAHs must report any 24 of the measures.

In the Stage 1 final rule (75 FR 44418), the title for the clinical quality measure NQF #438 was listed as "Ischemic or hemorrhagic stroke – Antithrombotic therapy by day 2." The corrected measure title, which is also included in Table 9 is "Stroke-5 Ischemic stroke – Antithrombotic therapy by day 2."

Table 9 lists all of the clinical quality measures that we are proposing for eligible hospitals and CAHs to report for the EHR Incentive Programs beginning with FY 2014. The measures titles and descriptions in Table 9 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. Measures which are designated as "New" in the "New Measures" column were not finalized in the Stage 1 final rule. Some of the clinical quality measures in this table will require the development of electronic specifications. Therefore, we propose to consider these clinical quality measures for possible inclusion beginning with FY 2014 based on our expectation that their electronic specifications will be available at the time of or within a reasonable period the

publication of the final rule. All clinical quality measure specification updates, including a schedule for updates to electronic specifications, would be posted on the EHR Incentive Program website (https://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp), and we would notify the public.

Additionally, some of these measures have been submitted by the measure steward and are currently under review for endorsement consideration by the National Quality Forum. The finalized list of clinical quality measures that would apply for eligible hospitals and CAHs beginning with FY 2014 will be published in the final rule.

TABLE 9: CLINICAL QUALITY MEASURES PROPOSED FOR ELIGIBLE HOSPITALS AND CRITICAL ACCESS HOSPITALS BEGINNING WITH FY 2014

NQF #	Title	Measure Steward and Contact Information	Other Quality Measure Programs that use the same Measure***	New Measure	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.	Oklahoma Foundation for Medical Quality (OFMQ) www.ofmq.com and click on "Contact"	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 from admit decision time to time of departure from the emergency department for emergency department patients admitted to inpatient status.	Oklahoma Foundation for Medical Quality (OFMQ) www.ofmq.com and click on "Contact"	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

NQF #	Title	Measure Steward and Contact Information	Other Quality Measure Programs that use the same Measure***	New Measure	Domain
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
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

NQF #	Title	Measure Steward and Contact Information	Other Quality Measure Programs that use the same Measure***	New Measure	Domain
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 Overlap of Anticoagulation Therapy 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. Overlap therapy must be administered for at least five days with an international normalized ratio (INR) = 2 prior to discontinuation of the parenteral anticoagulation therapy or the patient must be discharged on both medications.	The Joint Commission www.jointcommission.org and click on "Contact Us"	IQR	New	Clinical Process/ Effectiveness
0374	Title: VTE Patients Unfractionated Heparin (UFH) Dosages/Platelet Count Monitoring by Protocol (or Nomogram) Receiving Unfraction-ated Heparin (UFH) with Dosages/Platelet Count Monitored 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

NQF #	Title	Measure Steward and Contact Information	Other Quality Measure Programs that use the same Measure***	New Measure	Domain
0375	Title: VTE-5 VTE discharge instructions Description: This measure assesses the number of patients diagnosed with confirmed VTE that are discharged to home, to home with home health, or home hospice 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 on arrival) 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
0132	Title: AMI-1-Aspirin at arrival for acute myocardial infarction (AMI) Description: Percentage of acute myocardial infarction (AMI) patients without aspirin contraindications who received aspirin within 24 hours before or after hospital arrival.	The Joint Commission (TJC) www.jointcommission.org and click on "Contact Us"	IQR, TJC	New	Clinical Process/ Effectiveness
0142	Title: AMI-2-Aspirin Prescribed at Discharge for AMI Description: Percentage of acute myocardial infarction (AMI) patients without aspirin contraindications who are prescribed aspirin at hospital discharge.	The Joint Commission (TJC) www.jointcommission.org and click on "Contact Us"	IQR	New	Clinical Process/ Effectiveness
0469	Title: Elective Delivery Prior to 39 Completed Weeks Gestation Description: Percentage of babies electively delivered prior to 39 completed weeks gestation.	The Joint Commission (TJC) www.jointcommission.org and click on "Contact Us"	TJC		Clinical Process/ Effectiveness

NQF #	Title	Measure Steward and Contact Information	Other Quality Measure Programs that use the same Measure***	New Measure	Domain
0137	Title: AMI-3-ACEI or ARB for Left Ventricular Systolic Dysfunction- Acute Myocardial Infarction (AMI) Patients Description: Percentage of acute myocardial infarction (AMI) patients with left ventricular systolic dysfunction (LVSD) and without both Angiotensin converting enzyme inhibitor (ACEI) and Angiotensin receptor blocker (ARB) contraindications who are prescribed an ACEI or ARB at hospital discharge. For purposes of this measure, LVSD is defined as chart documentation of a left ventricular ejection fraction (LVEF) less than 40% or a narrative description of left ventricular systolic (LVS) function consistent with moderate or severe systolic dysfunction.	The Joint Commission (TJC) www.jointcommission.org and click on "Contact Us"	IQR	New	Clinical Process/ Effectiveness
0160	Title: AMI-5-Beta Blocker Prescribed at Discharge for AMI Description: Percentage of acute myocardial infarction (AMI) patients without beta blocker contraindications who are prescribed a beta blocker at hospital discharge.	The Joint Commission (TJC) www.jointcommission.org and click on "Contact Us"	IQR	New	Clinical Process/ Effectiveness
0164	Title: AMI-7a- Fibrinolytic Therapy received within 30 minutes of hospital arrival Description: Percentage of acute myocardial infarction (AMI) patients receiving fibrinolytic therapy during the hospital stay and having a time from hospital arrival to fibrinolysis of 30 minutes or less.	The Joint Commission (TJC) www.jointcommission.org and click on "Contact Us"	IQR, HVBP	New	Clinical Process/ Effectiveness
0163	Title: AMI-8a- Primary Percutaneous Coronary Intervention (PCI) Description: Percentage of acute myocardial infarction (AMI) patients receiving percutaneous coronary intervention (PCI) during the hospital stay with a time from hospital arrival to PCI of 90 minutes or less.	The Joint Commission (TJC) www.jointcommission.org and click on "Contact Us"	IQR, HVBP	New	Clinical Process/ Effectiveness
0639	Title: AMI-10 Statin Prescribed at Discharge Description: Percent of acute myocardial infarction (AMI) patients 18 years of age or older who are prescribed a statin medication at hospital discharge.	The Joint Commission (TJC) 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 Measure***	New Measure	Domain
0148	Title: PN-3b-Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital Description: Percentage of pneumonia patients 18 years of age and older who have had blood cultures performed in the emergency department prior to initial antibiotic received in hospital.	The Joint Commission (TJC) www.jointcommission.org and click on "Contact Us"	IQR, HVBP	New	Efficient Use of Healthcare Resources
0147	Title: PN-6- Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients Description: Percentage of pneumonia patients 18 years of age or older selected for initial receipts of antibiotics for community-acquired pneumonia (CAP).	The Joint Commission (TJC) www.jointcommission.org and click on "Contact Us"	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.	The Joint Commission (TJC) www.jointcommission.org and click on "Contact Us"	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).	The Joint Commission (TJC) www.jointcommission.org and click on "Contact Us"	IQR, HVBP	New	Efficient Use of Healthcare Resources
0529	Title: SCIP-INF-3-Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time Description: Surgical patients whose prophylactic antibiotics were discontinued within 24 hours after Anesthesia End Time. The Society of Thoracic Surgeons (STS) Practice Guideline for Antibiotic Prophylaxis in Cardiac Surgery (2006) indicates that there is no reason to extend antibiotics beyond 48 hours for cardiac surgery and very explicitly states that antibiotics should not be extended beyond 48 hours even with tubes and drains in place for cardiac surgery.	The Joint Commission (TJC) www.jointcommission.org and click on "Contact Us"	IQR, HVBP, State use	New	Efficient Use of Healthcare Resources

NQF #	Title	Measure Steward and Contact Information	Other Quality Measure Programs that use the same Measure***	New Measure	Domain
0300	Title: SCIP-INF-4-Cardiac Patients with Controlled 6 AM Postoperative Serum Glucose Description: Percentage of cardiac surgery patients with controlled 6 a.m. serum glucose (</=200 mg/dl) on postoperative day (POD) 1 and POD 2.	The Joint Commission (TJC) www.jointcommission.org and click on "Contact Us"	IQR, HVBP	New	Clinical Process/ Effectiveness
0301	Title: SCIP-INF-6- Surgery patients with appropriate hair removal Description: Percentage of surgery patients with surgical hair site removal with clippers or depilatory or no surgical hair site removal.	The Joint Commission (TJC) www.jointcommission.org and click on "Contact Us"	IQR	New	Patient Safety
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.	The Joint Commission (TJC) www.jointcommission.org and click on "Contact Us"	IQR, TJC	New	Patient Safety
0136	Title: HF-1 Heart Failure (HF): Detailed Discharge Instructions Description: Percentage of heart failure patients discharged home with written instructions or educational material given to patient or caregiver at discharge or during the hospital stay addressing all of the following: activity level, diet, discharge medications, follow-up appointment, weight monitoring, and what to do if symptoms worsen.	The Joint Commission (TJC) www.jointcommission.org and click on "Contact Us"	IQR, HVBP	New	Patient & Family Engagement
0434	Title: Stroke-1 Venous Thromboembolism (VTE) Prophylaxis Description: Ischemic or a hemorrhagic stroke patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after hospital admission.	The Joint Commission (TJC) www.jointcommission.org and click on "Contact Us"	IQR	New	Patient Safety
0284	Title: SCIP-Card-2 Surgery Patients on a Beta Blocker Therapy Prior to Admission Who Received a Beta Blocker During the Perioperative Period Description: Percentage of patients on beta blocker therapy prior to admission who received a beta blocker during the perioperative period.	The Joint Commission (TJC) www.jointcommission.org and click on "Contact Us"	IQR, HVBP	New	Clinical Process/ Effectiveness

NQF #	Title	Measure Steward and Contact Information	Other Quality Measure Programs that use the same Measure***	New Measure	Domain
0218	Title: SCIP-VTE-2 Surgery Patients Who Received Appropriate Venous Thromboembolism (VTE)Prophylaxis Within 24 hours Prior to Surgery to 24 Hours After Surgery End Time Description: Percentage of surgery patients who received appropriate Venous Thromboembolism (VTE) prophylaxis within 24 hours prior to surgery to 24 hours after surgery end time.	The Joint Commission (TJC) www.jointcommission.org and click on "Contact Us"	IQR, HVBP	New	Patient Safety
0496	Title: ED-3 Description: 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	Oklahoma Foundation for Medical Quality (OFMQ) www.ofmq.com and click on "Contact"	OQR	New	Care Coordination
0338	Title: Home Management Plan of Care Document Given to Patient/Caregiver Description: Documentation exists that the Home Management Plan of Care (HMPC) as a separate document, specific to the patient, was given to the patient/caregiver, prior to or upon discharge.	The Joint Commission (TJC) www.jointcommission.org and click on "Contact Us"	State use	New	Patient & Family Engagement
0341	Title: PICU Pain Assessment on Admission Description: Percentage of PICU patients receiving: a. Pain assessment on admission, b. Periodic pain assessment.	National Association of Children's Hospitals and Related Institutions (NACHRI) www.nachri.org and click on "Contact Us"	State use	New	Patient & Family Engagement
0342	Title: PICU Periodic Pain Assessment Description: Percentage of PICU patients receiving: a. Pain assessment on admission, b. Periodic pain assessment.	National Association of Children's Hospitals and Related Institutions (NACHRI) www.nachri.org and click on "Contact Us"	State use	New	Patient & Family Engagement

NQF #	Title	Measure Steward and Contact Information	Other Quality Measure Programs that use the same Measure***	New Measure	Domain
0480	Title: Exclusive Breastfeeding at Hospital Discharge Description: Exclusive Breastfeeding (BF) for the first 6 months of neonatal life has long been the expressed goal of WHO, DHHS, APA, and ACOG. ACOG has recently reiterated its position (ACOG 2007). A recent Cochrane review substantiates the benefits (Kramer, 2002). Much evidence has now focused on the prenatal and intrapartum period as critical for the success of exclusive (or any) BF (Shealy, 2005; Taveras, 2004; Petrova, 2007; CDC-MMWR, 2007). Exclusive Breastfeeding rate during birth hospital stay has been calculated by the California Department of Public Health for the last several years using newborn genetic disease testing data. HP2010 and the CDC have also been active in promoting this measure. Holding prenatal and intrapartum providers accountable is an important way to incent greater efforts during the critical prenatal and immediate postpartum periods where BF attitudes are solidified.	California Maternal Quality Care Collaborative www.cmqcc.org and click on "Contact Us"	State use	New	Clinical Process/ Effectiveness
0481	Title: First temperature measured within one hour of admission to the NICU Description: Percent of NICU admissions with a birth weight of 501-1500g with a first temperature taken within 1 hour of NICU admission.	Vermont Oxford Network www.vtoxford.org and click on "Contact Us"	State use	New	Clinical Process/ Effectiveness
0482	Title: First NICU Temperature < 36 degrees C Description: Percent of all NICU admissions with a birth weight of 501-1500g whose first temperature was measured within one hour of admission to the NICU and was below 36 degrees Centigrade.	Vermont Oxford Network www.vtoxford.org and click on "Contact Us"	State use	New	Clinical Process/ Effectiveness
0143	Title: Use of relievers for inpatient asthma Description: Percentage of pediatric asthma inpatients, age 2-17, who were discharged with a principal diagnosis of asthma who received relievers for inpatient asthma	The Joint Commission (TJC) www.jointcommission.org and click on "Contact Us"	State use	New	Clinical Process/ Effectiveness
0144	Title: Use of systemic corticosteroids for inpatient asthma Description: Percentage of pediatric asthma inpatients (age 2 – 17 years) who were discharged with principal diagnosis of asthma who received systemic corticosteroids for inpatient asthma	The Joint Commission (TJC) www.jointcommission.org and click on "Contact Us"	State use	New	Clinical Process/ Effectiveness

NQF #	Title	Measure Steward and Contact Information	Other Quality Measure Programs that use the same Measure***	New Measure	Domain
0484	Title: Proportion of infants 22 to 29 weeks gestation treated with surfactant who are treated within 2 hours of birth Description: Number of infants 22 to 29 weeks gestation treated with surfactant within 2 hours of birth.	Vermont Oxford Network www.vtoxford.org and click on "Contact Us"	State use	New	Clinical Process/ Effectiveness
0716	Title: Healthy Term Newborn Description: Percent of term singleton livebirths (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: Hearing screening prior to hospital discharge (EHDI-1a) 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
1653	Title: IMM-1 Pneumococcal Immunization (PPV23) Description: This prevention measure addresses acute care hospitalized inpatients 65 years of age and older (IMM-1b) AND inpatients aged between 6 and 64 years (IMM-1c) who are considered high risk and were screened for receipt of 23-valent pneumococcal polysaccharide vaccine (PPV23) and were vaccinated prior to discharge if indicated. The numerator captures two activities; screening and the intervention of vaccine administration when indicated. As a result, patients who had documented contraindications to PPV23, patients who were offered and declined PPV23 and patients who received PPV23 anytime in the past are captured as numerator events.	Oklahoma Foundation for Medical Quality (OFMQ) www.ofmq.com and click on "Contact"	IQR	New	Population/ Public Health

NQF #	Title	Measure Steward and Contact Information	Other Quality Measure Programs that use the same Measure***	New Measure	Domain
1659	Title: IMM-2 Influenza Immunization Description: This prevention measure addresses acute care hospitalized inpatients age 6 months and older who were screened for seasonal influenza immunization status and were vaccinated prior to discharge if indicated. The numerator captures two activities: screening and the intervention of vaccine administration when indicated. As a result, patients who had documented contraindications to the vaccine, patients who were offered and declined the vaccine and patients who received the vaccine during the current year's influenza season but prior to the current hospitalization are captured as numerator events. Influenza (flu) is an acute, contagious, viral infection of the nose, throat and lungs (respiratory illness) caused by influenza viruses. Outbreaks of seasonal influenza occur annually during late autumn and winter months although the timing and severity of outbreaks can vary substantially from year to year and community to community. Influenza activity most often peaks in February, but can peak rarely as early as November and as late as April. In order to protect as many people as possible before influenza activity increases, most flu-vaccine is administered in September through November, but vaccine is recommended to be administered throughout the influenza season as well. Because the flu vaccine usually first becomes available in September, health systems can usually meet public and patient needs for vaccination in advance of widespread influenza circulation.,	Oklahoma Foundation for Medical Quality (OFMQ) www.ofmq.com and click on "Contact"	IQR	New	Population/ Public Health

***

IQR = Inpatient Quality Reporting
TJC = The Joint Commission
HVBP = Hospital Value-Based Purchasing
OQR = Outpatient Quality Reporting

8. Proposed Reporting Methods for Eligible Hospitals and Critical Access Hospitals

(a) Reporting Methods in FY 2013

In the CY 2012 Hospital Outpatient Prospective Payment System (OPPS) final rule with comment period (76 FR 74122), we implemented a pilot program for Medicare eligible hospitals

and CAHs for 2012 that is intended to test and demonstrate our capacity to accept electronic reporting of clinical quality measure information. The title of this pilot program is the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs. The EHR Incentive Program Registration and Attestation System is located at https://ehrincentives.cms.gov/hitech/login.action.

(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 clinical quality measures selected by the Secretary "in a form and manner specified by the Secretary" as part of demonstrating meaningful use of Certified EHR Technology. Medicare eligible hospitals and CAHs that are in their first year of Stage 1 of meaningful use may report the 24 clinical quality measures from Table 9 through attestation for a continuous 90-day EHR reporting period as described in section II.B.1. of this proposed rule. Readers should refer to the discussion in the Stage 1 final rule for more information about reporting clinical quality measures through attestation (75 FR 44430 through 44431). Medicare eligible hospitals and CAHs would select one of the following two options for submitting clinical quality measures electronically.

- Option 1: Submit the selected 24 clinical quality measures through a CMS-designated portal.

For this option, the clinical quality measures 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 the eligible hospitals and CAHs to log into a CMS-designated portal. Once the eligible hospitals and CAHs have logged into the portal, they would be required to submit

through an upload process, data that is based on specified structures produced as output from their Certified EHR Technology.

- Option 2: Submit the selected 24 clinical quality measures in a manner similar to the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs using Certified EHR Technology.

We propose that, as an alternative to the aggregate-level reporting schema described previously under Option 1, Medicare eligible hospitals and CAHs that successfully report measures in an electronic reporting method similar to the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs using Certified EHR Technology would satisfy their clinical quality measures 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 are considering an "interim submission" option for Medicare eligible hospitals and CAHs that are in their first year of Stage 1 beginning in FY 2014 and available in subsequent years 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 submit clinical quality measures data for a continuous 90-day EHR reporting period, and the data must be received no later than July 1 to meet the requirements of the EHR Incentive Program. We request public comment on this potential option.

We are considering 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 request 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 intend 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.

We note that the Hospital IQR program does not currently have an electronic reporting mechanism. We invite comment on whether an electronic reporting option would be appropriate for the Hospital IQR Program and whether it would provide further alignment with the EHR Incentive Program.

(c) Electronic Reporting of Clinical Quality Measures for Medicaid Eligible Hospitals

States that have launched their Medicaid EHR Incentive Programs plan to collect clinical quality measures electronically from Certified EHR Technology 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 Stage 1 clinical quality measures electronically will be similar for Stage 2. However, we note that subject to our prior approval, the process, requirements, and the timeline is within the States' purview.

C. Demonstration of Meaningful Use and Other Issues

1. Demonstration of Meaningful Use

a. Common Methods of Demonstration in Medicare and Medicaid

We propose to continue our common method for demonstrating meaningful use in both the Medicare and Medicaid EHR incentive programs. The demonstration methods we adopt for Medicare would automatically be available to the States for use in their Medicaid programs. The Medicare methods are segmented into clinical quality measures and meaningful use objectives.

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

We do not propose changes to the attestation process for Stage 2 meaningful use objectives, except the group reporting option discussed in section II.C.1.c. of this proposed rule. Several changes are proposed for clinical quality measure reporting, as discussed in section II.B.3. of this proposed 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 would revise §495.8 to accommodate the Stage 2 objective and measures, as well as changes we are making to Stage 1.

As HIT matures we expect to base demonstration more on automated reporting by certified EHR technologies, such as the direct electronic reporting of measures both clinical and nonclinical and documented participation in HIE. As HIT advances we expect to move more of the objectives away from being demonstrated through attestation. However, at this time we do not believe that the advances in HIT and the certification of EHR technologies allow us to propose an alternative to attestation in this proposed rule. We continue to evaluate the possible alternatives to attestation and the changes to certification and/or meaningful use. As discussed later, while we would continue to require analysis of all meaningful use measures at the individual EP, eligible hospital or CAH level, we are proposing a batch file process in lieu of individual Medicare EP attestation through the CMS Attestation website beginning with CY 2014. This batch reporting process will ensure that meaningful use of certified EHR

technology continues to be measured at the individual level, while promoting efficiencies for group practices that must submit attestations on large groups of individuals.

We would continue to leave open the possibility for CMS and/or the States to test options to utilize existing and emerging HIT products and infrastructure capabilities to satisfy other objectives of the meaningful use definition. The optional testing could involve the use of registries or the direct electronic reporting of some measures associated with the objectives of the meaningful use definition. We would not require any EP, eligible hospital or CAH to participate in this testing in either 2013 or 2014 in order to receive an incentive payment or avoid the payment adjustment.

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

For Stage 1, EPs were required to attest and report on core and menu objectives on an individual basis and did not have an option to report collectively with other EPs in the same group practice. Under section 1848(o)(2)(A) of the Act, the Secretary may provide for the use of alternative means for eligible professionals furnishing covered professional services in a group practice (as defined by the Secretary) to meet the requirements of meaningful use. For EHR reporting periods occurring in CY 2014 and subsequent years, we are proposing a group reporting option to allow Medicare EPs within a single group practice to report core and menu objective data through a batch file process in lieu of individual Medicare EP attestation through the CMS Attestation website. The purpose of proposing a group reporting option is to provide administrative relief to group practices that have large numbers of EPs who need to attest to meaningful use. This option is intended to allow a batch reporting of each individual EP's core and menu objective data, and each EP would still have to meet the required meaningful use

thresholds independently. This option does not permit any EP to meet the required meaningful use thresholds through the use of a group average or any other method of group demonstration.

We would establish a file format in which groups would be required to 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.

States would have the option of offering batch reporting of meaningful use data for Medicaid EPs. States would need to outline their approach in their State Medicaid HIT Plan.

For purposes of this group reporting option, we propose to 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). This is the same definition as one proposed in the group reporting option of clinical quality measures. States choosing to exercise this option would 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 would 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 would 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.

This group reporting option would be limited to data for the core and menu objectives, but it would not include the reporting of clinical quality measures, which is also required in order to demonstrate meaningful use and receive an EHR incentive payment. Clinical quality measures must be reported separately through one of the electronic submission options that are described in section II.B. of this proposed rule. Because we are proposing multiple group reporting methods for clinical quality measures, EPs would not have to report core and menu objective data in the same EHR Incentive Group as they report their clinical quality measures. An EP would be able to submit the core and menu objectives as part of a group and the clinical quality measures as an individual or vice versa (that is, use clinical quality group reporting, while using individual reporting for the core/menu objectives).Please note that EPs would not be required to batch report as part of a group, and would still be permitted to attest individually through the CMS Attestation website (as long as they did not also report as part of a group). In order to demonstrate meaningful use and avoid any payment adjustments applicable under the Medicare EHR Incentive Program, EPs would be required to individually meet all of the thresholds of the core and menu objectives. In other words, an EP cannot avoid payment adjustments through the use of a group average or any other method of group demonstration. Payment adjustments would be applied to individual EPs, as described in section II.C. of this proposed rule and not to Medicare EHR Incentive Groups.

An EP's incentive payment would not be automatically assigned to the Medicare EHR Incentive Group with which they batch report under this option. The EP would still have to select the payee TIN during the registration process.

EPs that practice in multiple practices or locations would be responsible for submitting complete information for all actions taken at practices/locations equipped with Certified EHR

Technology. Under 42 CFR 495.4, to be considered a meaningful EHR user, an EP must have 50 percent or more of their patient encounters in practice(s) or location(s) where Certified EHR Technology is available. In the July 28, 2010 final rule (75 FR 44329), we also made clear that an EP must include encounters for all locations equipped with Certified EHR Technology. We are not proposing to change these requirements in this rulemaking. Therefore, an EP who chooses the group reporting option would be required to include in such reporting core and menu objective information on all encounters where Certified EHR Technology is available, even if some encounters occurred at locations not associated with the EP's Medicare EHR Incentive Group. We are not proposing 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 Certified EHR Technology 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, provided they report all of the data from the other locations through the batch reporting process.

We also seek public comment on a group reporting option that allows groups an additional reporting option in which groups report for their EPs a whole rather than broken out by individual EP.

In the January 18, 2011 **Federal Register** (76 FR 2910), the Health IT Policy Committee published a request for comment, to which 422 organizations and individuals submitted comments. In it, the committee invited comment on the following question, "Should Stage 2 allow for a group reporting option to allow group practices to demonstrate meaningful use at the group level for all EPs in that group?"

The majority of those responding to this question supported this approach as one reporting option for EPs. Commenters often cited that a group reporting option will reduce administrative burden. Many commenters expressed an opinion that permitting group reporting may harness EP competition that will improve performance with peers within the group practice. Furthermore, commenters also stated that this option would: facilitate physician teamwork and care coordination, be helpful for specialists and community health centers, and highlight system-level performance, thus creating incentives to invest in system-wide improvement programs.

When commenting on the group reporting option we are providing the following list of suggested topics, but this list is by no means exhaustive:

- What should the definition of a group be for the exercise of group reporting? For example, under the PQRS Group Reporting Option, a group is defined as a physician group practice, as defined by a single Tax Payer Identification Number, with 25 or more individual eligible professionals who have reassigned their billing rights to the TIN. We could adopt this definition or an alternative definition.
- Should there be a self nomination process for groups as in PQRS or an alternative process for identifying groups?
- Regarding the availability of Certified EHR Technology across the group, should the group be required to utilize the same Certified EHR Technology?
- Should a group be eligible if Certified EHR Technology (same or different) is not available to all associated EPs at all locations?
- Should a group be eligible if they use multiple Certified EHR Technologies that cannot share data easily?

- With respect to EPs who practice in multiple groups or in a group and practice individually, how should meaningful use activities be calculated?
- As the HITECH Act requires all meaningful users to be paid 75 percent of all covered services, how should the covered services performed by EPs in another practice be assigned to the group TIN?
- How will meaningful use activities performed at other groups be included?
- Should these services be included in the attesting group, or should CMS just ignore this information or account for it in other ways?
- How should the government address an EPs failure to meet a measure individually?
- If an EP chooses not to participate in a particular objective should they be a meaningful EHR user under the group if their non-participation still allows group compliance with a percentage threshold?
- How should yes/no objectives be handled in this situation?
- Some EPs in a group participate in Medicaid while others participate in Medicare; what covered services should the meaningful use calculation capture?
- Incentive payment assignment.
- Should the incentive payment be reassigned to the group automatically or does the EP still need to assign it to the group at registration?
- Should the same policy exist if the EP has covered services billed to other TINs?
- How should covered services for EPs who leave a group during an active EHR reporting period be handled?
- How should payment adjustments for Group reporting be handled?
- What alternative options should be considered for reporting meaningful use, while

capturing necessary data?

For options presented, please share how each would be effectively implemented while meeting the objectives of the statute. For example, should EPs continue to report individually, use the batch file process proposed in this proposed rule or be included in a report of all EP data combined under one TIN?

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

In addition to the data already being collected under our regulations (§495.10), we propose to collect the business email address of EPs, eligible hospitals and CAHs to facilitate communication with providers. We do not propose to post this information online. We propose to amend §495.10 accordingly. We propose to begin collection 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 do 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.

3. Hospital-Based Eligible Professionals

We propose changes to the definition of a hospital-based eligible professional only to recognize the determination of hospital-based once Medicare providers are subject to payment adjustments. We refer readers to section II.D.2. of this proposed rule for that discussion.

While we are not proposing changes to the definition, we do seek comments on the following discussion. The definition of "hospital-based" in the Social Security Act discusses the eligible professional 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). In the Stage 1 final rule, we addressed comments on this portion of the definition (75 FR 44441). Nevertheless, during implementation of Stage 1, we have been 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 in-patient) definition of meaningful use. These inquiries point out that such situations are uncommon and might not be generalized under the uniform definition used by place of service codes.

We solicit comments on this issue. Specifically, comments should address and provide documentation supporting whether specialized hospital units are using stand-alone certified EHR technology separate from that of the hospital. In addition, the comments should address (and we would request documentation on) whether EPs are using the facilities and equipment of the hospital. We consider hospital facilities and equipment to refer to the physical environment needed to support the necessary hardware; internet access 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.

Thus, comments should address whether EPs using stand-alone certified EHR technology separate from that of the hospital, are truly not accessing the facilities and equipment of the hospitals. We would appreciate discussions of EP workflow to demonstrate how the EPs avoid use of such facilities and equipment.

Were we to adopt a policy on this issue, we believe additional attestation elements would need to be added to the determination of whether an EP is hospital-based. Such attestations would be subject to audit and the False Claims Act. In addition, were we to adopt a policy on

this issue, EPs found not to be hospital-based would not only be potentially eligible for incentive payments, but also subject to payment adjustments under Medicare.

We also request 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 would 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.

We reiterate this policy in section II.A.3.d.(2). of this proposed rule, where we explain that all meaningful use policies for EPs apply only to outpatient settings (all settings except the inpatient and emergency department of a hospital). 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 it is unclear whether the EPs in this case would have inpatient or ambulatory technology. We request comments on this issue. Finally, we request comments as to whether patients affected by this situation would essentially be "double-counted;" once for the hospital's EHR incentive payment, and once for the EP's incentive payment, and whether and how this issue should be addressed, such as potentially excluding discharges associated with EPs who receive an incentive payment based upon the same inpatient.

4. Interaction with Other Programs

There are no proposed changes to the ability of providers to participate in the Medicare and Medicaid EHR incentive programs and other CMS programs. We continue to work on aligning the data collection and reporting of the various CMS programs, especially in the area of clinical quality measurement. See section II.B. of this proposed rule for the proposed alignment initiatives for clinical quality measures.

D. Medicare Fee-For-Service

1. General Background and Statutory Basis

As we discussed in the Stage 1 final rule (75 FR 44447), sections 4101(a) and 4102(a) of the HITECH Act amended sections 1848, 1886, and 1814(l) of the Act to provide for incentive payments to EPs, hospitals, and CAHs that are meaningful users of certified EHR technology. Depending upon when the EP, hospital, or CAH first qualifies as a meaningful user of EHR technology, these incentive payments could begin as early as CY 2011 for EPs, FY 2011 for hospitals, or a cost reporting period beginning during FY 2011 for CAHs. In no case may these incentive payments be made later than CY 2016 for EPs, FY 2016 for hospitals or a cost reporting period beginning after the end of FY 2015 for CAHs.

As we also discussed in the Stage 1 final rule, sections 4101(b) and 4102(b) of the HITECH Act provide as well for reductions in payments to EPs, hospitals, and CAHs that are not meaningful users of certified EHR technology, 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 proposals for implementing these mandatory payment reductions.

2. Payment Adjustment Effective in CY 2015 and Subsequent Years for EPs who are not

Meaningful Users of Certified EHR Technology

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 who are not meaningful EHR users during the relevant EHR reporting period for the year. (As defined in §495.100 of the regulations, for these purposes an EP is a physician, which includes a doctor of medicine or osteopathy, a doctor of dental surgery or medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor.) 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 would 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: "(1) for 2015, 99 percent (or, in the case of an EP who was subject to the application of the payment adjustment if the EP is not a successful electronic prescriber in 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."

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 for EPs who are not Meaningful Users of Certified EHR Technology in CY 2015 and Subsequent Calendar Years

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 would 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 are proposing 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. We expect to base the determination each year on the most recent CY for which we have sufficient data. The computation would be based on the ratio of EPs who have qualified as meaningful users in the numerator, to Medicare-enrolled EPs in the denominator. We note that the statute requires us to base this determination on "the proportion of eligible professionals who are meaningful EHR users (as determined under subsection (o)(2)." Both hospital-based EPs and EPs who have been granted any of the exceptions that we are proposing remain EPs within the statutory definition of the term, as implemented in our regulations in §495.100 of our regulations. However, hospital-based EPs and EPs granted a exception would not be subject to the determination of meaningful use status "under subsection (o)(2)." Therefore, we are proposing to exclude from the denominator of the requisite ratio both the total number of EPs granted an exception in the most recent CY for which we have sufficient data, and all hospital-based EPs from the relevant period. We anticipate that we would compute the requisite ratio of EPs who are meaningful EHR users based on 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 would provide more specific detail on this computation in future guidance after the final regulation is published. We note that, in general terms, these two 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 would 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 also subject to the application of the

payment adjustment for e-prescribing under section 1848(a)(5) of the Act would be 98 percent of the Medicare PFS amount. In CY 2016, the adjustment to the Medicare PFS amount that would otherwise apply will be 98 percent. Similarly, the adjustment to the Medicare PFS amount that would otherwise apply would 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.

It is important to note 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 certified EHR technology, as provided in §495.8(a)(2)(iv). However, AIU does not constitute meaningful use of certified EHR technology. Therefore, those EPs who receive an incentive payment for AIU would 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 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 participation). 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.

TABLE 10: PERCENT ADJUSTMENT FOR CY 2015 AND SUBSEQUENT YEARS, ASSUMING THAT THE SECRETARY FINDS THAT LESS THAN 75 PERCENT OF EPs ARE MEANINGFUL EHR USERS FOR CY 2018 AND SUBSEQUENT YEARS

	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 11: PERCENT ADJUSTMENT FOR CY 2015 AND SUBSEQUENT YEARS, ASSUMING THAT THE SECRETARY ALWAYS FINDS THAT AT LEAST 75 PERCENT OF EPs ARE MEANINGFUL EHR USERS FOR CY 2018 AND SUBSEQUENT YEARS

	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%

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 would 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 the case of EPs, we have 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. 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 discuss in the separate sections later 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 do 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 are proposing that EHR reporting periods for payment adjustments would begin and end prior to the year of the payment adjustment. Furthermore, we are proposing 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 believe that the following rules should 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 second bulleted paragraph, we propose 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. This proposal would align reporting periods for multiple physician reporting programs. For EPs this would generally be a full calendar year (unless 2013 is the first year of demonstrating meaningful use, in which case a 90-day EHR reporting period would apply). Under this 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 for 2013 would be subject to a payment adjustment in 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 CY 2015, the EHR reporting period for the payment adjustment would continue to be the calendar year 2 years prior to the payment adjustment period, subject again to the special exception for new meaningful users of the Certified EHR Technology as follows:

We would create an exception for those EPs who have never successfully attested to meaningful use in the past nor during the regular EHR reporting period we are proposing in the first bulleted paragraph. For these EPs, as it is their first year of demonstrating meaningful use, for the 2015 payment adjustment, we propose 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 actually 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, this means specifically that 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, is October 1, 2014. Thus, the EP's EHR reporting period must 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). 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.

We believe that these proposed EHR reporting periods provide adequate time both for the systems changes that will be required for us to apply any applicable payment adjustments in CY 2015 and subsequent years, and for EPs 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. We welcome comments on this proposal.

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 would 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, we believe that given the timeframes of the HITECH Act payment

adjustments there are hardships for which an exception should be granted. We propose three types of exceptions in this proposed rule and are considering a potential fourth. We request public comments on all four exception options. Three types are by definition time limited and should not be at risk of existing for more than 5 years. The potential fourth refers to barriers facing EPs as discussed further. We believe that these barriers will be lowered over time as internet access, health information exchange and Certified EHR Technology itself becomes available more widely. However, we note that the 5 year limitation is statutory and cannot be altered by regulations.

In the Stage 1 final rule, we provided for this exception in our regulations at §495.102(d)(3). However, we did not specify the specific circumstances, process, or period for which an exception would be granted. We therefore propose to modify the provision (in a renumbered §495.102(d)(4)) to specify the circumstances under which an exception would be granted.

First, we propose that the Secretary may grant an exception to EPs who practice in areas without sufficient Internet access. This is in keeping with the language at section 1848(a)(7)(B) of the Act that a significant hardship may exist "in the case of an eligible professional who practices in a rural area without sufficient Internet access." It also recognizes that a non-rural 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.

Because exceptions on the basis of insufficient Internet connectivity must intrinsically be considered on a case-by-case basis, we believe that it is appropriate to require EPs to demonstrate insufficient Internet connectivity to qualify for the exception through an application process. As we have noted, 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, summary of care documents, electronic prescribing, making health information available online and submission of public health information. Therefore, we believe that the application must demonstrate insufficient Internet connectivity to comply with the meaningful use objectives listed previously and insurmountable barriers to obtaining such infrastructure, such as a high cost of extending the Internet infrastructure to their facility. The hardship would be shown for the year that is 2 years prior to the payment adjustment year. We would 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.

We are proposing to establish the hardship period 2 years prior to the payment adjustment year because, by definition, the majority of EPs without sufficient Internet connectivity would not have previously been meaningful EHR users. EPs who have never demonstrated meaningful use would generally have a short (90-day) EHR reporting period that occurs in the year before the payment adjustment year. However, if there is insufficient Internet connectivity in the year prior to that reporting period, we believe it is reasonable to assume that the EP would face hardships during the reporting period year, if the EP acquired Internet connectivity and then were required to obtain Certified EHR Technology, implement it, and become a meaningful EHR user all in the same year.

We also encourage EPs to apply for the exception as soon as possible, which would be 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.

Secondly, we propose to provide an exception for new EPs for a limited period of time after the EP has begun practicing. Newly practicing EPs would 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 are proposing that for 2 years after they begin practicing, EPs could receive an exception from the payment adjustments that would otherwise apply in CY 2015 and thereafter. We note that, for purposes of this exception, an EP who switches specialties and begins practicing under a new specialty would not be considered newly practicing. For example, an EP who begins practicing in CY 2015 would receive an exception from the payment adjustments in CYs 2015 and 2016. However, as discussed previously, the new EP would 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 would be subject to the payment adjustment in CY 2017. We will 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.

Thirdly, we are proposing an additional exception in this proposed 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 believe that it is appropriate to require EPs to qualify for the exception through an application process.

We would 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 for EPs who would have otherwise be able to become meaningful EHR users and avoid the payment adjustment for a given year. Therefore, it is not necessary to account for circumstances that arise during a payment adjustment year, but rather those that arise in the two years prior to the payment adjustment year (that is in the calendar year immediately prior to the payment adjustment year, or the calendar year that is 2 years prior).

Finally, we are soliciting comments on the appropriateness of granting an exception for EPs meeting certain criteria. These include--

- 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 is able to 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 transporting information online are significantly easier to meet if a provider immediate contact with or follows up with or contact patients; and
- Lack of control over the availability of Certified EHR Technology at their practice locations.

We do not believe that any one of these barriers taken independently constitutes 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. One option is to provide a time-limited, two 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 is to provide such an exception with no specific time limit. However, we note that even under this less restrictive option, by statute no individual EP can receive an exception for more than five years. As discussed earlier, we believe the proliferation of both Certified EHR Technology 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 request comment on how soon EPs who meet the previous criteria would reasonably be able to achieve meaningful use.

We believe that EPs who meet the criteria listed previously face unique challenges in trying to successfully achieve meaningful use. However, we encourage comment on whether these criteria, or additional criteria not accounted for in the meaningful use exclusions constitute

a significant hardship to meeting meaningful use. For the final rule, we will consider whether to adopt an exception based on these or similar criteria, and, if so, whether such an an exception should apply to individual EPs or across-the-board based on specialty or other groupings that generally meet the appropriate criteria.

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 penalty:

TABLE 12: TIMELINE FOR ELIGIBLE PROFESSIONALS (OTHER THAN HOSPITAL-BASED) TO AVOID PAYMENT ADJUSTMENT

EP Payment Adjustment Year (Calendar Year)	Establish Meaningful Use for the Full Calendar Year 2 Years Prior:	OR	For an EP Demonstrating Meaningful Use for the First Time in the Year Prior to the Payment Adjustment Year in a Continuous 90-day Reporting Period Beginning No Later Than:	OR	Apply for an Exception No Later Than:
2015	CY 2013 (with submission period the 2 months following the end of the reporting period)		July 3, 2014 (with submission no later than October 1, 2014)		July 1, 2014
2016	CY 2014 (with submission period the 2 months following the end of the reporting period)		July 3, 2015 (with submission no later than October 1, 2015)		July 1, 2015
2017	CY 2015 (with submission period the 2 months following the end of the reporting period)		July 3, 2016 (with submission no later than October 1, 2016)		July 1, 2016
2018	CY 2016 (with submission period the 2 months following the end of the reporting period)		July 3, 2017 (with submission no later than October 1, 2017)		July 1, 2017
2019	CY 2017(with submission period the 2 months following the end of the reporting period)		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.

d. 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 believe 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 would also be subject to adjustments). Therefore, 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. Section 495.4 defines a hospital-based EP as "an EP who furnishes 90 percent or more of his or her covered professional services in a hospital setting in the year preceding the payment year. A setting is considered a hospital setting if it is a site of service that would be identified by the codes used in the HIPAA standard transactions as an inpatient hospital, or emergency room setting." We further specified in the definition of hospital-based eligible professional that, 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 that 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 would 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 will 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, we are 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. While 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 would 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 would 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 do not believe this is sufficient time for the EP to implement Certified EHR Technology. Therefore, we are proposing 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 Certified EHR Technology and begin the EHR reporting period to avoid the CY 2015 payment adjustment. We consider 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 non-hospital-based under this "2 years prior" policy when they would 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 non-hospital-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 do not believe the EP should be penalized for having been non-hospital based as of January 1, 2013, especially if the EP has never demonstrated meaningful use, and the EP's first EHR reporting period would have fallen within CY 2014. Therefore, for the final rule, we are considering expanding the hospital-based determination to encompass

determinations made either 1 or 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.

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

In addition to providing for incentive payments for meaningful use of EHRs, 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 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 13: PERCENTAGE DECREASE IN APPLICABLE HOSPITAL PERCENTAGE INCREASE FOR HOSPITALS THAT ARE NOT MEANINGFUL EHR USERS

	2015	**2016**	**2017+**
Hospital is subject to EHR payment adjustment	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 would 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 would 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 will also 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.). It is important to note 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 would not 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 we thus continues to assign the same CCN, we would continue to recognize the demonstration of meaningful use under that CCN. The same policy would apply to 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 would 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.) We advise hospitals that are changing ownership, merging, or otherwise reorganizing to take this policy into account.

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 of this chapter, three-fourths of the applicable percentage change specified in paragraph (d)(1) of this section is reduced--
>
> (i) For fiscal year 2015, by 33 1/3 percent;
>
> (ii) For fiscal year 2016, by 66 2/3 percent; and
>
> (iii) 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 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.

In this proposed rule, we have no further proposals specifically regarding the establishment of the applicable percentage increase adjustment for eligible hospitals who are not meaningful EHR users for FY 2015 and subsequent FYs beyond the provisions we have just cited. However, we believe that the existing regulatory provisions establishing the applicable percentage increase adjustment need to be supplemented to ensure that it is clear that 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, will be a prior EHR reporting period (as defined in §495.4 of the regulations). We have also proposed an amendment to §412.64(d) to recognize the availability of the exception, 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 issues and present our proposals 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" the EHR reporting period that will apply "with respect to a [calendar or 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 wish 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 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. 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 affect the settlement of final payment amounts under the cost report reconciliation process. Since the EHR payment adjustment in FYs 2015 and subsequent years is an adjustment to the applicable percentage increase, 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 are proposing, 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 will establish EHR reporting periods that begin and end prior to the year of the payment adjustment. Furthermore, we are proposing that the EHR reporting periods for purposes of such determinations will 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 believe that the following rules should apply for 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, we propose that the EHR reporting period for the FY 2015 applicable percentage increase adjustment would be the same EHR reporting period that applies in order to receive the incentive for FY 2013. For hospitals this would generally be the full fiscal year (unless FY 2013 is the first year of demonstrating meaningful use, in which case a 90-day EHR reporting period would apply). Under this 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 would 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 would continue to be the FY 2 years before the payment period, subject again to the special provision for new meaningful users of certified EHR technology.

- We would create an exception for those hospitals that have never successfully attested to meaningful use in the past nor during the regular EHR reporting period we are proposing in

the first bulleted paragraph previously. For these hospitals, as it is their first year of demonstrating meaningful use, we propose 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 3, 2014 (allowing the hospital a 90-day EHR reporting period, followed by one extra day to successfully submit the attestation and any other information necessary to earn an incentive payment). 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 would 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 would need to be completed by July 1. (As we discuss later, exception requests would be due by the April 1 before the beginning of the next fiscal year.)

In conjunction with adopting these rules for determining the EHR Reporting Period for determining whether a hospital is subject to the applicable percentage increase adjustment for FY 2015 and subsequent FYs, we are specifically proposing 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 believe 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. We welcome comments on this proposal.

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 would 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.

In this proposed rule we are proposing to add a new§412.64(d)(4), specifying the circumstances under which we would 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 or both of the following 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 would result in a significant hardship, such as in the case of a hospital in a rural area without sufficient Internet access." We are therefore proposing 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 non-rural area may also lack sufficient Internet access to make complying with meaningful use requirements a significant hardship for a hospital. Therefore, we are providing 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 believe that it is appropriate 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 believe 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 would 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 would 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.)

For the same reasons we are proposing an exception for new EPs, we propose an exception for a new hospital for a limited period of time after it has begun services. We would 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, it is important to ensure that the exception is not 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, the following hospitals would not be considered new hospitals 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 would 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 this 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 would 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 would 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 have 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 welcome 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 would be appropriate in the EHR context.

Finally, we are proposing an additional exception in this proposed 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.

We would 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. The purpose of this exception is for hospitals who would have otherwise be able to become meaningful EHR users and avoid the payment adjustment for a given year. Therefore, it is not necessary to account for circumstances that arise during a payment adjustment year, but rather those that arise in the 2 years prior to the payment adjustment year.

The following table 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 14: TIMELINE FOR ELIGIBLE HOSPITALS TO AVOID PAYMENT ADJUSTMENT

Hospital Payment Adjustment Year (Fiscal Year)	**Establish Meaningful Use the Full Fiscal Year 2 Years Prior:**	**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 period the 2 months following the end of the reporting period)		April 3, 2014 (with submission no later than July 1, 2014)		April 1, 2014
2016	FY 2014 (with submission period the 2 months following the end of the reporting period)		April 3, 2015 (with submission no later than July 1, 2015)		April 1, 2015
2017	FY 2015 (with submission period the 2 months following the end of the reporting period)		April 3, 2016 (with submission no later than July 1, 2016)		April 1, 2016
2018	FY 2016 (with submission period the 2 months following the end of the reporting period)		April 3, 2017 (with submission no later than July 1, 2017)		April 1, 2017
2019	FY 2017 (with submission period the 2 months following the end of the reporting period)		April 3, 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.

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. Such adjustments shall 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. In this context, we would consider 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 propose a new §412.64(d)(5) that includes this statutory requirement. States operating under a payment waiver under section 1814(b)(3) of the Act must 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.

In this context, we are also proposing 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).

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 would 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 certified EHR technology for an applicable reporting period, then for a cost reporting period that begins in FY 2015, its reimbursement would be reduced from 101 percent of its reasonable costs to 100.66 percent. For a cost reporting period beginning in FY 2016, its reimbursement would be reduced to 100.33 percent of its reasonable costs. For a cost reporting period beginning in FY 2017 and each subsequent FY, its reimbursement would be reduced to 100 percent of reasonable costs.

However, as provided for eligible hospitals, a CAH may, on a case-by-case basis, be granted an exception from this adjustment if CMS or its Medicare contractor determines, on an annual basis, that a significant hardship exists, such as in the 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 stage 1 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 propose 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 for its cost reporting period that begins in FY 2015. This differs from what is being proposed for eligible hospitals where the EHR

reporting period will be prior to the market basket adjustment year. We believe 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 have proposed an amended 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 would 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).

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

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 are proposing to revise these regulations to align them with the exceptions being proposed for EPs and subsection (d) hospitals. As with EPs and subsection (d) hospitals CAHs could apply for an exception on the basis of lack of sufficient Internet connectivity. Applications would 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, the insufficient Internet connectivity would need to be demonstrated for each applicable payment adjustment year. For example, 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.

As with new EPs and new eligible hospitals, we are also proposing an exception for a

new CAH for a limited period of time after it has begun services. We would 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 one year after the CAH accepts its first patient. If the CAH is established March 15 of 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 of 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).

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, 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.

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 penalty provision in FY 2015 and subsequent years if they fail to demonstrate

meaningful use of EHR technology during an applicable reporting period. Therefore, we are proposing 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, 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 are proposing 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 propose 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 propose 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.

Finally, we are proposing an additional exception in this proposed 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.

As described previously, we are proposing 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 that EHR reporting period (or November 30th of the subsequent EHR reporting period) otherwise the payment penalty could be applied to the CAH's cost reporting period that begins in that payment adjustment year. We are proposing 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, a CAH will be subject to the payment penalty 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 the payment penalty will be applied. 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.

Table 15, 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.

TABLE 15: TIMELINE FOR CAHs TO AVOID PAYMENT ADJUSTMENT

CAH with Cost Reporting Period Beginning During Payment Adjustment Year:	Establish Meaningful Use for the EHR Reporting Period:	OR	For a CAH demonstrating meaningful use 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.

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

The Stage 1 final rule established requirements in 42 CFR 495.370 for States to create appeals processes under the Medicaid EHR Incentive Program, but did not establish an appeal process for all of the EHR Incentive Program. In §495.404, we are proposing a process for Medicare EPs, eligible hospitals, CAHs, qualifying MA organizations on behalf of an EP, and qualifying MA-affiliated hospitals in a limited circumstance to file an appeal in the Medicare FFS EHR Incentive Program. (See proposed §495.213 of the regulations text for a discussion of

the appeal process proposed for the MA EHR Incentive Program). In §495.404(f), we are proposing an appeal process for Medicaid providers in a limited circumstance, specifically when we conduct a meaningful use audit of the Medicaid eligible hospital and make an adverse audit finding.

Although 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), we believe a limited appeal process is warranted in certain cases involving individual applicability; that is, where a provider, as defined in §495.400, is challenging not the standards and methods themselves, but whether the provider met the regulatory standards and methods promulgated by CMS in its rules.

The proposed administrative appeals process applies to both Stage 1 and Stage 2 of meaningful use. We will post 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 seek public comments both on the guidance and the proposed rule.

We note that in all cases, we would require that requests for appeals, all filings, and all supporting documentation and data be submitted through an online mechanism in a manner specified by CMS.

a. Permissible Appeals

We propose to limit permissible appeals to the following three types of appeals:

(1) Eligibility Appeals

These appeals could be filed by EPs, eligible hospitals, or CAHs. The provider would

need to demonstrate that it meets all the EHR Incentive Program requirements except for the issue raised and should have received a payment but could not because of a circumstance outside the provider's control. A circumstance outside a provider's control is any event, as defined by us, which reasonably prevented a provider from participating in the EHR Incentive Program, and which the provider could not under any circumstance control. For example, system issues wholly within the control of CMS that could not be resolved to allow a provider to participate in the EHR Incentive Program or natural disasters that prevent the provider from registering or attesting might be circumstances outside the control of the provider, depending upon the specific situation.

In limited circumstances, an MA-affiliated eligible hospital could also file an eligibility appeal based on common corporate governance with a qualifying MA organization, for which at least two thirds of the Medicare hospital discharges (or bed-days) are of (or for) Medicare individuals enrolled under MA plans or whether it meets the requirement of section 1853(m)(3)(B)(i) of the Act to be an MA-affiliated hospital because it has less than one-third of Medicare bed-days covered under Part A rather than Part C.

(2) Meaningful Use Appeals

These appeals could be filed by EPs, eligible hospitals, CAHs, and MA organizations on behalf of MA providers to challenge adverse audit or other findings that the provider did not, in fact, demonstrate that it is a meaningful EHR user, or, that it did not demonstrate it was using certified EHR technology. (See section II.F. of this proposed rule, explaining proposed amendments to §495.316 and §495.332). These appeals could be filed by Medicaid providers in a limited circumstance, specifically when we conduct a meaningful use audit of the Medicaid eligible hospital and make an adverse audit finding. States would agree in their State Medicaid

Health Information Technology Plans (SMHPs) to be bound by our audit and appeal determinations on meaningful use). Medicaid EPs would continue to use the State appeal process for all appeals under the Medicaid EHR Incentive Program.

(3) Incentive Payment Appeals

These appeals could be filed by Medicare EPs. The appeal would need to challenge the claims count used at attestation for determining the incentive payment. The appeal could not contest an individual claims payment or coverage decisions, but only the inclusion of final claims used to calculate the incentive payment amount. The appeal could also challenge a recoupment of an incorrect incentive payment based on any Federal determination (including a recoupment based on duplicative payment). Any issue involving incentive payment based upon a hospital cost report must be filed with the Provider Reimbursement and Review Board (PRRB); thus appeals raising hospital cost report issues will be dismissed in accordance with these proposed rules. However, we wish to make clear that the PRRB would not have jurisdiction over issues to be decided under the administrative process described in this proposal (for example, eligibility issues or whether a provider was a meaningful EHR user).

b. Filing Requirements

(1) Filing Deadlines

Appeals filed by a provider after the specified deadline would be dismissed and could not be re-filed, except under extenuating circumstances. If the filing deadline falls on a Saturday, Sunday, or a Federal holiday, then, the filing deadline would be extended to the next business day. We propose the following filing deadlines for each appeal:

- An eligibility appeal must be filed no later than 30 days after the 2-month period following the payment year.

- A meaningful use appeal must be filed no later than 30 days from the date of the demand letter or other finding that could result in the recoupment of an EHR incentive payment.

- An incentive payment appeal must be filed no later than 60 days from the date the incentive payment was issued or 60 days from any Federal determination that the incentive payment calculation was incorrect (including determinations that payments were duplicative).

A provider could request to extend the filing deadline by showing extenuating circumstances existed, which prevented the provider from filing the appeal by the applicable deadline. To demonstrate extenuating circumstances, a provider would need to present documentation (in its late filing) that occurrences, events, or transactions prevented the provider from filing by the applicable deadline. Extenuating circumstances will be decided on a case-by-case basis. Extenuating circumstances include, but are not limited to, system issues that affect a provider's incentive payment. We may extend the filing deadline for providers in response to extenuating circumstances that occur within the EHR Incentive Program. We will provide information on our website at least 7 calendar days before the filing deadline providing the new filing deadline.

A provider could withdraw an appeal at any time after the initial appeal filing and before an informal review decision is issued. The issues raised in the appeal filing could be refiled by the provider if prior to the specified filing deadline as specified in §495.408(b).

(2) Issues Raised at Time of Filing

A provider would be required to raise all relevant issues at the time of the initial filing of an appeal. Except under extenuating circumstances, issues not raised at the initial appeal filing could not be raised at a later time and would be dismissed. To demonstrate extenuating

circumstances, a provider would need to show (in its amendment filing) that circumstances beyond the provider's control prevented all relevant issues from being included at the time of the initial appeal filing. For example, the provider received documentation from another entity after the initial appeal filing, which raised additional issues that should have been be included in the initial appeal filing. The provider would be required to provide (with its amendment filing) documentation of occurrences, events, or transactions that prevented the additional issues from being raised at the initial appeal filing. We propose that any amendment must be filed no later than 15 days after the initial appeal filing deadline.

c. Preclusion of Administrative and Judicial Review

Any provider using our administrative appeal process would have the burden of showing at the time of the initial appeal filing that any issue raised in the appeal is not precluded from administrative and judicial review under the HITECH Act and our regulations at 42 CFR 413.70(a)(7), 495.106(f), 495.110, 495.212. Appeal issues found to be precluded would be dismissed.

d. Inchoate Review

We propose that issues raised in an appeal would also be reviewed for premature or inchoate issues. Issues are considered inchoate or premature if a provider is challenging a program issue that we still have an opportunity to resolve before the end of the respective payment period as indicated in the filing deadlines. The provider would have the burden of demonstrating in the initial appeal filing that the provider allowed us an opportunity to resolve the issue, and provide documentation of such resolution efforts (for example, documentation from contacting the EHR Information Center and demonstrating the issue was still not resolved or a demand letter has been issued asking for recoupment of an incentive payment.) A provider

that is unable to meet the burden would have their appeal dismissed and have the opportunity to refile when the provider can demonstrate: (1) that it has met all the program requirements other than the issue raised and should have received an incentive payment; (2) CMS was not able to resolve the issue before the end of the payment year; and (3) the appeal challenges the same program issues from the dismissed inchoate or premature appeal and is filed no later than 30 days after the 2-month period following the payment year for which the initial appeal was filed.

e. Informal Review Process Standards

Properly filed appeals (using the filing rules discussed previously) would first be subject to informal review, in accordance with the following process and standards:

For eligibility appeals, the provider would be required to demonstrate at the initial appeal filing that it meets all of the requirements of the EHR Incentive Program except for the issue raised, that the issue raised was the result of a circumstance outside of the provider's control that prevented the provider from receiving an incentive payment, and submit evidence that the provider took action to participate in the EHR Incentive Program. We are also proposing special rules for MA-affilated hospitals appealing determinations regarding common corporate governance with a qualifying MA organization, for which at least two-thirds of the Medicare hospital discharges (or bed-days) are of (or for) Medicare individuals enrolled under MA plans or that the hospital has less than one third of Medicare bed-days for the year covered under Part A rather than Part C.

For meaningful use appeals, the provider would be required to demonstrate that it met the meaningful use objectives and associated measures discussed in the demand letter issued by CMS or other findings that could result in a recoupment of the EHR incentive payment and that the provider used certified EHR technology during the EHR reporting period for the payment

year for which the appeal was filed.

For incentive payment appeals, the provider would be required to demonstrate that all relevant claims were submitted timely, according to the requirements set forth in the EHR Incentive Program but that the timely and appropriately filed claims were not included in calculating the amount of the EHR incentive payment. The EHR Incentive Program requires all claims be filed no later than 2 months after the end of the payment year. Nevertheless, we believe there may be situations in which timely filed claims are not reflected in our integrated data repository (IDR) due to claims processing delays. In this case, we will nevertheless calculate incentive payments based on the allowed charges for covered professional services included in the IDR (by our deadline for making incentive payments). However, EPs will be able to file appeals of these payment amounts, if they can show that timely filed claims were not included in the calculation, and that they would have received a higher incentive payment had such claims been included. We believe that at the time such appeals are filed, the IDR will have more up-to-date information, thereby allowing us to determine these appeals based on the allowed charges for the timely filed claims.

f. Request for Supporting Documentation--Documentation Essential to Validate an Issue Raised in the Appeal

We propose that providers would have 7 calendar days to comply with the request for supporting documentation. Missing this 7-day deadline would result in dismissal of the appeal, except in extenuating circumstances. A provider would be required to demonstrate that extenuating circumstance existed that prevented the provider from submitting supporting documentation within the required 7-day deadline. Extenuating circumstances would be decided

on a case-by-case basis, for example, if a provider received documentation from another entity after the 7 calendar days to respond to the request for supporting documentation.

g. Informal Review Decision

We propose that an informal review decision would be rendered within 90 days after the initial appeal filing, unless extensions or amendments are granted.

h. Final Reconsideration

We propose that providers dissatisfied with an informal review decision could file a request for reconsideration of issues denied in the informal review decision. All comments and documentation supporting the provider's position that the issues denied in the appeal should have been approved would be required to be submitted within 15 days from the date of the informal review decision. Requests for reconsideration would be reviewed with the same standards of review as the informal review. One-time extensions of 15 additional days could be requested, if the provider could demonstrate that it did not receive the informal review decision within 5 days of the date on the informal review decision.

We would render a final decision on the request for reconsideration within 10 days after the request for reconsideration and all supporting documentation and data are received.

If the provider does not request reconsideration, the informal review decision is a final decision by CMS.

i. Exhaustion of Administrative Review

We expect all providers to exhaust the administrative review process proposed in this rule, prior to seeking review in Federal Court.

E. Medicare Advantage Organization Incentive Payments

1. Definitions (§495.200)

We propose to add definitions of the terms "Adverse eligibility determination," "Adverse payment determination" and "MA payment adjustment year." Please see the discussion in section II.E.5 of this proposed rule. We also would 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 propose 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 qualifying MA organizations might be considered "hospital based" solely on the basis of the fact that 90 percent of their FFS covered professional services were provided in a hospital setting. For example, a qualifying MA EP might bill FFS 10 times over a year because of emergency room services provided to various patients. Although the vast majority of the MA EP's covered services were reimbursed under his or her arrangement with the MA organization, 100 percent (or 10) of the MA EP's FFS covered services would be for hospital-based services, which would otherwise prohibit the MA organization from receiving reimbursement under the MA EHR incentive program for the MA EP. We do not believe we should exclude MA EPs from the MA EHR Incentive Program due to only a few FFS claims. In addition, MA Organizations may not have access to an MA EP's FFS covered professional service data if the professional services were rendered outside of the employment arrangement between the qualifying MA organization and the qualifying MA EP. Therefore, we are clarifying in the definition of "qualifying MA EP" 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.

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

We propose a technical change to §495.202(b)(1) to indicate that the qualifying MA organizations must identify those MA EPs and MA-affiliated eligible hospitals that the qualifying MA organization believes will be meaningful users of certified EHR technology during the reporting period, if a qualifying MA organization intends to claim an incentive payment for a given qualifying MA EP or MA-affiliated eligible hospital.

In §495.202(b)(2), we clarify that qualifying MA organizations must report the CMS Certification Number (CCN) for qualifying MA-affiliated eligible hospitals. As this program matures, this is a detail that became necessary to report in order to properly administer the program.

We propose a new §495.202(b)(3) to include a reporting requirement to ensure that we can identify which qualifying MA EPs a given qualifying MA organization believes have furnished more than 50 percent of his or her 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 propose to redesignate the current §495.202(b)(3) as (b)(4), and revise the introductory language in (b)(2) to reflect this redesignation.

We require in the current §495.202(b)(3) that MA organizations identify qualifying MA EPs or MA-affiliated eligible hospitals within 60 days of the close of the payment year. We are proposing to change the 60-day requirement to a 2-month requirement in order to be more

consistent with the Medicare FFS EHR Incentive Program. 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 are proposing conforming amendments to §495.204(b)(2) and §495.210(b) and (c).

Because the redesignated §495.202 (b)(4) relates to both the payment phase and the payment adjustment phase of the program, we added the word "qualifying" to the text of the regulation. Therefore this regulation applies to both qualifying MA EPs and MA-affiliated eligible hospitals (payment and payment adjustment phases) and potentially qualifying MA EPs and MA-affiliated eligible hospitals (payment adjustment phase) of the program.

We redesignated the current §495.202(b)(4) as §495.202(b)(5), and indicated that the qualifying MA organization must identify the MA EPs and MA-affiliated eligible hospitals that it believes will be both "qualifying" and "potentially qualifying." In order to calculate the payment adjustment, we will need to know how many qualifying MA EPs and MA-affiliated eligible hospitals are and are not meaningful users. We also propose to correct a cross-reference.

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 propose to clarify that methods relating to overhead costs may be submitted for MA EPs regardless of whether the MA EP is salaried or paid in another fashion, such as on a capitated basis, where appropriate.

As stated previously, we also propose to require MA organizations, to submit revenue amounts relating to their qualifying MA EPs within 2 months of the close of the calendar year, as opposed to 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) (the current paragraph (e) would be redesignated paragraph (f)), we propose to add a provision governing whether a qualifying MA organization is entitled to a HPSA increase for a given qualifying MA EP. 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 if the MA EP predominantly furnishes his or her covered professional services during the MA EHR payment year in a geographic HPSA. Consistent with the Medicare FFS EHR Incentive Program, we interpret the term "predominantly" to mean more than 50 percent. For the MA EHR Incentive Program, we propose 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.

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. In order for the MA organization to receive the 10 percent increase, the MA EP would need 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 would need to provide more than $24,000 of Medicare Part B covered professional services to MA plan enrollees of the qualifying MA organization in order to begin earning the HPSA bonus – up to $26,400 to earn the maximum HPSA-enhanced bonus of $19,800 for first payment years 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 MAO with respect to the MA EP were 2011 or 2012. If an MA organization can 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, 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 are proposing a conforming amendment in §495.202(b)(2)(ii) to require MA organizations to notify CMS whether the qualifying MA EP predominantly provides covered services to MA plan enrollees in a HPSA.

We also would add a new paragraph (5) to redesignated paragraph (f). This new paragraph (5) would clarify that if-- (1) a qualifying MA EP; (2) an entity that employs a qualifying MA EP (or in which a qualifying MA EP has a partnership interest); (3) an MA-affiliated eligible hospital; or (4) any other party contracting with the qualifying MA organization, fails to comply with an audit request to produce documents or data needed to audit the validity of an EHR incentive payment, we will recoup the EHR incentive payment related to the applicable documents or data not produced. While we believe that we presently have the authority to do this under the current §495.204(e)(4), (to be redesignated as (f)(4)), we believe it would be helpful for the regulations to specifically address what happens in the case of a failure to produce documents or data related to an audit request.

We propose to add a new paragraph (g) to §495.204 to clarify that in the unlikely event we pay a qualifying MA organization for a qualifying MA EP, and it is later determined that the MA EP-- (1) is entitled to a full incentive payment under the Medicare FFS EHR Incentive

Program; or (2) has received payment under the Medicaid EHR Incentive Program, we will recover the funds paid to the qualifying MA organization for such an MA EP from the MA organization. (The former 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 by FFS to have earned the full amount. 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 now due.) If the organization still has an MA contract, we will recoup the amount from the MA organization's monthly payment under section 1853(a)(1)(A) of the Act. If the organization no longer has an MA contract, we will recoup any amounts through other means, such as formal collection. As duplicate and overpayments are prohibited by statute (sections 1853(l)(3)(B), 1853(m)(3)(B), 1903(t)(2) of the Act), we would recover overpaid MA EHR incentive payments for all MA EHR payment years, including payment year 2011.

We also clarify that, in accordance with statutory requirements, if it is determined that an MA organization has 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 will 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 duplicate and overpayments are prohibited by statute, this rule applies beginning with payment year 2011.

4. Avoiding Duplicate Payments

Qualifying MA EPs are eligible for the Medicare FFS EHR incentive payment if they meet certain requirements under that program. However, an EHR incentive payment is only allowed under one program. We believe the requirement that MA organizations notify MA EPs that the MA organization intends to claim them for the MA EHR Incentive Program will minimize misunderstandings among MA EPs (particularly if they expect to receive an incentive payment under the Medicare FFS Incentive Program). It is important for MA EPs to understand certain aspects of the program such as when a qualifying MA organization claims an MA EP under the MA EHR Incentive Program and the MA EP is not entitled to a full FFS EHR Incentive payment, the MA organization would prevent a partial payment under the Medicare FFS EHR Incentive Program from being paid directly to the MA EP.

We propose to require each qualifying MA organization to attest that it has notified the MA EPs it intends to claim. We propose 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 propose to revise §495.208 by adding-- (1) a new paragraph (a) requiring 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) requiring qualifying MA organizations to notify MA EPs when they are 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) requiring the qualifying MA organization to attest to CMS that these notification

requirements have been satisfied by the MA organization. We also propose to redesignate the current paragraphs (a) through (c) of §495.208 as (d) through (f), respectively.

As discussed previously, in a revised §495.210 we are proposing 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.

5. Payment Adjustments Effective for 2015 And Subsequent MA Payment Adjustment Years(§495.211).

Beginning in 2015, the Act 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 are proposing to add a definition of "MA Payment Adjustment Year" to the definitions in §495.200. The definition is needed in part because the payment adjustment phase of the MA EHR program continues indefinitely – beyond the last year for which MA EHR incentive payments can be made to qualifying MA organizations. Additionally, since we are proposing to operationalize MA EHR payment adjustments in a different manner than under the FFS Medicare program, we believe a definition is warranted.

We are proposing that an MA organization must have 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 in order 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 must continue to qualify for participation in the program as a "qualifying MA organization" as

defined for purposes of this program. Such 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 take this approach because we believe 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 has first demonstrated that it meets 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. Note that although MA EHR payment years for both MA EPs and MA-affiliated eligible hospitals can theoretically continue through 2016, the last first MA EHR payment year for which an MA organization can receive an EHR incentive payment is 2014 for MA EPs, and 2015 for MA-affiliated hospitals.

Furthermore, we believe payment adjustments under section 1853 of the Act will have limited applicability in the MA EHR Incentive Program because the HITECH Act limits 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 are making incentive payments, and the phase of the program when we are adjusting payments under sections 1853(l)(4) and 1853(m)(4) of the Act). Section 1853(l)(5) of the Act limits which MA organizations may participate by defining the term "qualifying MA organization." 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 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). 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. Organizations that do not meet the PHS definition of "HMO" cannot 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, 1853(l)(2) of the Act requires that MA EPs be as described in that paragraph. 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 do not expect many qualifying MA organizations to meet this test.

The current §495.202(b)(4) (which is being redesignated 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. This reporting requirement would include only qualifying MA organizations that participated in and received MA EHR incentive payments.

There may be MA organizations that participated in the payment phase of the program that no longer, in practice, are qualifying MA organizations, or that no longer have qualifying MA EPs or MA-affiliated eligible hospitals. For example, if a qualifying MA organization that contracted with one entity to deliver physicians' services during the payment phase of the EHR

Incentive Program, loses its contract with that entity, or if the entity subsequently contracts with other MA organizations, the MA organization may no longer meet the basic requirements to participate in the program (that is, may no longer be subject to adjustments due to not meeting the 80/80/20 rule). (See §495.200, for the definition of "Qualifying MA EP" in the Stage 1 final rule). Therefore, 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 would adjust payments beginning for payment adjustment year 2015 only for qualifying MA organizations that received MA EHR payments and that have potentially qualifying MA EPs or MA-affiliated eligible hospitals that are not meaningful EHR users. We would rely on the existing self-reporting requirement in redesignated §495.202(b)(5) and subsequent audits to ensure compliance.

We propose 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 will 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 are proposing 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 will 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 will 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 will obviate an adjustment. Through audit we will verify the accuracy of an applicable MA organization's assertions or nonreporting.

We are proposing 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 attests to the percent of hospitals and professionals that either are or are not meaningful users of certified EHR technology. To the extent a formerly qualifying MA organization does not report under §495.202(b)(4) or (5), we would verify, upon audit, the accuracy of the applicable MA organization's nondisclosure of 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. An MA-affiliated eligible hospital must attest to meaningful use by November 30th. Therefore, 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 expect (and prefer) to make an adjustment to one MA monthly payment totaling the adjustment for the year, we request comments on whether more than one monthly payment should be adjusted. 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's monthly payment).

For payment adjustments based on potentially qualifying MA EPs that are not meaningful users of certified EHR technology, we also propose 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 could calculate the payment adjustment based on the prior MA payment year's payment, and apply that adjustment to one or more of the prospective Part C payments. While we prefer to make an adjustment to one MA prospective payment for the full amount of the payment adjustment when possible, we solicit comment on whether we should make adjustments over several months or in a single month (for the entire adjustment amount), 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 for 2015. However, while the payment adjustment for the 2015 payment adjustment year would be collected as soon as possible, 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.

Proposed §495.211(c) makes clear that the potentially qualifying MA EP and MA-affiliated eligible hospital payment adjustments are calculated separately, and that each adjustment is applied to the qualifying MA organization's monthly payment under section 1853(a)(1)(A) of the Act, as discussed previously.

While 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 are not meaningful users of certified EHR technology. This paragraph makes clear that if a potentially qualifying MA EP is not a meaningful user of certified EHR technology in payment adjustment year 2015 (and subsequent

payment adjustment years), the qualifying MA organization's monthly Part C payment may 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 are claiming. During the payment adjustment phase of this program, we would need to know the percentage of both qualifying and potentially qualifying MA EPs and MA-affiliated eligible hospitals that are not meaningful users of certified EHR technology. This percentage can 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 are not meaningful EHR users. We would use this percentage to make the adjustment proportional to the percent that are 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 are not meaningful users), we would exclude EPs and hospitals that were neither qualifying nor potentially qualifying MA EPs 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 is a hospital-based EP would not be a qualifying or potentially qualifying MA EP since such an EP does not meet the 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. The formula we are proposing for purposes of applying the payment adjustments proposed in §495.211(d)(2) with respect to MA EPs is:

[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 are proposing for purposes of applying payment adjustments in §495.211(e)(2)(iii) with respect to MA-affiliated hospitals is:

[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) require 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 are asking for 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. Commenters should take into account that MA-affiliated eligible hospitals may still be required to perform a reporting function on behalf of their MA-affiliated organization in the National Level Repository (NLR), and are generally bound to "subsection (d)" hospital reporting requirements of the NLR, so we are primarily interested in stakeholders' thoughts on the requirements related to MA EPs.

While we wish to minimize burden, we are concerned about our ability to audit the information reported to ensure compliance with MA program requirements. Therefore, should we adopt the proposal in the final rule to require qualifying MA organizations to report only a percentage of MA EPs and MA-affiliated hospitals that are not meaningful users along with

identifying information in §495.202(b)(2)(i) through (iii), we also propose to require such 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 propose that payment adjustments for MA EPs be calculated by multiplying: (1) the percent established under §495.211(d)(4) of this proposed rule, (which 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 are not meaningful users. The statute at section 1853(l)(4)(B)(i) of the Act says that the "percentage points" in section 1848(a)(7)(A)(ii) of the Act apply to qualifying MA organizations with potentially qualifying MA EPs that are not meaningful users. We would also apply the additional reductions required under section 1848(a)(7)(A)(iii) of the Act to MA payment adjustments. We propose 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, 5 percent in 2019 and subsequent years. We also note that we have not proposed the possibility of a 2 percent reduction for 2015 (consistent with the Medicare FFS EHR Incentive Program), because that increased reduction applies in the case of EPs that were subject to an adjustment in 2014 under the e-prescribing program. MA organizations are not independently subject to the e-prescribing payment adjustments. Proposed regulations may be found in §495.211(d)(4)(iv) through (vi).

The Medicare Physician 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 physician services. While this proportion would be uniform across all MA organizations, in accordance with the requirement in section 1853(l)(1) of the Act that payment adjustments be with respect to the eligible professionals described in paragraph (2) of 1853(l) of the Act, we also propose 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. Therefore, we would adjust each MA organization's Physician Expenditure Proportion to recognize that not all of the EPs would meet the nonmeaningful use requirements to be potentially qualifying or qualifying MA EPs. For example, not all EPs might furnish 80 percent of their Title XVIII professional services to enrollees of the qualifying MA organization. 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.

An example of our proposed MA payment adjustment for adjustment year 2015 is 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. 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.

The formula would result in an adjustment that is 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.

The percentage point reduction specified by section 1886(b)(3)(B)(ix)(I) of the Act is based on the point reduction that results when three-fourths of the otherwise applicable percentage increase for the fiscal year is 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. This has 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).

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. As mentioned previously, we propose that this proportion reflect only the MA-affiliated eligible hospitals that are either qualifying or potentially qualifying MA-affiliated eligible hospitals.

We also propose to use the market basket percentage increase that would otherwise apply to "subsection (d)" hospitals for an MA payment adjustment year. A hypothetical example would be as follows. The market basket percentage increase for FY 2015 is hypothetically 4 percent. Three-quarters of one-third of 4 percent would be 1 percent. The hypothetical Medicare Hospital Expenditure proportion for the year is 15 percent, and one of two of the relevant MA-affiliated eligible hospitals is not a meaningful EHR user for the applicable period (FY 2015). The monthly payment to the MA organization in 2015 is $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 request comment on this aspect of the proposed rule.

6. Reconsideration Process for MA Organizations

We propose a new section, §495.213, which would set forth a reconsideration process for qualifying MA organizations that participate in the MA EHR Incentive Program. Under our proposal certain MA organization reconsiderations would be heard under the appeal process proposed in section II.D.5. of this proposed rule, while others would be heard using the process described in this section. This would allow us to take advantage of another reconsideration mechanism, and ensure consistency in decision-making for reconsiderations relating to, for example, meaningful use determinations.

Although the HITECH Act prohibits both administrative and judicial review of the standards and methods used to determine eligibility and payment (sections 1853(l)(8) and (m)(6) of the Act, and 42 CFR 495.212), we believe it is prudent to include a process for seeking reconsideration, in certain circumstances, of the application of those standards and methods. For eligibility issues, we would limit reconsiderations to those involving CMS system errors that did not allow the performance of a required function, and the qualifying MA organization or MA-affiliated eligible hospital missed a deadline (such as a registration or attestation deadline) because of such system malfunction. Thus, in §495.200 we define "Adverse eligibility determination" to include only determinations or omissions by CMS caused by a malfunction of a CMS system.

For qualifying MA-affiliated eligible hospitals (either acting on behalf of the qualifying MA organization or where the qualifying MA organization acts on the hospitals' behalf), we would require using the reconsideration process established for hospitals under the FFS EHR Incentive Program (described in section II.D.5. of this proposed rule). Reconsiderations of adverse meaningful use audits would also be heard using the process described in section

II.D.5. of this proposed rule.

The remainder of this preamble discussion relates to reconsiderations involving eligibility and payment issues for MA EPs. We would conduct reconsiderations of the application of payment requirements to, and eligibility requirements to participate in the program by a given MA EP under this section. We also request comment as to other issues that may require reconsideration, including a discussion of whether the issues are within our control. For example, if a qualifying MA organization's system incorrectly reports the identities of its qualifying MA EPs to us, we do not believe this could be used as a ground for reconsideration, because such a determination would be outside of our control. Of course, if a qualifying MA organization over-reports, we will recoup the applicable funds related to the over-reporting.

We request comment on defining the terms "adverse payment determination" and "adverse eligibility determination." We preliminarily believe the term "adverse eligibility determination" should be defined as "a determination or omission by CMS that prohibits a qualifying MA organization from participating in the EHR Incentive Program, that a representative of the MA organization believes was the result of a malfunction of a CMS system." We preliminarily believe the term "adverse payment determination" should be defined as "a determination by CMS that negatively affects an EHR payment determination."

We also propose to hear reconsiderations of payment adjustment amounts, when that phase of the program occurs.

We propose a two-level reconsideration process. The first level would be a request for an informal reconsideration. The second level would be a final reconsideration.

Requests for informal reconsideration would need to be submitted within 60 calendar days of an adverse eligibility or payment determination. If we find against the MA organization,

it will have 30 calendar days from the date on the informal reconsideration decision to file a request for final reconsideration. If the 30th or 60th calendar day (as applicable) is a Saturday, Sunday, or a Federal holiday, the reconsideration request will be due by the next business day. The MA organization would be required to submit all evidence and data in the initial request for informal reconsideration; no new evidence or data would be permitted at the final reconsideration stage. An MA organization could not use the reconsideration process to submit new payment-related information. Failure to file an informal or final reconsideration request pursuant to this CMS process would result in eligibility or payment determinations becoming final and binding, absent CMS reopening due to audit or other evidence of material misrepresentation.

F. Proposed Revisions and Clarifications to the Medicaid EHR Incentive Program

The proposals discussed in this section of the proposed rule would take effect upon finalization of this rule, not when Stage 2 of meaningful use of certified EHR technology takes effect.

1. Net Average Allowable Costs

In this proposed 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 propose 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.

TABLE 16: 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 stage 1final 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. Eligibility Requirements for Children's Hospitals

We propose 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 that 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.

3. 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 for care

of Medicaid populations. Otherwise, Medicaid funding could potentially be used to fund adoption and use of technology that does not benefit the Medicaid population directly. Therefore, we propose that at least one of the clinical locations used for the calculation of an EPs' patient volume have certified EHR technology during the payment year for which the EP is attesting to adopt, implement or upgrade in their first participation year, or to meaningful use in subsequent years. This will ensure that EPs receive Medicaid funding for certified EHR technology that is used on behalf of the EP's Medicaid patients. We have amended §495.304 and §495.332 accordingly.

a. Calculating Patient Volume Requirements

We propose to revise §495.306 (c) to allow States the option for their 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. This option would be in addition to the current regulatory language basing patient volume on the prior calendar or fiscal year. We believe this adjustment would provide greater flexibility in eligible providers' patient volume calculations.

Likewise, we propose 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 1 Medicaid encounter took place with the Medicaid patient in the 24 months prior to the beginning of the 90-day period. Also, we propose to revise §495.306 (d)(1)(ii)(A) accordingly, so that the numerator and denominator are using equivalent periods. Conforming changes would be made to §495.306(d)(2)(i) and (ii) for needy individual patient volume. We are proposing these changes 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 propose 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."

We propose to expand the current definition of "encounter" to also include any service rendered on any one day to an individual "enrolled" in a Medicaid program. Such a definition would 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 all of the item or service or the service is not covered under Medicaid). The definition would also 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 CHIP programs) could be counted in providers' patient volume calculations. This approach is consistent with existing policies that provide Title XIX protections to children enrolled in Title XXI-funded Medicaid expansions.

As of 2010, 33 States have Title XXI Medicaid expansions via approved State plan amendments. Therefore, 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 expect this change would increase the number of eligible providers who qualify for the Medicaid EHR Incentive Program, particularly those serving children. We expect that this change would represent an increase because States were more limited in their inclusion of Medicaid expansion populations based upon the July 28, 2010 final rule.

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 clarify 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.

b. Practices Predominantly

Similar to our proposed revisions for patient volume, we propose to revise the definition of "practices predominantly" at §495.302. EPs could use either: (1) the most recent calendar year; or (2) the most recent 12 months prior to attestation.

4. Medicaid Hospital Incentive Payment Calculation

a. Discharge Related Amount

In order to ensure that Medicaid regulations are consistent with Medicare, we are proposing 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 are revising our policy 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 would 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 is available.

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

We currently require that only discharges from the acute care part of the hospital are allowable to be counted in both the discharge-related amount and the Medicaid share. For example, in response to a frequently asked question (available at https://questions.cms.hhs.gov/app/answers/detail/a_id/10361) 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." Also, we explained 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.

In order to ensure that the regulations accurately reflect our current policy, we propose 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.

Such regulatory amendments do not represent a change in policy but rather a clarification of existing policy. The Medicaid share would count only those days that would 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.

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 1 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 would 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 would then assume the second State's payment cycle less the money that was paid from the first State. States should consult with us before addressing this specific scenario.

5. Hospital Demonstrations of Meaningful Use - Auditing and Appeals

We are proposing revisions to §495.316 under which we would conduct meaningful use audits and any subsequent appeals of such audits of any participating hospitals, including those that are eligible for only the Medicaid EHR Incentive program. In section 1903(t)(6)(C)(II) of the Act, all demonstrations of meaningful use must be "acceptable to the Secretary" and may be

based upon methods that are adopted under the Medicare program in section 1886(n) of the Act. Thus, under this standard, we would require that all Medicaid hospitals would be subject to audit and appeal by CMS just for demonstrations of meaningful use. Therefore, States will continue to provide the remaining audit functions for requirements under the Medicaid EHR Incentive Program. In addition (as discussed later), as we would be conducting the audit, hospitals would be subject to the CMS appeals process for any disputes regarding audit findings related to meaningful use, and States would be bound by our determinations regarding meaningful use findings. We have proposed to revise the SMHP requirements in §495.332 to clarify that States must indicate that if they are in agreement that they would be bound by our audit and appeal determinations in these circumstances. We also would revise our regulations at §495.370 to make clear that appeals of adverse CMS audits would be subject to the CMS administrative appeals process and not the State administrative process.

We believe it is essential for us to conduct the audits and appeals of hospital meaningful use because 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. This proposed revision would alleviate the burden on States developing processes, for which many States have indicated interest, and devoting resources to audit hospitals' meaningful use attestations when we estimate that a majority of States would have two or fewer Medicaid-only hospitals apply for incentive payments. Instead , we would leverage the resources we would have already devoted to auditing the vast majority of hospitals eligible for both incentive programs, to include the approximately 150 hospitals that are only eligible for Medicaid incentives. The meaningful use attestation data collected by States for

the Medicaid-only eligible hospitals will be shared with our auditors to enable this process. We are not proposing to audit Medicaid eligible professionals because the anticipated number of Medicaid eligible professionals demonstrating meaningful use would not provide the same level of cost/resource efficiency. However, we are leveraging our work in designing and implementing Medicare EP meaningful use audits by sharing strategic approaches with States. States 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 would also remain responsible for auditing EPs for compliance with meaningful use of certified EHR technology.

Please note that right to audit discussed in this proposed rule is in addition to, and not in lieu of, any other applicable rights to audit, such as those held by the Office of the Inspector General (OIG). We do not intend for anything in this rule to limit or restrict the authority of another Federal agency or another office within the Department of Health & Human Services to audit, evaluate, investigate, or inspect.

6. 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 are proposing 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 propose 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 are not changing the requirements of the circumstances of "as needed" IAPD updates as defined by §495.340.

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

We are proposing the following process for States that have had an HIT P-APD approved by CMS, 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, the State should explain in a narrative format to be included in the HIT IAPD 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 to be ongoing during the implementation period, these planning activities must be included as line items within the HIT IAPD budget.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to 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.

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

This analysis serves as a revision to the existing PRA package approved under OMB control number 0938-1158. The following is a discussion of the new information collection requirements contained in this proposed regulation that we believe are subject to PRA. The projected numbers of EPs, eligible hospitals, and CAHs, MA organizations, MA EPs and MA-affiliated hospitals are based on the numbers used in the impact analysis assumptions as well as estimated Federal costs and savings in the section V of this proposed rule. The actual burden would remain constant for all of Stage 2 as the EHR reporting period would be the entire calendar year for EPs and Federal fiscal year for eligible hospitals and CAHs. The only variable from year to year in Stage 2 would 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 2the 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 proposed 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 Physician Fee Schedule final rule with comment period (76 FR 73422 through 73425). For eligible hospitals and CAHs, the burden is discussed in the CY 2012 Hospital Outpatient Prospective Payment 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, we propose that to successfully demonstrate meaningful use of certified EHR technology 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 certified EHR technology 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 propose that providers must also successfully report the clinical quality measures selected by CMS to CMS or the States, as applicable. We estimate that the certified EHR technology adopted by the provider will 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 will enable the functionality required to complete the objectives and associated measures that require the provider to attest that they have done so.

We propose 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 propose that eligible hospitals and CAHs would be required to report on a total of 16 core objectives and associated measures, 2 of 4 menu set objectives and associated measures, and 24 clinical quality measures.

There are 13 core objectives and up to 2 menu set objectives that would require an EP to

enter numerators and denominators during attestation. Eligible hospitals and CAHs would have to attest they have met 11 core objectives and 4 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 certified EHR technology. We do not anticipate a provider would maintain two recordkeeping systems when certified EHR technology is present. Therefore, we assume that all patient records that would be counted in the denominator would be kept using certified EHR technology. We expect it would take an individual provider or 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 would require a "yes" or "no" response during attestation. For eligible hospitals and CAHs, there are 4 core objectives and that would require a "yes" or "no" response during attestation and no such menu set objectives. We expect that it would take a provider or their designee 1 minute to attest to each objective that requires a "yes" or "no" response.

Providers would also be required to attest that they are protecting 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 17 lists those objectives and associated measures for EPs and eligible hospitals and CAHs. We estimate the core set of objectives and associated measures will take an EP 8 hours 12 minutes to complete, and will take an eligible hospital or CAH 7 hours 54minutes to complete. For EPs, we estimate the completion of 3 menu set objectives and associated measures will take between 3 minutes and 21 minutes to complete, depending on the combination of objectives they choose to attest to. For EPs, we estimate the selection, preparation, and electronic submission of the 12 ambulatory clinical quality measures would take 2 hours. We estimate it would take eligible hospitals and CAHs 20 minutes to attest to the 2 menu set objectives they choose. For eligible hospitals and CAHs, we estimate the selection, preparation, and electronic submission of 24 required clinical quality measures would take 4 hours.

TABLE 17: BURDEN ESTIMATES

	Objectives - Eligible Professionals	Objectives - Eligible Hospitals/CAHs	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 to create the first record of the order.	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.	More than 60 percent of medication, laboratory, and radiology orders created by the EP or authorized provider 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 65 percent of all permissible prescriptions written by the EP are compared to at least one drug formulary and transmitted electronically using Certified EHR Technology.	10 minutes	
	Record the following demographics - Preferred Language - Gender - Race - Ethnicity - Date of birth	Record the following demographics - Preferred Language - Gender - Race - Ethnicity - Date of birth - Date and preliminary cause of death in the event of mortality	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) have demographics recorded as structured data	10 minutes	10 minutes
	Record and chart changes in vital signs: - Height - Weight - Blood pressure (age 3 and over) - Calculate and display BMI - Plot and display growth chart for patients 0-20 years, including BMI	Record and chart changes in vital signs: - Height - Weight - Blood pressure (age 3 and over) - Calculate and display BMI - Plot and display growth chart 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), blood pressure (for patients age 3 and over only) and height and weight (for all ages) recoded as structured data	10 minutes	10 minutes

	Objectives - Eligible Professionals	Objectives - Eligible Hospitals/CAHs	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 department (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 five or more clinical quality measures, if applicable, at a relevant point in patient care for the entire EHR reporting period. 2. The EP, eligible hospital, or CAH has enabled 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 into EHR as structured data	Incorporate clinical lab-test results into EHR as structured data	More than 55 percent of all clinical lab tests results 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 whose results are either in a positive/negative or numerical format are incorporated in Certified EHR Technology as structured data	10 minutes	10 minutes
	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		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	10 minutes	

	Objectives - Eligible Professionals	Objectives - Eligible Hospitals/CAHs	Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
			period were sent a reminder, per patient preference		
		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 are tracked using eMAR.. .		1 minute
	Provide patients the ability to view online, download and transmit their health information within 24 hours of an encounter or within four 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 (available to the patient within 24 hours of the encounter or within 3 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 10 percent of all unique patients seen by the EP during the EHR reporting period (or their authorized representatives) view and are provided the capability to download their health information	10 minutes	
		Provide patients the ability to view online and download information about a hospital admission	1. More than 80 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 10 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or		10 minutes

	Objectives - Eligible Professionals	Objectives - Eligible Hospitals/CAHs	Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
			23) of an eligible hospital or CAH view or download their information during the reporting period		
	Provide clinical summaries for patients for each office visit		Clinical summaries provided to patients within 24 hours for more than 50 percent of office visits.	10 minutes	
	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	For more than 10 percent of all office visits by the EP, patients are provided patient-specific education resources identified by Certified EHR Technology. More than 10 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient and emergency departments (POS 21 or 23) are provided patient-specific education resources identified by Certified EHR Technology.	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 Certified EHR Technology for more than 10 percent of unique patients seen during the EHR reporting period	10 minutes	
	The EP who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.	The eligible hospital or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation	The EP, eligible hospital or CAH performs medication reconciliation for more than 50 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).	10 minutes	10 minutes
	The EP who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for	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 should provide	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 65 percent of transitions	10 minutes	10 minutes

	Objectives - Eligible Professionals	Objectives - Eligible Hospitals/CAHs	Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
	each transition of care or referral.	summary care record for each transition of care or referral.	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 electronically transmits a summary of care record using certified EHR technology to a recipient with no organizational affiliation and using a different Certified EHR Technology vendor than the sender for more than 10 percent of transitions of care and referrals..		
	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 from the beginning to the end of the 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 Certified EHR Technology to public health agencies from the beginning to the end of the EHR reporting period as authorized, and in accordance with applicable State law and practice.		1 minute
		Capability to submit electronic syndromic surveillance data to public health agencies, 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 from the date of initiation to the end of the EHR reporting period		1 minute
	Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate	Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate	Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308 (a)(1), including addressing the	6 hours	6 hours

	Objectives - Eligible Professionals	Objectives - Eligible Hospitals/CAHs	Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
	technical capabilities	technical capabilities.	encryption/security of data at rest and implement security updates as necessary and correct identified security deficiencies as part of its risk management process		
	Core Set Burden			8 hours 12 minutes	7 hours 54 minutes
MENU SET		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.		10 minutes
	Incorporate imaging results and information into Certified EHR Technology	Incorporate imaging results and information into Certified EHR Technology	More than 40 percent of all scans and tests whose result is an image 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 incorporated into Certified EHR Technology	10 minutes	10 minutes
	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 or an indication that family health history has been reviewed	10 minutes	10 minutes

	Objectives - Eligible Professionals	Objectives - Eligible Hospitals/CAHs	Measures	Burden Estimate per Respondent (EPs)	Burden Estimate per Respondent (Hospitals)
		Generate and transmit permissible discharge prescriptions electronically (eRx)	More than 10 percent of hospital discharge medication orders for permissible prescriptions (for new or changed prescriptions) are transmitted electronically using Certified EHR Technology		10 minutes
	Capability to submit electronic syndromic surveillance data to public health agencies, 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 from the beginning to the end of the EHR reporting period	1 minute	
	Capability to identify and report cancer cases to a State cancer registry where authorized, and in accordance with applicable law and practice.		Successful ongoing submission of cancer case information from Certified EHR Technology to a cancer registry from the beginning to the end of the 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 Certified EHR Technology to a specialized registry for the entire EHR reporting period	1 minute	
	Menu Set Least Burdensome Criteria			3 minutes	20 minutes
	Menu Set Most Burdensome Criteria			21 minutes	20 minutes
	Time to Attest and Report Clinical Quality Measures			2 hours	4 hours
	Total - Core Set (including CQMs) + Least Burdensome Menu Set Criteria			10 hours 15 minutes	12 hours 14minutes
	Total - Core Set (including CQMs) + Most Burdensome Menu Set Criteria			10 hours 33 minutes	12 hours 14minutes

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 12 minutes to attest that during the EHR reporting period, they used the certified EHR technology, specify the EHR technology used and satisfied each of the applicable core objectives and associated measures. We estimate it will take an EP 21 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 no longer than 3 minutes. We also estimate that it will take an EP an additional 2 hours 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 33 minutes. The total burden hours for an EP to attest to the least burdensome criteria previously specified is 10 hours 15 minutes. We estimate that there could be approximately 537,600non-hospital-based Medicare and Medicaid EPs in 2014. We anticipate approximately 37% (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 requirement for an EP is 10 hours 33 minutes (8 hours 12 minutes + 21 minutes + 2 hours). 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 $188,783,003(198,912 EPs x 10 hours 33 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 requirement for an EP is 10 hours 15 minutes (8 hours 12 minutes + 3 minutes + 2 hours). 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 $183,414,766 (198,912 EPs x 10 hours 15 minutes x $89.96 (mean hourly rate for physicians based on May 2010 BLS data)). We invite public comments on the estimated percentages and numbers of (registered) EPs that will attest to the aforementioned criteria because such information would help use more accurately determine the burden on the EPs.

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 54 minutes to attest that during the EHR reporting period, they used the certified EHR technology, 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 20 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 4 hours 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 12 hours 14 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 proposed rule. We estimate the total burden associated with these requirements for an eligible hospital or CAH is 12 hours 14 minutes (7 hours 54 minutes + 20 minutes + 4 hours). 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 $2,375,564 (4,993 eligible hospitals and CAHs x $62.23 (12 hours 14 minutes x $62.23 (mean hourly rate for lawyers based on May 2010 BLS) data)). We invite public comments on the estimated percentages and numbers of (registered) eligible hospitals and CAHs that will attest to the aforementioned criteria because such information would help use more accurately determine the burden on the eligible hospitals and CAHs. We also invite comments on the type of personnel or staff that would most likely attest on behalf of the eligible hospital or CAH.

B. ICRs Regarding Qualifying MA Organizations (§495.210)

We estimate that the burden would 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 certified EHR technology 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 certified EHR technology. In other words, qualifying MA organizations can make the determination en masse if the certified EHR technology is required to be used at its facilities, whereas under FFS, each EP likely must make the determination on an individual basis. We 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 professional, 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 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]).

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 certified EHR technology 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. However, we are proposing 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 are proposing 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. Therefore, annual IAPD updates are only required if the State has not submitted an IAPD-U in the past 12 months, which we create less of a burden on the States. We expect that it would take a State 70 hours to update an annual IAPD. We believe that the proposed requirements 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, proposed alternatives for calculating patient volume will alleviate State burden as patient volume will be more easily calculated.

TABLE 18: 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 incl. CQMs (EPs)	0938-New	198,912	198,912	8.20	1,631,078	$89.96	$146,731,812.86
§495.6 - Menu Set Objectives/Measures (EPs) HIGH	0938-New	198,912	198,912	0.35	69,619	$89.96	$6,262,943.23
§495.6 - Menu Set Objectives/Measures (EPs) LOW	0938-New	198,912	198,912	0.05	9,946	$89.96	$894,706.18
§495.6 - Menu Set Objectives/Measures (EPs) AVERAGE	0938-New	198,912	198,912	0.20	39,782	$89.96	$3,578,824.70
§495.8 - CQMs for EPs	0938-New	198,912	198,912	2.00	397,824	$89.96	$35,788,247.04
§495.6 - EHR Technology Used, Core Set Objectives/Measures (hospitals/CAHs)	0938-New	2,696	2,696	7.90	21,298	$62.23	$1,325,399.43
§495.6 - Menu Set Objectives/Measures (hospitals/CAHs)	0938-New	2,696	2,696	0.33	890	$89.96	$80,035.61
§495.8 - CQMs for hospitals/CAHs	0938-New	2,696	2,696	4.00	10,784	$89.96	$970,128.64
§495.210 - Gather information for attestation (MA EPs)	0938-New	13,000	13,000	0.75	9,750	$25.00	$243,750.00
§495.210 - Attesting on behalf of MA EPs	0938-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)	0938-New	13,000	13,000	1.00	13,000	n/a	$435,500.00
§495.210 - Gather information for attestation (MA-affiliated hospitals)	0938-New	30	30	7.00	210	$25.00	$5,250.00

Reg Section	OMB Control No.	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Cost ($)
§495.210 - Attesting on behalf of MA-affiliated hospitals	0938-New	30	30	1.48	44	$59.00	$2,619.60
§495.210 - Total cost of attestation for Stage 2 (MA-affiliated hospitals)	0938-New	30	30	8.48	254	n/a	$7,869.60
§495.342 - 1. Frequency of Health Information Technology (HIT) Implementation Advanced Planning Document (IAPD) Updates	0938-New	56	56	70.00	3,920	$56.24	$220,460.80
Burden Total for 2014					**2,118,831.28**		**$189,138,279**

Note: All non-whole numbers in this table are rounded to 2 decimal places.

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

1. Submit your comments electronically as specified in the ADDRESSES section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, [CMS-0044-P]

Fax: (202) 395-6974; or

Email: OIRA_submission@omb.eop.gov

IV. Response to Comments

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

V. Regulatory Impact Analysis

A. Statement of Need

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

As noted in section I. of this proposed rule, this proposed rule is one of two coordinated rules related to the adoption and meaningful use of certified EHR technology. The other is ONC's proposed 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 2 requirements for meaningful use, the changes in quality measures that will take effect beginning in 2014, and other changes being proposed for 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 proposed provisions of the 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 certified EHR technology. Additionally, the Medicaid program also provides incentives for the adoption, implementation, and upgrade of certified EHR technology. 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 would 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 impossible to predict with precision the timing or rates of adoption and ultimately meaningful use. Further, little new data is currently available regarding rates of adoption or costs of implementation since the publication of our Stage 1 final rule. Because of this continued uncertainty and because there is little new data on which to base alternate forecasts, we are maintaining the high and low estimates for adoption rates that we established in our Stage 1 final rule (75 FR 44548 through 44563). Therefore, we show two scenarios, which illustrate how different scenarios would impact overall costs. Our high scenario of meaningful use demonstration assumes that by 2019, nearly 100 percent of hospitals and 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. To emphasize the uncertainties involved, we have also created a low scenario estimate for the

demonstration of meaningful use each year, which assumes less robust adoption and meaningful use. Our low scenario of meaningful use demonstration assumes that by 2019, nearly 95.6 percent of hospitals and 36 percent of EPs will be meaningful users.

Data from the EHR Incentive Program to date has shown that about 4 percent of EPs and 8 percent of hospitals received incentive payments in 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. 2011 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 is not very useful in estimating penetration rates when stage 2 is implemented.

Overall, we expect spending under the EHR incentive program for transfer payments to Medicare and Medicaid providers between 2014 and 2019 to be $3.3 billion under the low scenario, and $12.7 billion under the high scenario (these estimates include net payment adjustments for Medicare providers who do not achieve meaningful use in 2015 and beyond in the amount of $3.9 billion under the high scenario and $8.1 billion under the low scenario). 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 who would like to qualify as meaningful users of EHRs will need to purchase certified EHR technology. However, we believe that providers who have already purchased certified EHR technology 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 certified EHR technology 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 proposed rule.

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 an Initial Regulatory Flexibility Analysis to describe and analyze the impact of the proposed rule on small entities unless the Secretary can certify that the 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 Initial 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 non-certified EHR systems will require significant changes to achieve certification and that EPs, CAHs, and eligible hospitals will have to make process changes to achieve meaningful use.

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 Office of the National Coordinator for Health IT (ONC) and the American Hospital Association (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 Centers for Disease Control and

Prevention (CDC) survey found the percentage of physicians who adopted basic electronic health records (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 45,000 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 MAO 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 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 would 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 would 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 proposed rule would 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 proposed rule would create a significant impact on a substantial number of small entities, and have prepared a Regulatory Flexibility Analysis as required by the RFA and, for small rural hospitals, section 1102(b) of the Act. Furthermore, any impacts that would arise from the implementation of certified EHR

technology in a rural eligible hospital would be positive, with respect to the streamlining of care and the ease of sharing information with other EPs to avoid delays, duplication, or errors. However, we have statutory authority to make case-by-case exceptions for significant hardship, and have proposed certain case-by-case applications that may be made when there are barriers to internet connectivity that would 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 would require spending in any 1 year $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately $136 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 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 $136 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 proposed rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This proposed rule would not have a substantial direct effect on State or local governments, preempt State law, or otherwise have a Federalism implication. 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 proposed 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 proposed 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 criteria for the demonstration of meaningful use of certified EHR technology has been finalized for stage 1 and is being proposed for stage 2, 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 570,300 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 non-hospital-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 non-physicians 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) would 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 proposed 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 would be $5 million to achieve meaningful use, because providers who would like to qualify as meaningful users of EHRs will need to purchase certified EHRs. We further acknowledge that "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 propose 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 .

d. Costs of EHR Adoption for Eligible Hospitals

The American Hospital Association (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 the smallest of 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, administrative costs related to reporting, and the like are unknown at this time and difficult to quantify.

4. Medicare Incentive Program Costs

a. Medicare Eligible Professionals (EPs)

We propose to 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 would qualify for Medicaid incentive payments and would 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 certified EHR technology are uncertain. The percentage of

Medicare EPs who will satisfy the criteria for demonstrating meaningful use of certified EHR technology 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 certified EHR technology over the period CYs 2014 through 2019 is as shown in Table 19.

TABLE 19: MEDICARE EPs DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY, HIGH AND LOW SCENARIO

	Calendar Year					
	2014	**2015**	**2016**	**2017**	**2018**	**2019**
EPs who have claims with Medicare (thousands)	570.3	576.0	581.7	587.5	593.3	599.0
Non-Hospital Based EPs (thousands)	492.2	497.1	502.1	507.1	512.0	517.0
EPs that are both Medicare and Medicaid EPs (thousands)	98.4	99.4	100.4	101.4	102.4	103.4
Low Scenario:						
Percent of EPs who are Meaningful Users	18	21	24	28	32	36
Meaningful Users (thousands)	70.2	83.1	97.3	112.9	129.9	148.1
High Scenario:						
Percent of EPs who are Meaningful Users	49	53	58	62	66	70
Meaningful Users (thousands)	192.6	212.2	231.9	251.3	270.4	288.8

Our estimates of the incentive payment costs and payment adjustment savings are presented in Table 20. These costs 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 certified EHR technology. 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 electronic health records (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 for the low scenario of the Medicare EP portion of the HITECH Act are shown in Table 20.

TABLE 20: ESTIMATED COSTS (+) AND SAVINGS (–) FOR MEDICARE EPS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY, LOW SCENARIO (IN 2012 BILLIONS)

Fiscal Year	Incentive Payments	Payment Adjustment Receipts	Benefit Payments	Net Total
2014	$0.6	—	—	$0.6
2015	$0.5	–$0.6	—	–$0.1
2016	$0.3	–$1.0	—	–$0.6
2017	$0.1	–$1.4	—	–$1.3
2018	—	–$1.6	—	–$1.6
2019	—	–$1.6	—	–$1.6

Estimated net costs for the high scenario of the Medicare EP portion of the HITECH Act are shown in Table 21.

TABLE 21: ESTIMATED COSTS (+) AND SAVINGS (–) FOR MEDICARE EPS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY, HIGH SCENARIO (IN 2012 BILLIONS)

Fiscal Year	Incentive Payments	Payment Adjustment Receipts	Benefit Payments	Net Total
2014	$1.3	—	—	$1.3
2015	$1.1	–$0.4	—	$0.7
2016	$0.7	–$0.6	—	$0.1
2017	$0.3	–$0.8	—	–$0.5
2018	—	–$0.8	—	–$0.8
2019	—	–$0.8	—	–$0.8

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 would 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 admission 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 2008 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 21 provides these proportions.

TABLE 22: 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	176	19%	440	48%	293	32%	909	23%
Small/Medium	817	31%	1,352	51%	462	18%	2,631	67%
Large (400+beds)	216	54%	163	41%	18	5%	397	10%
Total	1209	31%	1955	50%	773	20%	3,937	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 would 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 2008 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 high scenario estimated net costs for section 4102 of the HITECH Act are shown in Table 23: Estimated costs (+) and savings (–) for eligible hospitals adopting certified EHRs. This provision is estimated to increase Medicare hospital expenditures by a net total of $5.4 billion during FYs 2014 through 2019.

TABLE 23: ESTIMATED COSTS (+) AND SAVINGS (–) FOR MEDICARE ELIGIBLE HOSPITALS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR

TECHNOLOGY, HIGH SCENARIO
(IN 2012 BILLIONS)

Fiscal Year	Incentive Payments	Payment Adjustment Receipts	Benefit Payments	Net Total
2014	$1.9	—	([1])	$1.9
2015	$2.1	-$0.3	([1])	$1.8
2016	$1.3	-$0.1	([1])	$1.2
2017	$0.5	-$0.1	([1])	$0.5
2018	—	([1])	([1])	([1])
2019	—	—	([1])	([1])

[1] Savings of less than $50 million.

We are also providing the estimates for a low scenario in Table 24.

TABLE 24: ESTIMATED COSTS (+) AND SAVINGS (–) FOR MEDICARE ELIGIBLE HOSPITALS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY, LOW SCENARIO
(IN 2012 BILLIONS)

Fiscal Year	Incentive Payments	Payment Adjustment Receipts	Benefit Payments	Net Total
2014	$1.2	—	([1])	$1.2
2015	$1.4	–$0.9	([1])	$0.5
2016	$1.2	–$0.6	([1])	$0.6
2017	$0.6	-$0.3	([1])	$0.3
2018	—	-$0.2	([1])	-$0.2
2019	—	-$0.1	([1])	-$0.1

[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 and 26, related to the prevalence of certified EHR technology 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 25 shows the scenario's estimates:

TABLE 25: ASSUMED PROPORTION OF ELIGIBLE HOSPITALS WITH CERTIFIED EHR TECHNOLOGY, BY PERCENTAGE OF SYSTEM COST COVERED BY MEDICARE INCENTIVE PAYMENTS HIGH SCENARIO

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	0.75	0.6
2015	1.0	1.0	0.95	0.9	0.8
2016	1.0	1.0	1.0	0.95	0.9
2017	1.0	1.0	1.0	1.0	0.95
2018	1.0	1.0	1.0	1.0	1.0

For instance, under the high scenario 95 percent of eligible hospitals whose incentive payments would 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.

Table 26 shows the low scenario estimates.

TABLE 26: ASSUMED PROPORTION OF ELIGIBLE HOSPITALS WITH CERTIFIED EHR TECHNOLOGY, BY PERCENTAGE OF SYSTEM COST COVERED BY MEDICARE INCENTIVE PAYMENTS LOW SCENARIO

Fiscal Year	Incentive Payments as Percentage of EHR Technology Cost				
	100+%	75-100%	50-75%	25-50%	0-25%
2014	0.9	0.75	0.55	0.4	0.3
2015	1.0	0.9	0.75	0.6	0.5
2016	1.0	1.0	0.9	0.85	0.75
2017	1.0	1.0	0.95	0.9	0.85
2018	1.0	1.0	1.0	0.95	0.9
2019	1.0	1.0	1.0	1.0	1.0

For large, organized facilities such as hospitals, we believe that the revenue losses caused by these payment adjustments would be a substantial incentive to adopt certified EHR technology, even in instances where the Medicare incentive payments would 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 27, we estimated that the great majority of eligible hospitals would qualify for at least a portion of the Medicare incentive payments that they could potentially receive, and only a modest number would incur payment adjustments. Nearly all eligible hospitals are projected to have implemented certified EHR technology by FY 2019. Table 27 shows our high scenario 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 would 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, HIGH SCENARIO

Fiscal Year	Percent Associated with Eligible Hospitals	Percent Payable in Year
2014	82.6%	82.6%
2015	92.6%	54.2%
2016	96.9%	43.4%
2017	99.0%	—
2018	100.0%	—

For instance in FY 2014 under the high scenario, 82.6 percent of the total amount of incentive payments which could be payable in that year would be for eligible hospitals who have demonstrated meaningful use of certified EHR technology and therefore will be paid. In FY 2015 under the high scenario, 92.6 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 would have already received 4 years of incentive payments, and therefore 54.2 percent of all possible incentive payments actually paid in that year.

Table 28 shows the low scenario estimates.

TABLE 28: ESTIMATED PERCENTAGE OF MEDICARE INCENTIVES WHICH COULD BE PAID FOR THE MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY ASSOCIATED WITH ELIGIBLE HOSPITALS AND ESTIMATED PERCENTAGE PAYABLE IN YEAR, LOW SCENARIO

Fiscal Year	**Percent associated with eligible hospitals**	**Percent payable in year**
2014	47.6%	47.6%
2015	66.4 %	49.6%
2016	85.9%	64.1%
2017	91.4%	—
2018	95.6 %	—

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 would 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) would also achieve meaningful use by 2016. Current program payment data, as well as current data from the Regional Extension Centers, does not provide enough information for us to alter these estimates. Therefore, we are maintaining these estimates for the current impact analysis. Our estimates regarding the incentives that will be paid to CAHs are incorporated into the overall Medicare and Medicaid program costs.

5. 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 proposed rule 43 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 29 shows our high estimates for the net Medicaid costs for eligible hospitals and EPs.

TABLE 29: ESTIMATED FEDERAL COSTS (+) AND SAVINGS (–) UNDER MEDICAID, HIGH SCENARIO (IN 2012 $BILLIONS)

Fiscal Year	Incentive Payments		Benefit Payments	Net Total
	Hospitals	Eligible Professionals		
2014	0.7	0.9	([1])	1.6
2015	0.6	1.1	([1])	1.7
2016	0.5	1.1	([1])	1.7
2017	0.4	0.9	([1])	1.3
2018	0.2	0.6	([1])	0.7
2019	0.0	0.3	([1])	0.3

[1] Savings of less than $50 million.

Table 30 shows the low estimates for Medicaid costs and savings.

TABLE 30: ESTIMATED FEDERAL COSTS (+) AND SAVINGS (–) UNDER MEDICAID, LOW SCENARIO (IN 2012 $BILLIONS)

Fiscal Year	Incentive Payments		Benefit Payments	Net Total
	Hospitals	Eligible Professionals		
2014	0.4	0.4	([1])	0.8
2015	0.5	0.5	([1])	1.0
2016	0.7	0.6	([1])	1.3
2017	0.8	0.5	([1])	1.3

Fiscal Year	Incentive Payments		Benefit Payments	Net Total
	Hospitals	Eligible Professionals		
2018	0.4	0.4	([1])	0.9
2019	0.1	0.3	([1])	0.4

[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 non-hospital-based Medicare EPs would 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 high scenario estimates are listed in Table 31.

TABLE 31: ASSUMED NUMBER OF NONHOSPITAL BASED MEDICAID EPS WHO WILL BE MEANINGFUL USERS OF CERTIFIED EHR TECHNOLOGY, HIGH SCENARIO
(ALL POPULATION FIGURES ARE IN THOUSANDS)

		Calendar Year					
		2014	2015	2016	2017	2018	2019
	EPs who have claims with Medicare	570.3	576.0	581.7	587.5	593.3	599.0
	Non Hospital –Based EPs	492.2	497.1	502.1	507.1	512.0	517.0
A	EPs who meet the Medicaid patient volume threshold	98.4	99.4	100.4	101.4	102.4	103.4
B	Medicaid[1] only EPs	46.3	47.1	47.8	48.6	49.3	50.1
	Total Medicaid EPs (A + B)	144.7	146.5	148.2	150.0	151.7	153.5
	Percent of EPs receiving incentive payment during year	82.2%	85.6%	88.8%	43.8%	25.0%	14.4%
	Number of EPs receiving incentive payment during year	119.0	125.4	131.7	65.7	38.0	22.1
	Percent of EPs who have ever received incentive payment	82.2%	85.6%	88.8%	91.9%	94.7%	95.9%
	Number of EPs who have ever received incentive payment	119.0	125.4	131.7	137.7	143.6	147.2

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 certified EHR technology as well. Table 32 shows our low scenario estimates.

TABLE 32: ASSUMED NUMBER OF NONHOSPITAL BASED MEDICAID EPS WHO WILL BE MEANINGFUL USERS OF CERTIFIED EHR TECHNOLOGY LOW SCENARIO
(All Population Figures are in Thousands)

		Calendar Year					
		2014	**2015**	**2016**	**2017**	**2018**	**2019**
	EPs who have claims with Medicare	570.3	576.0	581.7	587.5	593.3	599.0
	Non Hospital –Based EPs	492.2	497.1	502.1	507.1	512.0	517.0
A	EPs who meet the Medicaid patient volume threshold	98.4	99.4	100.4	101.4	102.4	103.4
B	Medicaid[1] only EPs	46.3	47.1	47.8	48.6	49.3	50.1
	Total Medicaid EPs (A + B)	144.7	146.5	148.2	150.0	151.7	153.5
	Percent of EPs receiving incentive payment during year	36.0%	40.5%	45.3%	30.7%	21.9%	15.1%
	Number of EPs receiving incentive payment during year	52.1	59.4	67.2	46.0	33.2	23.1
	Percent of EPs who have ever received incentive payment	36.0%	40.5%	45.3%	50.4%	55.7%	59.9%
	Number of EPs who have received ever incentive payment	52.1	59.4	67.2	75.5	84.4	91.9

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 33. 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 certified EHR technology 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 non-children's hospitals.

TABLE 33: ESTIMATED PERCENTAGE OF POTENTIAL MEDICAID INCENTIVES ASSOCIATED WITH ELIGIBLE HOSPITALS AND ESTIMATED PERCENTAGE PAYABLE EACH YEAR, HIGH SCENARIO

Fiscal Year	Percent Associated with Eligible Hospitals	Percent Payable in Year
2014	83.1%	44.0%
2015	92.9%	38.5%
2016	97.1%	26.2%
2017	99.0%	14.0%
2018	100.0%	4.2%
2019	100.0%	0.0%

Table 34 shows our low scenario estimates.

TABLE 34: ESTIMATED PERCENTAGE OF POTENTIAL MEDICAID INCENTIVES ASSOCIATED WITH ELIGIBLE HOSPITALS AND ESTIMATED PERCENTAGE PAYABLE EACH YEAR, LOW SCENARIO

Fiscal Year	Percent Associated with Eligible Hospitals	Percent Payable in Year
2014	49.2%	30.9%
2015	67.8%	44.5%
2016	86.5%	52.8%
2017	91.8%	37.3%
2018	95.9%	18.7%
2019	100.0%	0.0%

6. Benefits for all EPs and all Eligible Hospitals

In this proposed rule we have not quantified the overall benefits to the industry, nor to eligible hospitals or EPs in the Medicare, Medicaid, or MA programs. Although information on the costs and benefits of adopting systems that specifically meet the requirements for the EHR Incentive Programs (for example, certified EHR technology) has not yet been collected, and although some studies question the benefits of health information technology, a 2011 study completed by ONC (Buntin et al. 2011 "The Benefits of Health Information Technology: A Review of the Recent Literature Shows Predominantly Positive Results" Health Affairs.) found that 92 percent of articles published from July 2007 up to February 2010 reached conclusions that showed the overall positive effects of health information technology on key aspects of care, including quality and efficiency of health care. Among the positive results highlighted in these articles were decreases in patient mortality, reductions in staffing needs, correlation of clinical decision support to reduced transfusion and costs, reduction in complications for patients in hospitals with more advanced health IT, and a reduction in costs for hospitals with less advanced health IT. 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 four 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 proposed 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.

7. 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 would likely be in the reductions in the cost of providing care, and that external savings could accrue to the health insurance plan or even the patient, such as the ability to exchange information more efficiently. However, it is important to note that the CBO identifies the highest gains accruing to large provider systems and groups and claims that office-based physicians may not realize similar benefits from purchasing health IT products. At this time, there is limited data regarding the efficacy of health IT for smaller practices and groups, and the CBO report notes that this is a potential area of research and analysis that remains unexamined. The benefits resulting specifically from this proposed regulation are even harder to quantify because they represent, in many cases, 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.

8. 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 certified EHR technology 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 certified EHR technology in the early years of the Medicare EHR incentive program. We expect that a steadily growing proportion of practices will implement certified EHR technology 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 certified EHR technology 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 would achieve these efficiencies sooner than would otherwise occur, without the EHR incentives. 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.

9. Summary

Consistent with the estimates we are maintaining from the Stage 1 final rule, the total cost to the Medicare and Medicaid programs between 2014 and 2019 is estimated to be $3.3 billion in transfers under the low scenario, and $12.7 billion under the high scenario. 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 35: ESTIMATED EHR INCENTIVE PAYMENTS AND BENEFITS IMPACTS ON THE MEDICARE AND MEDICAID PROGRAMS OF THE HITECH EHR INCENTIVE PROGRAM. (FISCAL YEAR) – (IN 2012 BILLIONS) LOW SCENARIO

Fiscal Year	Medicare Eligible		Medicaid Eligible		Total
	Hospitals	Professionals	Hospitals	Professionals	
2014	$1.2	$0.6	$0.4	$0.4	$2.6
2015	$0.5	-$0.1	$0.5	$0.5	$1.4
2016	$0.6	-$0.6	$0.7	$0.6	$1.3
2017	$0.3	-$1.3	$0.8	$0.5	$0.3
2018	-$0.2	-$1.6	$0.4	$0.4	-$1.0
2019	-$0.1	-$1.6	$0.1	$0.3	-$1.3

Table 36 shows the total costs from 2014 through 2019 for the high scenario.

TABLE 36: ESTIMATED EHR INCENTIVE PAYMENTS AND BENEFITS IMPACTS ON THE MEDICARE AND MEDICAID PROGRAMS OF THE HITECH EHR INCENTIVE PROGRAM. (FISCAL YEAR) – (IN 2012 BILLIONS) HIGH SCENARIO

Fiscal Year	Medicare Eligible		Medicaid Eligible		Total
	Hospitals	Professionals	Hospitals	Professionals	
2014	$1.9	$1.3	$0.7	$0.9	$4.8
2015	$1.8	$0.7	$0.6	$1.1	$4.2
2016	$1.2	$0.1	$0.5	$1.1	$2.9
2017	$0.5	-$0.5	$0.4	$0.9	$1.3
2018	—	-$0.8	$0.2	$0.6	0.0
2019	—	-$0.8	—	$0.3	-$0.5

10. Explanation of Benefits and Savings Calculations

In our analysis, we assume that benefits to the program would accrue in the form of savings to Medicare, through the Medicare EP 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 proposed 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 proposed rule.

Expected qualitative benefits include improved quality of care, better health outcomes, reduced errors and the like. Private industry costs would include the impact of EHR activities such as temporary reduced staff productivity related to learning how to use the EHR, the need for additional staff to work with HIT issues, and administrative costs related to reporting.

TABLE 37: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES CYs 2014 THROUGH 2019 (in 2012 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	2012	$186.5	$191.8	7%	CYs 2014-2019
		$186.5	$191.8	3%	
Qualitative--Other private industry costs associated with the adoption of EHR technology.	These costs would include the impact of EHR activities such as reduced staff productivity related to learning how to use the EHR technology, the need for additional staff to work with HIT issues, and administrative costs related to reporting.				
	TRANSFERS				
	Year Dollar	**Estimates (in millions)**		**Unit Discount Rate**	**Period Covered**
		Low Estimate	**High Estimate**		
Federal Annualized Monetized	2012	$705.7	$2,345.6	7%	CYs 2014-2019
		$618.2	$2,216.9	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 record-keeping 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 would 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 object of the Regulatory Flexibility Analysis to minimize burden on small entities are met by this proposed rule. We invite public comments on the analysis and request any additional data that would help us determine more accurately the impact on the EPs and eligible hospitals affected by the proposed 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 proposes to amend 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 (d)(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 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 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). Such exceptions are subject to annual renewal, but in no case may a hospital be granted such an exception for more than 5 years. (See §495.4 for definitions of payment adjustment year, EHR reporting period, and meaningful EHR user.)

(A) During the fiscal year that is 2 years 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 no later than April 1 of the year before the applicable payment adjustment year.

(B) During either of the 2 fiscal years before the payment adjustment year, the hospital faces extreme and uncontrollable circumstances that prevent it from becoming a meaningful EHR user. Applications requesting this exception must be submitted no later than 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 as a new hospital. 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 has been in operation for more than 2 years but has participated in the Medicare program for less than 2 years.

(4) A hospital that changes its status from a CAH to a hospital that is subject to the capital prospective payment systems.

(5) A State in which hospitals are paid for services under section 1814(b)(3) of the Act must 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. Such a State must 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.

* * * * *

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) for the applicable payment adjustment year no later than 60 days after the close of the applicable EHR reporting period. The Secretary may grant an exception for one or more than one of the following:

(A) A CAH that is 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.

(C) A new CAH, which, for the purposes of this exception, means a CAH that has operated (under previous or present ownership) for less than 1 year. 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 as a new CAH. 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 in operation for more than 1 year but has participated in the Medicare program for less than 1 year.

(4) 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," and paragraphs (1) and (3) of the definition of "Meaningful EHR user".

D. Adding the definition of “Payment adjustment year” in alphabetical order.

The additions and revisions 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) For the subsequent payment years following the payment year in which the EP first successfully demonstrates he or she is a meaningful EHR user, the calendar year.

(2) 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) 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.

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

(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) Except as provided in paragraphs (2)(ii) and (iii) of this definition, the Federal fiscal year that is 2 years before the payment adjustment year.

(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 is an EP (as defined under this section) who furnishes 90 percent or more of his or her covered professional services in a hospital setting in the year preceding the payment year, or in the year 2 years before the payment adjustment year. For Medicare, this will be calculated based on the Federal FY before the payment year for purposes of determining qualification for incentive payments, or 2 years before the or payment adjustment year for purposes of determining whether a payment adjustment applies. For Medicaid, it is at the State's discretion if the data is gathered on the Federal FY or CY before the payment year. A setting is considered a hospital setting if it is a site of service that would be identified by the codes used in the HIPAA standard transactions as an inpatient hospital, or emergency room setting.

* * * * *

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 during an applicable EHR reporting period for a 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 495.6 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. Redesignating paragraph (d)(1)(ii) as paragraph (d)(1)(ii)(A).

F. Adding paragraphs (d)(1)(ii)(B) and (C).

G. Redesignating paragraph (d)(8)(i)(E) as paragraph (d)(8)(i)(E)(1).

H. Adding a paragraph (d)(8)(i)(E)(2).

I. Redesignating paragraph (d)(8)(ii) as paragraph (d)(8)(ii)(A).

J. Adding paragraphs (d)(8)(ii)(B) and (C).

K. Redesignating paragraph (d)(8)(iii) as paragraph (d)(8)(iii)(A).

L. Adding paragraphs (d)(8)(iii)(B) and (C).

M. Redesignating paragraph (d)(10)(i) as paragraph (d)(10)(i)(A).

N. Adding paragraph (d)(10)(i)(B).

O. Redesignating paragraph (d)(10)(ii) as paragraph (d)(10)(ii)(A).

P. Adding a paragraph (d)(10)(ii)(B).

Q. Redesignating paragraph (d)(12)(i) as paragraph (d)(12)(i)(A).

R. Adding a paragraph (d)(12)(i)(B).

S. Redesignating paragraph (d)(12)(ii) as paragraph (d)(12)(ii)(A).

T. Adding a paragraph (d)(12)(ii)(B).

U. Redesignating paragraph (d)(12)(iii) as paragraph (d)(12)(iii)(A).

V. Adding a paragraph (d)(12)(iii)(B).

W. Redesignating paragraph (d)(14)(i) as paragraph (d)(14)(i)(A).

X. Adding a paragraph (d)(14)(i)(B).

Y. Redesignating paragraph (d)(14)(ii) as paragraph (d)(14)(ii)(A).

Z. Adding a paragraph (d)(14)(ii)(B).

AA. In paragraph (e) introductory text--

(i) Removing the ":" and adding a "." in its place.

(ii) Adding a sentence at the end of the paragraph.

BB. Redesignating paragraph (e)(5)(i) as paragraph (e)(5)(i)(A).

CC. Adding a paragraph (e)(5)(i)(B).

DD. Redesignating paragraph (e)(5)(ii) as paragraph (e)(5)(ii)(A).

EE. Adding paragraph (e)(5)(ii)(B).

FF. Redesignating paragraph (e)(9)(i) as (e)(9)(i)(A).

GG. Adding paragraph (e)(9)(i)(B).

HH. Redesignating paragraph (e)(10)(i) as (e)(10)(i)(A).

II. Adding paragraph (e)(10)(i)(B).

JJ. Redesignating paragraph (f)(1)(ii) as paragraph (f)(1)(ii)(A).

KK. Adding paragraphs (f)(1)(ii)(B) and (C).

LL. Redesignating paragraph (f)(7)(i)(E) as paragraph (f)(7)(i)(E)(1).

MM. Adding a paragraph (f)(7)(i)(E)(2).

NN. Redesignating paragraph (f)(7)(ii) as (f)(7)(ii)(A).

OO. Adding paragraphs (f)(7)(ii)(B) and (C).

PP. Redesignating paragraph (f)(9)(i) as paragraph (f)(9)(i)(A).

QQ. Adding a paragraph (f)(9)(i)(B).

RR. Redesignating paragraph (f)(9)(ii) as paragraph (f)(9)(ii)(A).

SS. Adding a paragraph (f)(9)(ii)(B).

TT. Redesignating paragraph (f)(12)(i) as paragraph (f)(12)(i)(A).

UU. Adding a paragraph (f)(12)(i)(B).

VV. Redesignating paragraph (f)(12)(ii) as paragraph (f)(12)(ii)(A).

WW. Adding a paragraph (f)(12)(ii)(B).

XX. Redesignating paragraph (f)(13)(i) as paragraph (f)(13)(i)(A).

YY. Adding a paragraph (f)(13)(i)(B).

ZZ. Redesignating paragraph (f)(13)(ii) as paragraph (f)(13)(ii)(A).

AAA. Adding a paragraph (f)(13)(ii)(B).

BBB. In paragraph (g) introductory text--

(i) Removing the ":" and adding a "." in its place.

(ii) Adding a sentence at the end of the paragraph.

CCC. Redesignating paragraph (g)(8)(i) as paragraph (g)(8)(i)(A).

DDD. Adding a paragraph (g)(8)(i)(B).

EEE. Redesignating paragraph (g)(9)(i) as paragraph (g)(9)(i)(A).

FFF. Adding a paragraph (g)(9)(i)(B).

GGG Redesignating paragraph (g)(10)(i) as paragraph (g)(10)(i)(A).

HHH. Adding a paragraph (g)(10)(i)(B).

III. Revising paragraphs (h) and (i).

JJJ. 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 in 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 exclusions apply. 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 (e)(10) of this section, unless the EP meets five or more exclusions specified in paragraph (e) of this section, in which case the EP must meet all remaining objectives and associated measures.

* * * * *

(b) * * *

(2) * * *

(ii) * * *

(B) Beginning in 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), (g)(9), or (g)(10) of this section.

(d) * * *

(1) * * *

(ii) * * *

(B) For 2013, 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 CPOE or the measure specified in paragraph (d)(1)(ii)(A) of this section.

(C) Beginning 2014, only the measure specified in paragraph (d)(1)(ii)(B) of this section.

* * * * *

(8)(i) * * *

(E) * * *

(2) For 2013, plot and display growth charts for patients 0-20 years, including BMI.

(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) of this section.

(iii) * * *

(B) For 2013, 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/length, weight, and blood pressure have no relevance to their scope of practice is excluded from recording them;

(3) 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

(4) 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 exclusion in paragraph (d)(8)(iii)(B) 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 in 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 in 2014, an EP must meet five of the following objectives and associated measures, one of which must be either paragraph (e)(9) or (e)(10) of this section unless the EP meets five or more exclusions specified in this paragraph (e), in which case the EP

must meet all remaining objectives and associated measures:

* * * * *

(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 in 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 in 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) Beginning 2013, 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 CPOE. or the measure specified in paragraph (f)(1)(ii)(A) of this section.

(C) Beginning 2014, only the measure specified in paragraph (f)(1)(ii)(B) of this section.

* * * * *

(7) * * *

(i) * * *

(E) * * *

(2) Beginning 2013, plot and display growth charts for patients 0-20 years, including BMI.

(ii) * * *

(B) For 2013, 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) are recorded as structured data.

(C) Beginning 2014, only the measure specified in paragraph (f)(7)(ii)(B) 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 (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 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.

* * * * *

(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 in 2014, eligible hospitals or CAHs must meet five of the following objectives and associated measures, one which must be specified in paragraph (g)(8), (g)(9), or (g)(10) of this section:

* * * * *

(8)(i) * * *

(B) Beginning in 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 in 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 in 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 paragraphs (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 4 or more exclusions apply. For example, an EP that has an exclusion for 1 of the objectives in paragraph (k) of this section must meet 3 of the 4 nonexcluded objectives from such paragraph to meet the definition of a meaningful EHR user. If an EP has an exclusion for 4 of the objectives in paragraph (k) of this section, then he or she must meet the remaining the nonexcluded objective 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 two 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 unless 3 or more exclusions apply. For example, an eligible hospital that has an exclusion for 1 of the objectives in paragraph (m) of this section must meet 2 of the 3 non-excluded objectives from such paragraph to meet the definition of a meaningful EHR user. If an eligible hospital has an exclusion for 3 of the objectives in paragraph (m) of this section, then the hospital must meet the remaining nonexcluded objective 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 (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.

(ii) Measure. More than 60 percent of medication, laboratory, and radiology orders created by the EP during the EHR reporting period are recorded using CPOE.

(iii) Exclusion in accordance with paragraph (h)(2) of this section. Any EP who writes fewer than 100 medication, laboratory, and radiology orders during the EHR reporting period.

(2)(i) Objective. Generate and transmit permissible prescriptions electronically (eRx).

(ii) 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 Certified EHR Technology.

(iii) Exclusion in accordance with paragraph (h)(2) of this section. Any EP who writes fewer than 100 prescriptions during the EHR reporting period or does not have a pharmacy within their organization and there are no pharmacies that accept electronic prescriptions within 25 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) Gender.

(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 BMI.

(ii) Measure. 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. 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 five or more clinical quality measures, if applicable, at a relevant point in patient care for the entire EHR reporting period; and

(B) The EP has enabled the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

(7)(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 the EP

during the EHR reporting period whose results are either in a positive/negative 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 or numeric 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.

(ii) Measure. More than 10 percent of all unique patients who have had an office visit with the EP within the 24 months before the beginning of the EHR reporting period were sent a reminder, per patient preference.

(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 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.

(iii) Exclusion in accordance with paragraph (h)(2) of this section. Any EP who neither orders nor creates any of the information listed for inclusion as part of this measure is excluded from both paragraphs (i)(10)(ii)(A) and (B) of this section Any EP that conducts the majority (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 is excluded from paragraph (i)(10)(ii)(B) of this section.

(11)(i) Objective. Provide clinical summaries for patients for each office visit.

(ii) Measure. Clinical summaries provided to patients within 24 hours 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 office visits by the EP.

(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. The EP performs medication reconciliation for more than 65 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 should provide summary care record for each transition of care or referral.

(ii) Measures. (A) 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 65 percent of transitions of care and referrals; and

(B) The EP that transitions or refers their patient to another setting of care or provider of care electronically transmits using n Certified EHR Technology to a recipient with no organizational affiliation and using a different Certified EHR Technology vendor than the sender a summary of care record for more than 10 percent of transitions of care and referrals.

(iii) Exclusion in accordance with paragraph (h)(2) of this section. Any EP who neither transfers a patient to another setting nor refers a patient to another provider during the EHR reporting period is excluded from both measures.

(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) The EP does not administer any of the immunizations to any of the populations for which data is collected by the jurisdiction's immunization registry or immunization information system during the EHR reporting period.

(B) The EP 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 Certified EHR Technology at the start of their EHR reporting period.

(C) The EP 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's Certified EHR Technology can send at the start of their EHR reporting period.

(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 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 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 10 percent of unique patients 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.

(k) Stage 2 menu set criteria for EPs. An EP must meet 3 of the following objectives and associated measures, unless the EP meets 4 or more exclusions specified in this paragraph (k), in which case the EP must meet all remaining objectives and associated measures.

(1)(i) Objective. Imaging results and information are accessible through Certified EHR Technology.

(ii) Measure. More than 40 percent of all scans and 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 does not perform diagnostic interpretation of scans or tests whose result is an image during 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) The EP is not in a category of providers who collect ambulatory syndromic surveillance information on their patients during the EHR reporting period.

(B) The EP 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) The EP operates in a jurisdiction for which no public health agency is capable of accepting the version of the standard that the EP's Certified EHR Technology can send at the start of their EHR reporting period.

(4)(i) Objective. Capability to identify and report cancer cases to a State 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 cancer registry for the entire EHR reporting period.

(iii) Exclusion in accordance with paragraph (h)(2) of this section. Any EP who--

(A) Does not diagnose or directly treat cancer; or

(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.

(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--

(A) Does not diagnose or directly treat any disease associated with a specialized registry; or

(B) Operates in a jurisdiction for which no registry is capable of receiving electronic specific case information in the specific standards required under Stage 2 at the beginning of their EHR reporting period.

(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 (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.

(ii) Measure. More than 60 percent of medication, laboratory, and radiology orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE.

(2)(i) Objective. Record all of the following demographics:

(A) Preferred language.

(B) Gender.

(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 BMI.

(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 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. 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 five or more clinical quality measures, if applicable, at a relevant point in patient care for the entire EHR reporting period; and

(B) The eligible hospital or CAH has enabled the functionality for drug-drug and drug-allergy interaction checks for the duration of the 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 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 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.

(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 4Mbps broadband availability according to the latest information available from the FCC at the start 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. The eligible hospital or CAH performs medication reconciliation for more than 65 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 should provide summary care record for each transition of care or referral.

(ii) Measures. (A) 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 65 percent of transitions of care and referrals; and

(B) The eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care electronically transmits using Certified EHR Technology to a recipient with no organizational affiliation and using a different Certified EHR Technology vendor than the sender a summary of care record for more than 10 percent of transitions of care and referrals.

(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 the 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 receiving electronic immunization data in the specific standards required for Certified EHR Technology at the start of their EHR reporting period.

(C) The eligible hospital or CAH does not have an immunization registry or immunization information system capable of accepting the version of the standard that the eligible hospital's or CAH's Certified EHR Technology can send at the start of their EHR

reporting period.

(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 as authorized, and in accordance with applicable State law and practice.

(iii) Exclusion in accordance with paragraph (i)(2) of this section. Any eligible hospital or CAH that 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.

(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) The eligible hospital or CAH does not have an emergency or urgent care department.

(B) The 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.

(C) The eligible hospital or CAH operates in a jurisdiction for which no public health agency is capable of accepting the version of standard that the eligible hospital's or CAH's

Certified EHR Technology can send at the start of their EHR reporting period.

(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 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 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. eMAR is implemented and in use for the entire EHR reporting period in at least one ward/unit of the hospital.

(m) Stage 2 menu set criteria for eligible hospitals or CAHs. An eligible hospital or CAH must meet the measure criteria for two 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. 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

(2)(i) Objective. Imaging results and information are accessible through Certified EHR Technology.

(ii) Measure. More than 40 percent of all scans and 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 or changed prescriptions) are compared against at least one 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 25 miles.

8. 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.

* * * * *

9. 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 (d)(1), (d)(2)(iii), and (d)(3).

B. Adding paragraphs (d)(2)(iv), (d)(4), and (d)(5).

The revisions and additions read as follows:

§495.102 Incentive payments to EPs.

* * * * *

(d) Payment adjustment effective in CY 2015 and subsequent years for nonqualifying EPs. (1)(i) Subject to paragraphs (d)(3) and (d)(4) of this section, beginning in 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 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 with 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). 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 the calendar year that is 2 years before the payment adjustment year, the EP was located in an area without sufficient Internet access to comply with the meaningful EHR 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) During either of the 2 calendar years before the payment adjustment year, the EP

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.

(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]

11. 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.

12. Section 495.200 is amended by--

A. Adding definitions for "Adverse eligibility determination," "Adverse payment determination," "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.

Adverse eligibility determination means a determination or omission by CMS that was the result of a malfunction of a CMS system that prohibits a qualifying MA organization, qualifying MA EP, or qualifying MA-affiliated eligible hospital from participating in the Medicare Advantage EHR Incentive Program.

Adverse payment determination means a determination by CMS that negatively affects an EHR payment determination under this subpart.

* * * * *

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 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.

* * * * *

13. 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 "(b)(4)" in its place.

C. In paragraph (b)(2)(iii), removing the term "NPI." and adding the phrase "NPI or CCN." in its place.

D. Redesignating paragraphs (b)(3) and (b)(4) as paragraphs (b)(4) and (b)(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.

* * * * *

(3) When reporting under either paragraph (b)(1) or (b)(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

* * * * *

14. Section 495.204 is amended as follows:

A. Revising the section heading.

B. Revising paragraphs (b)(2) and (b)(4).

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.

15. 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.

* * * * *

16. 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.

17. A new §495.211 is added 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.

(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.

18. A new §495.213 is added to subpart C to read as follows:

§495.213 Reconsideration process for a qualifying MA organization.

(a) In general. A qualifying MA organization may seek reconsideration of an adverse eligibility or payment determination in accordance with the requirements of this section.

(b) Rejection of requests barred from administrative and judicial review. Reconsideration requests prohibited under §495.212 will be rejected.

(c) Rejection of requests including new payment information. Reconsideration requests that seek to include new payment-related information will be rejected.

(d) Channeling of hospital and meaningful use reconsideration requests. (1) All reconsideration requests involving MA-affiliated eligible hospitals must meet the requirements of and be channeled through the reconsideration process in subpart E of this part and will be rejected for reconsideration under this section.

(2) All reconsideration requests involving the meaningful use of Certified EHR Technology must follow the requirements of and be channeled through the reconsideration process in subpart E of this part and will be rejected for reconsideration under this section.

(e) Informal reconsideration. (1)(i) A qualifying MA organization must request an informal reconsideration in writing within 60 calendar days of an adverse eligibility or payment determination.

(ii) If the 60th calendar day occurs on a Saturday, Sunday or Federal holiday, the request for an informal reconsideration is due the calendar day following the Sunday or Federal holiday.

(2) The request for an informal reconsideration--(i) Must specify the finding(s) or issue(s) with which the qualifying MA organization disagrees and the reason(s) for the disagreement; and

(ii) May include additional documentary evidence that the qualifying MA organization wishes CMS to consider.

(3) An informal reconsideration decision is final and binding, absent reopening due to audit or other evidence of material misrepresentation, unless a request for a final reconsideration is requested in accordance with paragraph (f) of this section.

(f) Final reconsideration. (1)(i) A qualifying MA organization seeking a final reconsideration must request the final reconsideration in writing within 30 calendar days of the date on the notice issued as a result of the informal reconsideration.

(ii) If the 30th calendar day occurs on a Saturday, Sunday or Federal holiday, the request for a final reconsideration is due the calendar day following the Sunday or Federal holiday.

(2) The request for a final reconsideration must --

(i) Specify the finding(s) or issue(s) with which the qualifying MA organization disagrees and the reason(s) for the disagreement;

(ii) Include a copy of the documents and evidence submitted for the informal reconsideration and a copy of the decision issued in accordance with the informal reconsideration.

(iii) Not include new evidence or documents not presented at the informal reconsideration level.

(3) A final reconsideration is final and binding, absent reopening due to audit or other evidence of material misrepresentation.

19. Section 495.302 is amended as follows:

A. In the definition of "Children's hospital," by revising paragraph (1), redesignating paragraph (2) as paragraph (3), and adding a new paragraph (2).

B. In the definition of "Practices predominantly," by removing the phrase "in the most recent calendar year occurs" and adding the phrase "(within the most recent calendar year or within the 12-month period preceding attestation)"..

The revision and addition reads as follows:

§495.302 Definitions.

* * * * *

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 (c)(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. At least one clinical location used in the calculation of patient volume must have Certified EHR Technology Certified EHR Technology--

(1) During the payment year for which the EP attests to having adopted, implemented or upgraded Certified EHR Technology 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 "." 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 "." 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 "." 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 "; " and adding "." in its place.

L. In paragraph (e)(3)(iii), by removing "; or" and adding "." 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 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 per inpatient discharge 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 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 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 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 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 the second sentence of 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.

(a) * * *

(1) * * *

(ii) [Reserved].

(2) * * *

(ii) [Reserved].

* * * * *

(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) * * *

(B) * * *. 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 495.332 is amended as follows:

A. Adding a new paragraph (b)(6).

B. Revising paragraph (c) introductory text.

C. Removing paragraph (d)(9).

D. Adding a new paragraph (g).

The revisions and additions 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 Certified EHR Technology during the payment year for which the EP is attesting.

(c) Subject to paragraph (g) of this section, for monitoring and validation of information States must include the following:

* * * * *

(g) 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.

25. 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 a minimum of 12 months from the date of the last CMS approved HIT IAPD and must contain the following:

* * * * *

26. Section 495.370 is amended by adding a new 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.

27. Add a new subpart E to read as follows:

Subpart E—Administrative Review of Certain Electronic Health Record Incentive Program Determinations

Sec.

495.400 Basis and purpose.

495.402 Definitions.

495.404 Provider scope and eligibility to file.

495.406 Filing appeals.

495.408 General filing rules.

495.410 Other requirements.

495.412 Informal review process and decision.

495.414 Final reconsiderations.

Subpart E—Administrative Review of Certain Electronic Health Record Incentive Program Determinations

§495.400 Basis and purpose.

This subpart--

(a) Contains an administrative appeal process for Medicare EPs, eligible hospitals, and CAHs, and, in certain cases, Medicaid eligible hospitals and potentially qualifying MA EPs and MA-affiliated eligible hospitals; and

(b) Defines the types of appeals and issues that may be raised on appeal as well as the documents or data, or both, that must be submitted to support issues raised in the appeal filing.

§495.402 Definitions.

For purposes of this subpart, the following definitions apply:

Circumstance outside a provider's control means any event that reasonably prevented a provider from participating in the EHR Incentive Program and which the provider could not under any circumstances control.

Eligibility appeal means any of the following:

(1) An appeal filed by a provider that can demonstrate it met all program requirements for the EHR Incentive Program and should have received a payment but could not because of circumstances outside a provider's control. A provider must also demonstrate an action to participate in the EHR Incentive Program.

(2) An appeal of whether a hospital may be considered a potentially qualifying MA-affiliated eligible hospital, as defined under §495.200, based on common corporate governance with a qualifying MA organization, for which at least two-thirds of the Medicare hospital discharges (or bed-days) are of (or for) Medicare individuals enrolled under MA plans, as well as whether less than one-third of Medicare bed-days for the year are covered under Part A rather than Part C.

Incentive payment appeal means an appeal challenging only the total estimated allowed charges for a qualifying EP's covered professional services under §495.102(b) of this part. The appeal could not contest an individual claims payment or coverage decisions, but only the inclusion of final claims used to calculate the incentive payment amount or the inclusion of claims used to calculate the incentive payment amount. Incentive payment appeals may also include appeals challenging a subsequent Federal determination that the incentive payment calculation amount was incorrect (including determinations that the incentive payment was duplicative).

Meaningful use appeal means an appeal challenging a determination or finding that a provider was not a meaningful EHR user, or that it did not use Certified EHR Technology.

Permissible appeal means an eligibility appeal, a meaningful use appeal, or an incentive payment appeal.

Provider means one of the following entities that is permitted to file an appeal in accordance with the requirements specified in this subpart:

(1) An EP.

(2) An eligible hospital.

(3) A CAH.

(4) A qualifying MA organization on behalf of a potentially qualifying MA EP.

(5) A potentially qualifying MA-affiliated eligible hospital.

(6) A Medicaid eligible hospital.

§495.404 Provider scope and eligibility to file.

Subject to the limitations and requirements contained in this subpart, only permissible appeals are permitted to be filed, only the following providers may file appeals, and only for the types of appeals specified in this section:

(a) An EP as defined under §495.100 is permitted to file an eligibility appeal, a meaningful use appeal, or an incentive payment appeal.

(b) An eligible hospital as defined under §495.100 is permitted to file an eligibility appeal or a meaningful use appeal.

(c) A CAH as defined under § 495.4 is permitted to file an eligibility appeal or a meaningful use appeal.

(d) A qualifying MA organization as defined under § 495.200 is permitted to file a meaningful use appeal for a potentially qualifying MA EP as defined under §495.200 who has been determined not to be meaningful EHR user.

(e) A potentially qualifying MA-affiliated eligible hospital as defined under §495.200 is permitted to file an eligibility appeal described in paragraph (ii) of the definition (that is, an

appeal based on common corporate governance with a qualifying MA organization, for which at least two-thirds of the Medicare hospital discharges (or bed days) are of (or for) Medicare individuals enrolled under MA plans and/or whether less than one-third of Medicare bed-days for the year are covered under Part A rather than Part C) and a meaningful use appeal if determined not to be a meaningful EHR user.

(f) A Medicaid-eligible hospital under subpart D of this part is permitted to file a meaningful use appeal, but only in the case that an adverse audit has been conducted by CMS.

§495.406 Filing appeals.

A provider must make all filings or requests, and submit all documentation, comments, and data through an online mechanism and in a manner specified by CMS.

§495.408 General filing rules.

(a) All relevant issues raised in initial filing of appeal. Except under extenuating circumstances described in paragraph (c)(1) of this section, a provider must raise all relevant issues at the time of the initial filing of an appeal.

(b) Deadlines for filing appeals. (1) General rules. (i) Except under extenuating circumstances described in paragraph (c)(2) of this section, an appeal filed by a provider after the specified deadline is dismissed and cannot be refiled.

(ii) If the filing deadline falls on a Saturday, Sunday, or a Federal holiday then the deadline for filing the appeal is extended to the next business day.

(iii) CMS may extend the filing deadline for providers in response to extenuating circumstances that occur within the EHR Incentive Program. CMS will provide information on our website at least 7 calendar days before the filing deadline providing the new filing deadline.

(2) Deadline for an eligibility appeal. An eligibility appeal must be filed no later than 30 days after the 2-month period following the payment year.

(3) Deadline for a meaningful use appeal. A meaningful use appeal must be filed no later than 30 days from the date of the demand letter or other finding that could result in the recoupment of an EHR incentive payment.

(4) Deadline for an incentive payment appeal. An incentive payment appeal must be filed no later than 60 days from the date the incentive payment was issued or 60 days from any Federal determination that the incentive payment amount was incorrect (including determinations that the payment was duplicative).

(c) Extenuating circumstances for filing. (1) Amendment to raise additional issues. A provider--

(i) May file an amendment to raise additional issues, if the provider can demonstrate an extenuating circumstance existed that prevented all relevant issues from being included at the time of the initial filing of the appeal;

(ii) Must show, in its amendment request, that extenuating circumstances existed by submitting documentation of occurrences, events, or transactions that prevented the additional issues from being raised in the initial appeal filing; and

(iii) Must file its amendment claiming an extenuating circumstance within 15 days after the initial filing of the appeal.

(2) Request an extension of the filing deadline. (i) A provider--

(A) May file a request to extend the deadline under paragraph (b) of this section, if the provider can demonstrate an extenuating circumstance existed that prevented the appeal from being filed by the applicable deadline; and

(B) Must show, in its extension request, that extenuating circumstances existed by submitting documentation of occurrences, events, or transactions that prevented the appeal from being filed by the applicable deadline.

(ii) The length of an extension granted by CMS is based upon documentation filed and the reason(s) requested.

(iii) A request to extend the deadline must be filed before the deadline expires for the appeal the provider is filing.

(d) Withdrawal of appeal filing. A provider may withdraw an appeal at any time after the initial appeal filing and before an informal review decision is issued. The issues raised in the appeal filing may be re-filed by the provider before the deadline specified in paragraph (b) of this section.

§495.410 Other requirements.

(a) General rule. CMS reviews each issue raised in the appeal filing to determine if each issue is precluded from the appeals process. Appeal issues found to be precluded will be dismissed.

(b) Judicial and administrative review. Providers have the burden of demonstrating that each issue raised in the appeal filing is not precluded from administrative and judicial review under the Act and implementing regulations at 42 CFR 413.70(a)(7), 495.106(f), 495.110, and 495.212.

(c) Inchoate issues. (1) A provider has the burden of doing all of the following:

(i) Demonstrating that the provider met all the EHR Incentive Program requirements other than the issue raised and should have received an incentive payment for the payment year for which the appeal is filed.

(ii) Demonstrating that before the end of the payment year for which the appeal is filed, the provider allowed CMS an opportunity to resolve the issue that is raised in the appeal.

(iii) Demonstrating that CMS was not able to resolve the issue by the end of the 2 months following the payment year for which the appeal is filed.

(2) The provider must provide documentation of the resolution efforts described in paragraph (c)(1)(ii) of this section.

(d) Hospital cost report issues. Any issue involving an incentive payment based upon a hospital cost report must be filed with the Provider Reimbursement and Review Board. Issues raised in an appeal filing that involve a hospital cost report will be dismissed in accordance with these rules.

§495.412 Informal review process and decision.

(a) General rule. The informal review process is the first level review in the appeals process.

(b) Supporting documentation. (1) Request for additional supporting documentation essential to validate an issue raised in the appeal. During the informal review process, CMS may request supporting documentation from a provider for an issue that is raised in the appeal. Except in extenuating circumstances described in this paragraph (b), a provider has 7 calendar days to comply with the request for supporting documentation.

(2) Failure to submit supporting documentation. An issue raised in the appeal is dismissed if a provider fails to submit supporting documentation within 7 calendar days from the date of the request by CMS.

(3) Request for extension before the supporting documentation deadline. A request for an extension to submit supporting documentation may be filed if a provider can demonstrate an

extenuating circumstance existed that prevented the supporting documentation from being filed by the provider within 7 calendar days.

(i) A provider must show extenuating circumstances existed by providing, with its request for extension, documentation of occurrences, events, or transactions that prevented a request from being complied within 7 calendar days. A request for an extension must be filed before the 7 calendar days to respond to the request has expired.

(ii) A request for an extension of the time period to submit supporting documentation must be filed within 7 calendar days from the date the request was made by CMS.

(iii) The length of an extension granted by CMS is based upon documentation submitted and the reasons requested.

(c) Informal review standards. All appeal requests are reviewed according to the guidelines associated with the specific appeal type.

(1) Eligibility appeals. A provider must do all of the following:

(i) Demonstrate that the provider can meet all of the requirements of the EHR except for the issue raised.

(ii) Except for eligibility appeals described in part (ii) of the definition (that is, appeals involving common corporate governance with a qualifying MA organization, for which at least two-thirds of the Medicare hospital discharges (or bed-days) are of (or for) Medicare individuals enrolled under MA plans and/or whether less than one third of Medicare bed-days for the year are covered under Part A rather than Part C), demonstrate that the issue raised in the appeal filing was the result of a circumstance outside of a provider's control and prevented the provider from receiving an incentive payment.

(iii) Submit evidence that an action was taken to participate in the EHR Incentive

Program.

(iv) For eligibility appeals described in part (ii) of the definition, demonstrate in accordance with subpart C of this part that either:

(A) The MA-affiliated hospital is under common corporate governance with a qualifying MA organization, for which at least two-thirds of the Medicare hospital discharges (or bed-days) are of (or for) Medicare individuals enrolled under MA plans; and/or

(B) The MA-affiliated eligible hospital has less than one third of Medicare bed-days for the year covered under Part A rather than Part C.

(2) Meaningful use appeals. A provider must do all of the following:

(i) Demonstrate that the provider successfully meets the meaningful use objective and associated measure discussed in the demand letter or other finding for recoupment of the EHR incentive payment.

(ii) Demonstrate that the provider used Certified EHR Technology during the EHR reporting period for the payment year for which the appeal was filed.

(3) Incentive payment appeals. Providers appealing the amount of the incentive payment must do the following:

(i) Demonstrate that all relevant claims were submitted timely and appropriately and were either not used or misused in accordance with §495.102(a)(2) of this part.

(ii) Demonstrate that the timely and appropriately submitted claims were not used in calculating the amount of the EHR incentive payment.

(d) Informal review decision. (1) CMS issues an informal review decision within 90 days of the initial appeal filing, unless an extension or amendment was granted to the provider or CMS.

(2) An informal review decision under this section represents CMS's final decision, unless a provider files a reconsideration request under §495.414 of this subpart.

§495.414 Final reconsiderations.

(a) Reconsideration request. A provider dissatisfied with the CMS informal review decision under §495.412 of this part may file a request for reconsideration of issues denied in that decision. The request for reconsideration may include comments and documentation to support the position that the issues raised in the appeal should not have been denied.

(b) Deadline for reconsideration requests. (1) Except as provided in paragraph (b)(2) of this section, reconsideration requests must be filed within 15 days from the date of the informal review decision.

(2) A provider may request a one-time extension of 15 additional days to file the reconsideration request, if the provider can demonstrate that the informal review decision was not received by the provider (or provider's representative) within 5 days from the date of the decision.

(c) Final decision. CMS renders a final decision within 10 days of the date the provider files the request for reconsideration.

(d) Reconsideration request not filed. If a provider does not file a request for reconsideration within the time period specified in paragraph (b) of this section, then the informal review decision is CMS's final decision.

CMS-0044-P

(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: February 8, 2012

Marilyn Tavenner,

Administrator,

Centers for Medicare & Medicaid Services.

Approved: February 21, 2012

Kathleen Sebelius,

Secretary,

Department of Health and Human Services.

BILLING CODE 4120-01-P

[FR Doc. 2012-4443 Filed 02/23/2012 at 4:15 pm; Publication Date: 03/07/2012]